MINISTRY OF HEALTHCARE

OF THE REPUBLIC OF UZBEKISTAN

TASHKENT PHARMACEUTICAL INSTITUTE

UZBEK LANGUAGE AND LITERATURE DEPARTMENT

TEACHING-METHODICAL COMPLEX

ON THE SUBJECT

"PRACTICAL FOREIGN LANGUAGE"

FOR THE 1ST -YEAR STUDENTS

OF MASTER DEGREE

TASHKENT-2021

MINISTRY OF HEALTHCARE

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"CONFIRM"
Rector of the TashParmi
Doctor of Medicine. K.S. Rizayev_____
"_____" _____2021

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Knowledge domain: 900 000 - Healthcare and Social Provision

Educational domain: 910 000 - Healthcare

Educational directions:

70910801 - Biotechnology of Medicinal Plants
70910703 - Experimental and Sport Pharmacology
70910803 - Industrial Technology of Drugs
70910702 - Organization of Pharmaceutical Affairs and Administration
70911001 - Pharmaceutical biotechnology and bioengineering
70911001 - Quality Assurance and Quality Control in Pharmacy
70710104 - Technology of Medicinal Forms and Preparations
709108701 - Pharmaceutical chemistry and pharmacognosy

TASHKENT - 2021

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TMC on the subject "Practical Foreign Language" is intended for the 1st- year students of Master Degree for teaching Practical English.

TMC is discussed and recommended to confirm on the Branch Methodical Council on Languages on the "____" of _____ in 2021 Record № _____

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Scientific Secretary _____ **V.Khaydarov**

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Confirmed on Chair meeting

Record №21 24.06. 2021

LESSON PLAN
on Practical Foreign (English) Language
for the 1st year students of Master Degree
(1st term of the academic year of 2021-2022)

№	Theme names	Hours	Max. ball	Duration
1	**Unit 1. The Kick-off meeting** (EforPI, p.5). **R:** Fab Pharmaceuticals (EforPI, p.6). **W:** Academic Degrees. **L:** Dialogue (EforPI, p.10) **S:** Pharmaceutical Industry in Uzbekistan (OTM, p.4)	2	-	
2	**The Kick-off meeting.** Useful phrases (EforPI, p.11). **L:** Harvey summary (EforPI, p.12) **R:** Newspaper article (EforPI, p.16) **W:** Job Advertisements. **S:** Pharmaceutical Industry in Uzbekistan (OTM, p.4)	2	100	
3	**Unit 2. Substance Discovery and Product Development (**EforPI, p.17**)** **R:** Mensamint (EforPI, p.18) **L:** Minutes of Tuesday's brainstorming meeting (EforPI, p.20) **W:** Drug Discovery. **S:** Pharmaceutical Industry in the UK (OTM, p.6)	2	100	
4	**Substance Discovery and Product Development.** **L:** Hospital In-Patient Dosage Form Survey Results (EforPI, p.23) **R:** How many drug categories do we need? (EforPI, p.26) **W:** Dosage Forms. **S:** Pharmaceutical Industry in the UK (OTM, p.6)			
5	**Unit 3. Quality Assurance and Auditing (**EforPI, p.27**)** **R:** Berner Pharmaceuticals Ltd (EforPI, p.28) **L:** Laboratory staff meeting (EforPI, p.33) **W:** Laboratory safety systems. **S:** Pharmaceutical Education in the UK (OTM, p.6)	2	100	

6	**Quality Assurance and Auditing.** **L:** Conversation (EforPI, p.34) **R:** Drug contamination**:** Lessons to be learned? **(**EforPI, p.38**)** **W:** My Company. **S:** Pharmaceutical Education in the UK (OTM, p.6)	2	100	
7	**Unit 4. Ready for testing in live organisms (**EforPI, p.39**)** **R:** Text **(**EforPI, p.40**)** **L:** Conversation (EforPI, p.42) **W:** Preclinical Development. **S:** Drugs Made by Medicinal Plants (OTM, p.8)	2	100	
8	**Ready for testing in live organisms (**EforPI, p.39**)** **R:** Text **(**EforPI, p.45**)** **L:** Clinical Trials for RFI (EforPI, p.47) **W:** Short Summary. **S:** Drugs Made by Medicinal Plants (OTM, p.8)	2	100	
9	**Unit 5. Drug Safety and Regulatory Affairs (**EforPI, p.51**)** **R:** Report **(**EforPI, p.52**)** **L:** True or False? (EforPI, p.56) **W:** Adverse Drug Reactions. **S:** Plants as a Source of Drugs (OTM, p.9)	2	100	
10	**Drug Safety and Regulatory Affairs.** **R:** E-Mail **(**EforPI, p.59**)** **L:** PIL for Mensamint (EforPI, p.60) **W:** PIL VS. Pills. **S:** Plants as a Source of Drugs (OTM, p.9)	2	100	
11	**Unit 6. Production and Packaging (**EforPI, p.63**)** **R:** Fatal fakes - counterfeit medicines **(**EforPI, p.62**)** **L:** Stephany Baker (EforPI, p.65) **W:** Packaging. **S:** Clinical Pharmacy (OTM, p.10)	2	100	
12	**Unit 6. Production and Packaging.** **L:** Instructions (EforPI, p.66) **R:** Henry's handwritten notes **(**EforPI, p.70**)** **W:** Types of Letters. Formal and Informal. **S:** Clinical Pharmacy (OTM, p.10)	2	100	
13	**R:** Article (EforPI, p.73) **W:** How to write CV? **L:** Yesterday (The Beatles) **S:** Medicinal Chemistry (OTM, p.13)	2	100	
14	**R:** Text for outlesson reading: "Veterinary Pharmacy" (OTM, p. 30)	2	100	

	W: How to write an Essay? **L:** I just want to say (Steavy Wonder) **S:** Medicinal Chemistry (OTM, p.13)			
15	**Mid-term Control**	2	100	
16	**R:** Text for outlesson reading: "Poisonous Plants" (OTM, p. 33) **W:** How to write a Summary? **L:** What a wonderful world (Louis Armstrong) **S:** Pharmaceutical Industry (OTM, p.14)	2	100	
17	**R:** Text for outlesson reading: "Biotechnology" (OTM, p.37) **W:** Summary **L:** Let it be (The Beatles) **S:** Pharmaceutical Industry (OTM, p.14)	2	100	
18	Making individual presentations on the topic "Biological Engineering" (OTM, p.25)	2	100	
19	Making individual presentations on the topic "My Scientific Work"	2	100	
20	**Final lesson. Review.**	2	100	

I. TEACHING MATERIAL

LESSON 1

Unit 1. The Kick-off meeting (EforPI, p.5).
R: Fab Pharmaceuticals (EforPI, p.6).
W: Academic Degrees.
L: Dialogue (EforPI, p.10)
S: Pharmaceutical Industry in Uzbekistan (OTM, p.4)

TARTER **Match what people are saying below with the department they work in.**

1
We compound the raw materials into drugs, package them, and put in the leaflets for the patients. We also keep careful records of all the steps in this process.

2
We find new substances to make new drug formulations or change existing dosage forms, for example, from tablets to capsules.

3
We compile the drug documentation and send it to the regulatory drug authorities so we can get authorization to market the product.

4
We plan the promotion and distribution of drugs which will be launched, and make decisions about the packaging or tablet colour of new products.

5
We test or organize testing on live subjects, and make sure that our drugs are safe and effective for the patients.

6
We ensure that products meet the standards which the law requires, and contain the active ingredients advertised.

- ☐ Clinical Affairs
- ☐ Marketing and Sales
- ☐ Production
- ☐ R & D (Research and Development)
- ☐ Regulatory Affairs
- ☐ QA (Quality Assurance)

- Does your company have all of these departments?
- Which department do you work in? Which one would you like to work in?
- Which departments do you work with most often?

MEMO

Fab Pharmaceuticals

From: Harvey Jones, project manager

To: Heads of departments

Re: 'CoolHead' – Kick-off meeting

Dear colleagues

The main reason I am writing to you today is to remind you that we still need you to propose people from your departments to work on our new soft gel capsule for headaches and to liaise with your departments. As you know, it will be a prescription drug, so people with experience in analgesics are the ones we'd most like to have on board.

Here is an update on the project. Since the conclusion of our successful feasibility study, we have also obtained very encouraging preclinical data. This means that we can soon start with the clinical trials and are now ready to get the project team together. The kick-off meeting will take place on 6 March in the Intercontinental Hotel. More details will follow soon.

You are probably aware that 'CoolHead' is just the working name of the new drug. The soft gel capsule will be followed soon afterwards by two other dosage forms also in the pipeline: patches and sugar-coated tablets. We plan to launch all of these products in Europe first and to apply for Food and Drug Administration (FDA) approval in the US the following year.

We still need project team members from R&D, Regulatory Affairs, and QA. As far as Marketing is concerned, Carole Marks will be flying in from France. She'll give us more information on the marketing claims and a target patient profile. From Clinical Affairs in Italy, Anna Edicola will present the clinical requirements. She, as well as Charley Wu from Production, will be connecting with us by video conference.

I'd like to get the team members' names you propose, as well as their contact details, and a brief bio on each one from you this week. Then I can invite them to the meeting. Let me know if you foresee any major difficulties at this stage.

Are the following statements true (✓) or false (✗)?

1 ☐ The most important reason for this memo is to give information about a new drug.

2 ☐ Patients who want to buy this drug will not need to see a doctor first.

3 ☐ There are three dosage forms planned at the moment.

4 ☐ The company plans to sell the drug in Europe and the United States.

5 ☐ Project members from Marketing, Production, and Clinical Affairs are already on board.

2 Match the term on the left with the definition on the right.

1 dosage form	a Medicine bought in a pharmacy and requiring a written note from the doctor.
2 feasibility study	b Future drugs, not yet on the market.
3 over-the-counter drug	c The final form of the medicine, e.g. tablet, powder, gel, spray, etc.
4 products in the pipeline	d An investigation to determine the advantages, practicality, and profitability of a proposed project.
5 prescription drug	e A product which can be sold without the patient seeing a doctor.

USEFUL PHRASES – PROVIDING INFORMATION

The main reason ...
Here is an update on the project.
As you know, ...
You are probably aware that ...
As far as ... is concerned, ...

3 Here is an extract from a memo sent by Harvey to the Head of Finance. Insert the expressions from the Useful Phrases box above in the gaps below.

_____[1] I am writing to you is to get your input on a new product. _____[2], we plan to market a new prescription drug for headaches.

But first, _____[3]. The feasibility study has just been successfully completed. _____[4] it will be marketed in Europe first. _____[5] your input _____[6], we need the financial data from your department as soon as possible.

4 **Read the job profiles and match the words in italics with the definitions on page 9.**

A

I collect drug safety information about patients *on our medications*. I must report any *serious adverse events* to the health authorities.

B

When a company starts to test drugs on live *subjects*, I work closely with the doctors to make sure that the studies are done correctly.

C

I operate complex scientific instruments and perform tests to determine whether *ingredients* in liquids, powders, or tablets meet requirements.

D

It's my job to research, write, and edit clinical and study reports before we submit them to regulatory authorities. I summarize and interpret clinical data.

E

I co-ordinate and manage the cross-functional teams that develop and launch a drug. It's not easy to get people to meet deadlines.

F

According to European law, I am personally responsible for the quality of each product that leaves the production line. I must manage all the processes in production, QA, and the labs to make sure *Standard Operating Procedures (SOPs)* are followed.

G

My job is to make sure that suitable, clean containers are used to get the product from the company to the patient. In general, I check for compliance with *health regulations*.

H

In my work, I develop pharmaceutical dosage forms. At the moment, I am changing a tablet formulation into *ointment* and gel forms.

1 _____ taking our medicine

2 _____ a substance in a drug

3 _____ a description of a working method or process

4 _____ a human or animal drugs are tested on

5 _____ any health problem which starts while on a new medicine

6 _____ rules or laws about health

7 _____ an oily substance like a cream

Now match the job profiles in A–H with the job titles below.

8 _____ clinical research associate

9 _____ formulation scientist

10 _____ laboratory technician

11 _____ medical writer

12 _____ packaging technician

13 _____ pharmacovigilance manager

14 _____ project manager

15 _____ qualified person

5 Underline the correct verb.

1 Companies must conduct / report serious adverse events to the health authorities.
2 New drugs are tested / determined on live subjects.
3 Laboratory technicians operate / perform complex scientific instruments and determine / perform whether liquids, powders, or tablets meet requirements.
4 Clinical research associates report / perform clinical trials. They must also summarize, interpret / regulate and process clinical data.
5 Regulatory Affairs reports / submits documents to regulatory authorities.
6 Formulation scientists develop / summarize pharmaceutical dosage forms.

TOPIC 1

PHARMACEUTICAL INDUSTRY IN UZBEKISTAN

Pharmaceutical industry is a development priority of ever increasing significance in Uzbekistan.

Uzbekistan has certain comparative advantages, which may be envisaged in the medium-term and long-term development strategy of the pharmaceutical industry. The competitive advantages of the domestic pharmaceutical industry, which concurrently requires development assistance, are as follows:

- Availability of research base and domestic experience of manufacturing substances and medications;
- Existence of research institutions involved in development of medical drugs, chemistry, genetics, etc., the efforts, which require major coordination, development base of clinical testing and reinforcement of international cooperation;
- Availability of research staff, capable of research work for development of new medical drugs as well as human resources training system, which could also be involved in research efforts;
- Relatively low cost of development of new medications because of low costs, compared to developed countries, main factors of their production.

Development of pharmaceutical industry enables Uzbekistan to address a number of vitalsocial objectives related to public health.

The pharmaceutical sector of Uzbekistan has set the goal for nearest future – provision of modern highly-effective medical drugs to the households and health institutions, which must be implemented based on sectoral development strategy.

1. Technological modernization of the pharmaceutical sector of Uzbekistan by setting up production of innovative medical drugs;
2. Protection of the domestic market from unfair competition and providing equal market access for domestic and foreign manufacturers;
3. Improvement of quality control of medical drugs including actions to remove redundant administrative barriers in the registration of domestically manufactured drugs;
4. Training the highly-skilled workers for development and production of pharmaceutical products according to the international standards.

The pharmaceutical market of Uzbekistan recently has demonstrated impressive trends: average annual growth rate was approximately 25% in the last two years.

The mechanism of cooperation of specialized institutions of the Academy of Sciences and the Ministry of Health with the pharmaceutical companies is being developed. To this end, Uzfarmsanoat SJSC is co-financing innovative projects to set up new technologies for production of medical drugs. Serial production of 35 medical drugs has been organized based on mutual cooperation at the experimental bases of academic and sectoral institutions in the last 3 years.

To this end, the concern is actively making business and research contracts to develop and start manufacturing new competitive medical drugs. Close collaboration is underway with the Academy of Sciences, Uzkimyosanoat SJSC, Ministry of Health, specialized departments of the Ministry of Higher and Secondary Special Education to start the production of medical drugs and introduction of new original drugs. It is planned to organize production of 44 medical substances at the experimental bases of research

institutions for production of finished medical drugs including 26 original drugs.
The list of main medical drugs includes347 drugs including 136 (or 39.1%) produced by domestic companies. Domestic manufacturers have got registered 130 medical drugs in 11 non-CIS and CIS countries (Afghanistan, Azerbaijan, Armenia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Russia, Tajikistan, Turkmenistan, and the Ukraine). Upon expansion of manufacturing base of research institutions and starting production of substances with consideration for mineral resources and industrial potential, production of a wide range of substances and components for medical drugs of animal and plant origin as well as based on inorganic, mineral, synthetic materials, production of radiopharmaceutical preparations and blood products can be arranged in Uzbekistan.

NOTES

1. envisage – imagine
2. effort – attempt
3. reinforcement – strengthening
4. implement – put into action
5. redundant – not needed, especially for a particular job
6. mutual – given or done to each other
7. collaboration – working together on a job
8. expansion – a wide area

LESSON 2.

The Kick-off meeting. Useful phrases (EforPI, p.11).
L: Harvey summary (EforPI, p.12)
R: Newspaper article (EforPI, p.16)
W: Job Advertisements.
S: Pharmaceutical Industry in Uzbekistan (OTM, p.4)

Useful phrases

PROVIDING INFORMATION

The main reason ...
Here is an update on the project.
As you know, ...
You are probably aware that ...
As far as ... is concerned, ...

INFORMING

This ... is to advise ... that ...
The ... will be reviewed ...
Our goal is to ...
... department is scheduled for ...
The ... is as follows: ...
Please make sure that ...
Please send us ...
Please confirm ...

GETTING INFORMATION AND MAKING SUGGESTIONS

Asking for and clarifying information
Could somebody fill me in on ... ?
I'd like to know what has happened.
Does that mean ... ?
I have heard ... . Is that correct?

Making suggestions
I suggest making ...
I suggest we take ...
We could consider trying ...
So, we'd better test ...

Responding to suggestions
I'll let you know what we come up with.
I'm not sure I agree with you on that.

ASKING FOR AND GIVING OPINIONS

Asking for opinions
What do you think ... ?
What's your opinion on ... ?
What's your view of ... ?

Avoiding/Withholding opinions
I would rather not say ...
I'm sorry I cannot comment on ...
I'm afraid I am not in a position to answer that.

Giving opinions
I think/I feel ...
In my opinion, ...
From my point of view, ...

Giving strong opinions
I firmly believe ...
I feel very strongly that ...
I'm sure/certain/convinced ...

SUMMARIZING ACTION POINTS

Before we close, I'd like to review ...
First of all, ...
... is to finish work by the end of the month.
... will be looking after the ...
... is going to find ...
Finally, ...
Each department needs to get back to me by ...

GIVING PRESENTATIONS

Welcoming the audience
Good morning/afternoon, ladies and gentlemen.
I'm happy to welcome you to our company.

Introducing your topic
Let me give you a brief overview of ...
I'm here to give you some information on ...
Today, I'll be talking about ...

Signposting
Moving on to the next point, ...
As I mentioned earlier, ...
Coming back to ...
Let me come back to what I said before ...

Adding points
In addition to this, ...
Moreover/Furthermore, ...
Apart from this, ...

Dealing with interruptions
Could I please finish what I was saying?
If I could just finish what I was saying ...

Dealing with questions
There will be time for questions after my talk.
Feel free to ask questions as we go along.
If you would like to ask anything, go ahead.

Finishing
Finally, I would like to add ...
As a final point, I would like to say ...
To recap, ...
I hope this has given you an idea about ...

LINKING IDEAS

Certain words are added to make additional points, or to compare or contrast ideas.

Adding a relevant point
In addition,/Additionally, ...
... not only... , but also ...
Besides, ...
Furthermore, ...

Making a comparison or a contrast
... , whereas ...
... , while
... (even) though
However, .../But ...

Read the following newspaper article.

Cross-cultural differences in marketing drugs internationally

Some companies are successful at marketing their drugs all over the world without making any major changes to them. Others have different formulations, advertising, and packaging in each country, due to differences in customs and laws. See what various experts think about this topic.

Marie Simone, European marketing consultant: In France, medicines should not only cure a disease, but also look fresh and interesting. For example, pink eye drops have been popular here, which would be unthinkable in our subsidiary in Germany. There people expect medicine to look more 'clinical'.

Sabine Schmitz, Regulatory Affairs, Germany: The strength of medicine varies considerably depending on what health authorities allow. Here, health authorities prefer companies to sell drugs with only one active ingredient, rather than in combinations. They also prefer lower drug dosages as compared to those set by authorities in other places.

Brad Townsend, consumer specialist, Canada: Some people prefer to take several small tablets per day, whereas others prefer to swallow only one big one. In some countries they would take one look at such a large tablet and say, 'I'd give it to a horse, but there's no way that is going down my throat!'

Swetlana Sheremetieva, Russian pharmacist: In Russia, we prefer to buy over-the-counter products, like cold remedies or cough syrup, from people in pharmacies wearing white lab coats. So, when foreign companies try to introduce drugs here, we ask them for good in-pharmacy training programmes because our staff will have to answer many questions before people are willing to buy such cures.

Miko Tanaka, QA specialist, Japan: Quality is important all over the world, but in Japan we take it one step further. We will reject a whole shipment of drugs if we find the smallest scratch or imperfection in one single package, even if it makes no difference to the product at all.

Harry Hart, advertising agent, USA: US patients tend to self-medicate and buy drugs online. Unlike in many countries, you'll also find many cheerful, bright coloured ads in magazines, which promote anti-depressants and other prescription drugs in the US. Of course, the next page is always full of all the warnings, possible side effects and things to ask your doctor about.

OVER TO YOU

- Can you name any medicines that are marketed differently in different countries?
- Should companies try to keep their medicines as similar as possible wherever they are sold?
- Are there any cultural preferences in the way medicines are marketed throughout the world? Do you think any of these differences are important?

9 **Put information about yourself in the form below. Then use it to introduce yourself to the group.**

Name:

Nationality:

Educational background:

Work experience:

Expertise:

Current position:

Responsibilities:

Current tasks:

AUDIO 3

10 **Listen to Harvey summarize the decisions taken at the meeting. Match the list of action points with their deadlines to build sentences.**

1	☐	Iris is to place all job ads for clinical research associates in trade journals	a by Friday.
2	☐	Walter is to prepare a progress report on his work on the other dosage forms	b within the next two weeks.
3	☐	Department heads are to estimate the time needed for their department's work	c by the beginning of next week.
4	☐	Charley is to describe the technical equipment needed with a cost estimate	d before the next meeting.
5	☐	Harvey is to work out the timelines, milestones, and budgeting	e by the end of next month.
6	☐	Rasheed is to review any legal or regulatory issues	f by the end of the month.

USEFUL PHRASES – SUMMARIZING ACTION POINTS

Before we close, I'd like to review ...
First of all, ...
... is to finish work by the end of the month.
... will be looking after the ...
... is going to find ...
Finally, ...
Each department needs to get back to me by ...

13 **Use the expressions above to fill the gaps in the job advertisement.**

JOB TITLE – CHEMIST

WJH

DESCRIPTION

CRO _____[1] someone to co-ordinate and perform analytical testing for stability studies of new products. You _____ _____[2] review data in accordance with Good Manufacturing Guidelines. You will be _____[3] checking laboratory documentation and chemical specifications. It is _____[4] to use a wide variety of physical and chemical analyses to support shelf-life studies of patented pharmaceutical products.

REQUIREMENTS

- At a minimum a BS in Chemistry or a related science is _____[5], an MSc is _____[6].
- You should have at least three _____[7] in pharmaceutical analytical techniques and test methods.

JOBS IN THE PHARMACEUTICAL INDUSTRY

PTA: Assistant or Technician?

Direct translations of job titles can be misleading. For example, if a PTA is described to someone in the US or UK as 'pharmaceutical technical assistant', it would sound as if this person has an entry-level position, possibly without any previous job training. In English, 'pharmaceutical technician' or 'pharmaceutical laboratory technician' would be better descriptions.

Junior vs. Senior; Scientist 1, 2, 3

The amount of training, the number of years of experience, and the salary scientists have, can often be seen in their job titles. Whereas a recent university graduate may start as a junior scientist, or scientist 1, the more experienced colleague would be a senior scientist, or scientist 2 or 3.

Associate

Many job titles include the word 'associate', for example, a research associate, a QA associate, an associate research scientist, or drug safety associate. This very general title roughly means 'partner'. In a pharmaceutical company, it usually refers to a professional with a degree, or specialized training, who has a certain area of responsibility.

14 **Choose a job title and write an email to Iris. Describe the main points for the position.**

Dear Iris

We will need to fill the position of _____ (job title) shortly.

I'd appreciate it if you could write up a job advertisement with the input below and place it in the pharmaceutical journal we normally use.

Here is a list of the main points:

Key duties / responsibilities

_____

_____

Educational background

_____

_____

Other skills needed

_____

_____

Let me know if you need any further information.

Thanks for your help.

Best regards

_____ (Name)

15 **Each column contains a category and some terms listed under it. Cross out the term that does <u>not</u> fit in each category.**

non-production pharmaceutical professions	dosage forms	What goes into drugs?	pharmaceutical documentation
clinical research associate	capsules	chemicals	clinical reports
formulation scientist	gel	formulation	dossiers
laboratory technician	ointment	ingredient	marketing claims
line worker	prescription drug	raw materials	protocols
pharmacovigilance manager	sugar-coated tablets	substances	study reports

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- Relatively low cost of development of new medications because of low costs, compared to developed countries, main factors of their production.

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To this end, the concern is actively making business and research contracts to develop and start manufacturing new competitive medical drugs. Close collaboration is underway with the Academy of Sciences, Uzkimyosanoat SJSC, Ministry of Health, specialized departments of the Ministry of Higher and Secondary Special Education to start the production of medical drugs and introduction of new original drugs. It is planned to organize production of 44 medical substances at the experimental bases of research

institutions for production of finished medical drugs including 26 original drugs.
The list of main medical drugs includes347 drugs including 136 (or 39.1%) produced by domestic companies. Domestic manufacturers have got registered 130 medical drugs in 11 non-CIS and CIS countries (Afghanistan, Azerbaijan, Armenia, Georgia, Kazakhstan, Kyrgyzstan, Latvia, Russia, Tajikistan, Turkmenistan, and the Ukraine). Upon expansion of manufacturing base of research institutions and starting production of substances with consideration for mineral resources and industrial potential, production of a wide range of substances and components for medical drugs of animal and plant origin as well as based on inorganic, mineral, synthetic materials, production of radiopharmaceutical preparations and blood products can be arranged in Uzbekistan.

NOTES

9. envisage – imagine

10. effort – attempt

11. reinforcement – strengthening

12. implement – put into action

13. redundant – not needed, especially for a particular job

14. mutual – given or done to each other

15. collaboration – working together on a job

16. expansion – a wide area

LESSON-3.

Unit 2. Substance Discovery and Product Development (EforPI, p.17**)**

R: Mensamint (EforPI, p.18)

L: Minutes of Tuesday's brainstorming meeting (EforPI, p.20)

W: Drug Discovery.

S: Pharmaceutical Industry in the UK (OTM, p.6)

Read the following newspaper article.

Cross-cultural differences in marketing drugs internationally

Some companies are successful at marketing their drugs all over the world without making any major changes to them. Others have different formulations, advertising, and packaging in each country, due to differences in customs and laws. See what various experts think about this topic.

Marie Simone, European marketing consultant: In France, medicines should not only cure a disease, but also look fresh and interesting. For example, pink eye drops have been popular here, which would be unthinkable in our subsidiary in Germany. There people expect medicine to look more 'clinical'.

Sabine Schmitz, Regulatory Affairs, Germany: The strength of medicine varies considerably depending on what health authorities allow. Here, health authorities prefer companies to sell drugs with only one active ingredient, rather than in combinations. They also prefer lower drug dosages as compared to those set by authorities in other places.

Brad Townsend, consumer specialist, Canada: Some people prefer to take several small tablets per day, whereas others prefer to swallow only one big one. In some countries they would take one look at such a large tablet and say, 'I'd give it to a horse, but there's no way that is going down my throat!'

Swetlana Sheremetieva, Russian pharmacist: In Russia, we prefer to buy over-the-counter products, like cold remedies or cough syrup, from people in pharmacies wearing white lab coats. So, when foreign companies try to introduce drugs here, we ask them for good in-pharmacy training programmes because our staff will have to answer many questions before people are willing to buy such cures.

Miko Tanaka, QA specialist, Japan: Quality is important all over the world, but in Japan we take it one step further. We will reject a whole shipment of drugs if we find the smallest scratch or imperfection in one single package, even if it makes no difference to the product at all.

Harry Hart, advertising agent, USA: US patients tend to self-medicate and buy drugs online. Unlike in many countries, you'll also find many cheerful, bright coloured ads in magazines, which promote anti-depressants and other prescription drugs in the US. Of course, the next page is always full of all the warnings, possible side effects and things to ask your doctor about.

OVER TO YOU

- Can you name any medicines that are marketed differently in different countries?
- Should companies try to keep their medicines as similar as possible wherever they are sold?
- Are there any cultural preferences in the way medicines are marketed throughout the world? Do you think any of these differences are important?

Read the explanations and put the following words or expressions into the correct column.

Research – the process of testing chemical compounds, with the goal of finding a substance which has a beneficial effect on a targeted disease.

Development – the process of carrying forward scientific discoveries made during the research process, with the goal of producing a marketable drug.

analysis of disease • analytical testing • clinical trials • dosage forms • drug safety • discovery • new chemical entities (NCEs) • target identification

Research	Development
_____	_____
_____	_____
_____	_____
_____	_____

What kinds of R & D projects are there in your company at the moment?
Which process takes longer – research or development? Why?
What factors help pharmaceutical companies decide what drugs they should develop?

1 **Read the memo and the information about Mensamint™.**

MEMO MEMO MEMO

Caduceus Pharmaceuticals Ltd

Date: Tuesday

To: Pharmaceutical department – Chemists and Pharmacologists

From: John Keyes, Vice President R&D

Subject: Breakthrough in search for NCE for *Mensapatch*™ development

As some of you will already know, a new chemical entity has just been synthesized in our own labs, which we think may be useful in our *Mensapatch*™ development plans.

A meeting will be held tomorrow at 9.30 a.m. in conference room 308 to brainstorm ideas for this new substance, and to discuss the further development. Your participation would be appreciated.

JK

MENSAMINT™

Mensamint™ is a new dosage form of *Mensadent*™ (obtainable with physician's prescription only). It uses the newly synthesized active substance mensagitatum (Latin origin: the mind moves/animates).

The formulation for adult patients is in lozenge form (or as *Mensadent*™ in chewing gum form for young patients), and the indication is to stimulate brain activity and thinking power.

Known side effects often include loss of sleep if taken in the late afternoon or evening. Occasionally, an increase in blood pressure may occur. Rare instances of heart palpitations and headaches have also been reported. It is not possible to overdose and mensagitatum is non-addictive.

Answer the following questions.

1 What is the meeting about, and what needs to be discussed? _____

2 What kind of product is *Mensamint*™? _____

3 What do patients have to do to obtain it? _____

4 What are the dosage forms of this product? _____

5 Are there any known side effects? _____

2 **An R& D meeting takes place, in which John answers questions about a new chemical substance. Read his answers below and write your own version of the questions. Then listen to the meeting and check your answers. Note: not every question is asked during the meeting.**

1 _____

It is already available in lozenge and chewing gum form, but we hope to develop a time-release patch in the near future.

2 _____

We will have to test the bioavailability to be able to calculate dosages for non-intravenous routes of drug administration for this NCE.

3 _____

As you know, when substances are taken with alcohol or antibiotics, their chemical form could change and even cause harmful side effects. I'll keep you informed.

4 _____

Not completely. However, we do have a partner to help us develop a patch form which provides the desired effects for at least six hours.

5 _____

I'm afraid it may take a year or more before we can start the first tests on healthy humans.

ASKING ABOUT DRUG DISCOVERY AND DEVELOPMENT

Dosage	**Development**
What kind of formulation could we develop?	What is the toxicity of this NCE?,
What about using other forms?	What about the bioavailability of this NCE?
Are tablets, capsules, or drops possible?	When can we start the first in-man study?
What about the dosage for these forms?	Do we have the technology to make patches?

3 **Put the correct form of one of the vocabulary items from the box into the sentences below.**

chemist • dosage form • formulation • in-man study • prescription • toxicology

1 A specialist or expert in the scientific field of chemistry is called a _____. In the UK, this word is also used for the person who prepares and sells medicine, also known as a pharmacist in the US.

2 Using the right _____ is especially important when giving medicine to children, because they often have problems swallowing pills.

3 The science of poisons, including their source, chemical composition, action, tests, and even their antidotes, is what we call _____.

4 If a drug or medicine is not available 'over-the-counter', it normally means that a _____ from a physician is needed to obtain it from a pharmacy.

5 Chemists and pharmacologists are also interested in how the medicine is administered, so they often ask about its _____.

6 Before drugs or medicines can be made available to the public, they have to be tested on human beings. We call this an _____. It is also called a phase 1, stage 1 study, or clinical trial.

4 **A few days later, the participants received the minutes of the meeting. Listen again to exercise 2 and put the paragraphs in the correct order.**

Minutes of Tuesday's brainstorming meeting

The Vice President of R & D began the meeting on time and welcomed all the participants. He also mentioned that Derek from Pharmacokinetics was out of town and was not able to attend.

A ☐ *Finally*, Brian asked if the new dosage form could be made with current technology.

B ☐ *Next*, there was some discussion about the time frame necessary for in-man studies.

C ☐ *Then* Marcus brought up the subject of the NCE's toxicity.

D ☐ Hilda *initially* asked what kind of formulation could be developed from the new NCE.

E ☐ *After that*, Frank asked about the bioavailability of the new chemical entity.

The meeting finished at 10.30 a.m. The next meeting for all participants, including Derek, will take place in one week. We will then decide how to proceed.

PHARMACOKINETICS VS. PHARMACOLOGY

Pharmacology is the study of drugs, how they work, and what they do in the body. Pharmacology can be divided into two separate areas: pharmacodynamics and pharmacokinetics. Pharmacodynamics studies what the drug does to the body, and pharmacokinetics studies what the body does to the drug.

TOPIC 2

PHARMACEUTICAL INDUSTRY IN THE UNITED KINGDOM

The pharmaceutical industry in the United Kingdom directly employs around 72,000 people. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The British pharmaceutical sector enters the top 3 leading industrial sectors in the frame of the whole economy, which export stably exceeds import over the past 25 years. As to the number of employed (more than 73 thou men), the sector takes the 6 place among the leading British industrial fields.

The pharmaceutical field of Great Britain is dynamic and fast growing. Great Britain takes the 2 place following after the USA by the total volume of the occupied share in market, exceeding all European states. Interests of the British pharmaceutical branch are presented by the Association of the British Pharmaceutical Industry. The Association represents the interests of the most of producers and suppliers of medicines at the National Health Care Service.

One of the highly important questions for the government of the state is to preserve a status of Great Britain to be advantageous for investments into the pharmaceutical sector. Due to thus condition the state creates all necessary terms for development of R&D in the pharmaceutical sector. The pharmaceutical companies of Great Britain share a quarter of all expenses of the state in the R&D area. At least 20% of known medicines in the world were produced in Great Britain. 12 in 25 widely used medicines in the world, as prescription drugs in Great Britain, are produced within the state. A registration of medicines in Great Britain is put into effect by a specialized agency the Medicines and Healthcare products Regulatory Agency (MHRA) in accordance with the EU directives.

NOTES

1. ensure – guarantee
2. devices – equipment
3. share – each of the equal parts

LESSON-4.

Substance Discovery and Product Development.

L: Hospital In-Patient Dosage Form Survey Results (EforPI, p.23)

R: How many drug categories do we need? (EforPI, p.26)

W: Dosage Forms.

S: Pharmaceutical Industry in the UK (OTM, p.6)

Talk about a drug in research at your company. Mention the following points:

development period • dosage form • study results • toxicity

7 **Match the words from the box with the pictures, and fill in the gaps in the following text with the correct dosage form.**

dosage • drops • patch • pills • suppository • syrup • tablets

a _____ b _____ c _____

d _____ e _____ f _____ g _____

1 Calculating the correct _____ for some patients isn't always easy.

2 Children and older people often have trouble swallowing large _____ or _____.

3 Wearing a _____ may create problems for people with skin allergies.

4 Some medications are available in liquid form, such as _____ or _____.

5 We often use a _____ to administer medication to babies or other patients who are not able to take drugs orally.

8 **Helen from Marketing Research calls John, Vice President of R & D, to discuss the results of a hospital in-patient survey on dosage forms for a new medication. The company needs to know which drug dosage forms patients prefer. Listen to the telephone call and fill in the form below.**

Hospital In-patient Dosage Form Survey Results

1. Total number of in-hospital patients surveyed (a) _____

2. Male patients (b) _____ Female patients (c) _____

3. Average patient age (d) _____

4. Which of the following *oral* dosage forms are the patients *currently* using?

tablet (e)	_____	gel tablet (f)	_____	capsule (g)	_____	pill (h)	_____
solution	_____	drops	_____	syrup	_____	other(s)	_____

5. Which of the following dosage form(s) do the patients favour?

oral dosage forms

tablet	_____	gel tablet (i)	_____	capsule (j)	_____	pill	8 %
solution	_____	drops (k)	_____	syrup (l)	_____	other(s)	_____

inhaled dosage forms

aerosol (m)	_____	inhaler	_____	other(s)	_____

topical dosage forms

cream (n)	_____	ointment (o)	_____	liniment	_____	lotion	_____
gel	_____	patch (p)	_____	other(s)	_____		

other dosage forms

nasal spray	_____	eye drops	_____	suppository	_____

6. What kinds of side effects did the patients have with their current medication?
The following side effects were experienced:

allergic reactions	794	diarrhoea	29	dizziness	3
fever	75	headache	91	indigestion	422
insomnia	47	itching	70	nausea	253
skin rashes	59	vomiting	17	other(s)	

7. Do the patients have any suggestions for other future forms of medication?
List all suggestions here:

_____

8. Do the patients have any of the following chronic health conditions?

asthma	794	anaemia	121	bronchitis	805	diabetes	83	heart condition	21

9 Answer the following questions using the information in exercise 8.

1 How many patients were surveyed in all?

_____

2 Were more male or female patients interviewed?

_____

3 What kind of dosage form is most preferred by the patients surveyed?

_____

4 What kinds of side effects were experienced by the least number of patients?

_____

5 What chronic health conditions did most patients have?

_____

10 Match the dosage form on the left to its definition on the right.

1 ☐	aerosol	a	A very small amount of liquid that forms a round shape.
2 ☐	drops	b	An smooth, thick substance to rub on the skin for healing.
3 ☐	inhaler	c	An oily liquid to rub on painful body parts to reduce pain.
4 ☐	liniment	d	A medication on material or cloth placed on the skin.
5 ☐	ointment	e	A small, round piece of medicine to be swallowed without chewing.
6 ☐	patch	f	A container with a liquid that is administered in spray form.
7 ☐	pill	g	A liquid in which another substance has been dissolved.
8 ☐	solution	h	A solid medicine which melts slowly in the rectum or vagina.
9 ☐	suppository	i	A sweet, liquid medicine taken with a spoon or cup.
10 ☐	syrup	j	A small device with medicine to breathe in through the mouth.

ASKING FOR AND GIVING OPINIONS

Asking for opinions
What do you think ... ?
What's your opinion on ... ?
What's your view of ... ?

Giving opinions
I think/I feel ...
In my opinion, ...
From my point of view, ...

Avoiding/Withholding opinions
I would rather not say ...
I'm sorry I cannot comment on ...
I'm afraid I am not in a position to answer that.

Giving strong opinions
I firmly believe ...
I feel very strongly that ...
I'm sure/certain/convinced ...

11 Rephrase the following statements for conducting or taking part in a survey. Use the Useful Phrases above.

1 A new drug has recently been developed to cure heart disease. (Ask for opinion)

_____

2 More than one dosage form is being considered: pill, and patch. (Ask for opinion)

_____

3 The in-man studies for this drug will take more than six months. (Give opinion)

_____

4 Additional clinical trials should be done in other countries. (Give opinion)

_____

5 This new formulation will be successful. (Give strong opinion)

_____

6 A third dosage form should be developed: nasal spray. (Give strong opinion)

_____

7 You don't have enough information to make a statement. (Avoid opinion)

_____

8 You don't want to share the information you have yet. (Avoid opinion)

_____

What kind of medication is often taken on a regular basis, and in what form?
Which side effects do you feel people dislike the most?
Do you prefer to take medication in a particular form? If so, which form, and why?

TOPIC 2

PHARMACEUTICAL INDUSTRY IN THE UNITED KINGDOM

The pharmaceutical industry in the United Kingdom directly employs around 72,000 people. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency which is responsible for ensuring that medicines and medical devices work and are acceptably safe. The British pharmaceutical sector enters the top 3 leading industrial sectors in the frame of the whole economy, which export stably exceeds import over the past 25 years. As to the number of employed (more than 73 thou men), the sector takes the 6 place among the leading British industrial fields.

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NOTES

4. ensure – guarantee
5. devices – equipment
6. share – each of the equal parts

LESSON-5.

Unit 3. Quality Assurance and Auditing (EforPI, p.27**)**
R: Berner Pharmaceuticals Ltd (EforPI, p.28)
L: Laboratory staff meeting (EforPI, p.33)
W: Laboratory safety systems.
S: Pharmaceutical Education in the UK (OTM, p.6)

Berner Pharmaceuticals Ltd

Internal Audit Checklist – Laboratory Systems

Date: _____ **Audited by:** _____ **and** _____

Objective:
To monitor the laboratory quality system and take any needed corrective or preventive action to assure industry compliance in laboratory procedures.

Interviews with personnel (who?):

_____

_____

_____

Examination of documentation (what?):

_____

_____

_____

Observation of activities and conditions (list these on separate page):

Review of quality and technical procedures (list these on separate page):

Results (write preliminary report with suggested corrective action with copies to head of audited department):

Action (list of corrective or preventive action taken by whom and when):

_____

_____

_____

_____

_____

Date of next audit (six months from now):

_____

_____

_____

Read the article below about different classes of drugs in different countries.

How many drug categories do we need?

On the whole, countries establish specific rules and regulations not only on the type of drugs made available, but also on how they reach the consumer. On the one hand, medicine needs to be easily accessible. This is, of course, a question of public health. On the other hand, these same products can do harm if used incorrectly. This danger must be avoided.

For this reason, regulatory authorities in every country set the number of categories for drugs. For example, in Canada, there are four:

1) drugs available only with a prescription
2) those without a prescription, but only with the personal involvement of a pharmacist
3) medicine which customers can pick off open shelves, but only in a pharmacy, and
4) products which can be openly sold in any kind of retail outlet.

By contrast, the US only has two official categories: drugs needing a prescription and drugs that do not. The former are prescription drugs and are available in pharmacies and only by prescription. The latter are over-the-counter drugs which can be sold in any type of retail outlet that chooses to stock them.

In general, in the US, medication must meet four criteria in order to obtain the status of a non-prescription or over-the-counter (OTC) product. It must have:

- a large margin of safety
- low incidence of side effects
- low potential for misuse and abuse, and
- labelling that provides adequate directions for sale and effective use.

At present, the Food and Drug Administration is reviewing its current policy on the number of categories. It is discussing the introduction of a new intermediate category for the US market called 'behind-the-counter' (BTC) medicine. Drugs of this type would need no prescription, but would require a pharmacist's intervention and resemble category 2) in Canada. One reason is that consumers in many Western countries have found this new category beneficial.

In Europe, the concept of BTC has been practised with great success for years. People can just go to their local pharmacy and describe their medical need. The pharmacist simply recommends an appropriate drug without first requiring a doctor's prescription. He or she can also suggest a less expensive drug in generic form. The disadvantage, however, for many Europeans is that the cost of these drugs or medications is not taken on by the health insurance system.

Currently, the FDA is faced with a difficult decision. If it decides to add the category BTC, this will have definite consequences for the pharmaceutical industry in the US. In the short term, this change would immediately force the pharmaceutical companies to reorganize their marketing efforts. In the long term, companies and research institutes would need to reassess their own potential and reconsider which type of drugs are worth testing. ■

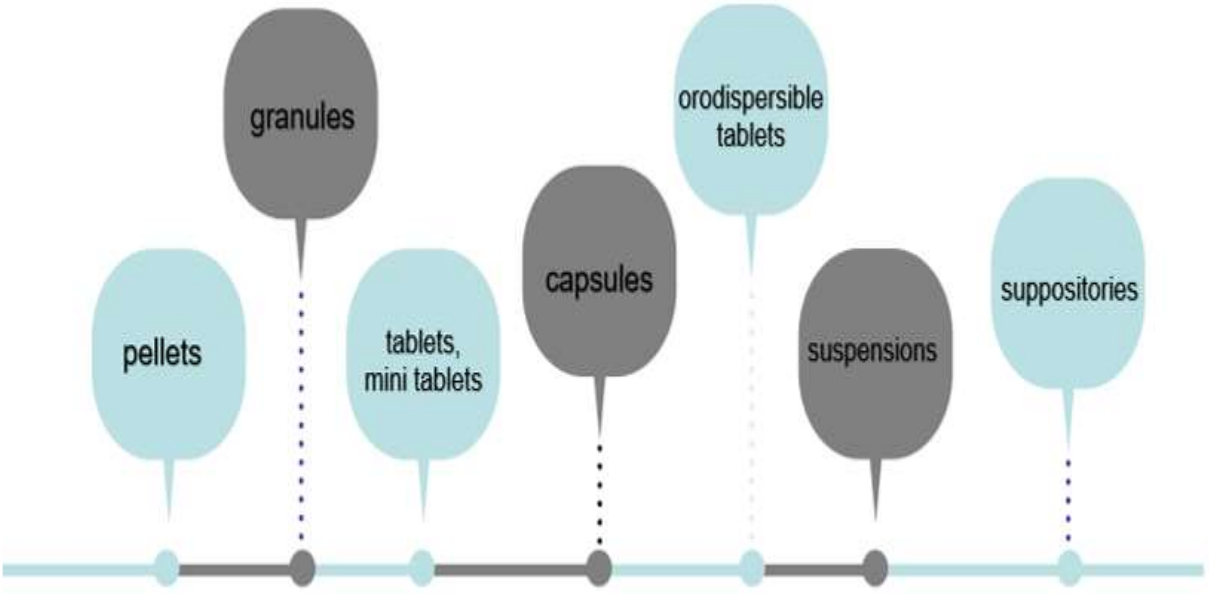
Formulation Development

BOC Sciences provides powerful formulation development services to support the development of many chemical substances. Our experts are fully aware of the

importance of developing stable and compliant formulations to help customers find the right API and the best dosage forms for pharmaceuticals. Our R & D team has extensive experience in formulation research and analysis, as well as in collaborative practice with global customers for formulation development and analytical support. Our goal is to help the testing of molecules speed through the early stages and prepare our customers for commercial success faster.

We have experience formulating a variety of dosage forms including but not limited to:

We have experience formulating a variety of dosage forms including but not limited to:



Drug development process

A variety of approaches is employed to identify chemical compounds that may be developed and marketed. The current state of the chemical and biological sciences required for pharmaceutical development dictates that 5,000–10,000 chemical compounds must undergo laboratory screening for each new drug approved for use in humans. Of the 5,000–10,000 compounds that are screened, approximately 250 will enter preclinical testing, and 5 will enter clinical testing. The overall process from discovery to marketing of a drug can take 10 to 15 years. This section describes some of the processes used by the industry to discover and develop new drugs. The flowchart provides an overall summary of this developmental process.

Discovery

Typically, researchers discover new drugs through:

- New insights into a disease process that allow researchers to design a product to stop or reverse the effects of the disease.
- Many tests of molecular compounds to find possible beneficial effects against any of a large number of diseases.
- Existing treatments that have unanticipated effects.
- New technologies, such as those that provide new ways to target medical products to specific sites within the body or to manipulate genetic material.

At this stage in the process, thousands of compounds may be potential candidates for development as a medical treatment. After early testing, however, only a small number of compounds look promising and call for further study.

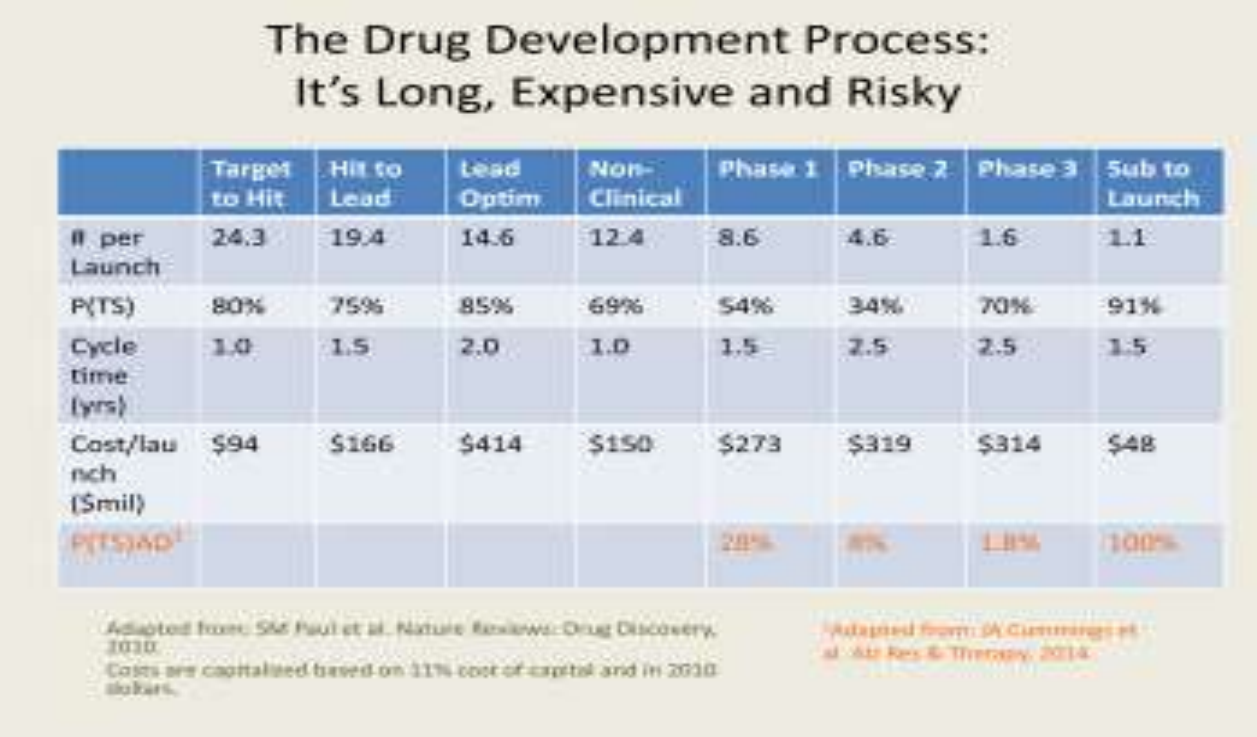
Development

Once researchers identify a promising compound for development, they conduct experiments to gather information on:

- How it is absorbed, distributed, metabolized, and excreted.
- Its potential benefits and mechanisms of action.
- The best dosage.
- The best way to give the drug (such as by mouth or injection).
- Side effects or adverse events that can often be referred to as toxicity.
- How it affects different groups of people (such as by gender, race, or ethnicity) differently.
- How it interacts with other drugs and treatments.
- Its effectiveness as compared with similar drugs.

Pharmaceuticals are produced as a result of activities carried out by a complex array of public and private organizations that are engaged in the development and manufacture of drugs. As part of this process, scientists at many publicly funded institutions carry out basic research in subjects such as chemistry, biochemistry, physiology, microbiology, and pharmacology.

Basic research is almost always directed at developing new understanding of natural substances or physiological processes rather than being directed specifically at development of a product or invention. This enables scientists at public institutions and in private industry to apply new knowledge to the development of new products. The first steps in this process are carried out largely by basic scientists and physicians working in a variety of research institutions and universities. The results of their studies are published in scientific and medical journals. These results facilitate the identification of potential new targets for drug discovery. The targets could be a drug receptor, an enzyme, a biological transport process, or any other process involved in body metabolism. Once a target is identified, the bulk of the remaining work involved in discovery and development of a drug is carried out or directed by pharmaceutical companies.



TOPIC 3

PHARMACY EDUCATION IN THE UNITED KINGDOM

This article provides an overview of the current status of pharmacy education in the United Kingdom. A characteristic program is described which is based on the master of pharmacy (MPharm) model, which is an “undergraduate” master's degree. The type and length of training, numbers entering and leaving the profession, and criteria for admission are discussed, and an overview of the curriculum, which is normally based over 4 years, is given. The career opportunities of UK pharmacy graduates are discussed, as well as educational challenges such as plagiarism and the changing profile of schools of pharmacy, which is affecting supply and demand of pharmacists. The changing face of the profession in the UK is then addressed, including the advent of the prescribing pharmacist.

Historically, entrance to the pharmacy profession required successful completion of a 3-year Bachelor of Science (BSc) degree followed by 1 year preregistration work under appropriate supervision. Since the turn of the century, however, the recognized qualification that permits registration with the Royal Pharmaceutical Society of Great Britain (RPSGB) has been the 4-year MPharm program, followed by the compulsory 1-year work program prior to application for registration as a pharmacist.

The United Kingdom's 4-year degree is the shortest of the European pharmacy degrees. The MPharm programs fulfill all of the criteria required under European regulations concerning equivalence of qualifications: a European Union citizen achieving an MPharm degree is thus eligible to apply for registration in any of the European member states having completed their work placement experience.

There are 22 schools of pharmacy in the United Kingdom offering MPharm degrees. Each school admits an average of 150 students to their MPharm program each year; thus, the United Kingdom provides approximately 3300 undergraduate pharmacy places per year (for a total population of about 60 million); this may rise in the future.

In the case of medical school, students can apply to 4 medical programs only, plus 1 other non-medicine program. The majority of students applying for pharmacy apply exclusively to pharmacy programs, although approximately 20% list pharmacy as their fifth choice after the 4 medicine applications. On average, each school of pharmacy receives approximately 8-10 applicants for each place on their MPharm program, but taking into account that each applicant has applied to 4 other schools of pharmacy, this translates to 10,000 applicants for the 3,300 places across the UK per year.

Entry qualifications vary slightly across the 22 UK schools of pharmacy, but the most important deciding factor for most applicants is performance in the national school-leaving examinations (Advanced Levels also known as A-Levels). A-Levels are the final

examinations taken by 18-year-old school-leavers. The 3 subjects normally studied at A-Level before applying for the MPharm program are chemistry, math, and biology.

In recent years, funding of UK higher education has changed. There are no formal requirements for experiential education or clinical placements (which is the term used in the UK) within the MPharm program, but it has become an expectation. Most schools offer at least 1 week total over the 4 years; some offer much more (up to 4 weeks). It is clinical placements that have created most anguish to program leaders over the last few years. Hospitals and some other pharmacists have made it a requirement that students have been fully screened by the UK Criminal Records Bureau (CRB) before being allowed entry to hospital premises. In comparison to other European pharmacy programs, the UK programs stand out in that they provide the underlying scientific and theoretical knowledge, alongside experimental and clinical expertise. Therefore, at the end of the 4-year program, the graduate is fully equipped to enter the clinical/practice arena. This differs from some other European programs where the university components of the education concentrates purely on the scientific aspects before the students graduate and enter the pharmacy practice training arena. The UK programs, at 4 years, are the shortest university programs in Europe (elsewhere in Europe, pharmacy programs are 5-6 years).

NOTES

1. overview – general survey or summary
2. curriculum – the subjects included in a course of study
3. compulsory – obligatory
4. eligible – meeting the conditions to do or receive something
5. admit – allow to enter
6. requirement – something that is compulsory (needed)
7. anguish – severe pain or distress
8. experiential – relating to experience and observation

LESSON-6.

Quality Assurance and Auditing.

L: Conversation (EforPI, p.34)

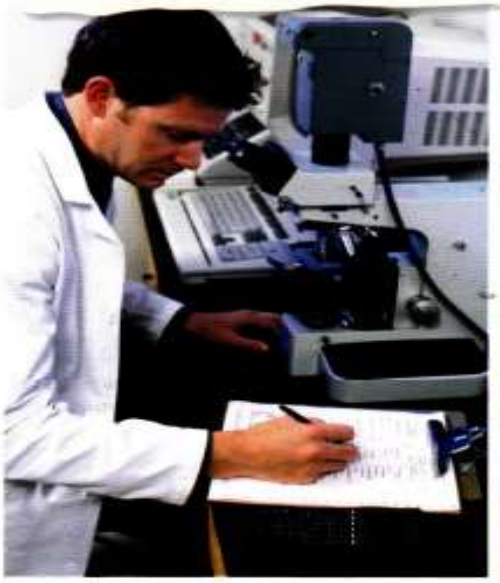
R: Drug contamination**:** Lessons to be learned? **(**EforPI, p.38**)**

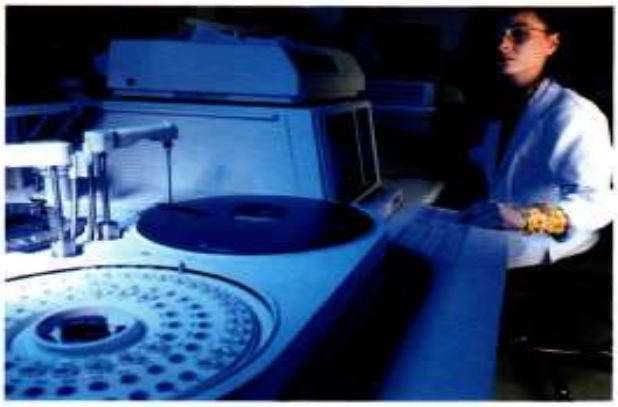
W: My Company.

S: Pharmaceutical Education in the UK (OTM, p.6)

Read the definition of 'good practice', then match the words with the correct abbreviations.

GxP is an abbreviation for 'good practice'. The 'x' is used to indicate the many different areas of 'good practice' which are required by international regulatory authorities.





GAP, GCP, GDP, GLP, GMP, GRP, GSP

auditing • clinical • documentation • laboratory • manufacturing • research • safety

It's good _____ *practice.*

- Which of these forms of good practice are you familiar with?
- Can you give examples of good practice requirements used in your company?

According to the text, which answer is <u>not</u> correct?

1 Why is product sampling carried out?
a To introduce product quality.
b To check product quality.
c To make sure SOPs are followed.
d To meet high industry standards.

2 Which aspect of drug manufacturing enables traceability?
a quality assurance
b quality control
c holistic approach
d documentation

3 Why do operational methods and procedures have to be validated?
a To complete the quality assurance process.
b To make sure products perform their intended function.
c To complete the inspection process.
d To isolate products of high quality.

Berner Pharmaceuticals Ltd provides employees with general information on GMP on its intranet. Read the following text and answer the questions.

Berner Pharmaceuticals Ltd

Login User: Password:

In the pharmaceutical industry, different **quality assurance** processes are required for each area of good practice (GxP).

It is easiest to understand how good practice works in the area of manufacturing. The quality assurance process in good manufacturing practice (GMP) includes product **quality control**, sampling, and testing. Quality control ensures that the product quality remains high. The reason for interim testing, or **product sampling**, is to check the quality of pharmaceutical products. This is important to make sure that the product is **suitable** for its intended use and for sale. **Endpoint testing** is carried out at the end of every manufacturing process. This is to ensure that all procedures have been performed in compliance with industry and company standards.

Documentation is important and necessary at every step of the processes, activities, and operations involved in drug manufacturing. If the documentation is not in order, or if the required specifications are not met, then the product is considered **contaminated**. Proper documentation not only enables **traceability**, but also allows a complete **product recall** from the market, if necessary.

Inspection and **validation** are required to prove that the manufacturing and testing equipment is functional. All operational methods and procedures must also be inspected for accuracy. Most companies do this voluntarily through internal audit processes.

However, beyond the field of manufacturing, good practice must be adhered to in all processes in a pharmaceutical company. No process can be considered isolated from the others. For example, laboratory and manufacturing processes cannot be regarded separately. A **holistic approach** looks at all these environments to make sure that the entire process meets high industry standards.

Standard operating procedures (SOPs) are written and used by companies to make it easier for them to follow GxP. These are a set of written instructions to maintain performance and results. They are also the basis of every good quality assurance and quality control system.

5 **In order to comply with the internal audit requirements for Good Laboratory Practice (GLP) of the European Medicines Agency (EMEA) for pharmaceutical firms, Berner Pharmaceuticals Ltd needs to complete an audit of their current laboratory safety systems and procedures. Read the memo from the Quality Assurance Internal Auditing Department and answer the questions.**

Berner Pharmaceuticals Ltd B|P

– Interoffice Memorandum –

Date:	Monday
To:	Philip Reuter, Laboratory Management
From:	Joseph Mason, Quality Assurance Internal Auditing
Subject:	Annual audit of SOPs for laboratory safety
Cc:	Richard Jacobs, Senior Quality Auditor; Gail Webber, Operations Auditor
Attachment:	Audit checklist for laboratory systems and procedures (see p. 86)

This memo is to advise you that your department has been scheduled for a periodic audit of the laboratory safety systems and procedures.
The timetable for the various laboratory audits is as follows:

Laboratory 1: Tuesday and Wednesday
Laboratory 2: Wednesday and Thursday
Laboratory 3: Thursday and Friday

Please make sure that all the laboratory staff are advised and prepared in accordance with standard audit procedure. Two members of our audit team (Richard Jacobs and Gail Webber) will begin this internal audit on Tuesday, two weeks from tomorrow, using the latest company-approved audit checklist (see attachment).

The completed checklist and original audit results will be reviewed with you and the Research and Development Vice President. Our goal is to identify any areas requiring corrective or preventive action before a summary report of the status of these actions is issued. This is done to assure compliance with industry standards, especially for safety procedures.

Please confirm receipt of this memo and send us a copy of all your correspondence with regard to this scheduled audit.

J. Mason

1 What kind of internal audit has been scheduled? _____

2 What is the objective of this audit? _____

3 How often does this type of audit have to be done? _____

4 When will the audit take place? _____

5 What documentation is necessary for the audit? _____

- Does your company also have planned or scheduled audits? If so, for which areas and how often are they carried out?
- Have you ever been part of an internal audit? What did you do?
- What kind of special procedure(s) does your company follow for internal audits?

CAPA

Corrective Action/Preventive Action (CAPA) is a part of the overall Quality Management System (QMS) required for GMP. It focuses on the systematic investigation of non-conformance events (errors or deviations), to prevent their occurrence (for preventive action) or recurrence (for corrective action).

USEFUL PHRASES – INFORMING

This ... is to advise ... that ...	The ... is as follows: ...
The ... will be reviewed ...	Please make sure that ...
Our goal is to ...	Please send us ...
... department is scheduled for ...	Please confirm ...

4 Match the tasks on the left with the phrases on the right.

1	☐ You state the reason for a memo.	a	Please send us ...
2	☐ You state the objective of a course of action.	b	This memo is to advise you that ...
3	☐ You say the planned schedule.	c	Our goal is to ...
4	☐ You ask for verification of some information.	d	The laboratory procedures will be reviewed ...
5	☐ You need to have a copy of something.	e	Please confirm ...
6	☐ You say which department in the company is involved.	f	Please make sure that ...
7	☐ You say what areas will be audited.	g	The lab management department is scheduled for an audit ...
8	☐ You say what should be done.	h	The timetable is as follows ...

TOPIC 3

PHARMACY EDUCATION IN THE UNITED KINGDOM

This article provides an overview of the current status of pharmacy education in the United Kingdom. A characteristic program is described which is based on the master of pharmacy (MPharm) model, which is an “undergraduate” master's degree. The type and length of training, numbers entering and leaving the profession, and criteria for admission are discussed, and an overview of the curriculum, which is normally based over 4 years, is given. The career opportunities of UK pharmacy graduates are discussed, as well as educational challenges such as plagiarism and the changing profile of schools of pharmacy, which is affecting supply and demand of pharmacists. The changing face of the profession in the UK is then addressed, including the advent of the prescribing pharmacist.

Historically, entrance to the pharmacy profession required successful completion of a 3-year Bachelor of Science (BSc) degree followed by 1 year preregistration work under appropriate supervision. Since the turn of the century, however, the recognized qualification that permits registration with the Royal Pharmaceutical Society of Great Britain (RPSGB) has been the 4-year MPharm program, followed by the compulsory 1-year work program prior to application for registration as a pharmacist.

The United Kingdom's 4-year degree is the shortest of the European pharmacy degrees. The MPharm programs fulfill all of the criteria required under European regulations concerning equivalence of qualifications: a European Union citizen achieving an MPharm degree is thus eligible to apply for registration in any of the European member states having completed their work placement experience.

There are 22 schools of pharmacy in the United Kingdom offering MPharm degrees. Each school admits an average of 150 students to their MPharm program each year; thus, the United Kingdom provides approximately 3300 undergraduate pharmacy places per year (for a total population of about 60 million); this may rise in the future.

In the case of medical school, students can apply to 4 medical programs only, plus 1 other non-medicine program. The majority of students applying for pharmacy apply exclusively to pharmacy programs, although approximately 20% list pharmacy as their fifth choice after the 4 medicine applications. On average, each school of pharmacy receives approximately 8-10 applicants for each place on their MPharm program, but taking into account that each applicant has applied to 4 other schools of pharmacy, this translates to 10,000 applicants for the 3,300 places across the UK per year.

Entry qualifications vary slightly across the 22 UK schools of pharmacy, but the most important deciding factor for most applicants is performance in the national school-leaving examinations (Advanced Levels also known as A-Levels). A-Levels are the final

examinations taken by 18-year-old school-leavers. The 3 subjects normally studied at A-Level before applying for the MPharm program are chemistry, math, and biology.

In recent years, funding of UK higher education has changed. There are no formal requirements for experiential education or clinical placements (which is the term used in the UK) within the MPharm program, but it has become an expectation. Most schools offer at least 1 week total over the 4 years; some offer much more (up to 4 weeks). It is clinical placements that have created most anguish to program leaders over the last few years. Hospitals and some other pharmacists have made it a requirement that students have been fully screened by the UK Criminal Records Bureau (CRB) before being allowed entry to hospital premises. In comparison to other European pharmacy programs, the UK programs stand out in that they provide the underlying scientific and theoretical knowledge, alongside experimental and clinical expertise. Therefore, at the end of the 4-year program, the graduate is fully equipped to enter the clinical/practice arena. This differs from some other European programs where the university components of the education concentrates purely on the scientific aspects before the students graduate and enter the pharmacy practice training arena. The UK programs, at 4 years, are the shortest university programs in Europe (elsewhere in Europe, pharmacy programs are 5-6 years).

NOTES

1. overview – general survey or summary
2. curriculum – the subjects included in a course of study
3. compulsory – obligatory
4. eligible – meeting the conditions to do or receive something
5. admit – allow to enter
6. requirement – something that is compulsory (needed)
7. anguish – severe pain or distress
8. experiential – relating to experience and observation

LESSON-7.

Unit 4. Ready for testing in live organisms (EforPI, p.39**)**
R: Text **(**EforPI, p.40**)**
L: Conversation (EforPI, p.42)
W: Preclinical Development.
S: Drugs Made by Medicinal Plants (OTM, p.8)

Preparation: Pre-listening: Match the words and phrases in the table to their definitions.

retire	degree	postgraduate	clinical
consultant	paediatrician	paediatric nurse	a GP

A special nurse for children	
Describes a course for people who already have a degree	
A special doctor for children	
To leave your job or stop working because of old age or ill health	
A specialist, paid by a company to give advice	
A general practitioner, a family doctor	
A qualification from a college or university	
Describes medical work or teaching about examination and treatment of people who are ill	

professionals-podcasts-interview-with-a-doctor.mp3

Task 1: Comprehension 1. Listen to the interview and put the questions in the order they are asked.

Did you have any problems when you first started working in Britain?	
Do you ever regret not returning to India?	

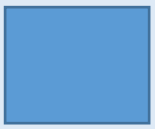
What was the National Health Service like when you first came here?	
When did you come to the UK?	
Why did you come to the UK?	
Why did you stay longer?	

Task 3: Grammar. Find and correct the error with verb form or tense in each of these sentences.

1. Experience of to work in the British National Health Service was highly valued in India. 2. I have just finished my medical degree and I thought this would be a good way to get experience. 3. I only intended stay for five years. 4. I thoroughly enjoyed to work for the NHS. 5. The clinical training I have received was fantastic.

6. My wife has been working as a pediatric nurse. 7. There was a lot more respect for the medical profession than there was now. 8. There wasn't so many problems with long waiting lists.

Task 3: Comprehension 2. Listen again and complete this postcard that Rajan wrote to a friend in India in 1967.



Dear Anoo,
I hope you're well. I'm fine and having an excellent time.
I've just finished my postgraduates _____ and I can't
Believe I've been here for f_____ years already. _____
I've decided to stay here because the clinical t_____ is _____
So good, and the National H_____ Service is so
impressive. And there's another reason. I've met a _____
beautiful English woman. She's a pediatric n_____, and
she's agreed to marry me! I've got a job as a p _____in _____
the same hospital, so everything is going well.
Of course, I miss you all in Bombay, but I hope to visit you
soon, and with my new wife. _____

All the best,
Rajan

Speaking (Сўзлаш)-Speaking: B2

Talk About It! Before you begin to talk about the activities, think about your answers to the following questions. Record your opinion and upload it into Moodle.

1. Is there a history of **heart disease**, **hypertension**, **diabetes**, **cancer**, or other illness in your family? If yes, what illnesses or conditions?

2. Has anyone in your family ever had surgery? If yes, what kind of surgery?

3. Do you have any allergies to medication or food?

4. Are you currently taking any medications?

5. What immunizations have you had? What? When?

6. Do you smoke?

7. Do you drink (alcohol)?

8. Do you exercise?

9. How many hours do you sleep each night? Do you have any problems sleeping?

10. Do you know your normal blood pressure?

Activity One: "Role-play" a visit to the doctor using the questions above. Take turns being the doctor and the patient.

Activity Two: Tell about your family's health history in the space below. Then, share your story with your groupmates and instructor. Work online via Moodle elements.

Reading (Ўқиш) -"A medicine label". Reading: B2

Reading: What does a medicine label tell you?

A medicine label tells you about the medicine. It tells you:

• the name of the medicine.

• who the medicine is for.

• about possible side effects.

• about possible dangers (warnings).

A medicine label tells you how to take the medicine. It tells you:

• **how to take** the medicine.

• **how much** medicine to take.

• **how often** to take it.

Do not share prescription medicines with friends or family. Medicines can cause sickness and even kill a person when used the wrong way.

Alicia's Story

Read the story and answer the questions.

Alicia went to the doctor. The doctor gave her a prescription. Alicia took the prescription to the pharmacy. She gave the prescription to the pharmacist. The pharmacist filled the prescription and gave her the medicine. Alicia asked the pharmacist, "How do I take this medicine?" The pharmacist said, "Take two pills, twice a day."

ABC/Pharmacy, 615 E. 23rd Street, Hialeah, FL 33107 **(305) 555-6554**
Rx# 10178 13222
Rodrigues, Alicia
54 Bloom Street
Hialeah, FL 33024

Take 2 tablets by mouth twice daily
Minocycline 100 MG tablets
Dr. HANES, A
No refills Qty. 30 Discard After 03/24/2015

Important: Finish all medicine unless otherwise directed by your doctor.

Writing (Ёзиш)- "Your health history" Writing: B2

HEALTH HISTORY

Name: _____Date: _____
(First) (Middle) (Last)
Street Address:
_____
City: _____ State: _____
Zip:_____
Telephone: (_____)_____
Date of Birth: ____/____/____ Gender: Female __ Male __
Height: ____ feet ____inches Weight: _____lbs
Martial Status: Single __ Married __ Widowed __

This history form provides us with information to help us understand all your healthcare needs. Please complete the entire form by answering each question as through as possible.

GENERAL INFORMATION

1. When was your last physical exam? (exam in a doctor's office**)**
___/___/___
Name of Doctor: _____Telephone:(_____)_____
2. Place of Birth (**Where were you born?**): _____
3. What is your current occupation (**job now**)? _____
4. Please list all allergies (foods, drugs, environment)_____

LIFESTYLE & HABITS:

Smoking
1. Do you smoke? Yes __ No __

If yes, how many packs a day do you smoke? _____

Alcohol

2. Do you drink alcohol? Yes __ No __

If yes, how times a week do you drink? _____

Caffeine

3. Do you drink caffeine (coffee, soda, tea)? Yes __ No __

If yes, how many cups a day? _____

Daily Exercise

4. How many times a week do you exercise? _____

Television Habits

5. How many hours a day do you watch television? _____

Sleep Habits

6. How well do you sleep? _____

How many hours a night? _____

ILLNESS OR OPERATION

1. Please list all serious illnesses and accidents you have experienced.

Illness or Operation	Year of Illness	Were you hospitalized? (Write YES or NO)

CURRENT MEDICATIONS

1. What medications do you take? Please list both prescription drugs (**medicine with a note from doctor)** and nonprescription drugs (**medicine without a doctor's note**):

_____ _____

Think about your family health history. Write a story about your family's health history in the space below. Upload your story into Moodle.

TOPIC 4

DRUGS MADE BY MEDICINAL PLANTS

Ancient medical texts, some dating back to the early Greeks, talk about medicinal plants. Now modern science is taking this ancient art to new levels.

***Artemisia annua*.**

This grey-green aromatic plant and its relatives in the genus *Artemisia* have been used to make absinthe and flavoured wines since earliest times. Now this plant family could

bring anew gift: Its natural pest-fighting defence may protect humans from malaria. It's no secret that malaria-fighting drugs have done a lot for civilization—the Panama canal is one testimony of their success. But what happens when the organisms that cause the disease develop resistance to current treatments?

Right now, scientists are preparing to solve this problem before it ever occurs by having alternative treatments ready. One of these under study cures could be artemisinin, a natural compound produced by *Artemisia* plants.

Medical researchers, especially in the military, want to know more about worm wood's malaria-fighting properties. Knowing the physiologywould play a role in increasing the supply of this beneficial compound.

It was already known that worm wood has little balloon like glands on its leaf surface. It was that as the plant matures, these balloons fill with artemisinin. Pest-protection is nature's goal. As the plant matures, the glands swell big gerand finally burst, covering the plant with self-made pesticide. Knowing how a plant's DNA program sit for pest protection may lead researchers to ways to provide the same pest resistance to currently vulnerable plants.

Besides the crop protection aspects of their research, scientists are also looking at the pharmaceutical value of these plants. In fact, *Artemisia* is just one of the plants they're exploring.

Another plant is St. John's-wort, which belongs to the genus *Hypericum*.

Greek texts dating back to 2000 B.C. have noted uses and harvesting techniques for this plant. Currently, its claim to fame is as an alternative treatment for depression.

St. John's-wort is the preferred treatment for mild depression in Europe. "Physicians there choose it four to five times more often than synthetic drugs because they believe it has fewer side effects. Europeans get their supply from Albania, but it grows wild in the United States.

St. Jones-wort tablets are standardized by the amount of red pigment, called hypericin, which some researchers suspect is the active ingredient. Hypericin is being studied as both an anti-viral and anti-cancer drug.

It was already known that hypericin was concentrated in small black and red dots found on the flowers and leaves of St. Jones-wort and that it was effective in pest control. But hypericin, if given in a high enough concentration, is toxic to all living things including St. Jones-wort. The plant protects itself by scaling the hypericin dots off with a thin cell layer.

Notes

1. testimony – evidence or proof of something
2. beneficial – having a good effect
3. vulnerable – exposed to being attached or harmed
4. suspect – believe to be likely or possible
5. scale – remove scale or scales from

LESSON-8.

Ready for testing in live organisms (EforPI, p.39**)**

R: Text **(**EforPI, p.45**)**

L: Clinical Trials for RFI (EforPI, p.47)

W: Short Summary.
S: Drugs Made by Medicinal Plants (OTM, p.8)

SUGGESTING CORRECTIVE ACTION

Neutral	Strong
I suggest you put 'No toxic waste' on the bin.	The only solution is to rethink the process.
My suggestion is that we redo the equipment list.	I strongly suggest that we try to prevent it in future.
My recommendation is to talk to the lab workers.	I'm convinced we must repeat the last tests.
It might be possible to relocate the equipment.	It is absolutely essential to learn the safety rules.

12 **Write five suggestions for corrective action to solve the safety problems in the Berner Pharmaceuticals labs (see exercise 11). Use the Useful Phrases above.**

1 _____

2 _____

3 _____

4 _____

5 _____

13 **Read excerpts from Berner Pharmaceuticals' SOP on laboratory procedures. Then match them to warning signs a–e.**

a 

b 

c 

d 

e 

1 ☐ All toxic waste materials must be disposed of properly.

2 ☐ Good sanitary hygiene must be practised by all lab staff.

3 ☐ Protective clothing must be worn in the labs at all times.

4 ☐ Lab animals must be transported in covered cages.

5 ☐ Eye protection must be worn as signposted.

ASKING QUESTIONS DURING AN AUDIT

Talking to staff
What is your name?
What is your job?
What is your supervisor's name?
What is your supervisor's job?

Asking about processes and procedures
How have you been trained to perform this procedure?
How much time does it take to complete this part of the process?
What special procedures must be followed in a laboratory?
What special procedures must be followed for this process?

Asking about possible actions taken
How do you handle toxic waste in the lab?
How do you handle the transportation of animals in the lab?
What would you do if you got a toxic substance on your lab coat?
What would you do if you noticed non-compliance with safety procedures by a colleague?

DISCUSSING SOPS – PROCESSES, PROCEDURES, DOCUMENTATION, TIMING

Requesting information
Please describe the procedure for the ... process.
Would you please clarify how you ... ?
Could you explain the procedure for the documentation of ... ?

Asking questions
What are the guidelines for ... ?
How often do you have to ... ?
What special procedures do you follow for ... ?
How would you ensure good hygiene in the laboratory?

Formulating SOP guidelines
Proper protective clothing and safety equipment *must be worn* at all times.
Proper safety procedures *must be carried out* by laboratory staff.
Toxic or hazardous materials *must be disposed of* properly.

Note: SOPs often use the following structure: *must* or *should be* + verb.

Formulate SOP guidelines. Convert the following sentences.

Example: Use safety SOPs for working with laboratory animals.
Safety SOPs must be used for working with laboratory animals.

1 Perform all work with virus-infected animals in the bio-safety cabinet.

_____

2 Use disinfectant on equipment following any experiments with laboratory animals.

_____

3 Wipe up all chemical spills in the laboratory immediately.

_____

4 Wear laboratory gowns or lab coats, latex gloves, and safety glasses at all times.

_____

5 Cover small biological agent spills with a paper towel and treat them with bleach.

_____

6 Document all laboratory work in accordance with GLP.

_____

10 **Practise asking and answering audit questions with a partner. Use the laboratory clothing and equipment from the list below and the Useful Phrases on page 34.**

- eye bath
- gas mask
- hairnet
- laboratory coat
- latex gloves
- overshoes
- safety glasses/goggles
- safety gloves
- bins for toxic substances

Read part of the internal audit report done on the three laboratories at Berner Pharmaceuticals. There are five non-compliance areas which were observed by auditors Jacobs and Webber.

Berner Pharmaceuticals Ltd Internal Audit Report – Friday 13 June 2010

Purpose and area description: Annual audit of safety procedures in all laboratories

Major facts: Although there were no serious instances of non-compliance, a number of incidents of undesirable conditions and practices were observed. These need to be corrected before the follow-up review in 30 days.

Observations:
a) Six laboratory technicians wore unsuitable clothing and safety equipment.
b) One lab assistant did not wash her hands after a procedure involving mice.
c) Times of the experiments were not entered on two of the daily lab reports.
d) Mice were transported in open cages (in public) to a second lab.
e) Improper disposal of toxic waste material was recorded.

Follow-up: A review of the procedures in Labs 1, 2, and 3 will be carried out …

Now match the areas of non-compliance found by the auditors with their observations.

Non-compliance areas	Auditors' observations
1 ☐ improper clothing/safety equipment	a chemicals found in normal waste bins
2 ☐ improper hygiene after handling animals	b lab mice moved outdoors in open cages
3 ☐ improper documentation	c safety gloves too big, no safety goggles
4 ☐ improper transportation of lab animals	d no recording of experiment times
5 ☐ improper disposal of toxic waste	e hand-washing or sanitizing forgotten

6 Listen to a laboratory staff meeting in which preparations for an internal audit of laboratory safety procedures are discussed. Are the statements true (✓) or false (✗)?

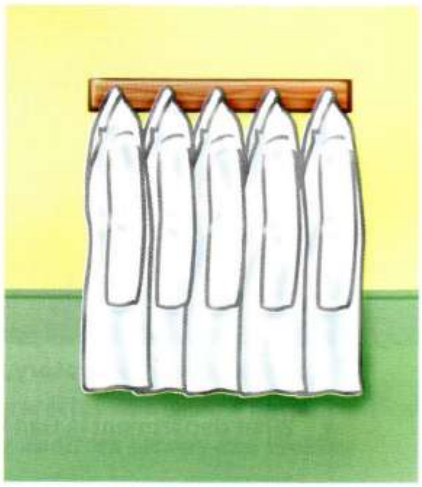
1 ☐ This is a planned audit.

2 ☐ The auditors will be giving information to the lab technicians during the audit.

3 ☐ One of the lab technicians will be in London during the audit.

4 ☐ The laboratory staff will only be cleaning the laboratories to prepare for the audit.

5 ☐ The junior lab technicians will be cleaning the laboratories and checking the workstation equipment lists.



Complete the sentences with words from the box.

checklist • finding • non-compliance • observe • safety • short • updated • up to date

1 Advance notice of this meeting was very _____.

2 _____ procedures make sure that the health and well-being of laboratory workers are guaranteed.

3 Auditors generally watch or _____ safety procedures in the lab.

4 To ensure that laboratory workers are asked certain questions about safety procedures, auditors use a _____.

5 If any _____ is observed during the audit, the department will be informed so they can take corrective action.

6 Standard operating procedures (SOPs) are _____ on a regular basis, often after an audit has been carried out.

7 Scientists often read journals and go to international conferences, because they need to stay _____ in their scientific fields.

8 Any observation or _____ noted by the auditors is categorized as either major, minor, or critical.

Complete the memo to your own staff. Let them know about an upcoming audit. Use the Usefu Phrases from page 31.

_____
(your company)

– Interoffice Memorandum –

Date: _____

To: _____

From: _____

Subject: _____

Cc: _____

Attachment: _____

This memo _____[1] that your department has been scheduled for a periodic audit of laboratory safety systems and procedures.

The timetable for the various laboratory audits is as follows:

Building 1: Tuesday and Wednesday
Building 2: Wednesday and Thursday

Please _____[2] that all the employees are informed and prepared in accordance with standard audit procedure. Two members of our audit team (_____) will carry out this internal audit from _____ to _____, using the latest company-approved audit checklist.
(names) (date) (date)

The completed checklist and original audit results _____[3] with you and the Director of Laboratory Management, to identify areas requiring corrective or preventive action before a report of the status of these corrective or preventive actions is issued. _____[4] is to identify and correct any quality system defects and to assure compliance with industry standards, especially for laboratory procedures.

_____[5] receipt of this memo and _____[6] a copy of all your correspondence with regard to this scheduled audit.

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Greek texts dating back to 2000 B.C. have noted uses and harvesting techniques for this plant. Currently, its claim to fame is as an alternative treatment for depression.

St. John's-wort is the preferred treatment for mild depression in Europe. "Physicians there choose it four to five times more often than synthetic drugs because they believe it has fewer side effects. Europeans get their supply from Albania, but it grows wild in the United States.

St. Jones-wort tablets are standardized by the amount of red pigment, called hypericin, which some researchers suspect is the active ingredient. Hypericin is being studied as both an anti-viral and anti-cancer drug.

It was already known that hypericin was concentrated in small black and red dots found on the flowers and leaves of St. Jones-wort and that it was effective in pest control. But hypericin, if given in a high enough concentration, is toxic to all living things including St. Jones-wort. The plant protects itself by scaling the hypericin dots off with a thin cell layer.

Notes

1. testimony – evidence or proof of something
2. beneficial – having a good effect
3. vulnerable – exposed to being attached or harmed
4. suspect – believe to be likely or possible
5. scale – remove scale or scales from

LESSON-9.

Unit 5. Drug Safety and Regulatory Affairs (EforPI, p.51**)**

R: Report **(**EforPI, p.52**)**

L: True or False? (EforPI, p.56)

W: Adverse Drug Reactions.

S: Plants as a Source of Drugs (OTM, p.9)

Ready for testing in live organisms

Here are some opinions about preclinical and clinical trials. Do you agree or disagree?

		Agree	Disagree
1	An open day allows pharmaceutical companies to be more transparent about their animal testing policies.	☐	☐
2	Many people don't realize that animal trials are required by law, before testing in humans can take place.	☐	☐
3	Test animals often have better conditions than farm animals.	☐	☐
4	Participating in clinical trials is a good way to earn some extra money.	☐	☐
5	I wouldn't like to risk my health as a subject in clinical trials.	☐	☐
6	Heavy drinkers are more at risk than subjects in clinical trials.	☐	☐
7	Volunteers make a big contribution to the field of medicine, no matter what their motivation is.	☐	☐
8	If I were seriously ill, I would definitely take part in a clinical study. It could be my last hope!	☐	☐

During an internship at Vine Pharmaceuticals, Miki, a lab technician, is learning about preclinical and clinical testing. She has found some general information on the Internet about requirements before an investigational drug can be tested in human volunteers. Complete the text with words from the box.

active • administer • development • formulate • purity

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In the preclinical stage of drug development, an investigational drug must be tested extensively in the laboratory. This is to *ensure* it will be safe to _____[1] to humans. Testing at this stage can take from one to five years and must provide information about the pharmaceutical composition of the drug, its safety, and how the drug will be formulated and manufactured.

Preclinical Technology: During the preclinical _____[2] of a drug, laboratory tests document the effect of the investigational drug in living organisms (in vivo), and in cells in a test tube (in vitro).

Chemistry, Manufacturing and Controls (CMC)/Pharmaceutics: The results of preclinical testing are used by experts in pharmaceutical methods to *determine* how to best _____[3] the drug for its intended clinical use. For example, a drug that is intended to act on the sinuses may be formulated as a time-release capsule, or as a nasal spray. Regulatory agencies *require* testing that documents the characteristics – chemical composition, _____[4], quality, and potency – of the drug's _____[5] ingredient, and of the formulated drug.

Pharmacology/Toxicology: Pharmacology is the study of drugs and the body's reaction to drugs. Toxicology is the study of the *potential* risks to the body.

The results of all testing must be provided to the FDA in the United States and/or other appropriate regulatory agencies in other countries in order to *obtain* permission to begin clinical testing in humans. Regulatory agencies review the specific tests and documentation that are required in order to *proceed* to the next stage of development.

Use information from the text in exercise 1 to answer the following questions.

a How long can it take to finish the preclinical stage?

_____

b What needs to be documented in laboratory tests?

_____

c What do regulatory agencies require?

_____

d What is the difference between pharmacological and toxicological studies?

_____

e When can a pharmaceutical company start clinical testing in humans?

_____

Find the word in italics in the text on page 40 which means:

a receive, get _____

b demand _____

c make sure _____

d fix conclusively _____

e possible _____

f go on _____

Complete the table using a word from the text in exercise 1.

verb		document		intend		inform
noun	permission		administration		formulation	

drug at Vine Pharmaceuticals. Complete the excerpt using the correct form of the words in exercise 4.

First of all, it is the _____ [1] of the company to complete the preclinical trials by the end of the year. After that, regulatory agencies have to give _____ [2] to commence with the clinical testing in humans, which is also done at our company. But before that can happen, our scientists determine how to _____ [3] the active pharmaceutical ingredient into a suitable administration form. We have to _____ [4] each step of every test very thoroughly before the regulatory agencies give their approval to proceed to the next stage. The _____ [5] must show that the _____ [6] of the investigational drug is safe for our subjects.

Now listen and check your answers.

DESCRIBING A PROCESS (PART 1)

The passive is often used to describe a process. We use it because it focuses on the action, rather than on the person or thing (agent) doing the action. Often the agent is unclear, unknown, or irrelevant.

An experiment A trial/study	is/was	carried out/conducted/done/performed.
A drug		absorbed/administered/formulated/manufactured/prescribed/taken.
The data	are/were	provided/transmitted.
A number of experiments Several tests		conducted/done/performed.
The criteria	can must be will	met.
A study		carried out/ conducted/done/performed.

Complete the sentences about preclinical development using the correct form of the verbs in the box.

be administered • be conducted • be determined • be formulated • be provided • be used

1 We started the trial after tests on investigational drugs _____ in vivo and in vitro over a period of up to five years.

2 Last year, results of preclinical testing _____ to come up with the best formulation of the intended drug.

3 Extensive documentation must _____ to the appropriate regulatory authorities.

4 A drug intended to act on the skin can _____ as a cream.

5 Potential risks to humans _____ in toxicity studies.

6 The requirements of drug bioavailability determine how it will _____ to humans.

Now describe an SOP or process in your company using the phrases above.

Miki has been invited to join an impromptu lab meeting about drug substance MPP 010098, which is being tested in dogs. Miki, Linda, an animal caretaker, Jake, a biological lab technician, and their supervisor, Roger, are talking about a problem. Listen to the conversation and decide if the statements below are true (✓), false (✗), or not mentioned (–).

1 Someone told Linda that the dogs were vomiting. ☐

2 Some dogs were not affected negatively by the drug substance. ☐

3 Linda doesn't know if the animals in the control group are affected. ☐

4 Dogs are more sensitive than mini-pigs. ☐

5 The study protocol will have to be changed. ☐

6 Roger will contact the study director by the end of the day. ☐

7 Miki is going to write the report on what happened. ☐

THE INS AND OUTS OF CLINICAL TRIALS

A **chemistry lab technician** assists chemists and chemical engineers using chemicals and related products, whereas a **biology lab technician** works with living organisms.

A **control group** in preclinical studies is a group of test animals that is not exposed to the medication under study. In an experiment, this group is treated just like the other animals, but does not receive the active ingredient. This group is then compared with the treated animals in order to validate the results of the test.

Low-dose/mid-dose/high-dose groups are three groups of animals which receive different concentrations of the medication under study.

In preclinical trials, at least **two different animal models** are necessary:
1 Testing is done in rodents (e.g. mice, rats, but also rabbits, and/or guinea pigs).
2 Testing is then carried out in animals which have systems more similar to humans, e.g. dogs, mini-pigs, and/or monkeys.

The active ingredient can be tested in humans only after these tests have been successfully completed and authorization has been given.

Roger needs to write the required amendment. Here are Linda's notes, which sum up the points in the meeting. Read her notes, and match the sentence halves to make a summary of the meeting.

Notes

The general health of the dogs was regularly checked. In addition, the overall appearance and behaviour of each animal was assessed twice a day. On Day 2, however, abnormalities regarding food consumption were observed shortly after administration in the high-dose group. The dogs' food consumption was lower, whereas their water consumption was higher. The dogs started retching and vomiting and were separated to allow closer observation. No other clinical symptoms were observed, though.
In comparison with the high-dose groups, animals in the low-dose and mid-dose groups showed no clinical symptoms at all.

1	☐ The animals that showed clinical symptoms	a	were checked twice a day.
2	☐ Clinical symptoms in the high-dose group	b	were separated to be watched more intensively.
3	☐ The general health and behaviour of the dogs	c	were found in the low- and mid-dose groups.
4	☐ No major clinical symptoms	d	were discovered soon after administration.

Now write a short summary of the situation you discussed in exercise 9.

LINKING IDEAS

Certain words are added to make additional points, or to compare or contrast ideas.

Adding a relevant point	**Making a comparison or a contrast**
In addition,/Additionally, ...	... , whereas ...
... not only... , but also ...	... , while
Besides, ...	... (even) though
Furthermore, ...	However, .../But ...

TOPIC 5

PLANTS AS A SOURCE OF DRUGS

The use of natural products with therapeutic properties is as ancient as human civilisation and, for a long time, mineral, plant and animal products were the main sources of drugs. Furthermore, throughout the development of human culture, the use of natural products has had magical-religious significance and different points of view regarding the concepts of health and disease existed within each culture. About 25% of the drugs prescribed worldwide come from plants, 121 such active compounds being in current use. Of the 252 drugs considered as basic and essential by the World Health Organisation (WHO), 11% are exclusively of plant origin and a significant number are synthetic drugs obtained from natural precursors. It is estimated that 60% of anti-tumour and anti-infectious drugs already on the market or under clinical trial are of natural origin. The vast majority of these cannot yet be synthesised economically and are still obtained from wild or cultivated plants. Natural compounds can be lead compounds, allowing the design and rational planning of new drugs, biomimetic synthesis development and the discovery of new therapeutic properties not yet attributed to known compounds. In addition, compounds such as muscarine, physostigmine, cannabinoids, yohimbine, forskolin, colchicine and phorbol esters, all obtained from plants, are important tools used in pharmacological, physiological and biochemical studies.

The potential use of higher plants as a source of new drugs is still poorly explored. Of the estimated 250,000–500,000 plant species, only a small percentage has been investigated phytochemically and even a smaller percentage has been properly studied in terms of their pharmacological properties; in most cases, only pharmacological screening or preliminary studies have been carried out. It is estimated that 5000 species have been studied for medical use.

The approach for drug development from plant resources depends on the aim. Different strategies will result in a herbal medicine or in an isolated active compound. However, apart from this consideration, the selection of a suitable plant for a pharmacological study is a very important and decisive step. There are several ways in which this can be done, including traditional use, chemical content, toxicity, randomised selection or a combination of several criteria. The most common strategy is careful observation of the use of natural resources in folk medicine in different cultures; this is known as ethnobotany or ethnopharmacology.

The choice of a biological material to be screened for active compounds and the subsequent development of a drug must take into account that the exploration of natural resources should meet global and regional needs for new efficient and safe drugs, while preserving natural diversity and the environment. The present situation of exploitation of the world's vegetation may lead to the extinction of some species, which means not only the loss of interesting chemical compounds as potential drugs, but also the loss of genes, which could be of use in plant improvement or in the biosynthesis of new compounds. It is, therefore, crucial; both for the development of areas with rich flora,

such as Asia and Latin America, and for the pharmaceutical industry, to protect and promote the rational exploitation of biodiversity as a source of chemical compounds that have direct biological activity or can be used for the rational planning of new drugs.

The dried or stabilised plant material should then be powdered and subjected to a suitable extraction process. When the chemical nature of the compounds involved is known, extraction methods should be directed at obtaining these compounds in as high a yield and purity as possible. When the chemical composition is unknown, the extraction procedure can be based on how the plant is used in folk medicine, or several extractions with solvents of increasing polarity can be performed.

To obtain isolated active compounds, the plant extracts are first qualitatively analysed by thin layer chromatography (TLC) and/or other chromatographic methods and screened to determine the biological activity or to obtain a general evaluation of biological activities. For purification and isolation, the active plant extracts are sequentially fractionated each fraction and/or pure compound being subjected to bioassay and toxicity evaluation in animals. This strategy is called bioactivity-guided fractionation. Bioassays can be performed using microorganisms, molluscs, insects, cellular systems (enzymes, receptors, etc), cell culture (animal and human), and isolated organs or in vivo (mammals, amphibians, birds, etc).

In general, a plant extract contains low concentrations of active compounds and a large number of promising compounds, requiring the use of sensitive bioassays suitable for the wide chemical variety and small amounts of the tested samples. Tests must be simple, reproducible, fast and cheap.

In summary, research into medicinal plants and the search for plant-derived drugs require a multidisciplinary approach with integrated projects, financial and technical support, and a very carefully planned strategy. The aims should consider demands in terms of public health, preservation of Biodiversity and the technical qualification of each laboratory or research group involved. Finally, advances in technology and knowledge of natural products must be viewed not merely from the perspective of drug development, but also as a special tool for the understanding biological phenomenon in order to contribute to the well-being of humanity.

NOTES

1. estimate – calculate the value, number or amount of something

2. decisive – having great importance for the outcome of a situation

3. random – done or happening without a deliberate order, purpose or choice

4. exploit – make good use of a resource

5. crucial – of great importance

LESSON-10.

Drug Safety and Regulatory Affairs.

R: E-Mail **(**EforPI, p.59**)**

L: PIL for Mensamint (EforPI, p.60)

W: PIL VS. Pills.

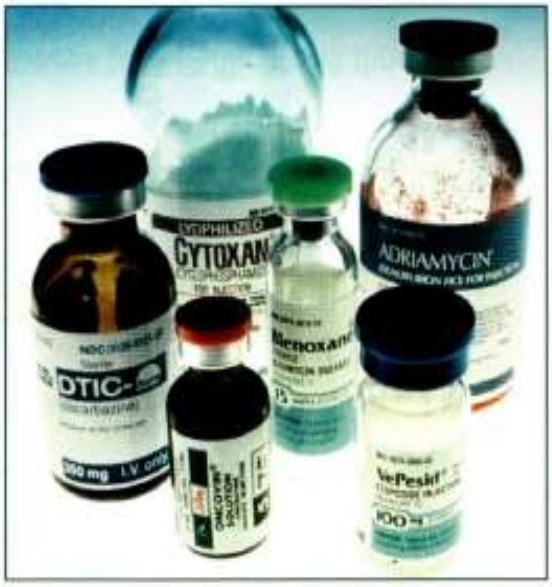
S: Plants as a Source of Drugs (OTM, p.9)

Experimental Drugs on Trial

The parents of a 21-year-old woman challenged the FDA. They took the authority to court after their daughter had died of cancer. The parents firmly believe that their daughter might have had a chance of surviving if she had been given access to a potentially life-saving experimental cancer drug that her doctor had recommended.

Many terminally ill people fall victim to the 'therapeutic misconception' that the objective of trials is to cure them. In truth, clinical trials are mainly aimed at answering scientific questions. In general, their goal is to gather statistics to determine whether an experimental drug is safe and effective.

On the whole, subjects in a trial must be willing to be randomly assigned to either the group which receives the unapproved medication or the one which gets a placebo. This is the only way to make sure clinical trials serve a scientific purpose. Subjects also have to be aware that the pharmaceutical company which is sponsoring the clinical trial can stop the trial at any time.



Do terminally ill patients have the legal right to try to prolong their lives by taking experimental drugs? The FDA has a clear position on this subject. It maintains that it would be difficult to find a sufficient number of patients to participate in clinical trials if it were possible to obtain the drug without actually being a subject in a trial. The safety and efficacy of a drug can only be determined by conducting rigorous clinical trials, according to the FDA.

Which phase does each description belongs to?

1 Phase _____ is performed after there is preliminary evidence that the drug is effective.

2 In phase _____, the lowest and highest doses are determined.

3 Phase _____ is the first phase in which patients with the target disease or disorder take part.

4 In phase _____, further information regarding the ideal use of the drug is collected.

5 Phase _____ is the final phase before getting marketing approval.

INSIDE CLINICAL TRIALS

An adverse event is any abnormal medical occurrence in a patient or clinical trial subject after a medicinal product has been administered. It does not necessarily have a causal relationship with the medicinal product.

Adverse reaction refers to all abnormal and unintended responses to an investigational medicinal product related to any dose administered.

In a **controlled study**, one group of test subjects is exposed to the substance, while the control group is not. Test subjects in the treatment group receive the medication under study, whereas the control group receives either a standard medication or a placebo. The results are then compared to determine the health effects of the substance being studied. **Uncontrolled clinical trials** do not have a comparison group.

The clinical trials for RFI 100089 were successful and the documents can be submitted. For this reason, Vine Pharmaceuticals has arranged a mock inspection to prepare for an upcoming visit by the regulatory authorities. Listen to part of the inspection and circle the correct ending to the sentences below.

1 The inspector wants to look at
   a an instruction manual.
   b the detailed data gathered during the clinical trial.

2 The inspector
   a did not accept the documentation about the change in temperature.
   b considered the incorrect change to the documentation to be minor.

3 In order to solve the problem
   a the temperature was increased.
   b the temperature was decreased.

Use the word or phrase in brackets to link the two ideas. In some cases you will still have two sentences.

1 There were no clinical findings in the mid-dose group. The high-dose-group animals showed clinical symptoms. (while)

2 The pulse rate was increased. The blood pressure was high. (not only ... but also)

3 There were no clinical findings in the oral administration studies. There were clinical findings in the intravenous-dose studies. (however)

4 Mini-pigs are easy to handle. Rhesus monkeys are difficult to work with. (whereas)

5 The drug was well tolerated by rats. It did not have any effect on blood pressure. (furthermore)

After getting a close insight into preclinical testing, Miki would like to know what comes next, and asks a colleague for help. She gets the following email.

From: jill.sanders@VinePharmaceuticals.com
To: miki.takashi@VinePharmaceuticals.com
Re: Phases in Clinical Testing

Dear Miki
At lunch yesterday you asked me to send you some general information on clinical trials. Here is a rough summary that might be useful.

Phase I Trials: These are studies which are performed to evaluate the safety of drugs in healthy people, and to determine the pharmacological properties of drugs. They are done to find out how the drug reacts in the body. Toxicity, metabolism, absorption, and excretion are observed and documented.

Phase II Trials: These are controlled studies conducted to evaluate the effectiveness of the drug in a particular indication and to determine possible side effects and risks. These studies are performed on volunteers and a number of patients with the target disease or disorder. In this phase, testing determines the safety and efficacy of the drug in treating the condition and establishes the minimum and maximum effective dose.

Phase III Trials: After gaining evidence that the drug is effective, these controlled and uncontrolled trials are carried out to obtain additional information to evaluate the overall benefit–risk relationship of the drug. In this phase, a large group of patients is studied and closely monitored by physicians for efficacy and any adverse events after long-term exposure to the drug.

Phase IV Trials: These are post-marketing studies after getting approval for general sale. They are carried out in order to gather further information about the drug's safety, efficacy, and optimal use.

Hope this helps. Call me if you need anything else.

Best wishes

REQUESTING INFORMATION AND RESPONDING DIRECTLY

Giving information at inspections

Here are the documents you requested.
I'll get it immediately.
You can find this on page three.
The change is crossed out, initialled, and dated.
Let me explain in more detail ...
I can give you more specific information on ...

Explaining and justifying decisions

Let me demonstrate ...
We had no alternative but to ...
I assure you ...
You can rest assured that we will ...
That led to ...
This way, you can/will avoid ...

Who would say this during an inspection, the expert (E) or the inspector (I)?

1 I'll send for that immediately. ☐
2 How do you account for the change? ☐
3 You can rest assured that this won't happen again. ☐
4 If you check page six you'll find it at the bottom of the page. ☐
5 It was initialled and dated by Dr Svenson. ☐
6 Where can I find the change that was made? ☐

Find a phrase in the dialogue in exercise 14 which means:

1 Have a look at ... _____

2 What's your explanation for ...? _____

3 I assure you ... _____

4 We have made a change due to ... _____

5 Do I understand correctly? You want me to ... _____

6 This is how you stop ... _____

The following words are often confused. Put the correct one into the sentences. If necessary, look back in the unit. At least one word of each pair has been used in this unit.

illness/disease

1 There is a history of lung _____ in the family.

2 He missed five days of work because of _____.

sensitive/sensible

3 Dogs are more _____ to drugs than mini-pigs.

4 It was a _____ decision to cancel the trial.

affect/effect

5 I felt the _____ of the new ointment right away.

6 The active ingredient currently being tested seems to _____ the kidneys.

shortly/briefly

7 The adverse event occurred _____ after the injection.

8 The trial director spoke _____ to his staff about the current status of the trial.

Richard Thompson, the expert responsible for the project, is hosting Paul Williams, a consultant, for a mock inspection. Work with a partner and role-play the inspection.

Paul Williams	Richard Thompson
Ask for current study protocol	Hand over document
Ask about documentation of a change	Say where to find it
Refer to a mistake in documentation	
Warn about possible problems with authorities	Accept warning
Ask for explanation of the change	Double-check request
Confirm	Explain the change
Show satisfaction with explanation	
Move on to next subject	

TOPIC 5

PLANTS AS A SOURCE OF DRUGS

The use of natural products with therapeutic properties is as ancient as human civilisation and, for a long time, mineral, plant and animal products were the main sources of drugs. Furthermore, throughout the development of human culture, the use of natural products has had magical-religious significance and different points of view regarding the concepts of health and disease existed within each culture. About 25% of the drugs prescribed worldwide come from plants, 121 such active compounds being in current use. Of the 252 drugs considered as basic and essential by the World Health Organisation (WHO), 11% are exclusively of plant origin and a significant number are synthetic drugs obtained from natural precursors. It is estimated that 60% of anti-tumour and anti-infectious drugs already on the market or under clinical trial are of natural origin. The vast majority of these cannot yet be synthesised economically and are still obtained from wild or cultivated plants. Natural compounds can be lead compounds, allowing the design and rational planning of new drugs, biomimetic synthesis development and the discovery of new therapeutic properties not yet attributed to known compounds. In addition, compounds such as muscarine, physostigmine, cannabinoids, yohimbine, forskolin, colchicine and phorbol esters, all obtained from plants, are important tools used in pharmacological, physiological and biochemical studies.

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5. crucial – of great importance

LESSON-11.

Unit 6. Production and Packaging (EforPI, p.63**)**
R: Fatal fakes - counterfeit medicines **(**EforPI, p.62**)**
L: Stephany Baker (EforPI, p.65)
W: Packaging.
S: Clinical Pharmacy (OTM, p.10)

Tick the department which is responsible for each of the following tasks:

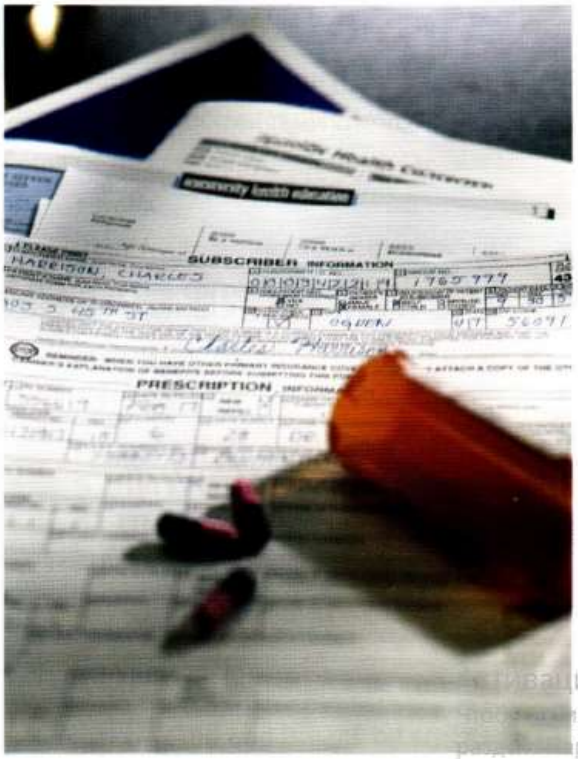
		Drug Safety	Regulatory Affairs
1	Reporting an adverse drug reaction to health authorities.	☐	☐
2	Submitting documents needed to obtain marketing approval for a drug.	☐	☐
3	Monitoring and evaluating suspected side effects.	☐	☐
4	Responding to a physician's report.	☐	☐
5	Compiling dossiers for submission to authorities.	☐	☐
6	Writing the drug information for the patient.	☐	☐

Why do healthcare professionals and pharmaceutical companies keep records of unexpected reactions to drugs?

How much should patients know about possible side effects before taking medication? Why?

WHAT IS PHARMACOVIGILANCE?

The Greek word 'pharmaco' (medicine) and the Latin term 'vigilantia' (watchfulness) were put together to form the word *pharmacovigilance*. Government agencies, pharmaceutical companies, and healthcare professionals work together to monitor and evaluate suspected side effects of medicines to improve the safety of drugs in use.



Read the following report.

ADDITIONAL EFFECTS OF TAKING DRUGS

Side effect – any unintended reaction caused by a drug or medical treatment. This term is used by the general public, but is often avoided by medical authorities.

Adverse event – an unwanted medical occurrence which a patient experiences during treatment. This may or may not be a side effect of a drug.

Serious adverse event (SAE) – an adverse event that threatens life, requires or prolongs hospitalization, or results in death.

Doctor's report:

On 24 Dec 2010, a woman of unknown age, Maria Gallois, fainted after developing a sudden, severe skin **rash** and **inflammation** all over her body.

Ms Gallois, the well-known opera singer, lost consciousness 30 minutes before she had planned to go on stage. She was taken to hospital and regained consciousness an hour later. She reported that she had not had anything to eat except some chocolate four hours before. In addition to small, red, **itching** spots all over her body, she also reported a racing heart, a headache, and **insomnia** after starting on *Mensamint*™ three weeks previously. At the hospital, the patient showed evidence of hyperactivity, accompanied by confusion and agitation. Subsequently, *Mensamint*™ was discontinued, but the symptoms **persisted** until a strong sedative was administered. After 24 hours, all symptoms except for a mild skin **irritation** had subsided and the patient was discharged from hospital. Some symptoms are suspected side effects of *Mensamint*™.

Vital signs:	temperature 100 °F (38.8 °C) and blood pressure 160/110
Known allergies:	peanuts, penicillin
Current medications:	two 100 mg *Mensamint*™ lozenges taken once daily for improved short-term and long-term memory.
	Mimifem oral contraceptive 0.2 mg daily.

The patient has a history of **hypertension**, mild heart **palpitations**, high adrenalin levels, and often suffers from insomnia.

Frederick M. Wright

Frederick M. Wright, MD

Now answer the following questions.

1 What were the patient's symptoms before she was admitted to hospital?

_____

_____

2 How was she treated by her physician?

_____

_____

3 What was her condition when she was discharged from the hospital?

_____

_____

Match the following symptoms in bold in the doctor's report with their definitions.

1	☐ hypertension	a	sleeplessness
2	☐ rash	b	general discomfort, bad feeling
3	☐ palpitation	c	red, warm, and swollen
4	☐ insomnia	d	you feel like you want to scratch
5	☐ inflammation	e	heart racing
6	☐ itching	f	high blood pressure
7	☐ irritation	g	a lot of spots on the skin

OVER TO YOU

- Is it ethically justifiable to deny terminally ill patients access to potentially life-saving, experimental drugs and medicine?
- Would easier access to experimental drugs have an effect on obtaining reliable data on the safety and efficacy of the drugs?
- What can authorities do to provide terminally ill patients with drugs that could help them?

Connect the following sentence halves. Then put them in the correct order to make a case report.

1	☐ A report received from the patient's sister	a	the attending physician reduced the dosage to 10 mg per day.
2	☐ After having taken *Mensamint*™, the patient experienced	b	and the symptoms cannot be ruled out.
3	☐ A correlation between *Mensamint*™	c	headaches and insomnia.
4	☐ The patient has now completely	d	indicated that she had a history of hypertension.
5	☐ After examining the patient,	e	recovered and is back on stage.

Correct order: _ _ _ _ _

REPORTING SEVERE ADVERSE EVENTS TO HEALTH AUTHORITIES

Pharmaceutical companies use details from doctors' reports to inform the authorities in a case report.

Patient history
The patient has a history of ...
A report was received from the physician indicating that ...
Before the event, the patient was on the following medication: ...

Description of adverse event
After examining the patient, the physician ...
After taking (drug), the patient experienced ...
At the time of the report, the patient's condition was/remained unchanged.
At the time of the report, the patient was recovering/had completely recovered.
This event led to the patient's death.

Drug information
... are known/suspected side effects of this drug.
(Drug) was administered for (condition).
Eye drops were instilled.
A bandage/cream/lotion/ointment was applied (to the skin).

Assessment of adverse event
(Drug) is (not) believed to be related to the event.
An interaction between (drug x) and (drug y) was suspected.
A correlation between (drug) and (symptom) can/cannot be ruled out.

HEALTH AUTHORITIES AND USEFUL TERMS

The names of health authorities and other terms used in pharmacovigilance are often shortened. Here are some typical examples:

EMEA European Medicines Agency (EU)
FDA Food and Drug Administration (US)
MHRA Medicines and Healthcare Products Regulatory Agency (UK)

PSUR Periodic Safety Update Report
SAE Serious Adverse Event
QPPV Qualified Person Responsible for Pharmacovigilance

Pharmaceutical companies have to submit a Safety Information and Adverse Event Report to the FDA and to the local authorities immediately. The medical director of your company asks you to complete the form based on the doctor's report on page 52. Complete section B.5 of the FDA form using the phrases below.

a a history of
b a report was received
c after examining the patient
d all symptoms had subsided
e be ruled out
f was concomitantly taking
g correlation between
h showed evidence of
i suspected side effects
j the patient reported
k vital signs

U.S. Department of Health and Human Services

MEDWATCH

The FDA Safety Information and Adverse Event Reporting Program

For VOLUNTARY reporting of adverse events, product problems and product use errors

Page 1 of ____

Form Approved: OMB No. 0910-0291. Expires: 12/31/2011
See OMB statement on reverse.

FDA USE ONLY
Triage unit sequence #

A. PATIENT INFORMATION

1. Patient Identifier	2. Age at Time of Event or Date of Birth:	3. Sex	4. Weight
Maria G In confidence	unknown	☐ Female ☐ Male	____ lb or ____ kg

B. ADVERSE EVENT, PRODUCT PROBLEM OR ERROR

Check all that apply:

1. ☒ Adverse Event ☐ Product Problem (e.g., defects/malfunctions)
☐ Product Use Error ☐ Problem with Different Manufacturer of Same Medicine

2. Outcomes Attributed to Adverse Event (Check all that apply)
☐ Death: _____ (mm/dd/yyyy)
☐ Life-threatening
☒ Hospitalization - initial or prolonged
☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
☐ Disability or Permanent Damage
☐ Congenital Anomaly/Birth Defect
☐ Other Serious (Important Medical Events)

3. Date of Event (mm/dd/yyyy)	4. Date of this Report (mm/dd/yyyy)
12/24/2...	12/26/2...

5. Describe Event, Problem or Product Use Error

2.	Dose or Amount	Frequency	Route
#1	2 x 100 mg	once a day	Lozenges
#2			

3. Dates of Use (If unknown, give duration) from/to (or best estimate)
#1 started medication 3 weeks
#2 prior to SAE

4. Diagnosis or Reason for Use (Indication)
#1 memory enhancement
#2

6. Lot #	7. Expiration Date
#1 12345678	#1 June 2...
#2	#2

5. Event Abated After Use Stopped or Dose Reduced?
#1 ☒ Yes ☐ No ☐ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

8. Event Reappeared After Reintroduction?
#1 ☐ Yes ☐ No ☒ Doesn't Apply
#2 ☐ Yes ☐ No ☐ Doesn't Apply

9. NDC # or Unique ID
unknown

E. SUSPECT MEDICAL DEVICE

1. Brand Name

5. Describe Event, Problem or Product Use Error

____[1] from a physician indicating that a woman had fainted after developing a sudden, severe skin rash and inflammation all over her body. She was taken to hospital and regained consciousness 30 minutes later. ____[2] not having had anything to eat but a chocolate candy bar 4 hours beforehand. In addition to small, red, itching spots all over her body, she also reported suffering from mild heart palpitations, headaches, and insomnia after starting on *Mensamint*™ three weeks previously. The patient ____[3] the following medication: *Mimifem* oral contraceptive pill 0.2 mg daily. As to her emotional state after hospital admission, the patient ____[4] hyperactivity, accompanied by confusion and a feeling of agitation. ____[5], the attending physician discontinued *Mensamint*™ and administered a strong sedative. After 24 hours, ____[6] except for a mild skin irritation and the patient was released from hospital. Symptoms are ____[7] of *Mensamint*™, although a ____[8] her peanut allergy, *Mensamint*™ and this event cannot ____[9].

____[10]: temperature 100 °F (38.8 °C); blood pressure 150/110.

Known allergies: peanuts, penicillin.

The patient has ____[11] hypertension, heart trouble, and insomnia.

7. Other Relevant History, Including Preexisting Medical Conditions *(e.g., allergies, race, pregnancy, smoking and alcohol use, liver/kidney problems, etc.)*

- allergy to peanuts
- heart palpitations
- headaches
- insomnia

C. PRODUCT AVAILABILITY

Product Available for Evaluation? *(Do not send product to FDA)*

☐ Yes ☐ No ☐ Returned to Manufacturer on: _____ *(mm/dd/yyyy)*

D. SUSPECT PRODUCT(S)

1. Name, Strength, Manufacturer *(from product label)*

#1 Name: Mensamint
Strength:
Manufacturer:

#2 Name:
Strength:
Manufacturer:

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

***Product names and therapy dates** (exclude treatment of event)*

Mimifem – dates unknown

G. REPORTER *(See confidentiality section on back)*

1. Name and Address

Name: CARDUCEUS PHARMACEUTICALS
Address: Mecklenburgische Straße 53
City: Berlin State: ZIP: 14197

Phone #: 0049-30-89785807

E-mail:

2. Health Professional? ☒ Yes ☐ No

3. Occupation: PV Officer

4. Also Reported to: ☐ Manufacturer ☐ User Facility ☐ Distributor/Importer

5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box: ☐

FORM FDA 3500 (1/09) Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

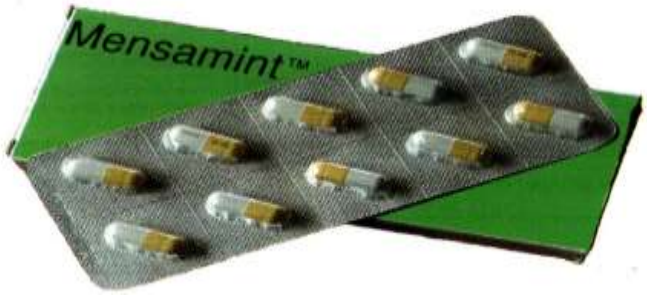
Now listen to the meeting in which Karl (CEO), Fred (Head of Regulatory Affairs), and Caroline (Head of Pharmacovigilance) discuss the SAE and its implications for the company. Are the following statements true (✓) or false (✗)?

1 ☐ There are two dosage forms of *Mensamint*™ currently on the market.

2 ☐ The serious adverse event is clearly linked to *Mensamint*™.

3 ☐ The documentation for the new dosage form of *Mensamint*™ will be submitted to the authorities soon.

4 ☐ Heart trouble is a known side effect of *Mensamint*™.



TOPIC 6

CLINICAL PHARMACY

Clinical pharmacy is the branch of Pharmacy where pharmacists provide patient care that optimizes the use of medication and promotes health, wellness, and disease prevention. Clinical pharmacists care for patients in all health care settings but the clinical pharmacy movement initially began inside hospitals and clinics. Clinical pharmacists often collaborate with physicians and other healthcare professionals.

Clinical pharmacists have extensive education in the biomedical, pharmaceutical, sociobehavioral and clinical sciences. Most clinical pharmacists have a Doctor of Pharmacy (Pharm.D.) degree and many have completed one or more years of post-graduate training (e.g. a general and/or specialty pharmacy residency).

Within the system of health care, clinical pharmacists are experts in the therapeutic use of medications. They routinely provide medication therapy evaluations and recommendations to patients and other health care professionals. Clinical pharmacists are a primary source of scientifically valid information and advice regarding the safe, appropriate, and cost-effective use of medications. Clinical pharmacists are also making themselves more readily available to the public. In the past, access to a clinical pharmacist was limited to hospitals, clinics, or educational institutions. However, clinical pharmacists are making themselves available through a medication information hotline, and reviewing medication lists, all in an effort to prevent medication errors in the foreseeable future.

In some states, clinical pharmacists are given prescriptive authority under protocol with a medical provider (i.e., MD or DO), and their scope of practice is constantly evolving. In the United Kingdom clinical pharmacists are given independent prescriptive authority.

NOTES

1. initially – at the beginning

2. extensive – large in amount or scale

3. foresee – be aware of something in advance of it happening

4. evolve – develop gradually

LESSON-12.

Unit 6. Production and Packaging.

L: Instructions (EforPI, p.66)

R: Henry's handwritten notes **(**EforPI, p.70**)**

W: Types of Letters. Formal and Informal.

S: Clinical Pharmacy (OTM, p.10)

Preparation task: Match the dosage form on the left to its definition on the right.

1. Aerosol	a. a very small amount of liquid that forms a round shape
2. Drops	b. an smooth, thick substance to rub on the skin for healing
3. Inhaler	c. an oily liquid to rub on painful body parts to reduce pain
4. Liniment	d. a medication on material or cloth placed on the skin
5. Ointment	e. a small, round piece of medicine to be swallowed without chewing
6. Patch	f. a container with a liquid that is administered in spray form
7. Pill	g. a liquid in which another substance has been dissolved
8. Solution	h. a solid medicine which melts slowly in the rectum or vagina
9. Suppository	i. a sweet, liquid medicine taken with a spoon or cup
10. Syrup	j. a small device with medicine to breathe in through the mouth

https://youtu.be/mdBzNCjMF0Q

Task 1. To discuss the results of a hospital in-patient survey on dosage forms for a new medication. The company needs to know which drug dosage forms patients prefer. Listen to the telephone call and fi1l in the form below.

Hospital in-patient dosage form survey results

1. Total number of in-hospital patients surveyed (a) _____

2. Male patients (b) _____ Female patients (c) _____

3. Average patient age (d) _____

4. Which of the following oral dosage forms are the patients currently using?

tablet (e) ____ gel tablet (f) ____ capsule (g) _____ pill (h) ____

solution _____ drops _____ syrup _____ other (s) _____

5. Which of the following dosage form(s) do the patients favour?

Oral dosage forms:

tablet ____ gel tablet (i) ____ capsule (j) _____ pill __8%__

solution _____ drops (k) _____ syrup (l) _____ other (s) _____

Inhaled dosage forms:

aerosol (m) _____ inhaler _____ other (s) _____

Topical dosage forms:

cream (n) ____ ointment (o) _____ liniment _____ lotion _____

gel _____ patch (p) _____ other (s) _____

Other dosage forms:

nasal spray _____ eye drops _____ suppository _____

6. What kind of side effects did the patients have with their current medication?

The following side effects were experienced:

allergic reactions 794	diarrhea 29	dizziness 3
fever 75	headache 91	indigestion 422
insomnia 47	itching 70	nausea 253
skin rashes 59	vomiting 17	other (s)

7. Do the patients have any suggestions for other future forms of medication?

List all suggestions here:

_____

8. Do the patients have any of the following chronic health conditions?

Asthma 794 anemia 121 bronchitis 805 diabetes 83 heart condition 21

Task 2. Answer the following questions via listening on Moodle.

1. How many patients were surveyed in all?

_____

1. Were more male or female patients interviewed?

_____

3. What kind of dosage form is most preferred by the patients surveyed?

_____

4. What kind of side effects were experienced by the least number of patients?

_____

5. What chronic health conditions did most patients have?

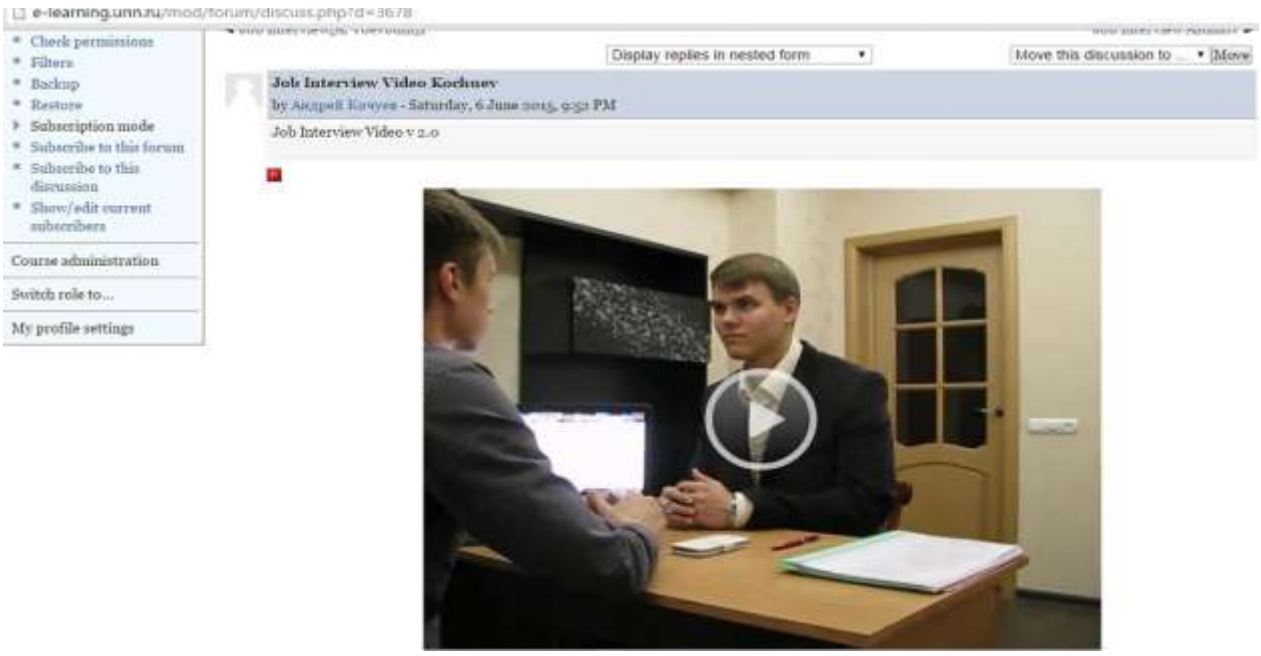
_____

Speaking (Сўзлаш)-Speaking: B2+

Talk about it: Make a dialog with your partner and record it. Upload it into Moodle.

Here are some sample questions:

The patient's full name	
The date	
The drug name in manufacturer or generic format	
The doctor's order for dosage amount (how much medication)	
The administration route (by mouth, IV, injection)	
The frequency with which the patient is to take the medication	
The duration, the number of days that the patient is to take the medication	
The total quantity or amount that the pharmacist is to dispense	
A check-off or box allowing a generic substitute (if provided)	
The physician's DEA number	



Reading (Ўқиш) -“ Drug facts”. Reading: B2+

Picture Story: What is different about these two pictures? What is the same?

Over-the-counter Medicine (OTC)

• What can you learn about this medicine from the label?

Prescription Medicine (Rx)

• What can you learn about this medicine from the label?

Reading: What does a medicine label tell you?

A medicine label tells you about the medicine. It tells you:

• the name of the medicine.

• who the medicine is for.

• about possible side effects.

• about possible dangers (warnings).

A medicine label tells you how to take the medicine. It tells you:

• **how to take** the medicine.

• **how much** medicine to take.

• **how often** to take it.

Do not share prescription medicines with friends or family. Medicines can cause sickness and even kill a person when used the wrong way.

Drug Facts

Active ingredient (in each tablet) — **Purpose**
Chlorpheniramine maleate 2 mg . . . . . Antihistamine

Uses temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- sneezing
- runny nose
- itchy, watery eyes
- itchy throat

Warnings

Ask a doctor before use if you have
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are taking tranquilizers or sedatives

When using this procuct
- You may get drowsy
- Avoid alcoholic drinks
- Alcohol, sedatives, and tranquilizers may increase drowsiness
- Be careful when driving a motor vehicle or operating machinery
- Excitability may occur, especially in children

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

Adults and children 12 years and over	Take 2 tablets every 4 to 6 hours; not more than 12 tablets in 24 hours
Children 6 years to under 12 years	Take 1 tablet every 4 to 6 hours; not more than 6 tablets in 24 hours
Children under 6 years	Ask a doctor

Other information Store at 20-25° C (68-77° F)
- Protect from excessive moisture

Inactive ingredients D&C yellow no. 10, lactose, magnesium stearate, microcrystalline cellulose, pregelatinized starch

Writing (Ёзиш)- “Complete Prescriptions” Writing: B2+

Worksheet 3B: Filling Complete Prescriptions Name _____

Prescription	Single dose	Daily dose	Complete prescription
Ampicillin 500 mg po qid x 5 d On hand: 250 mg capsules			
Digoxin elixir 150 mcg po tid x 10 d On hand: 50 mcg/mL			
Codeine sulfate 60 mg po q4h x 7 d On hand: 30 mg tablets			

Clondine 0.4 mg po bid x 3 d On hand: 0.1 mg tablets			
Amoxicillin 250 mg po qid x 10 d On hand: 125 mg capsules			
Lasix 40 mg po qd x 30 d On hand: 20 mg tablets			
Ampicillintrihydrate 250 mg po qid x 10 d On hand: 125 mg per 5 mL			

Quiz: Calculating Dosage **Name _____**

For each of the following doctor's orders, calculate the individual dose of medication.

1. Dr. Jones prescribed Plendil 7.5 mg. The drug label reads: Plendil 2.5 mg tab.
2. The doctor ordered Dilaudid 1.5 mg IM from a vial that is labeled 0.6 mg per mL
3. Dr. Sam prescribed 20 mg of a medication. You have 10 mg per 5 mL.
4. The physician ordered Procardia XL 60 mg. The drug on hand is Procardia XL 30 mg tablets.
5. Dr. Garza prescribed 30 mg of Phenobarbital. The pharmacy has 15 mg capsules available.

For each of the following prescriptions, calculate the individual dose, the daily dose, and the total amount needed to fill the complete prescription.

Prescription	Single dose	Daily dose	Complete prescription
Amoxicillin 500 mg capsule po tid x 10 d On hand: 500 mg/1 capsule			
Prednisone 40 mg po bid x 3 d On hand: 10 mg tablet			
Ciprofloxin 750 mg po qd x 10 d On hand: 500 mg scored tablet			
PenVK 250 mg po qid x 10 d On hand: PenVK 250 mg/1 tsp			
Acetaminophen 500 mg tab po q4h x 5 d On hand: 250 mg/1 tablet			

TOPIC 6

CLINICAL PHARMACY

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LESSON -13.

R: Article (EforPI, p.73)

W: How to write CV?
L: Yesterday (The Beatles)
S: Medicinal Chemistry (OTM, p.13)

DISCUSSING CAUSES OF SAES	ASKING ABOUT IMPLICATIONS FOR A DRUG
It could have been due to ...	How did the clinical trials go?
It is due to pre-existing conditions.	What is the status of approval?
The evidence is conclusive/inconclusive.	How far is it from approval?
A reaction to the product cannot be ruled out.	Could it jeopardize other products?
	What does it mean for the products in the pipeline?

Rewrite the following statements and questions using the Useful Phrases above.

1 It resulted from an old illness.

_____

2 Will it cause problems for other products?

_____

3 Maybe the side effect was a result of taking this product.

_____

4 How soon will we get permission to put the product on the market?

_____

5 Were the clinical trials successful?

_____

6 The facts neither prove nor disprove this.

_____

7 How will this affect other products which are not yet on the market?

_____

8 This product may or may not have caused the reaction.

_____

In order to get approval to sell a new drug, a company has to compile detailed documentation with all the information required by the drug authorities. Match the following sections with their descriptions.

1 ☐ Administrative Data

2 ☐ Common Technical Document Summaries

3 ☐ Quality

4 ☐ Non-clinical Study Reports

5 ☐ Clinical Study Reports

a biological, chemical, and pharmaceutical documentation with manufacture, quality control, and testing data

b overviews of quality, clinical, and non-clinical data

c documentation about clinical trials and post-marketing information

d general information, such as the marketing authorization application form, as well as product characteristics and labelling

e study reports, pharmacology, pharmacokinetics, toxicology, and references

PIL VS. PILL

Important information for any person taking a drug can be found in the 'PIL' or patient information leaflet. Such information is also called the patient leaflet, patient packet, or package insert. In the US, it is also referred to as a patient information sheet (PIS), or medication guide.

Note: When you talk about PILs, say each letter. If not, it might be confused with 'pills'.

Read the email from the Head of Regulatory Affairs and answer the questions below.

From: Fred Crow, Head of Regulatory Affairs
To: Regulatory Affairs staff, especially medical writers
Re: Recent audit, readability, and warnings

Dear RA staff

I just wanted to give you a brief update on the self-inspection conducted last week by QA. Most of the results were very positive. It seems our documentation is of a high standard, especially with respect to completeness and technical details. However, in terms of readability, we can still make some improvements in future patient information leaflets. We need to remember that not only healthcare professionals read these PILs, but also patients.

In addition, I have noticed something which, I think, some of you can improve on. It has to do with drug warnings. Yes, we do need to let patients know of any possible side effects. But, no, it is not necessary to alarm them unnecessarily. In other words, in future when describing possible side effects for products in the pipeline, we will need to differentiate more clearly between frequent and rare risks. In the case of the latter, we will need to be less direct in order to increase patient compliance.

Let's talk about these two points at our department meeting on Friday. I will also be asking Wendy, our senior medical writer, to coach junior staff members.

Best regards
Fred

1 What are the strong points in this department's documentation?

_____

2 How could it improve its documentation?

_____

3 What effect could a change in the style of language have on patients?

_____

Wendy, the senior medical writer in the Regulatory Affairs department, is training Mark, a ju staff member. Both write and translate patient information leaflets. Listen to the dialogue ar add the following headings to the PIL for *Mensamint*™.

Before you take this product • Further information • How to store • How to take/use • Read this leaflet carefully because it contains information you need to know • Possible side effects • What the product is, and what it is used for

PATIENT INFORMATION LEAFLET

MENSAMINT™

1 _____

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor, pharmacist, or healthcare professional. This medicine has been prescribed for you personally. Do not pass it on to others, even if their symptoms are similar to yours.

2 _____

Mensamint™ is a lozenge to support increased concentration. Regular use can lead to a marked improvement of both short-term and long-term memory and logical thinking skills. The active substance is mensagitatum. Other ingredients are peppermint, oil, sugar, talcum, and a preservative.

3 _____

Do not take *Mensamint*™ if you are allergic to peanuts.
If you have a history of heart trouble, consult your doctor before taking.

4 _____

Take two lozenges a day, mornings and early afternoons.

5 _____

Some patients may experience loss of sleep if the lozenges are taken too late in the day.

6 _____

Store below 25 °C in a dry place.

7 _____

Caduceus Pharmaceuticals
154 Freshfield Street
Milton Keynes

GIVING GENERAL ADVICE	GIVING STRONG WARNINGS
Mensamint™ may cause dizziness.	*Do not* use/take *Mensamint™* if ...
Mensamint™ can interact with other medicines.	*Stop use* and ask a doctor if ...
Like all drugs, this medicine can cause side effects.	*Keep out of reach* of children.
Use Mensamint™ with caution while driving or undertaking dangerous activities.	*Tell your doctor* immediately/right away if ...
It is possible that you may receive this medicine, or an alternative may be used.	You *must not* drive while taking this drug.
	You *should not* take *Mensamint™* if you have a history of ...

Here is some information from the PIL for a new drug called *Pogolox™*. Match the following sentences halves used in the leaflet.

1	*Pogolox™* may cause	a	are allergic to any antibiotics.
2	Tell your doctor right away if	b	your temperature continues to rise.
3	You must not	c	operate machinery while taking this drug.
4	Do not take *Pogolox™* if you	d	this medicine can cause diarrhoea.

Here is some information from the PIL for a new drug called *Pogolox™*. Match the following sentences halves used in the leaflet.

1	*Pogolox™* may cause	a	are allergic to any antibiotics.
2	Tell your doctor right away if	b	your temperature continues to rise.
3	You must not	c	operate machinery while taking this drug.
4	Do not take *Pogolox™* if you	d	this medicine can cause diarrhoea.
5	Stop use of *Pogolox™* immediately	e	serious liver damage.
6	Like all antibiotics,	f	if you experience any chest pain.

Choose a medicine you know. Write some general advice (GA) and some strong warnings (SW). Mark each sentence either GA or SW.

1 ☐ _____

2 ☐ _____

3 ☐ _____

4 ☐ _____

5 ☐ _____

6 ☐ _____

7 ☐ _____

TOPIC 9

MEDICINAL CHEMISTRY

Medicinal chemistry and pharmaceutical chemistry are disciplines at the intersection of chemistry, especially synthetic organic chemistry, and pharmacology and various other biological specialties, where they are involved with design, chemical synthesis and development for market of pharmaceutical agents, or bio-active molecules (drugs).

In particular, medicinal chemistry in its most common guise—focusing on small organic molecules—encompasses synthetic organic chemistry and aspects of natural products and computational chemistry in close combination with chemical biology, enzymology and structural biology, together aiming at the discovery and development of new therapeutic agents. Practically speaking, it involves chemical aspects of identification, and then systematic, thorough synthetic alteration of new chemical entities to make them suitable for therapeutic use. It includes synthetic and computational aspects of the study of existing drugs and agents in development in relation to their bioactivities, i.e., understanding their structure-activity relationships (SAR). Pharmaceutical chemistry is focused on quality aspects of medicines and aims to assure fitness for purpose of medicinal products.

At the biological interface, medicinal chemistry combines to form a set of highly interdisciplinary sciences, setting its organic, physical, and computational emphases alongside biological areas such as biochemistry, molecular biology, pharmacognosy and pharmacology, toxicology and veterinary and human medicine; these, with project management, statistics, and pharmaceutical business practices, systematically oversee altering identified chemical agents such that after pharmaceutical formulation, they are safe and efficacious, and therefore suitable for use in treatment of disease.

Medicinal chemistry is by nature an interdisciplinary science, and practitioners have a strong background in organic chemistry, which must eventually be coupled with a broad understanding of biological concepts related to cellular drug targets. Scientists in medicinal chemistry work are principally industrial scientists (but see following), working as part of an interdisciplinary team that uses their chemistry abilities, especially, their synthetic abilities, to use chemical principles to design effective therapeutic agents.

In the medicinal chemistry specialty areas associated with the design and synthesis of chemical libraries or the execution of process chemistry aimed at viable commercial syntheses, training paths are often much more varied (e.g., including focused training in physical organic chemistry, library-related syntheses, etc.).

NOTES

1. guise – an outward form, appearance, or way of presentencing someone or something
2. assure – make something certain to happen

3. eventually – occurring at the end of a process or period of time
4. viable – capable of working successfully

LESSON-14.

R: Text for outlesson reading: “Veterinary Pharmacy” (OTM, p. 30)
W: How to write an Essay?
L: I just want to say (Steavy Wonder)
S: Medicinal Chemistry (OTM, p.13)

Which of these signs would you expect to find when you visit a pharmaceutical company? Do you know what they mean?





A self-help group for cardiac diseases is visiting RRB Pharmaceuticals. Henry Naylor, a representative from Public Relations (PR), welcomes them. Listen and answer the questions.

1 What did RRB produce originally?

_____

2 What are the visitors not allowed to do?

_____

3 What do they have to do?

_____

4 When can the visitors ask their questions?

_____

EXPRESSING MOMENTS IN TIME

Past

When the company was founded, it only sold one product.
In the past we produced everything ourselves.

Present

Nowadays/Today many of our products are produced ...
Meanwhile, .../In the meantime, ...

Specifying particular moments

While watching the film, ...
During the tour, ...

Putting events in order

After the meeting has finished, we will ...
Once you have seen the company, you will ...
By the time we met them, the company had ...

Underline the most suitable expression to complete the sentences.

1 In the past, / In the meantime, requirements have reached a very high standard.
2 When it was founded, / Nowadays, the company only had one production site.
3 In the meantime, / When it was opened, they have developed a number of well-known products.
4 While / During you are waiting, you can look at these brochures.
5 In the past, / Meanwhile, our company is one of the ten largest drug companies in Europe.
6 By the time / During the safety film, I will give you more detailed information on the company.
7 Once / While the tour is finished, you will have seen the most important production areas.

Put the words into the correct order to make sentences.

1 effervescent company to The used powder only produce

_____

2 and process uncomplicated simple The be production to used

_____

3 documented use clothing The didn't be specifications to

_____

4 regulations strict to company's The safety be didn't so use

_____

5 inspections didn't so authorities be There use many by to

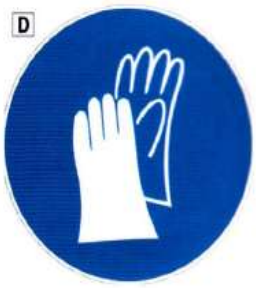
_____

Now look at these signs. Match them to the terms below.

A 

B 

C 

D 

E 

F 

G 

H 

1	_____	face mask ☐	5	_____	overshoes ☐
2	_____	hair covering ☐	6	_____	protective shoes ☐
3	_____	lab coat ☐	7	_____	rubber gloves ☐
4	_____	overalls ☐	8	_____	safety goggles ☐

Which diagram shows the person dressed correctly, according to Stephanie's instructions?

GIVING INSTRUCTIONS

If you give instructions in a very direct way, it may sound impolite. Therefore, it is important to watch your tone of voice, and how you phrase your instructions.

Note that when you tell people to do something mandatory, if you add a simple 'please', it makes your instructions sound much nicer.

e.g. *Please remember that the overshoes are only allowed to touch the white area.*

Note that 'mustn't' means that you are *not* allowed to do something.

e.g. *There mustn't be more than three people in the gowning room at a time.*

Polite instructions

Could you please ... ?	Please remember/Don't forget ...
Would you please ... ?	Please keep in mind ...
Please make sure that ...	I/We need you to ...

Listen to the instructions. Are they polite ☺, or impolite ☹? Tick the correct answer.

1 ☺ ☐ ☹ ☐

2 ☺ ☐ ☹ ☐

3 ☺ ☐ ☹ ☐

4 ☺ ☐ ☹ ☐

5 ☺ ☐ ☹ ☐

Rewrite the impolite sentences in a polite way. Practise saying the sentences politely.

1 _____

2 _____

3 _____

mailto:@n50u@n30l@nRewrltetheimpolltes€ntencerinapollteway.Practisesayingthesentencespotitety.7Llstentothetouragain.tUhatshouldStephaniedodlfferently?SAIETVYS.SECURITYSafetyisthefreedomfromdangeorrharm

Listen to the tour again. What should Stephanie do differently?

SAFETY VS. SECURITY

Safety is the freedom from danger or harm, whereas security is the protection from threats, such as attacks or crime.

OVER TO YOU

- In your opinion, how high is the risk of counterfeit prescription drugs?
- Who should try to stop such criminal activity? The industry? The government?
- Should online pharmacies be banned, or more tightly regulated?
- Are drugs in your company also tested for authenticity in the case of adverse events?

Now look at these signs. Give appropriate instructions for each one.

1 2 3 4 5

1 _____

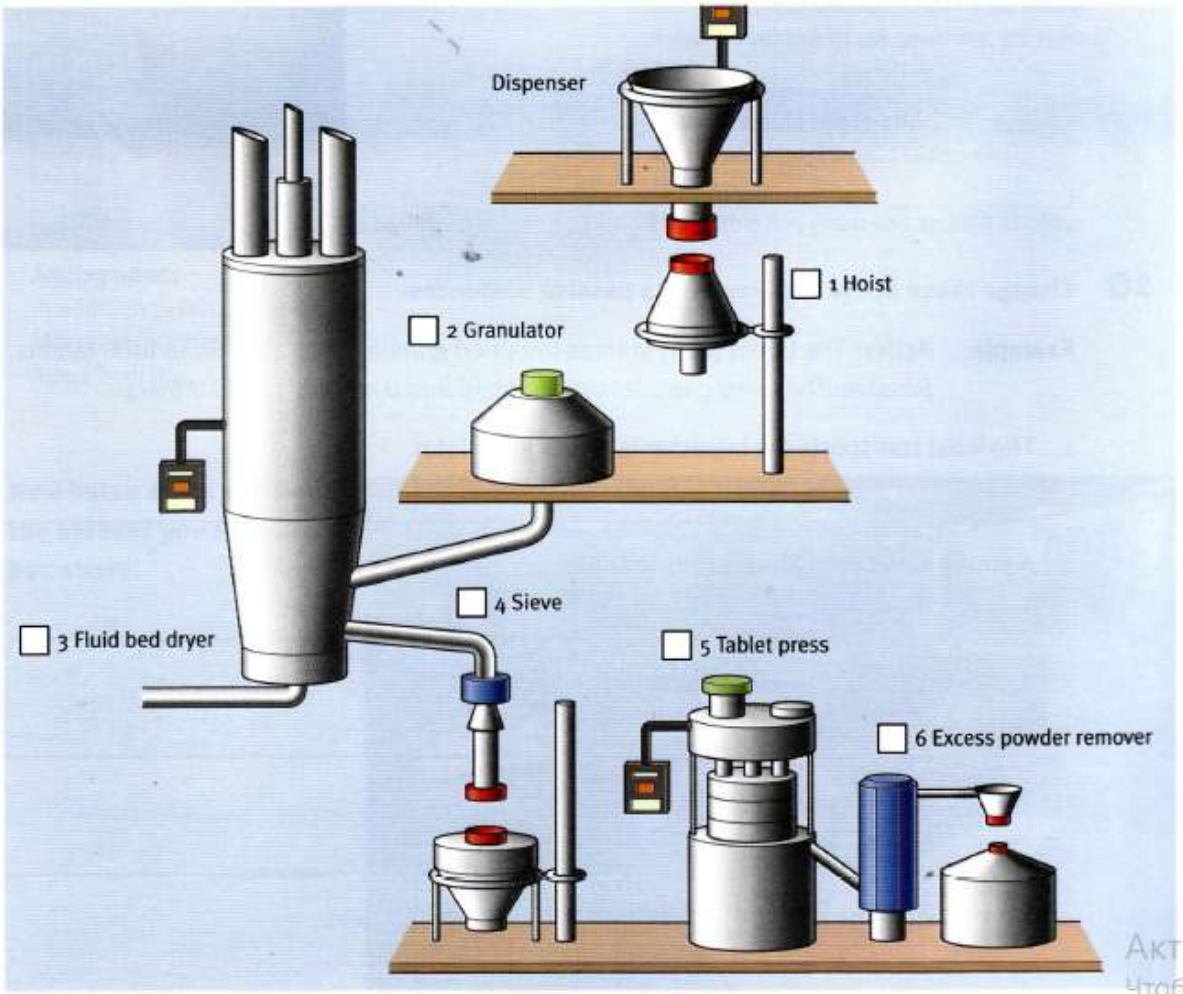
2 _____

3 _____

4 _____

5 _____

The group moves on to see the tablet production unit at RRB. Look at the diagram below.



Read the description of the production process, and number the steps according to the diagram.

A ☐ As the tablets go up a spiral, they are shaken, and the excess powder is vacuumed off. The pressed tablets are put into a drum and stored until it is time to coat them.
B ☐ In the granulator, the ingredients are mixed to create a wet mixture.
C ☐ The wet granules are pressed through a sieve on their way to the fluid bed dryer.
D ☐ The granules are air-dried.
E ☐ The dried granules are stamped into a mould to form tablets.
F ☐ Dry ingredients are weighed and transported to the granulator by the hoist.

DESCRIBING A PROCESS (PART 2)

The passive can also be used when the agent is known or relevant.
For this, *by + agent* is added.

The moisture	is	removed	by the hot air in the fluid bed dryer.
The granules	are	transported	by the hoist.

Change these active sentences into passive sentences.

Example: Active: The tablet press stamps the dried granules into a mould to form tablets.
Passive: *The dried granules are stamped into a mould to form tablets.*

1 The hoist transports dry ingredients to the granulator.

_____

2 A strong flow of hot air dries the granules.

_____

3 A shaker loosens the excess powder.

_____

4 A vacuum system sucks up the excess powder.

_____

5 A drum holds the pressed tablets until it is time to coat them.

_____

TOPIC 9

MEDICINAL CHEMISTRY

Medicinal chemistry and pharmaceutical chemistry are disciplines at the intersection of chemistry, especially synthetic organic chemistry, and pharmacology and various other biological specialties, where they are involved with design, chemical synthesis and development for market of pharmaceutical agents, or bio-active molecules (drugs).

In particular, medicinal chemistry in its most common guise—focusing on small organic molecules—encompasses synthetic organic chemistry and aspects of natural products and computational chemistry in close combination with chemical biology, enzymology and structural biology, together aiming at the discovery and development of new therapeutic agents. Practically speaking, it involves chemical aspects of identification, and then systematic, thorough synthetic alteration of new chemical entities to make them suitable for therapeutic use. It includes synthetic and computational aspects of the study of existing drugs and agents in development in relation to their bioactivities, i.e., understanding their structure-activity relationships (SAR). Pharmaceutical chemistry is focused on quality aspects of medicines and aims to assure fitness for purpose of medicinal products. At the biological interface, medicinal chemistry combines to form a set of highly interdisciplinary sciences, setting its organic, physical, and computational emphases alongside biological areas such as biochemistry, molecular biology, pharmacognosy and pharmacology, toxicology and veterinary and human medicine; these, with project management, statistics, and pharmaceutical business practices, systematically oversee altering identified chemical agents such that after pharmaceutical formulation, they are safe and efficacious, and therefore suitable for use in treatment of disease. Medicinal chemistry is by nature an interdisciplinary science, and practitioners have a strong background in organic chemistry, which must eventually be coupled with a broad understanding of biological concepts related to cellular drug targets. Scientists in medicinal chemistry work are principally industrial scientists (but see following), working as part of an interdisciplinary team that uses their chemistry abilities, especially, their synthetic abilities, to use chemical principles to design effective therapeutic agents.

In the medicinal chemistry specialty areas associated with the design and synthesis of chemical libraries or the execution of process chemistry aimed at viable commercial syntheses, training paths are often much more varied (e.g., including focused training in physical organic chemistry, library-related syntheses, etc.).

NOTES

1. guise – an outward form, appearance, or way of presentencing someone or something

2. assure – make something certain to happen

3. eventually – occurring at the end of a process or period of time

4. viable – capable of working successfully

LESSON-15. Mid-term Control

LESSON 16

R: Text for outlesson reading: “Poisonous Plants” (OTM, p. 33)
W: How to write a Summary?
L: What a wonderful world (Louis Armstrong)
S: Pharmaceutical Industry (OTM, p.14)

POISONOUS PLANTS

Plants cannot move to escape their predators, so they must have other means of protecting themselves from herbivorous animals. Some plants have physical defences such as thorns, but by far the most common protection is chemical. Over millennia, natural selection has produced a complicated and vast array of chemical compounds that deter herbivores. Many of the plant defence compounds arose to defend against consumption by insects, although when livestock or humans consume such plants, they may also experience negative effects, ranging from mild discomfort to death.

Many food plants possess toxic parts, are toxic unless processed, or are toxic at certain stages of their life. Notable examples include:

Apple (Malusdomestica). Seeds are mildly poisonous, containing a small amount of amygdalin, a cyanogenic glycoside. The quantity contained is usually not enough to be dangerous to humans, but it is possible to ingest enough seeds to provide a fatal dose. **Cherry** (Prunuscerasus), as well as other Prunus species such as **peach** (Prunuspersica), **plum** (Prunusdomestica), **almond** (Prunusdulcis), and **apricot** (Prunusarmeniaca). Leaves and seeds contain cyanogenic glycosides.

Kidney bean or common bean (Phaseolus vulgaris). The toxic compound phytohaemagglutinin, a lectin, is present in many varieties of common bean but is especially concentrated in red kidney beans. The lectin has a number of effects on cell metabolism; it induces mitosis, and affects the cell membrane in regard to transport and permeability to proteins. It agglutinates most mammalian red blood cell types. The primary symptoms of phytohaemagglutinin poisoning are nausea, vomiting, and diarrhoea.

Onions and garlic. Onions and garlic (genus Allium) contain thiosulphate, which in high doses is toxic to dogs, cats and some other livestock.

Potato (Solanumtuberosum). Potatoes contain toxic compounds known as glycoalkaloids, of which the most prevalent are solanine and chaconine. The concentration of glycoalkaloid in wild potatoes suffices to produce toxic effects in

humans. The toxin affects the nervous system, causing headaches, diarrhoea and intense digestive disturbances, cramps, weakness and confusion, and in severe cases coma and death. Poisoning from cultivated potatoes occurs very rarely, however, as the toxic compounds in the potato plant are, in general, concentrated in the green portions of the plant and in the fruits, and cultivated potato varieties contain lower toxin levels.

Rhubarb (Rheum rhaponticum). The leaf stalks (petioles) are edible, but the leaves themselves contain notable quantities of oxalic acid, which is a nephrotoxic and corrosive acid that is present in many plants. Symptoms of poisoning include kidney disorders, convulsions and coma. Rarely fatal.

Tomato (Solanumlycopersicum). Like many other nightshades, tomato leaves and stems contain solanine that is toxic if ingested, causing digestive upset and nervous excitement. Use of tomato leaves as a tea has been responsible for at least one death. Leaves, stems, and green unripe fruit of the tomato plant also contain small amounts of the poisonous alkaloid tomatine, although levels are generally too small to be dangerous. Ripe tomatoes do not contain any detectable tomatine.

Kalanchoedelagoensis (commonly known as mother of millions) contains bufadienolide cardiac glycosides, which can cause cardiac poisoning, particularly in grazing animals. During 1997, 125 head of cattle died after eating mother-of-millions on a travelling stock reserve near Moree.

Digitalis purpurea (commonly known as foxglove). The leaves, seeds, and flowers are poisonous, containing cardiac or other steroid glycosides. These cause irregular heartbeat, general digestive upset, and confusion. Can be fatal.

Jacobaea vulgaris (commonly known as ragwort). Contains many different alkaloids, including jacobine, jaconine, jacozine, otosenine, retrorsine, seneciphylline, senecionine, and senkirkine. Poisonous to livestock and hence of concern to people who keep horses and cattle. The danger is that the toxin can have a cumulative effect; the alkaloid does not actually accumulate in the liver but a breakdown product can damage DNA and progressively kills cells. Jacobaea vulgaris is also theoretically poisonous to humans, although poisoning is unlikely as it is distasteful and not used as a food.

Many plants are highly poisonous when ingested, this is common knowledge. It is remarkable, however, that simply touching certain plant species can also be a serious health hazard. The infamous Stinging Nettles are rather harmless in this respect, but there are much more dangerous contact-poisonous plants in many parts of the world, especially in the tropics. They can cause severe pain, rashes, blisters and leave scars. Some trees are reported to be so powerful that even raindrops falling from them can irritate the skin. Other plant species can cause blindness through the smoke of burning wood or by rubbing the eyes after touching the leaves.

Narcissus (commonly known as daffodil). The bulbs are poisonous and cause nausea, vomiting, and diarrhoea. Can be fatal. Stems also cause headaches, vomiting, and blurred vision.

Vegetation helps sustain life. We eat many plants, herbs and so forth in our daily diet. But, we must remember to be choosy. Some plants, trees or shrubs are potential killers of man. Some part of the ornamental plants or flowers in your yard may contain deadly poison. Many poisonous plants are so common and seemingly innocuous you do not suspect their toxic qualities.

Also known as burn plant or medicinal aloe, **Aloe Vera** is a clump-forming, succulent member of the lily family characterized by pointed, plump leaves and a rosette growth habit. Like many succulents, aloe prefers sunlight, though it will also grow in shadier sites. Excessive sun can be harmful to the plant if it is not irrigated properly.

Outdoor workers may be exposed to poisonous plants. Outdoor workers at risk include farmers, foresters, landscapers, groundskeepers, gardeners, painters, roofers, pavers, construction workers, laborers, mechanics, and any other workers who spend time outside. Forestry workers and firefighters who battle forest fires are at additional risk because they could potentially develop rashes and lung irritation from contact with damaged or burning poisonous plants.

Active Principles

Plants make use of different techniques to scare away unwanted visitors. The plants in the guide below are marked with symbols to indicate the techniques:

Mechanical. This defence mechanism is mostly obvious, like in prickles, thorns, or barbs. Less visible but also purely mechanical are the sharp edges of certain grasses which can cause unpleasant cuts. **Bamboos** also belong to the botanical family of grasses, and some bamboo species bear thin bristles on the surface, which can penetrate the skin and cause itching or irritation. There is an exceptional lot of mechanically active plants, and although injuries of the skin can cause secondary infections when dirt enters the human body, the mechanical principle is not subject of this document.

Chemical. These are poisons that can enter the skin without mechanical action. When the sap of some species gets onto the skin surface it can lead to painful skin irritation or irreversible damages. Some species can even cause temporary or permanent blindness if a person touches broken parts of the plant and then the own eyes. Throwing such plant material into a fire can also be dangerous as the smoke can irritate the skin or also lead to blindness. Typical representatives of this principle belong to the Euphorbiaceae family. There are many members of other botanical families, however, that act similar. Another kind of plants like the **Upas tree** contains sap that is not skin-irritating but can

be fatal if a very small amount of it gets into the bloodstream, for example through minor skin injuries.

Phototoxic. This principle occurs in a number of plants of which the best example is the **Giant Hogweed.** Phototoxic poison acts chemically, but only if the skin is exposed to sunlight at the same time.

Mechanical-chemical. Some Plants are sophisticated enough to penetrate the skin of the victim mechanically and then introduce a poisonous chemical. The result is an immediate burning sensation of the skin. The best known representatives of this kind are the **Stinging Nettles** and their close relatives in all parts of the world. Most mechanically-chemically acting plants belong to the botanical families Urticaceae and Euphorbiaceae, some of them being much more powerful than the Stinging Nettle. Under an electron microscope, fragile hollow needles are visible, with nettle cells at the base, filled with liquid poison. When touched, a needle breaks off, leaving an oblique tip, which can enter the human skin like a syringe and release the poison.

TOPIC 10

PHARMACEUTICAL INDUSTRY

The pharmaceutical industry develops, produces, and markets drugs or pharmaceuticals licensed for use as medications. Pharmaceutical companies are allowed to deal in generic and/or brand medications and medical devices. They are subject to a variety of laws and regulations regarding the patenting, testing and ensuring safety and efficacy and marketing of drugs.

The industry remained relatively small scale until the 1970s when it began to expand at a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products came into force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country.

The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation.[citation needed] Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process.

Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and

increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.

Drug discovery is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen, and manipulating these pathways using molecular biology or biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions.

Drug development refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate formulation and dosing, as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The amount of capital required for late stage development has made it a historical strength of the larger pharmaceutical companies.

Drug discovery and development is very expensive; of all compounds investigated for use in humans only a small fraction are eventually approved in most nations by government appointed medical institutions or boards, who have to approve new drugs before they can be marketed in those countries.

Drug researchers not directly employed by pharmaceutical companies often look to companies for grants, and companies often look to researchers for studies that will make their products look favourable. Sponsored researchers are rewarded by drug companies, for example with support for their conference/symposium costs. Lecture scripts and even journal articles presented by academic researchers may actually be 'ghost-written' by pharmaceutical companies.

There are special rules for certain rare diseases ("orphan diseases") involving fewer than 200,000 patients in the United States, or larger populations in certain circumstances. Because medical research and development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions, fee waivers, and market exclusivity on that drug for a limited time (seven years), regardless of whether the drug is protected by patents.

Depending on a number of considerations, a company may apply for and be granted a patent for the drug, or the process of producing the drug, granting exclusivity rights typically for about 20 years. However, only after rigorous study and testing, which takes 10 to 15 years on average, will governmental authorities grant permission for the company to market and sell the drug. Patent protection enables the owner of the patent to recover the costs of research and development through high profit margins for the branded drug. When the patent protection for the drug expires, a generic drug is usually developed and sold by a competing company. The development and approval of generics is less expensive, allowing them to be sold at a lower price. Often the owner of the branded drug will introduce a generic version before the patent expires in order to get a

head start in the generic market. Restructuring has therefore become routine, driven by the patent expiration of products launched during the industry's 'golden era' in the 1990s and companies' failure to develop sufficient new blockbuster products to replace lost revenues.

There is also huge concern about the influence of the pharmaceutical industry on the scientific process. Meta-analyses have shown that studies sponsored by pharmaceutical companies are several times more likely to report positive results, and if a drug company employee is involved (as is often the case, often multiple employees as co-authors and helped by contracted marketing companies) the effect is even larger. Influence has also extended to the training of doctors and nurses in medical schools, which is being fought.

The role of pharmaceutical companies in the developing world is a matter of some debate, ranging from those highlighting the aid provided to the developing world, to those critical of the use of the poorest in human clinical trials, often without adequate protections, particularly in states lacking a strong rule of law. Other criticisms include an alleged reluctance of the industry to invest in treatments of diseases in less economically advanced countries, such as malaria; Criticism for the price of patented AIDS medication, which could limit therapeutic options for patients in the Third World, where most of the AIDS infected people are living. However, a better policy of price discrimination would benefit to both patients and companies.

Patents have been criticized in the developing world, as they are thought to reduce access to existing medicines. There is mixed evidence on the efficacy of patents to stimulate pharmaceutical innovation, with recent evidence suggesting that patent grants slow down innovation. Reconciling patents and universal access to medicine would require an efficient international policy of price discrimination. Moreover, under the TRIPS agreement of the World Trade Organization, countries must allow pharmaceutical products to be patented.

NOTES

1. monger – referring to a person who engages in a particular activity

2. serendipity – the occurrence of events by chance in a beneficial way

3. disadvantage – something that makes success or progress less likely or causes a problem

4. rigorous – very thorough or accurate

5. launch – begin or introduce an enterprise or a new product

LESSON 17

R: Text for outlesson reading: “Biotechnology”
(OTM, p.37)
W: Summary
L: Let it be (The Beatles)
S: Pharmaceutical Industry (OTM, p.14)

TEXT 7

BIOTECHNOLOGY

Biotechnology is the use of living systems and organisms to develop or make useful products, or "any technological application that uses biological systems, living organisms or derivatives thereof, to make or modify products or processes for specific use". Depending on the tools and applications, it often overlaps with the fields of bioengineering and biomedical engineering. For thousands of years, humankind has used biotechnology in agriculture, food production and medicine. The term itself is largely believed to have been coined in 1919 by Hungarian engineer Karl Ereky. In the late 20th and early 21st century, biotechnology has expanded to include new and diverse sciences such as genomics, recombinant gene technologies, applied immunology, and development of pharmaceutical therapies and diagnostic tests. The concept of 'biotech' or 'biotechnology' encompasses a wide range of procedures (and history) for modifying living organisms according to human purposes — going back to domestication of animals, cultivation of plants, and "improvements" to these through breeding programs that employ artificial selection and hybridization. Modern usage also includes genetic engineering as well as cell and tissue culture technologies. In other words, biotechnology can be defined as the mere application of technical advances in life science to develop commercial products. Biotechnology also writes on the pure biological sciences (genetics, microbiology, animal cell culture, molecular biology, biochemistry, embryology, cell biology). And in many instances it is also dependent on knowledge and methods from outside the sphere of biology including:chemical engineering,bioprocess engineering,bioinformatics, a new brand of information technology, and biorobotics.

Thus, biotechnology is one of the powerful forces of raising national economy. The competition in biotechnology is growing all over the world. Each country is trying to find its place in this race, have its own face, get its “biotechnological passport”. According to experts, it is the level and state of biotechnology development that will be one of the important criteria of estimation for the development of the countries in the 21st century. Development of biotechnology is in many ways defined by the needs of the market, as the demand for foodstuffs, medications, energy, etc. is constantly growing. It may seem that being highly commercial, biotechnology doesn’t need any special regulations. Development of biotechnology will allow the country to overcome the crisis in the sphere that is so strategically important, contribute to the development of

new economy, based on knowledge, provide its competitiveness in globalization environment, allow to solve a number of important problems of economical and social development.

After the tour of the tablet production area, the visitors are given a presentation on some different aspects of the pharmaceutical industry. Listen to part of the presentation Henry Naylor is giving to the self-help group on one aspect of compliance. Decide whether the statements are true (✓) or false (✗).

1 ☐ Henry wants the visitors to ask their questions at the end of his presentation.

2 ☐ Pharmaceutical companies have to comply with GMP guidelines.

3 ☐ The different colour zones on the floors indicate the separation of certain functions.

4 ☐ Authorities sometimes come unannounced.

5 ☐ Production equipment does not need to be validated until it is taken into operation.

GIVING PRESENTATIONS

Welcoming the audience
Good morning/afternoon, ladies and gentlemen. ☐
I'm happy to welcome you to our company. ☐

Introducing your topic
Let me give you a brief overview of ... ☐
I'm here to give you some information on ... ☐
Today, I'll be talking about ... ☐

Signposting
Moving on to the next point, ... ☐
As I mentioned earlier, ... ☐
Coming back to ... ☐
Let me come back to what I said before ... ☐

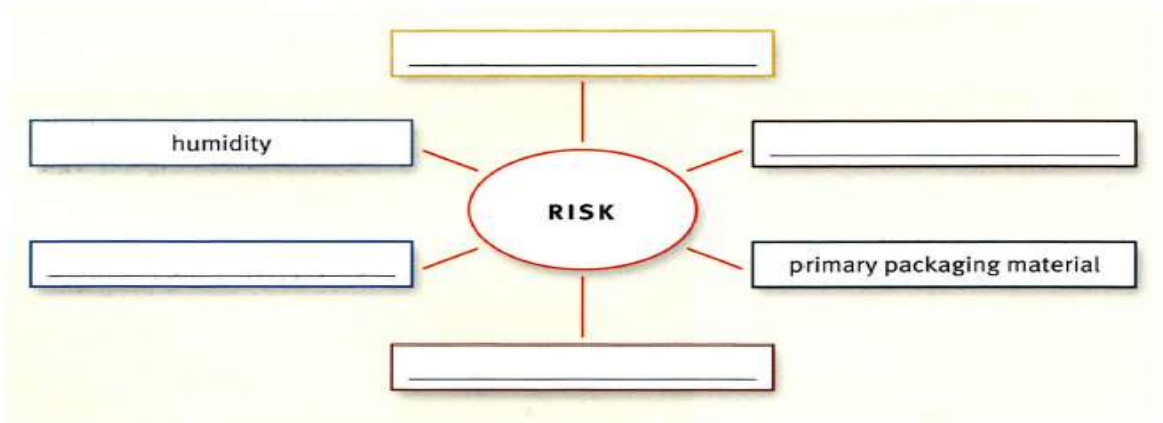
Adding points
In addition to this, ... ☐
Moreover/Furthermore, ... ☐
Apart from this ☐

Dealing with interruptions
Could I please finish what I was saying? ☐
If I could just finish what I was saying ... ☐

Dealing with questions
There will be time for questions after my talk. ☐
Feel free to ask questions as we go along. ☐
If you would like to ask anything, go ahead. ☐

Finishing
Finally, I would like to add ... ☐
As a final point, I would like to say ... ☐
To recap, ... ☐
I hope this has given you an idea about ... ☐

After Henry's presentation, the visitors see the packaging area. He explains that packaging protects the quality of the products during shipping and storage. However, there are always risks involved. Look at the diagram below. What risks would you add?



Here are Henry's handwritten notes. Which part of the presentation do they belong to?

a) Enjoying tour so far?

b) Continue on to packaging

c) Buildings, clothing, training

d) What is GMP?

e) Interrupting OK

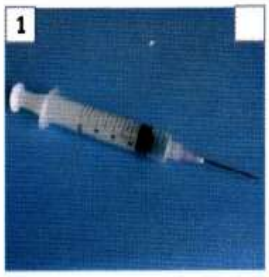
f) Recap

Parts of a presentation: a checklist

1) Welcome and introduction – ☐
2) Handling questions – ☐
3) State the topic – ☐
4) Main body – ☐
5) Summarize – ☐
6) Invite final questions – Open questions?
7) Finish – ☐

Are these primary or secondary packaging materials? Could they be both? Write P for primary, S for secondary, or B for both.

PRIMARY AND SECONDARY PACKAGING



Primary packaging is the material which is in direct contact with the product.

Secondary packaging is any packaging material that is not in direct contact with the product.

Match the types of packaging from exercise 16 with their descriptions below.

1 A(n) _____ is an aerosol dispensing device which releases medication into the mouth of the patient. The medication is breathed deeply into the lungs, or stays in the mouth or throat.

2 A(n) _____ is a type of single-use plastic container, and is used for pharmaceutical products as well as for other consumer goods. The product is placed in the formed cavity and sealed by lidding foil. The product is removed by pushing it through the foil.

3 A(n) _____ is a needle attached to a plastic tube used for putting medicine into the body or removing blood.

4 A(n) _____ is a multi-use glass container with a twist-on lid. It can hold pharmaceuticals, or any kind of fluids or solids. It can be opened and closed several times until the contents are used up. Sometimes a desiccant is integrated into the cap so that the contents remain dry.

5 A(n) _____ is a small disposable bag containing an individual dose of the medicine. It often has a lengthwise perforation which can be torn open.

6 A(n) _____ is a piece of paper attached with adhesive to the primary packaging to identify it and give details concerning its ownership, nature, and/or use.

Which of the verbs in the box are used with the following primary packaging forms? Why?

press • push through • remove • tear • twist

1 syringe _ _ _ _ _ _

2 sachet _ _ _ _

3 blister pack _ _ _ _ _ _ _ _ _ _ _

4 jar _ _ _ _ _

5 inhaler _ _ _ _ _

CHILDPROOF VS. ELDERLY-ACCESSIBLE

A lot of research is done to make packaging *childproof*, i.e. a child cannot open it alone. However, at the same time, the elderly must have easy access to their medication, i.e. it needs to be *elderly-accessible*.

Read the following text about childproof packaging and unscramble the letters in the brackets to find the correct word.

The latest *i* _____ [1] (vatinionson) in childproof packaging nowadays entail sophisticated *m* _____ [2] (sacnihmsem) that are physically easy to open, even for the *e* _____ [3] (dyelerl) or infirm, but that require actions to be thought through in a way small children would not be *c* _____ [4] (aaclbep) of. Psychologists, *e* _____ [5] (gieneesrn), and designers have *c* _____ [6] (bocallradeto) and come up with the following state-of-the-art features.

TOPIC 10

PHARMACEUTICAL INDUSTRY

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The industry remained relatively small scale until the 1970s when it began to expand at a greater rate. Legislation allowing for strong patents, to cover both the process of manufacture and the specific products came into force in most countries. By the mid-1980s, small biotechnology firms were struggling for survival, which led to the formation of mutually beneficial partnerships with large pharmaceutical companies and a host of corporate buyouts of the smaller firms. Pharmaceutical manufacturing became concentrated, with a few large companies holding a dominant position throughout the world and with a few companies producing medicines within each country.

The pharmaceutical industry entered the 1980s pressured by economics and a host of new regulations, both safety and environmental, but also transformed by new DNA chemistries and new technologies for analysis and computation.[citation needed] Drugs for heart disease and for AIDS were a feature of the 1980s, involving challenges to regulatory bodies and a faster approval process.

Drug development progressed from a hit-and-miss approach to rational drug discovery in both laboratory design and natural-product surveys. Demand for nutritional supplements and so-called alternative medicines created new opportunities and increased competition in the industry. Controversies emerged around adverse effects, notably regarding Vioxx in the US, and marketing tactics. Pharmaceutical companies became increasingly accused of disease mongering or over-medicalizing personal or social problems.

Drug discovery is the process by which potential drugs are discovered or designed. In the past most drugs have been discovered either by isolating the active ingredient from traditional remedies or by serendipitous discovery. Modern biotechnology often focuses on understanding the metabolic pathways related to a disease state or pathogen, and manipulating these pathways using molecular biology or biochemistry. A great deal of early-stage drug discovery has traditionally been carried out by universities and research institutions.

Drug development refers to activities undertaken after a compound is identified as a potential drug in order to establish its suitability as a medication. Objectives of drug development are to determine appropriate formulation and dosing, as well as to establish safety. Research in these areas generally includes a combination of in vitro studies, in vivo studies, and clinical trials. The amount of capital required for late stage development has made it a historical strength of the larger pharmaceutical companies.

Drug discovery and development is very expensive; of all compounds investigated for use in humans only a small fraction are eventually approved in most nations by government appointed medical institutions or boards, who have to approve new drugs before they can be marketed in those countries.

Drug researchers not directly employed by pharmaceutical companies often look to companies for grants, and companies often look to researchers for studies that will make their products look favourable. Sponsored researchers are rewarded by drug companies, for example with support for their conference/symposium costs. Lecture scripts and even journal articles presented by academic researchers may actually be 'ghost-written' by pharmaceutical companies.

There are special rules for certain rare diseases ("orphan diseases") involving fewer than 200,000 patients in the United States, or larger populations in certain circumstances. Because medical research and development of drugs to treat such diseases is financially disadvantageous, companies that do so are rewarded with tax reductions, fee waivers, and market exclusivity on that drug for a limited time (seven years), regardless of whether the drug is protected by patents.

Depending on a number of considerations, a company may apply for and be granted a patent for the drug, or the process of producing the drug, granting exclusivity rights typically for about 20 years. However, only after rigorous study and testing, which takes 10 to 15 years on average, will governmental authorities grant permission for the company to market and sell the drug. Patent protection enables the owner of the patent to recover the costs of research and development through high profit margins for the branded drug. When the patent protection for the drug expires, a generic drug is usually developed and sold by a competing company. The development and approval of generics is less expensive, allowing them to be sold at a lower price. Often the owner of the branded drug will introduce a generic version before the patent expires in order to get a head start in the generic market. Restructuring has therefore become routine, driven by the patent expiration of products launched during the industry's 'golden era' in the 1990s and companies' failure to develop sufficient new blockbuster products to replace lost revenues.

There is also huge concern about the influence of the pharmaceutical industry on the scientific process. Meta-analyses have shown that studies sponsored by pharmaceutical companies are several times more likely to report positive results, and if a drug company employee is involved (as is often the case, often multiple employees as co-authors and helped by contracted marketing companies) the effect is even larger. Influence has also extended to the training of doctors and nurses in medical schools, which is being fought.

The role of pharmaceutical companies in the developing world is a matter of some debate, ranging from those highlighting the aid provided to the developing world, to those critical of the use of the poorest in human clinical trials, often without adequate protections, particularly in states lacking a strong rule of law. Other criticisms include an alleged reluctance of the industry to invest in treatments of diseases in less economically advanced countries, such as malaria; Criticism for the price of patented AIDS medication, which could limit therapeutic options for patients in the Third World, where most of the AIDS infected people are living. However, a better policy of price discrimination would benefit to both patients and companies.

Patents have been criticized in the developing world, as they are thought to reduce access to existing medicines. There is mixed evidence on the efficacy of patents to stimulate pharmaceutical innovation, with recent evidence suggesting that patent grants slow down innovation. Reconciling patents and universal access to medicine would require an efficient international policy of price discrimination. Moreover, under the TRIPS agreement of the World Trade Organization, countries must allow pharmaceutical products to be patented.

NOTES

1. monger – referring to a person who engages in a particular activity

2. serendipity – the occurrence of events by chance in a beneficial way

3. disadvantage – something that makes success or progress less likely or causes a problem

4. rigorous – very thorough or accurate

5. launch – begin or introduce an enterprise or a new product

Now match each container system type to the action needed to use it.

1 ☐	slide	a	A closure must be pushed down before it can be unscrewed.
2 ☐	poke	b	A first layer must be peeled off a blister before the drug can be pushed through the second layer.
3 ☐	push-screw	c	A closure must be squeezed between two fingers before it can be unscrewed.
4 ☐	squeeze-screw	d	A container with three buttons that must be aligned in order to slide off the lid.
5 ☐	peel-push system	e	A tube that can only be released by an adult-length finger by pushing an internal catch.

OVER TO YOU

- Who do you think is responsible for the boy's death? The mother? The pharmaceutical company? Someone else?
- Do you know of any similar cases involving pharmaceutical products?
- Pharmaceutical companies are required to package their products in a childproof, but elderly-accessible way. Why is this so difficult?

BOY KILLED BY POTENT PAIN PATCH

A few years ago, a mother was convicted of negligence leading to her son's death. It was claimed that he had died from a pain medication overdose. Now the woman has taken measures to ensure that other children do not die the same way.

A four-year-old boy was found dead after he had stuck a highly potent, pain-relieving patch to his leg. His mother was sentenced to several years' community service for leaving a used patch in a place where her young son could have access to it. The patches had been prescribed for her as treatment for a serious intestinal disorder.

She claimed that she always put her used patches into an empty soda can, whenever possible. One day, however, she did not have one available, so she put the used patch directly into the garbage. Her son later found it and stuck it onto his leg, just the way he had seen his mother do it.

The authorities became interested in this case. The boy's death highlighted a problem that no one had anticipated up to that time. Because of her son's death, the young mother demanded that safe-disposal boxes be included in the packages of medicated patches. These boxes should have a small slit at the top to discard used patches and it should be impossible to open them.

In the meantime, many medications, especially those that involve needles, come with disposal boxes for discarding them. However, besides a warning about the effects of the medication, authorities have unfortunately not made the requirements regarding the disposal of potentially dangerous materials any stricter. Fortunately, though, many pharmaceutical companies have recognized the problem and now supply boxes for disposal with their products. ◆

LESSON-18.

Making individual presentations on the topic
“Biological Engineering” (OTM, p.25)

TEXT 3

BIOLOGICAL ENGINEERING

Biological engineering or bioengineering (including biological systems engineering) is the application of concepts and methods of biology (and secondarily of physics, chemistry, mathematics, and computer science) to solve real-world problems related to the life sciences and/or the application thereof, using engineering's own analytical and synthetic methodologies and also its traditional sensitivity to the cost and practicality of the solution(s) arrived at. In this context, while traditional engineering applies physical and mathematical sciences to analyze, design and manufacture inanimate tools, structures and processes, biological engineering uses primarily the rapidly developing body of knowledge known as molecular biology to study and advance applications of living organisms.

The differentiation between biological engineering and biomedical engineering can be unclear, as many universities loosely use the terms "bioengineering" and "biomedical engineering" interchangeably. Biomedical engineers are specifically focused on applying biological and other sciences toward medical innovations, whereas biological engineers are focused principally on applying engineering principles to biology - but not necessarily for medical uses. Hence neither "biological" engineering nor "biomedical" engineering is wholly contained within the other, as there can be "non-biological" products for medical needs as well as "biological" products for non-medical needs.

Biological engineering is a science-based discipline founded upon the biological sciences in the same way that chemical engineering, electrical engineering, and mechanical engineering can be based upon chemistry, electricity and magnetism, and classical mechanics, respectively.

The word bioengineering was coined by British scientist and broadcaster Heinz Wolff in 1954. The term bioengineering is also used to describe the use of vegetation in civil engineering construction. The term bioengineering may also be applied to environmental modifications such as surface soil protection, slope stabilization, watercourse and shoreline protection, windbreaks, vegetation barriers including noise barriers and visual screens, and the ecological enhancement of an area.

Biological Engineers or bioengineers are engineers who use the principles of biology and the tools of engineering to create usable, tangible, economically viable products.

Biological engineering employs knowledge and expertise from a number of pure and applied sciences, such as mass and heat transfer, kinetics, biocatalysts, biomechanics, bioinformatics, separation and purification processes, bioreactor design, surface science, fluid mechanics, thermodynamics, and polymer science. It is used in the design of medical devices, diagnostic equipment, biocompatible materials, renewable bioenergy, ecological engineering, agricultural engineering, and other areas that improve the living standards of societies.

Depending on the institution and particular definitional boundaries employed, some major fields of bioengineering may be categorized as:

Biological systems engineering;

Biomedical engineering: Biomedical technology, Biomedical diagnostics, Biomedical therapy, Biomechanics, Biomaterials.

LESSON 19

Making individual presentations on the topic

“My Scientific Work”

LESSON 20

FINAL LESSON

Test yourself!

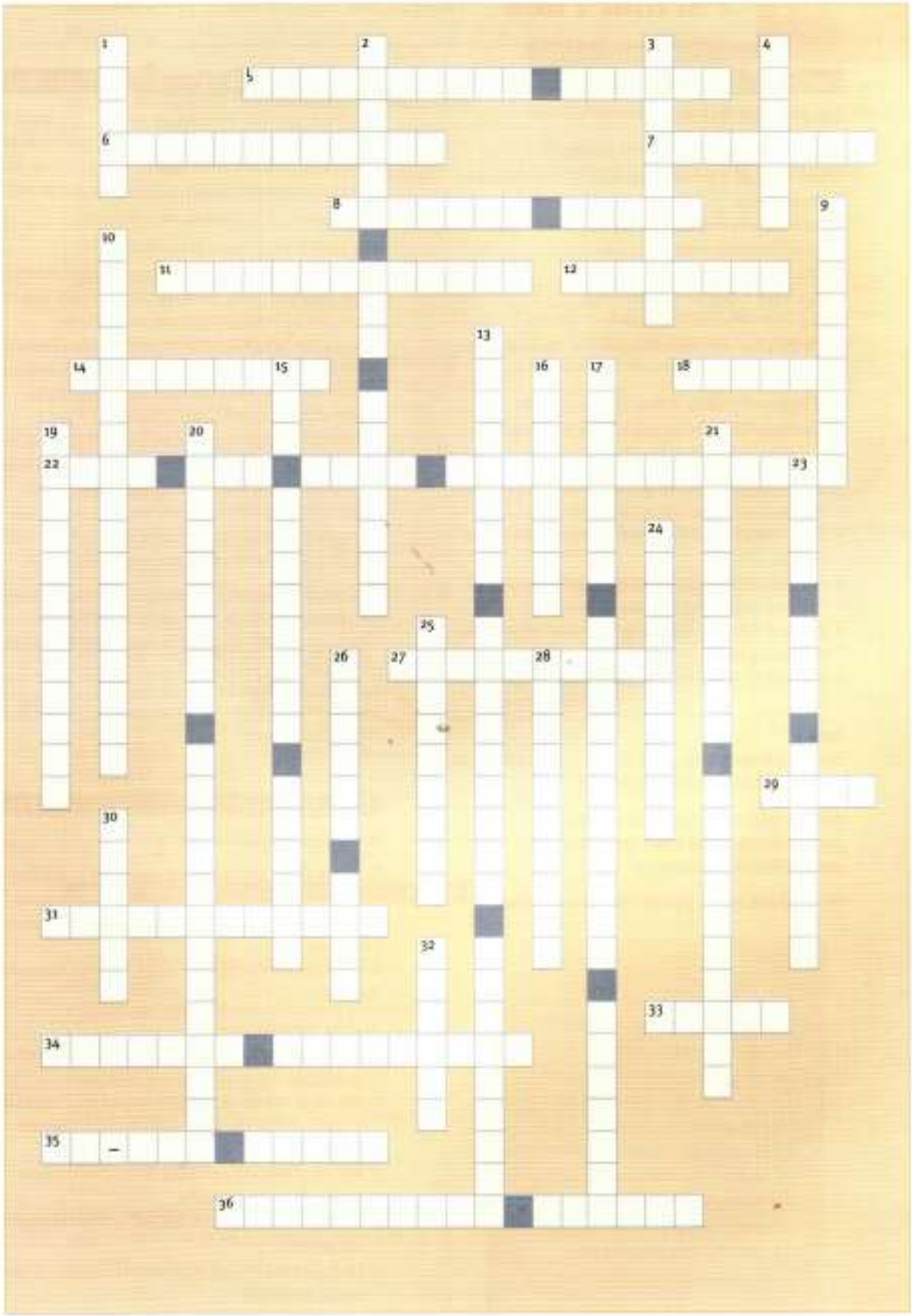
See how much vocabulary you have learned. Use the clues to complete the crossword puzzle.

Across

5 A task performed to fix something wrong.
6 A condition in which a part of the body becomes red, warm, and swollen.
7 A place where a company has its offices and/or factories.
8 An unwanted medical occurrence during a clinical trial.
11 Paperwork necessary to provide evidence or proof.
12 A careful study of a substance done before medicine is developed.
14 A written description of changes to a study or trial protocol.
18 To give or hand in, e.g. a documentation to an authority to obtain authorization.
22 An American drug authority.
27 Following rules and regulations made by people in authority.
29 To put a cover over tablets.
31 A written note from a doctor for medicine.
33 Equipment used to lift something.
34 The practice of making sure that goods and services fulfil defined standards.
35 Trials to test a drug in humans.
36 A task performed to stop something bad from happening.

Down

1 An examination of processes, procedures, and standards.
2 Medicine provided by a chemist or pharmacist without a prescription.
3 A mechanism which releases its contents in defined amounts.
4 A mechanism or piece of equipment designed to perform a special function.
9 A difference from a specification, not within the accepted range.
10 Monitoring or evaluating suspected side effects.
13 A fixed working method, often written down.
15 A substance recently developed.
16 The ability of a drug to treat the illness for which it was developed.
17 An information sheet explaining how to take a drug.
19 Giving off small bubbles of gas when added to liquids.
20 Permission to sell and distribute a new drug.
21 A person trained to do tests on drug ingredients.
23 Medicine obtained in retail outlets without a prescription.
24 Features or characteristics of a drug.
25 A person who agrees to participate in a clinical trial.
26 A type of medicine, e.g. tablets, powder, gel, spray.
28 A substance in a drug.
30 A small animal used as a subject in the earlier stages of preclinical trials, e.g. mouse or rat.
32 A prescribed amount of a medicine or drug.



True/False Questions

Indicate whether each sentence below is true (T) or false (F).

1. _____ **Documentation** of patient care is not mandatory.
2. _____ **DH** is the abbreviation for drug history, **FH** is the abbreviation for family history, and SH is the abbreviation for social history.
3. _____ **Legal liability** is a major reason for pharmacy documentation.
4. _____ **SOAP notes** are used to prescribe medications to patients.
5. _____ **DRP** is the abbreviation for drug-related problem.
6. _____ **Objective** information on a SOAP note refers to the information that is provided by the patient, and **subjective** information on a SOAP note refers to information obtained through prescription records, lab values, and physical examinations.
7. _____ The abbreviation **Q** means every hour, and the abbreviation **QH** means every.
8. _____ **Pharmacy documentation** should be concise, very clear, and patient-focused.
9. _____ **HEET** is the abbreviation for head, eyes, ears, and throat.
10. _____ The "A" in **SOAP** notes refers to assessment and the patient's medical and drug-related problems, and the "P" in **SOAP** notes refers to the plan for treatment, follow-up, and monitoring.

Multiple Choice Questions

Choose the correct answer from a, b, and c.

1. _____ **SID** is the abbreviation for:

a. four times a day
b. once daily
c. every other day

2. _____ The abbreviation **PMD** means:

a. post medical diagnosis
b. private medical doctor
c. past medical diagnosis

3. _____ The abbreviation **MedHx** means:

a. medical history
b. medication history
c. medical and medication history

PRE-ASSESSMENT

True/False Questions

Indicate whether each sentence below is true (T) or false (F).

1. _____ **Pelvic inflammatory disease,** or PID, does not lead to infertility.
2. _____ A symptom of erectile dysfunction, or ED, is the inability to obtain a full erection.
3. _____ **Fertility** is the inability to conceive a child.
4. _____ A discharge, itching, and pain in the vagina can be caused by **vaginitis.**
5. _____ **Gonorrhea** is a highly contagious, sexually transmitted disease, or STD, also known as "the clap."
6. _____ Some women who are lactating can develop **mastitis,** an infection of the breast tissue that can cause pain, redness, and swelling of the breast.
7. _____ Heavy bleeding during **menstruation** is called **amenorrhea.**
8. _____ **Hot flashes** refer to the feeling of a warm and hot sensation throughout the face and upper body and to the flushed appearance of hot, red, and blotchy skin on the face and upper body experienced by some perimenopausal women.
9. _____ **Genital herpes** is a highly contagious, sexually transmitted disease that affects only women.
10. _____ **Toxic shock syndrome** is a rare but life-threatening infection that affects mostly women who wear superabsorbent tampons, contraceptive sponges, and diaphragms.
11. _____ **Menorrhagia** refers to the absence of a menstrual cycle.
12. _____ A **yeast infection** is a type of **vaginitis** that causes itching and a white, thick discharge that looks like cottage cheese.
13. _____ **Uterine fibroids,** which are common in women, can cause heavy menstrual periods, urinary problems, constipation, anemia, and an enlarged abdomen.
14. _____ Several factors in males, including erectile dysfunction, premature ejaculation, lack of semen, and sexually transmitted diseases, can lead to **infertility.**
15. _____ The word **menstruation** is an adjective.

PRE-ASSESSMENT

True/False Questions

Indicate whether each sentence below is true (T) or false (F).

1. _____ Reversible scarring of the liver is called **cirrhosis.**
2. _____ One cause of **autoimmune hepatitis** is scarring of the liver.
3. _____ Intravenous drug users and people who share needles are not at risk for **hepatitis B,** a serious liver infection.
4. _____ One cause of damage to the liver is **alcoholic cirrhosis.**
5. _____ The noun form of **hepatic** is hepatitis.
6. _____ **Hepatitis B** is transmitted through food.
7. _____ **Cirrhosis** of the liver is caused by alcohol only.
8. _____ **Hepatitis A** is transmitted through blood and bodily fluids.
9. _____ **Autoimmune hepatitis** is caused by years of alcohol abuse.
10. _____ The noun form of **toxin** is toxic.
11. _____ Contaminated needles used in body piercing and body tattooing are one cause of **hepatitis C.**
12. _____ Cirrhosis makes it difficult for blood to flow through the liver to detoxify harmful substances and to purify the blood.
13. _____ Immune disorders such as diabetes, ulcerative colitis, and Sjögren's syndrome can be found in people with **autoimmune hepatitis.**
14. _____ **Hepatitis B** can be transmitted through sexual contact, needle sharing, accidental needle sticks, and from mother to child.
15. _____ The word **contagion** is an adjective.

PRE-ASSESSMENT

True/False Questions

Indicate whether each sentence below is true (T) or false (F).

1. _____ **Asthma** is a chronic heart condition.
2. _____ **Bronchitis** is a respiratory infection that causes a hacking cough and produces phlegm.
3. _____ **Inhalation** and **inhaler** are noun forms.
4. _____ Some individuals with **pneumonia** will experience a cold, a fever, **shaking chills,** and cough with sputum production.
5. _____ The adjective form of **perspiring** is perspiration.
6. _____ **Tuberculosis** cannot be treated successfully with antibiotics.
7. _____ The most common cause of **emphysema** is cigarette smoking.
8. _____ People with chronic obstructive pulmonary disease (COPD) experience **wheezing** and **shortness of breath.**
9. _____ **Pneumothorax** refers to a collapsed lung.
10. _____ The adjective form of **asthma** is asthmatic.
11. _____ A person with **bronchitis** may experience fatigue, shortness of breath, and itchiness.
12. _____ The most common forms of **COPD** are asthma and tuberculosis.
13. _____ **Pleurisy** is a blood clot in the lung, and a **pulmonary embolism** is fluid in the lung.
14. _____ Allergens such as pet dander, dust mites, molds, and pollen can trigger **asthma.**
15. _____ The word **wheeze** is a noun and an adjective.

PRE-ASSESSMENT

True/False Questions

Indicate whether each sentence below is true (T) or false (F).

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15. _____ The word **wheeze** is a noun and an adjective.

II. SELF- STUDY THEMES

SELF STUDY PLAN

FOR THE 1ST YEAR STUDENTS OF MASTER DEGREE

I TERM OF THE ACADEMIC YEAR OF 2021-2022

№	Themes	Fulfillment form	Hours	Duration
1	***Healthy Lifestyle***	1. Make an Essay on the theme. 2. Translation in written form. 3. Make presentation.	4	
2	***Healthcare System of Uzbekistan***	1. Make an Essay on the theme. 2. Make presentation. 3. Translation in written form.	4	
3	***Healthcare System of the UK***	1. Make an Essay on the theme. 2. Translation in written form.	4	
4	***Pharmaceutical Industry of Uzbekistan***	1. Make an Essay on the theme. 2. Translation in written form. 3. Make presentation.	4	
5	***New generation of Medicinal Forms***	1. Make an Essay on the theme. 2. Summaries on the themes. 3. Make presentation.	4	
6	***Traditional and Alternative Medicine***	1. Make an Essay on the theme. 2. Make presentation. 3.Translation in written form.	4	
7	***My Future plans***	1. Make an Essay on the theme. 2. Make tests. 3.Translation in written form.	4	
8	***My Dissertation work***	1. Make an Essay on the theme. 2. Make presentation. 3.Translation in written form.	4	

GLOSSARY

Term	Defininition in English
Achieving approach to learning	See strategic approach.
Strategic approach to learning	Typifies students who adapt their learning style to meet the needs of the set task. Intention is external to the real purpose of the task, as it focuses on achieving high marks for their own sake, not because they indicate high levels of learning. Also known as the achieving approach.
Action learning	An approach to learning involving individuals working on real projects with the support of a group (set) which meets regularly to help members reflect on their experience and to plan next actions.
Action research	Researching one's own practice in a cyclical manner. See Chapter 28, Case study 1.
Active learning	A process of engaging with the learning task at both the cognitive and affective level.
National training programm	- to make a radical reform of the system of training, the democratic state of the Republic and the steady progress towards the construction of a just civil society; the implementation of fundamental changes in the economy of the country, the national economy, particularly in the direction of raw materials through the path of production of competitive products, the establishment of the rule of the benefit of the state social policy and education, the rich ethnic, cultural and historical tradition and heritage of the attention of the authority and position of respect in the world to go from strength to strength.
National training model Person **The state and society** **Continuous education** **Science**	- its main components are as follows; - The training system subjects and objects in the field of consumers and implementation of their services. - education and training system regulating the activities to monitor and guarantee the preparation and adoption - training base of qualified competitive staff, include all types of education, state educational standards, as well as the structure of the system retraining. - training and development of highly qualified specialists using modern educational and information technologies.

Production	- The need for personnel as well as quality of training and basic requirements of the customer in terms of financial, logistical training system participants.
Educational Technology	- this trainer, education of students affect their particular circumstances, and it will act as a pre-defined intensive process of formation.
Technology	- is the Greek word "technical," that is the "master" and "Logos" - "science". Changes as sources. Research, technology, skills and techniques used in the process, a set of methods.
Learning technology **Basic concepts:**	-general information about the development of the information object after receiving information brought into the process and interconnection of between informational laws. innovation in the private diagnostics, innovation educational activities, axiology, acmiology, creativity, reflection.
Innovation	- Updating. Change in process of activity. Updating on the basis of scientific and technical achievements and advanced experience in the field of engineering, technology, management, news, as well as their different reflection.
Concept	- the purpose of drawing up the plan with the current legislation in this area is the concept stage
Invent	- the creation of innovation
Invention	- new ideas and technical solutions, creative product that allows to solve the specific problem.
Overview	-*noun*: [countable usually singular] a short description of a subject or situation that gives the main ideas without all the details
Sickness	-*noun*: [uncountable] the state of being sick, absence from work due to sickness
Consciousness	– *noun*: [uncountable] MEDICINE the condition of being awake and able to understand what is happening around
Psychoactive drugs	– *adjective*: technical psychoactive drugs, chemicals etc. have an effect on the mind

Spinal cord	– *noun*: [countable] the thick string of nerves enclosed in your SPINE by which messages are sent to and from your brain
Stimulants	-*noun*:[countable] a drug or substance that makes you feel more active and full of energy
Hallucination	-*noun*: [countable, uncountable] something you see, feel, or hear that is not really there, or the experience of this, usually caused by a drug or mental illness
Forth	- *adverb*: literary beginning on that day or at that time
Boredom	-*noun*: [uncountable] the feeling you have when you are bored
Tension	– [uncountable] nervous feeling:a nervous, worried, or excited feeling that makes it impossible for you to relax
Awareness	- *noun*: [uncountable] knowledge or understanding of a particular subject or situation.
Food and drug administration (FDA) **decipher**	- *verb*: [transitive] to find the meaning of something that is difficult to read or understand.
Proprietary	- *adjective*: [no comparative, usually before noun::] a proprietary product is one that is only sold under a particular name by a particular company
A generic	(nonproprietary) name, and a trade (proprietary or brand) name.
Cramp	-*noun*: [countable] a severe pain that you get in part of your body when a muscle becomes too tight, making it difficult for you to move that part of your body
Cramps	[plural] severe pains in the stomach, especially the ones that women get during MENSTRUATION
Nonprescription	-*adjective*: a nonprescription drug is one that you can buy in a store without a PRESCRIPTION (= written order) from a doctor SYN: over-the-counter.
Peer	-to look very carefully or hard, especially because you cannot see something well
Frustration	- *noun*: [countable, uncountable] the feeling of being annoyed, upset, or impatient, because you cannot control or change a situation, or achieve something
Ritual	- *noun*: [countable, uncountable] something that you do regularly and in the same way each time.
Fascinating	- *adjective*: extremely interesting

Involve	-*verb*: [transitive] to include something as a necessary part or result.
Euphoria	-*noun*: [uncountable] a feeling of extreme happiness and excitement.
Bloodstream	- *noun*: [singular] BIOLOGY blood as it flows around your body.
Mystery	-*noun*: plural mysteries [countable] something that is not understood or cannot be explained, or about which little is known.
Surrounding	- *adjective*: [only before noun::] near or around a particular place :
Eliminated	-*verb*: [transitive] 1 to completely get rid of something that is unnecssary or unwanted
Antiepileptic	
Frustration	-*noun*: [countable, uncountable] the feeling of being annoyed, upset, or impatient, because you cannot control or change a situation, or achieve something
Response	- [countable] a single reaction to a STIMULUS (= something that causes a reaction in living things) , for example the way your body reacts to a particular infection
Be rid of somebody/ something	to be no longer affected by someone or something unpleasant, annoying, or unwanted
Adverse	-*adjective:* [only before noun] not good or favorable
Reaction	-[singular] a bad effect, such as illness, caused by food that you have eaten or a drug that you have taken.
Unwanted	–.*adjective:* not wanted or needed
Cruise	- *verb*: informal to do something well or successfully, without too much effort.
Maintain	-*verb*: [transitive] to take care of something so that it stays in good condition.
Target	- *verb*: [transitive] to make something have an effect on a limited group or area.
Stuffy -	*adjective:* a stuffy room or building does not have enough fresh air in it
Over-the-counter	-*adjective:* [only before noun::] over-the-counter drugs can be obtained without a PRESCRIPTION (= a written order from a doctor)
Annoying -	*adjective*: making you feel slightly angry :
Safety	-[uncountable] the state of not being dangerous or likely to cause harm or injury
Life-threatening	- *adjective*: a life-threatening situation or injury could cause a person to die
Alternative	-*adjective*: [only before noun::] an alternative idea, plan etc. is one that can be used instead of another one SYN alternate :

Interfere:	-*verb*: [intransitive] to prevent something from succeeding or from happening in the way that is normal or planned
Clot	-*verb*: [intransitive, transitive]if a liquid such as blood or milk clots or something clots it, it becomes thicker and more solid
Schizophrenia around them	- *noun*: [uncountable] MEDICINE a serious mental illness in which someone's thoughts and feelings are not based on what is really happening
Hesitate	- *verb*: [intransitive] to pause before saying or doing something because you are nervous or not sure :
Outcome	-*noun*: [countable] the final result of a meeting, process, series of events etc., especially when no one knows what it will be until it actually happens :
Interactions	-*noun*: [countable, uncountable] a process by which two or more things have an effect on each other, or an occasion when this happens :
Assemble	means putting a medicinal product in a container which is labelled before the product is sold or supplied. If the medicinal product is already in the container in which it is to be sold or supplied, assemble means labelling the container before the product is sold or supplied. The legal definition of assemble can be found section 132 of the Medicines Act 1968
Approval	is the process through which we recognise qualifications and programmes that meet our education and training standards.
Awarding body	is an organisation responsible for the standards of delivery and assessment and award of a qualification approved by us that is included in a national qualifications framework.
Body corporate	is a limited company or limited liability partnership that has been incorporated with Companies House.
Colleagues	includes any individuals who pharmacy professionals work with. This includes students, support workers and other professionals.
Competence	is the requirement for a pharmacy professional to properly perform their role. It is a combination of skills, knowledge, character and health.
Continuing professional development	is the process by which pharmacy professionals keep up-to-date through learning.
Conscientious objection	is the refusal to provide pharmacy services due to religious or moral beliefs.
Delegate.	is when a pharmacy professional asks someone else, such as a colleague or student, to carry out a task on their behalf
Dispensing	is the process from receipt of a prescription to the supply of the dispensed medicine to the patient.

Fit to practice	is when someone has the skills, knowledge, character and health to do their job safely and effectively. This should not be confused with being fit to work.
Internet services	includes the supply of medicines, pharmaceutical products, medical devices and the provision of other professional services over the internet, or arrangements for the supply of such products or provision of such services over the internet.
Learning hours	includes all the time needed to achieve a unit of study and includes directed study, homework, assessment time and preparation time.
Learning outcomes	include knowledge, skills, attitudes and values demonstrated at a defined level.
Manufacture	includes any process carried out in the course of making a medicinal product. The legal definition of manufacture can be found in section 132 of the Medicines Act 1968
Medical device	means an article which is intended to be used for human beings or animals for the purpose of
	diagnosis, prevention, monitoring, treatment or alleviation of disease,
	diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
	investigation, replacement or modification of the anatomy or of a physiological process, or control of conception and does not achieve its purpose by pharmacological, immunological or metabolic means. The legal definition of medical device can be found in section 132 of the Medicines Act 1968
Medicinal products and **medicines**	means any substance or article (which is not a medical device) which is given to human beings or animals for a medicinal purpose. This includes prescription only medicines (POM), pharmacy medicines (P) and general sales list medicines (GSL) and all medicines listed as controlled drugs (CD). Pharmacy medicines and general sales list medicines are sometimes referred to as ‘over the counter’ medicines (OTC). The legal definition of medicinal products can be found in section 132 of the Medicines Act 1968
Medicinal purpose	means
	treating or preventing disease,
	diagnosing disease
	ascertaining the existence, degree or extent of a physiological condition,

Fit to practise	is when someone has the skills, knowledge, character and health to do their job safely and effectively. This should not be confused with being fit to work.
Internet services	includes the supply of medicines, pharmaceutical products, medical devices and the provision of other professional services over the internet, or arrangements for the supply of such products or provision of such services over the internet.
Owner patient	is a person or animal who receives care or treatment from a health professional is an individual pharmacist (sole trader), a pharmacist partnership, a partnership in Scotland where only one partner must be a pharmacist, a body corporate that owns a retail pharmacy business, or a representative of the above in the event of death or bankruptcy. In a hospital the owner may be a Trust .
Patients and the public	includes any individuals or groups, patients, customers, clients and their animals who use, or are affected by pharmacy services, advice or other services provided directly or indirectly by pharmacy professionals
Person carrying on a retail pharmacy business	is the pharmacist or pharmacists that owns the business, or in the case of a body corporate, the superintendent pharmacist. In a hospital this may be the Chief Pharmacist.
Pharmacy professional	means a pharmacist or registered pharmacy technician
Pharmacy student	in the standards for initial education and training of pharmacists is an MPharm student studying on a pharmacy course accredited by us. It does not mean a pharmacy technician studying on a course accredited by us who is a pre-registration trainee pharmacy technician.
Pharmacy services	means the activities, advice, products, treatment or care that is provided in a registered pharmacy
Position of authority	is when a pharmacy professional has management responsibilities in connection with carrying on a retail pharmacy business

Pre -registration scheme	is the 52 weeks of professional training completed by prospective pharmacists called pre-registration trainee pharmacists.
Pre-registration trainee pharmacy technician .	is a person who is undertaking education and training to become a pharmacy technician.
Training provider	is an organisation responsible for the delivery, assessment and award of qualification for a programme approved by us, or an organisation approved by an awarding body to deliver and assess a qualification included in a national qualifications framework approved by us. This can be a college or private training provider
Superintendent pharmacist	is a pharmacist who is a superintendent of a retail pharmacy business owned by a body corporate. In hospitals this may be the chief pharmacist.
Retail pharmacy business	is a business which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list, whether medicinal products on such a list are sold in the course of that business or not. Some hospitals and trusts have retail pharmacies within them. The legal definition of retail pharmacy business can be found in section 132 of the Medicines Act 1968.
Responsible pharmacist	is a pharmacist who is responsible for pharmacy procedures of registered pharmacy for the purposes of the Responsible Pharmacist Regulations 2008. The responsible pharmacist is recorded in the pharmacy record of the registered pharmacy.

Registered pharmacy	is a premises entered in the register
Professional services	means the activities, advice, products, treatment or care that pharmacy professionals provide.

IV. APPENDIX

a) Standardized programme

ЎЗБЕКИСТОН РЕСПУБЛИКАСИ
ОЛИЙ ВА ЎРТА МАХСУС ТАЪЛИМ ВАЗИРЛИГИ

ЎЗБЕКИСТОН ДАВЛАТ ЖАҲОН ТИЛЛАРИ УНИВЕРСИТЕТИ

"ТАСДИҚЛАЙМАН"
Ректор _____ Б.Кулматов
2020 йил "30" 07

"КЕЛИШИЛДИ"
Олий ва ўрта махсус таълим вазирлиги
2020 йил "14" 08

Рўйхатга олинди: № МД – 1.03
2020 йил "14" 08

АМАЛИЙ ХОРИЖИЙ ТИЛ

ФАН ДАСТУРИ

Барча мутахассисликлар учун

Фан/модуль коди AXTIL1035		Ўқув йили 2020-2021	Семестр 1/2	ECTS - Кредитлар 5
Фан/модуль тури Мажбурий		Таълим тили инглиз/немис/француз		Ҳафтадаги дарс соатлари 2
1	Фаннинг номи	Аудитория машғулотлари (соат)	Мустақил таълим (соат)	Жами юклама (соат)
	Амалий хорижий тил	60	90	150

2 Фан/модуль коди AXTIL1035 Ўқув йили 2020-2021 Семестр 1/2 ECTS - Кредитлар 5 Фан/модуль тури Мажбурий Таълим тили инглиз/немис/француз Ҳафтадаги дарс соатлари 2 1. Фаннинг номи Аудитория машғулотлари (соат) Мустақил таълим (соат) Жами юклама (соат) Амалий хорижий тил1 60 90 150 2. I. Фаннинг мазмуни Фанни ўқитишдан мақсад – ўрганилаётган амалий хорижий тил бўйича амалий коммуникатив компетенцияни шакллантириш, шунингдек магитрантларнинг ўрганаётган амалий чет тиллардан бирида равон ва аниқ сўзлашишларига ва ҳозирги пайтда дунёда содир бўлаётган сиёсий, иқтисодий ва ижтимоий воқеликка ўз муносабатларини билдира олишларини ҳамда мустақил фикрлаш, изланиш, билим, кўникма ва малакаларини шакллантиришдан иборат. Фаннинг вазифаси – магистрантларга ўрганилаётган амалий чет тилидан она тилига ёзма ва оғзаки таржима масалалари, лексик, грамматик ва стилистик сатҳларидаги ўхшаш ва тафовутли жиҳатлари, ўзига хос хусусиятлари тўғрисида маълумотлар бериш, магистрантларнинг матнни лексик, семантик ва стилистик таҳлил қилиш кўникмаларини ривожлантириш, маълумотни турли контекстларда таҳлил қилиш орқали унинг маъносини қайта ифода этиш усулларини ўргатиш, турли вазиятларда ўрганилаётган амалий хорижий тилда равон мулоқат қилишга ўргатишдан иборат. II. Асосий қисм (амалий машғулотлар) II.I. Амалий машғулотларда коммуникатив компетенцияни ривожлантириш учун қуйидаги умумлашган мавзулар тавсия этилади: 1. Келажакдаги мутахассис касбий фаолияти. 2. Ўзи эгаллаётган соҳа бўйича республикамизда эришилган ютуқлар, соҳа тараққиёти бўйича истиқбол режалар. 3. Ўзи эгаллаётган соҳа бўйича хорижий мамлакатларда эришилган ютуқлар, соҳа тараққиёти бўйича истиқбол режалар. 4. Экология ва саломатлик 1 Мазкур жадвалга 5А120102 – Лингвистика (роман-герман тиллари) магистратура мутахассислиги ўқув режасидаги “Амалий хорижий тил” фанига ажратилган соатлар ва унга тегишли маълумотлар киритилган. Ишчи дастур (силлабус) ларни тузишда ушбу фанга ҳар бир ОТМ томонидан ажратилган соат, кредит миқдори ҳамда соҳа ва мутахассисликнинг ўзига хос хусусиятлари эътиборга олиниши лозим.3 Ўрганилаётган хорижий тилнинг фонетика ва грамматика қисмлари бўйича қуйидаги мавзулар тавсия этилади: Ўрганилаётган тилнинг товуш тизими урғу, интонация, ритмик гуруҳ, сўзларнинг боғланиши ва морфологик тузилиши, сўз туркумлари: от, сифат, сон, феъл, равиш, ёрдамчи сўзлар, артикллар, предлоглар, равишдош, сифатдош феълларнинг актив ва пассив формалари, модал феъллар, конъюктив 1, конъюктив 2, инфинитив ва инфинитивли конструкциялар модал сўзлар, модал юкламалар, феъл замонлари, мураккаб тўлдирувчи, отларнинг кўплик формаси, сифатларда роднинг ифодаланиши, гап бўлаклари ва уларнинг умумий таснифи, замонларнинг мослашуви кўчирма ва ўзлаштирма гап. Ўрганилаётган хорижий тилнинг синтаксис қисми бўйича қуйидаги мавзулар тавсия этилади: Гап, содда гап, бир бўлакли гаплар, икки бўлакли гаплар. Қўшма гаплар. Аниқловчи эргашган, эга эргашган, мақсад эргашган, тўлдирувчи эргашган, ҳол эргашган, равиш эргашган, натижа эргашган, сабаб эргашган, шарт эргашган, тўсиқсиз эргаш гаплар, актив ва пассив форма, пассив форманинг альтернативалари. Ўрганилаётган хорижий тилнинг лексика қисми бўйича қуйидаги мавзулар тавсия этилади: Мутахассисликка оид термин ва тушунчалар. Аббревиатура, акроним ва топонимлар.

Идиомалар, фразеологик бирликлар. Кўп маъноли сўзлар, сўз бирикмалари, эркин бирикмалар, феълли турғун бирикмалар. Ўзлашган сўзлар. Клишелар. Луғатлар ва уларнинг таркиби. Тиллардаги реалиялар, муқобилсиз лексикалар. III. Амалий машғулотлар бўйича кўрсатма ва тавсиялар Амалий машғулотларда магистратура талабаси эгаллаётган мутахассислиги бўйича ўз давлати ва тили ўрганилаётган мамлакат таълим тизими, унинг ютуқ ва камчиликларини ўрганиши, таҳлил қилиши, мутахассисликка оид лингвистик атамалар билан ишлаши, эгаллаётган соҳаси бўйича хорижий тиллардаги интернет ресурсларидан самарали фойдаланиши назарда тутилади. Магистрантлар ўрганилаётган чет тили бўйича билим ва кўникмаларини жонли мулоқот, машқлар бажариш, иншо ва баёнлар ёзиш, машқларни таржима қилиш орқали янада бойитадилар. Шунингдек, дарслик ва ўқув қўлланмалар, аудио ва видео материаллар асосида билимларини мустаҳкамлаш, таржима материалларидан фойдаланиш, ўтилган мавзулар юзасидан диалог қилиш ва шу кабилар орқали магистрантлар билимини ошириш тавсия этилади. Амалий машғулотлар мультимедиа воситалари билан жиҳозланган 4 аудиторияда ўтказилиши зарур. Машғулотлар фаол ва интерфактив усуллар ёрдамида ўтилиши, мос равишда муносиб педагогик ва ахборот технологиялар қўлланилиши мақсадга мувофиқ. IV. Мустақил таълим ва мустақил ишлар Мустақил таълим учун тавсия этиладиган умумий мавзулар: Гиёҳвандлик ва унинг салбий оқибатлари, терроризм, жиноят ва жазо экология, этник низолар, касалликлар; Соғлиқни сақлаш тизими: Соғлом турмуш тарзи, соғлиқни сақлаш, тиббиётнинг Шарқ ва Ғарбда ривожланиши, анъанавий ва ноанъавий тиббиёт турлари; Илмий-техник прогресс ва унинг инсониятга бўлган таъсири: биоинженерия, нанотехнология, замонавий ахборот технологиялари, атрофмуҳитнинг ифлосланиши, ишсизлик; Ватанпарварлик, маданият ва маънавият, диний, миллий толерантлик, замонавий ахборот технологиялари. Мустақил ўзлаштириладиган мавзулар бўйича талабалар томонидан тақдимот устида ишлаш; берилган мавзу бўйича қўшимча тил материали йиғиш, уни таҳлил қила олиш (Library research, Reading Log, Writing Assignment); сўз бойлигини кенгайтириш (Programme of Vocabulary Development); дебатларга тайёргарлик кўриш; илмий постерларни лойиҳалаш ва уларни ҳимоя этишга тайёргарлик кўриш; портфолио тайёрлаш; гуруҳ муҳокамасига (Round Table) тайёрланиш; тил воситаларининг оғзаки ва ёзма нутқда қўлланиш имкониятлари билан янада кенгроқ танишиш; муайян кўрсатмалар бўйича берилган топшириқларни ёзма бажариш тавсия этилади. 3. V. Фан ўқитилишининг натижалари (шаклланадиган компетенциялар) Фанни ўзлаштириш натижасида талаба: − кенг кўламли нутқ ёки қатор мураккаб фикрлар баёнини; − маъруза, нутқ, баёнот, тафсилотли йўриқномалар, илмий ва ихтисослик тақдимотлар, сўров ва фикрларнинг моҳиятини; − эълон ва хабарларни; − таниш ва нотаниш контекстдаги мураккаб аутентик нутқни; − ўрганилаётган тил эгаси бўлган сўзлашувчиларнинг суҳбат ёки мунозарасининг аксарият қисмини; − радио, интернет ва телевидение дастурлари, интервьюларнинг аксарият қисмини тушуна олиши; − ўрганилаётган тилда сўзлашувчилар билан мулоқотга киришиш; − олдиндан тайёргарлик кўрилмаган жонли муҳокама ва мунозара юритиш; − ўз соҳаларига оид интервьюда иштирок эта олиш; − битимга келишув ёки муаммо ечимини топишда расмийлик ва 5 хушмуомалаликдан фойдаланиш; − расмий муҳокама доирасида ўз фикр ва мулоҳазаларини аниқ ифодалаши; − ўз ҳамкорлари билан музокара юритиши; − маълум масала юзасидан маданий тартибга амал қилиб маълумот сўраши; − муҳокамаларда ўз фикрларини асослаш, ўзгартириб талқин эта олиши ва тузатиши; − расмий доираларда (масалан, семинар ва ҳоказолар) ўз соҳаси бўйича савол-жавобга киришиш кўникмаларига эга бўлиши; − маълум мавзу бўйича тақдимот қилиш; − ўз соҳаси бўйича маълумотларни аниқ ва батафсил баён этиш; − маълум мавзу бўйича оғзаки маъруза қилиш; − мақола, маъруза ёки муҳокама юзасидан аниқ умумлашган хулоса қилиш; − таниш мавзуга оид қараш ёки фикрни ривожлантириш, далиллар, мисоллар келтириш орқали асослай олиши; − таниш ва нотаниш мавзулардаги матнларнинг асосий/айрим жиҳатларини; − ўз соҳалари ва қизиқишларига мос ёзишмаларни; − жадвал, графикларнинг қисқа изоҳини; − мураккаб номаларни; − махсус ва мураккаб ёзма йўриқнома ва йўналишларни; − тезислар, маъруза матнлари, конференция дастурлари, мундарижа ва шу каби матнларни; - касбий соҳаларига оид мақола ва маърузалардан тегишли маълумотни фарқлаш ва тушуниш малакаларига эга бўлиши лозим. 4. VI. Таълим технологиялари ва методлари: Амалий дарсларида замонавий компьютер технологиялари ёрдамида презентацион ва электрон-дидактик технологиялардан

фойдаланилади. Жумладан, • амалий машғулотларида “Ақлий ҳужум”, “Тарози”, “Бумеранг”, “Биргаликда ўқиймиз”, “Арра”; • интерфаол кейс-стадилар; • мантиқий фиклаш, тезкор савол-жавоблар; • гуруҳларда ишлаш; • тақдимотларни қилиш; • индивидуал лойиҳалар; • жамоа бўлиб ишлаш ва ҳимоя қилиш учун лойиҳалар. 5. VII. Кредитларни олиш учун талаблар: Магистрант ўрганилаётган амалий хорижий тилни барча компетенциялар бўйича эркин мулоқот ва касбий фаолиятда қўллай олиш даражада ўзлаштириши лозим. Хорижий тилда мулоқотга кириша олиши, ўз соҳасига оид мунозараларда иштирок эта олиши, жорий, оралиқ назорат 6 шаклларида берилган вазифа ва топшириқларни бажариши, якуний назоратни ижобий баҳога топшириши талаб этилади. 6. Асосий адабиётлар 2 Инглиз тили 1. David Bolke, Dorothy E. Zemach, Skillful 1 (Reading&Writing), Macmillan, 2013. 2. Louis Rogers&Jennifer Wilkin, Dorothy E. Zemach, Skillful 2 (Reading&Writing), Macmillan, 2013. 3. Malcolm M., Steve Taylore-Knowles, Destination (book 3&4), Macmillan Education UK, 2013 4. Mike Boyle, Ellen kisslinger, Skillful Listening & Speaking (Full set), Macmillan Education UK, 2013 Немис тили 1. Em neu Brückenkurs, Arbeits- und Kursbuch. – München: Max Hueber Verlag, Ismaning, 2010. – 128 s. 2. С.Саидов. Deutsche Grammatik in Übungen. – Тошкент, 2003. 3. С.А. Зияева, С.Д. Новикова, Die Übersetzung in die Muttersprache und ins Deutsche. Т.; 2010. 4. Завьялова В.М., Ильина Л.В. Практический курс немецкого языка. М. 2003. Француз тили 1. A. Volte. Belle ville “Methode de français”. Cahiers d’exercises. –Belgique, 2004. 2. Le français. Saïdjan Khajiyev. Tachkent. 2020 3. М.Н. Попова, Ж.А. Казакова, Г.М. Ковальчук. Француз язык. – М.; 2007. 4. Ph.Dominique. Le noveau sans frontiers. Paris, 1998 5. O.V. Saxno, R.S. Ibragimova. La vie de l’Ouzbekistan et de la France. – Т.; 2002. Қўшимча адабиётлар Инглиз тили 1.Крылова Л.Р. Сборник упражнений по грамматике английского языка. – М., Книжный дом, 2003 2.Боқиева Г.Х., Ирисқулов М.Т. In Touch Forever – Тошкент, 2006 3.Мўминов О. Public relations. История и теория. –Ташкент, Ijod dunyosi, 2004 4.Инглизча-русча, русча-инглизча, инглизча-ўзбекча луғат (барча нашрлари) 5.Don Shiach. How to write essay. – Oxford. 2009 6.Martin Hewings. Advanced Grammar in use. Cambridge. 1998 7.Elaine Walker, Steve Elsworth Grammar Practice for Upper Intermediate Students, Edinburg,Longman, 2000 2 Адабиётлар рўйхатига ОТМ ахборот-ресурс марказлари имкониятлари, соҳага оид замонавий манбалар ва ҳар бир тил хусусиятлари инобатга олинган ҳолда қўшимчалар киритилиши мумкин. Киритилган қўшимчалар ишчи дастурларда келтирилади.7 Немис тили 1. Ilse Sander, Birgit Braun, Margir Doubek u.a. DaF kompakt A1-B1 Kursbuch mit 3 Audio –CDs. Ernst Klett Sprachen. Stuttgart, 2011. 2. Birgit Braun, Margir Doubek, Andrea Frater -Vogel u.a. DaF kompakt A1-B1 Übungsbuch mit 3 Audio –CDs .Ernst Klett Sprachen. Stuttgart, 2011. 3. Hartmut Aufderstraße, Heiko Bock, Jutta Müller, Helmut Müller. Themen aktuell. Deutsch als Fremdsprache. Max Hueber Verlag. München, 2007 4. Specht Franz, Niebisch Daniela, Pude Angela, - Schritte international Neu. Max Hueber Verlag, München, 2017. 5. Norbert Becker und Jörg Braunert. Alltag, Beruf & Co. Kursbuch+Arbeitsbuch mit Audio und CDs. Hueber Verlag, Ismaning, Deutschland 2009. 6. Немисча-русча, русча-немисча, немисча-ўзбекча луғат (барча нашрлари) 7. Tangram B1. Deutsch als Fremdsprache. – Ismaning, Deutschland. 2002. Француз тили 1. Z. Noutchié Njiké Civilisation progressive de la Francophonie. –Paris, 2003 2. E.S.Kouvchinova «Manuel de français» Москва. «Высшая школа» - 1987 3. Костецкая Е.О., Карданивский В.И. Французкий язык. Практическая грамматика. –М., Высшая школа, 2002 4. Французча-русча, русча-французча луғат. Барча нашрлари. 5. Французча-ўзбекча, ўзбекча-французча луғат. Барча нашрлари Ахборот манбалари Инглиз тили 1. www.toefl.com 2. www.englishtrairing.ru 3. www.lingua.ru 4. www.teachingenglish.org.uk 5. www.onestopenglish.com 6. www.businessenglishonline.net 7. www.elgazette.com Немис тили 1. www.regma.de 2. www.krie.de 3. www.zum.de 4. www.lehrer-online.de 5. www.leixilotte.de 6. .lexikon.freenet.de/Literaturdidaktik Француз тили 1. www.granddictionnaire.com 2. www.francophonnie.hacherre-livre.com 3. www.portail.lettres.net8 4. www.citationsdumonde.com 5. www.français-affaires.com 7. Фан дастури Олий ва ўрта махсус, профессионал таълим йўналишлари бўйича ўқув-услубий бирлашмалар фаолиятини Мувофиқлаштирувчи кенгашнинг 2020 йил “14” августдаги 3-сонли баённомаси билан маъқулланган. Ўзбекистон Республикаси Олий ва ўрта махсус таълим вазирлигининг 2020 йил “14” августдаги 418-сонли буйруғи билан маъқулланган фан дастурларини таянч олий таълим муассасаси томонидан тасдиқлашга розилик берилган. 8. Фан/модуль учун масъул: С.А.Зияева – ЎзДЖТУ, “Филология” факультети декани педагогика

фанлари доктори, доцент. 9. Тақризчилар: Я.Ю.Арустамян – ЎзМУ, “Қиёсий тилшунослик” кафедраси доценти, филология фанлари номзоди Ж.А. Ёқубов – ЎзДЖТУ, “Француз тили назарияси ва амалиёти” кафедраси профессори, филология фанлари доктори

b) Working Programme

O‘ZBEKISTON RESPUBLIKASI SOG‘LIQNI SAQLASH VAZIRLIGI

TOSHKENT FARMATSEVTIKA INSTITUTI

O’ZBEK TILI VA ADABIYOTI KAFEDRASI

“TASDIQLAYMAN”
Toshkent farmatsevtika Instituti
O`quv ishlari bo`yicha prorektori
prof.Z.A.Yuldashev_____
2021 yil “_____” _____

MAGISTRATURA BOSQICHI

DORI VOSITALARI VA PREPARATLAR TEXNOLOGIYASI

MUTAXASSISLIGI 1 KURS TALABALARI UCHUN

«AMALIY XORIJIY TIL (INGLIZ TILI)» MODULINING

ISHCHI O‘QUV DASTURI

Bilim sohasi: 500000- Sog`liqni saqlash va ijtimoiy ta`minot

**Ta`lim sohasi:** 510000 - Sog`liqni saqlash

Ta’lim yo‘nalishi:
5A320406 - Dori vositalari va preparatlar texnologiyasi

TOSHKENT - 2021

Modulning ishchi o`quv dasturi O`zbekiston Respublikasi Oliy va o'rta maxsus ta'lim vazirligining 2020 yil 14 avgustdagi № 418 sonli buyrug'i bilan tasdiqlangan "Amaliy xorijiy til" modul dasturi asosida tayyorlangan.

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Modulning ishchi o`quv dasturi Toshkent farmatsevtika instituti Kengashida muhokama etilgan va tasdiqlangan (2021 yil " 29" iyundagi 11-sonli bayonnoma)

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1. O`quv modulini o`qitilishi bo`yicha uslubiy ko`rsatmalar

"Amaliy xorijiy til (ingliz tili)" moduli talabalarni nazariy bilimlar, amaliy ko'nikmalar, uslubiy yondashuv hamda ilmiy dunyoqarashini shakllantirib borish vazifalarini bajaradi.

2. Modulni o'qitish davomida rejalashtirilgan natijalar

2.1. O'quv modulining maqsadi

O'rganilayotgan amaliy xorijiy til bo'yicha amaliy kommunikativ kompetensiyalarni shakllantirish, shuningdek, talabalarlarning ingliz tilida ravon va aniq so'zlashishlari va hozirgi paytda dunyoda sodir bo'layotgan siyosiy, iqtisodiy va ijtimoiy voqelikka o'z munosabatlarini bildira olishlari hamda mustaqil fikrlash, izlanish, bilim, ko'nikma va malakalarini shakllantirishdan iborat.

Ingliz tili fanining maqsadi talabalarning ko'p millatli va madaniyatli dunyoda kasbiy, ilmiy va maishiy soxalarni faoliyat yuritishlarida kommunikativ kompetensiya va uning tarkibiy qismlari xisoblanuvchi lingvistik, sotsiolingvistik, pragmatik va boshqa kompetensiyalarini shaklllantirishdan iborat.

Magistratura bosqichida tillardan ta'lim berish magistratura bosqichi talabalarida chet tillari yordamida matnni tag'hlil qilish, og'zaki nutqni tushunish, umumgumanitar xarakterga ega bo'lgan, ijtimoiy-siyosiy xarakterdagi va mutaxasislikka oid adabiyotlarni tarjimasiz yoki tarjima qilib ulardan axborot olish axborot almashish qobiliyatlarini rivojlantiradi.

2.2. O`quv modulining vazifalari:

Magistratura bosqichi talabalariga o'rganilayotgan amaliy chet tilidan ona tiliga yozma va og'zaki tarjima masalalari, leksik, stilistik va grammatik sathlardagi o'xshash va tafovutli jihatlari, o'ziga hos xususiyatlari haqida ma'lumot berish, talabalarning matnni leksik, semantik va stilistik tahlil qilish ko'nikmalarini rivojlantirish, ma'lumotlarni turli kontekstlarda tahlil qilish orqali uning ma'nosini qayta ifoda etish usullarini o'rgatish, turli vaziyatlarda o'rganilayotgan amaliy xorijiy tilda ravon muloqot qilishga o'rgatishdan iborat.

Farmatsevtika institutida ingliz tili o'qitishning asosiy maqsadi ingliz tilidagi zamonaviy farmatsevtik atamalarni tushunib, savodli tarzda qo'llay oladigan, mutaxassislikka oid adabiyotlarni o'qib, tarjima qila oladigan, ingliz tilida muloqot yurita oladigan mutaxassislarni tayyorlashdir.

Ingliz tili farmatsevt uchun jahon fani yangiliklarini va yutuqlarini tezkor qabul qilish imkonini beradi. Talabani ingliz tilida og`zaki va yozma muloqotga tayyorlash uchun uning ingliz tili o`rganish jarayonida erishgan ko`nikma va malakalari quyidagi imkoniyatlarni beradi:

- o`z kasbi bo`yicha axborot olish maqsadida ingliz adabiyotini o`qish;
- ingliz tilida olingan axborotni tarjima, referat ko`rinishida rasmiylashtirish;
- ingliz tilida og`zaki muloqotga kirishish;
- ma'ruza va xabarnomalar tayyorlash;
- o`z sohasi bo`yicha ijtimoiy, siyosiy va o`lkashunoslik muammolari yuzasidan nazarda tutilgan dastur bo`yicha suhbat olib borish;
- o`z sohasi bo`yicha xujjatlarni rasmiylashtirish.
-og'zaki nutqiy kompetensiyani rivojlantirish;
- og'zaki va yozma nutqda sohaviy terminlarni samarali qo'llash ko'nikmalarini shakllantirish;
- ixtisoslikka oid matn tuza olish, uni tahrir va tahlil qila olish malakalarini xosil qilish;

2.3. Modul bo`yicha talababalarning bilim, ko`nikma va malakalariga qo`yiladigan talablar:

- talaffuz qoidalariga rioya qilish;

- asl chet tilidagi mutaxasisligi bo‘yicha hamda ijtimoiy-siyosiy adabiyotlarni erkin o‘qish va tushuna olish;
- lug‘at yordamida tub chet tilidagi mutaxassislik bo‘yicha adabiyotlarni tarjima qilish,mutaxassisilik hamda ijtimoiy-siyosiy adabiyotlar bo‘yicha referatlar va annotatsiyalar tuzish;
- mutaxassisilik bo‘yicha adabiyotlarda uchraydigan grammatik konstruksiyalarni bilish;
- chet tilida erkin gapira olish;
- mutaxassislik hamda ijtimoiy-siyosiy masalalar bo‘yicha suxbat olib bora bilish;
- kasbiy terminologiyani, og‘zaki va yozma nutq xususiyatlarini bilish va ulardan foydalana olish;
- o‘z sohasi doirasida xorijiy tilda fikr ifodalay olish,ilmiy texnik adabiyotlardan foydalana olish ko‘nikmasiga ega bo‘lishi kerak.

3. Modul tuzilmasi

3.1. Modul yuklamasi va o’quv ishlari turlari

Semestr	Umumiy yuklama hajmi	Amaliy mashg’ulot (soat)	Mustaqil ta’lim (soat)	Nazorat turi va shakli	Kredit hajmi
I	**72**	**40**	**32**	**Yozma**	**2**
Jami	**72**	**40**	**32**		**2**

Izoh: “Amaliy xorijiy til (ingliz tili)” moduli faqat 1 semestrga mo’ljallangan.

3.2. Ma’ruza mashg’ulotlari rejalashtirilmagan.

3.3. Amaliy mashg’ulotlarni tashkil etish

№	Mashg’ulot mavzulari	Soatlar soni	Egallanishi shart bo’lgan amaliy ko’nikmalar (ro’yxatdagi raqami)	O’quv-uslubiy ta’minot
	1- semestr			
1.	**Unit 1. The Kick-off meeting** (EforPI, p.5). **R:** Fab Pharmaceuticals (EforPI, p.6). **W:** Academic Degrees. **L:** Dialogue (EforPI, p.10) **S:** Pharmaceutical Industry in Uzbekistan (OTM, p.4)	**2**	**1**	O’quv qo’llanmasi, yozuv taxtasi, computer, quloqchinlar,
2.	**The Kick-off meeting.** Useful phrases (EforPI, p.11). **L:** Harvey summary (EforPI, p.12) **R:** Newspaper article (EforPI, p.16) **W:** Job Advertisements. **S:** Pharmaceutical Industry in Uzbekistan (OTM, p.4)	**2**	**2**	O’quv qo’llanmasi, darslik, tarqatma materiallar, computer, quloqchinlar
3.	**Unit 2. Substance Discovery and Product Development (**EforPI, p.17**)**	**2**	**3**	O’quv qo’llanmasi,

	R: Mensamint (EforPI, p.18) **L:** Minutes of Tuesday's brainstorming meeting (EforPI, p.20) **W:** Drug Discovery. **S:** Pharmaceutical Industry in the UK (OTM, p.6)			darslik, tarqatma materiallar, posterlar, markerlar, daftar-ruchkalar
4.	**Substance Discovery and Product Development.** **L:** Hospital In-Patient Dosage Form Survey Results (EforPI, p.23) **R:** How many drug categories do we need? (EforPI, p.26) **W:** Dosage Forms. **S:** Pharmaceutical Industry in the UK (OTM, p.6)	**2**	**4**	O'quv qo'llanmasi, darslik, tarqatma materiallar, computer, quloqchinlar
5.	**Unit 3. Quality Assurance and Auditing (**EforPI, p.27**)** **R:** Berner Pharmaceuticals Ltd (EforPI, p.28) **L:** Laboratory staff meeting (EforPI, p.33) **W:** Laboratory safety systems. **S:** Pharmaceutical Education in the UK (OTM, p.6)	**2**	**5**	O'quv qo'llanmasi, darslik, tarqatma materiallar, posterlar, markerlar, computer, quloqchinlar
6.	**Quality Assurance and Auditing.** **L:** Conversation (EforPI, p.34) **R:** Drug contamination**:** Lessons to be learned? **(**EforPI, p.38**)** **W:** My Company. **S:** Pharmaceutical Education in the UK (OTM, p.6)	**2**	**6**	O'quv qo'llanmasi, tarqatma materiallar, darslik, computer, quloqchinlar
7.	**Unit 4. Ready for testing in live organisms (**EforPI, p.39**)** **R:** Text **(**EforPI, p.40**)** **L:** Conversation (EforPI, p.42) **W:** Preclinical Development. **S:** Drugs Made by Medicinal Plants (OTM, p.8)	**2**	**7**	O'quv qo'llanmasi, tarqatma materiallar, darslik, yozuv taxtasi, computer, posterlar, markerlar, daftar-ruchkalar
8.	**Ready for testing in live organisms (**EforPI, p.39**)** **R:** Text **(**EforPI, p.45**)** **L:** Clinical Trials for RFI (EforPI, p.47) **W:** Short Summary. **S:** Drugs Made by Medicinal Plants (OTM, p.8)	**2**	**8**	O'quv qo'llanmasi, tarqatma materiallar, darslik, yozuv taxtasi, posterlar, markerlar, daftar-ruchkalar
9.	**Unit 5. Drug Safety and Regulatory Affairs (**EforPI, p.51**)** **R:** Report **(**EforPI, p.52**)** **L:** True or False? (EforPI, p.56) **W:** Adverse Drug Reactions. **S:** Plants as a Source of Drugs (OTM, p.9)	**2**	**9**	O'quv qo'llanmasi, yozuv taxtasi, computer, quloqchinlar, tarqatma

				materiallar, posterlar, markerlar
10.	**Drug Safety and Regulatory Affairs.** **R:** E-Mail **(**EforPI, p.59**)** **L:** PIL for Mensamint (EforPI, p.60) **W:** PIL VS. Pills. **S:** Plants as a Source of Drugs (OTM, p.9)	**2**	**10**	O'quv qo'llanmasi, yozuv taxtasi, computer, quloqchinlar, tarqatma materiallar, posterlar, markerlar
11.	**Unit 6. Production and Packaging** **(**EforPI, p.63**)** **R:** Fatal fakes - counterfeit medicines **(**EforPI, p.62**)** **L:** Stephany Baker (EforPI, p.65) **W:** Packaging. **S:** Clinical Pharmacy (OTM, p.10)	**2**	**11**	O'quv qo'llanmasi, darslik, tarqatma materiallar, posterlar, markerlar, daftar-ruchkalar
12.	**Unit 6. Production and Packaging.** **L:** Instructions (EforPI, p.66) **R:** Henry's handwritten notes **(**EforPI, p.70**)** **W:** Types of Letters. Formal and Informal. **S:** Clinical Pharmacy (OTM, p.10)	**2**	**12**	O'quv qo'llanmasi, darslik, tarqatma materiallar, computer, quloqchinlar
13.	**R:** Article (EforPI, p.73) **W:** How to write CV? **L:** Yesterday (The Beatles) **S:** Medicinal Chemistry (OTM, p.13)	**2**	**13**	O'quv qo'llanmasi, darslik, tarqatma materiallar, posterlar, markerlar, computer, quloqchinlar
14.	**R:** Text for outlesson reading: "Veterinary Pharmacy" (OTM, p. 30) **W:** How to write an Essay? **L:** I just want to say (Steavy Wonder) **S:** Medicinal Chemistry (OTM, p.13)	**2**	**14**	O'quv qo'llanmasi, tarqatma materiallar, darslik, computer, quloqchinlar
15.	**Mid-term Control**	**2**	**15**	O'quv qo'llanmasi, tarqatma materiallar, darslik, yozuv taxtasi, computer, posterlar, markerlar, daftar-ruchkalar
16.	**R:** Text for outlesson reading: "Poisonous Plants" (OTM, p. 33) **W:** How to write a Summary?	**2**	**16**	O'quv qo'llanmasi, tarqatma

	L: What a wonderful world (Louis Armstrong) **S:** Pharmaceutical Industry (OTM, p.14)			materiallar, darslik, yozuv taxtasi, posterlar, markerlar, daftar-ruchkalar
17.	**R:** Text for outlesson reading: "Biotechnology" (OTM, p.37) **W:** Summary **L:** Let it be (The Beatles) **S:** Pharmaceutical Industry (OTM, p.14)	**2**	**17**	O'quv qo'llanmasi, yozuv taxtasi, computer, quloqchinlar, tarqatma materiallar, posterlar, markerlar
18.	Making individual presentations on the topic "Biological Engineering" (OTM, p.25)	**2**	**18**	O'quv qo'llanmasi, yozuv taxtasi, computer, quloqchinlar, tarqatma materiallar, posterlar, markerlar
19.	Making individual presentations on the topic "My Scientific Work"	**2**	**19**	O'quv qo'llanmasi, darslik, tarqatma materiallar, posterlar, markerlar, daftar-ruchkalar
20.	**Final lesson. Review.**	**2**	**20**	O'quv qo'llanmasi, yozuv taxtasi, computer, quloqchinlar, tarqatma materiallar, posterlar, markerlar
	Jami	**40**		

Amaliy mashg'ulotlar multimedia qurilmalari bilan jihozlangan auditoriyalarda har bir akademik guruh uchun alohida o'tiladi.

4. Mustaqil ta'lim va mustaqil ishlar

4.1. Mustaqil ta'lim mavzulari

№	Mustaqil ta'lim mavzulari	Soatlar soni	Kompetensiyalar
1-semestr			
1	**Healthy Lifestyle**	**4**	Speaking and writing

			Reading and writing
2	**Healthcare System of Uzbekistan**	**4**	Speaking and writing Reading and writing
3	**Healthcare System of the UK**	**4**	Speaking and writing Reading and writing
4	**Pharmaceutical Industry of Uzbekistan**	**4**	Speaking and writing Reading and writing
5	**New generation of Medicinal Forms**	**4**	Speaking and writing Reading and writing
6	**Traditional and Alternative Medicine**	**4**	Speaking and writing Reading and writing
7	**My Future plans**	**4**	Speaking and writing Reading and writing
8	**My Dissertation work**	**4**	Speaking and writing Reading and writing

Mustaqil ta'lim mavzulari talabalar tomonidan auditoriyadan tashqarida o'zlashtiriladi va joriy baholashda inobatga olinadi.

4.2. Modul bo'yicha mustaqil ta'lim shakllari va ishlar turlari ro'yxati

1. Prezentatsiya tayyorlash
2. Referat tayyorlash
3. Tarjima qilish
4. Testlar to'plami
5. Mashqlar to'plami
6. Resume yozish
7. Videorolik tayyorlash
8. Interview tayyorlash
9. Slaydlar tayyorlash
10. Krossvord tuzish
11. Klaster tuzish

4.3. Modul bo'yicha mustaqil ta'limni tashkil qilish uchun tavsiya etiladigan o'quv-uslubiy ta'minot

- Qo'llanmalar;
- Adabiyot;
- Makro- yoki mikropreparatlar;
- Fotosuratlar;
- Fantom;
- Mulyaj;
- Simulatorlar;

- Jadvallar;
- O’rgatuvchi va nazorat qiluvchi testlar;
- Computer dasturlari va hkz.

Modul bo’yicha kurs ishi rejalashtirilmagan.

5. MODUL BO’YICHA TALABALAR BILIMINI NAZORAT QILISH MEZONLARI

5.1. Modul bo’yicha talabalarning amaliy ko’nikmalar egallashini nazorat qilish va bilimini baholash mezonlari (JN, ON, YN)

TALABALAR BILIMINI JORIY BAHOLASH TIZIMI

“Amaliy xorijiy til (ingliz tili)” modulidan talabalarning o`zlashtirishini baholash o`quv yili davomida muntazam ravishda olib boriladi va “Amaliy xorijiy til” moduli bo’yicha talabalar bilimini nazorat qilish va baholash tizimi quyidagicha belgilandi:
- joriy nazorat (JN; mustaqil ta’limni qamrab olgan holda);
- oraliq nazorat (ON);
- yakuniy nazorat (YN).

“Amaliy xorijiy til” moduli bo`yicha talabaning semestr davomida o`zlashtirish ko`rsatkichi baholashning reyting tizimi asosida ballarda aks ettiriladi va amaliy mashg`ulotlarning ikkinchi darsidan baholanadi.

Har bir nazorat turi unga ajratilgan maksimal ballning 100 % idan kelib chiqqan holda baholanadi.

Modulga ajratilgan kreditlar nazorat turlari bo‘yicha quyidagicha taqsimlanadi:

Joriy nazorat uchun 2 kredit quiydagicha taqsimlanadi:

1 semestr - 2 kredit

Izoh: “Amaliy xorijiy til” moduli faqatgina 1 semestrga mo’ljallangan.

Talabalarning modul bo`yicha o`zlashtirishini baholashda quyidagi namunaviy mezonlardan foydalaniladi:

Baholash usullari	Testlar, yozma ishlar, og‘zaki so’rov
“A” 86 - 100 ball - a’lo natija; minimal xatoliklar bilan	- modul dasturining barcha bo’limlari bo’yicha tizimli, to’la va chuqur bilimga ega bo’lishi, zarur dalillar bilan asoslantirishi; - ilmiy terminologiyadan aniq, o’z o’rnida foydalanishi, savollarga javobni mantiqan - olgan bilimini amalda qo‘llay oladi - fanning mohiyatini tushunadi, biladi, ifodalay oladi, aytib beradi hamda fan bo‘yicha tasavvurga ega bo`ladi - xorijiy tilda eshitish, yozish, o’qish va gapirish ko’nikmalari a’lo shakllangan bo’ladi; - tez va xatosiz o`qiydi; - yozishda 1 ta orfografik xatoga yo`l qo`yadi, - o`tilgan mavzuni tahlil qiladi va qo`llaydi, umumlashtiradi, - darsda faol qatnashadi; - uy vazifasini xatosiz bajaradi
“B” 81 - 85 ball - juda yaxshi; ayrim xatoliklar bilan	- xorijiy tilda eshitish, yozish, o’qish va gapirish ko’nikmalari shakllangan bo’ladi; talaba mustaqil mushohada yuritadi, olgan bilimini amalda qo‘llay oladi – fanning mohiyatni tushunadi, biladi, ifodalay oladi, aytib beradi hamda fan bo‘yicha tasavvurga ega bo’ladi; - so`zlarni o`qishda 1,2 ta xatoga yo`l qo`yadi; - yozishda 1,2 ta orfografik xatoga yo`l qo`yadi va1 yo 2 ta so`zni bilmaydi; -o`tilgan mavzuni tushunadi va darsda faol qatnashadi

	-uy vazifasini 1 ta yo 2 ta xato bilan bajaradi
“C” 71 - 80 ball - yaxshi; sezilarli xatoliklar bilan	-xorijiy tilda eshitish, yozish, o’qish va gapirish ko’nikmalari qoniqarli shakllangan bo’ladi; talaba olgan bilimini amalda qo‘llay oladi fanning mohiyatni tushunadi, ifodalashga harakat qiladi hamda fan bo‘yicha tasavvurga ega deb topilganda - so`zlarni o`qishda 3-4 ta xatoga yo`l qo`yadi, - yozishda 3-4 ta orfografik xatoga yo`l qo`yadi - 2-3 ta so`zni bilmaydi, - o`tilgan mavzuni tushunadi va biladi, darsda sust qatnashadi. uy vazifasini bajarishda 2-3 ta xatoga yo’l qo`yadi
“D” 60 - 70 ball - qoniqarli; sust natija qo’pol kamchiliklar bilan	talaba fan dasturini o‘zlashtirmagan fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi deb topilganda - talaba uy vazifasini bajarib kelgan, lekin mavzu bo`yicha savollarga javob bera olmaydi.
“E” 55 - 59 ball - o’rta; minimal natijaga ega	talaba fan dasturini o‘zlashtirmagan fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi deb topilganda - talaba uy vazifasini bajarib kelgan, lekin mavzu bo`yicha savollarga javob bera olmaydi.
“FX” 31 - 54 ball - qoniqarsiz; minimal baholanadi	– talaba fan dasturini o‘zlashtirmagan – fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi – talaba uy vazifasini bajarmagan, mavzu bo`yicha savollarga javob bera olmaydi.
“F” 0 - 30 ball - mutloq qoniqarsiz; to’liq qayta o’zlashtirilishi lozim	– talaba fan dasturini umuman o‘zlashtirmagan – fanning (mavzuning) mohiyatini umuman tushunmaydi hamda fan bo‘yicha umuman tasavvurga ega emas, mustaqil fikrlay olmaydi – talaba uy vazifasini bajarmagan, mavzu bo`yicha savollarga umuman javob bera olmaydi.

Ma’ruzalar rejalashtirilmagan.

JN baholashda Magistratura bosqichi talabasining mashg‘ulotda qatnashishi hisobga olinadi.

Joriy nazorat (JN)

Joriy nazoratda talabaning modul mavzulari bo‘yicha bilim, amaliy ko‘nikma va kompetensiyalarni egallash darajasini aniqlash va baholab borish ko‘zda tutiladi. Moduli bo‘yicha JN og‘zaki, testlari, tarqatma materiallari bilan ishlash, vaziyatli matnlar, uyga berilgan vazifalarni tekshirish va shu kabi boshqa shakllarda o‘tkazilishi mumkin.

Baholashda talabaning bilim darajasi, amaliy mashg‘ulot materiallarini o‘zlashtirishi va ta’limning interaktiv usullarida ishtirokining faollik darajasi, shuningdek, amaliy bilim va ko‘nikmalarni o‘zlashtirish darajasi, kompetensiyalarni egallash (ya’ni nazariy, analitik va amaliy yondoshuvlar) hisobga olinadi.

Joriy nazorat semestr davomida ikkinchi mashg’ulotdan oxirgi mashg’ulotga qadar har bir mashg’ulotda, ishchi fan dasturining tegishli bo’limi tugaganidan keyin talabaning bilim va amaliy ko’nikmalarini baholash maqsadida o’quv mashg’ulotlari davomida o’tkaziladi.

Maksimal ball 100, o‘tish bali 55 ball.

Modul bo‘yicha talaba reytingi quyidagicha aniqlanadi:

Ball	ECTS baho	ECTS ning ta’rifi		Baho	Ta’rifi
86-100	A	"a’lo" – a’lo natija, minimal hatolik lar bilan	Modul dasturining barcha bo‘limlari bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi; terminologiyadan (shu jumladan, ilmiy, xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; muammoli savollarni aniqlashi, o‘z qarashlarini xorijiy tilda asoslab bera olishi; modulning tayanch tushunchalarini bilishi va uni qisqa vaqt ichida echishda samarali qo‘llay olishi; nostandart vaziyatlarda muammolarni mustaqil va ijodiy hal qila olish qobiliyatini ko‘rsata olishi; amaliy ko‘nikmalarni mustaqil ravishda to‘liq bajara olishi (sifati va belgilangan soni jihatdan) va kompetensiyalarni to‘liq egallashi; amaliy masalalarni qisqa, asoslangan va ratsional ravishda hal etishi; modul dasturida tavsiya etilgan asosiy va qo‘shimcha adabiyotlarni to‘liq va chuqur o‘zlashtirishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda yuqori madaniyat darajasiga ega bo‘lishi lozim;	5	a’lo
81-85	B	"juda yaxshi" – o‘rtadan yuqori natija, ayrim hatolik lar bilan	modul dasturining barcha bo‘limlari bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi; terminologiyadan (xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; modulning tayanch tushunchalarini bilishi, qisqa vaqt ichida kasbiy vazifalarni qo‘yish hamda hal qilishda undan unumli foydalanishi; standart vaziyatlarda muammolarni o‘quv dasturi doirasida mustaqil hal qila olishi; modul dasturida tavsiya qilingan asosiy adabiyotlarni o‘zlashtirishi; o‘rganilayotgan modul bo‘yicha konsepsiyalar va yo‘nalishlar mohiyatini	4	Yaxshi

			anglay olishi va ularga tanqidiy baho berishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda juda yaxshi madaniyat darajasiga ega bo‘lishi lozim;		
71-80	C	"yaxsh" – o‘rtacha natija, sezilarli hatolik lar bilan	modul dasturining bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi, ammo bir oz kamchiliklar bilan; terminologiyadan (xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; o‘z fikrini isbotlashda yoki boshqa nazariy materialni bayon qilishda yuzaga kelgan noaniqliklarni mustaqil bartaraf eta olishi; modulning tayanch tushunchalarini bilishi, qisqa vaqt ichida kasbiy vazifalarni qo‘yish hamda hal qilishda undan unumli foydalanishi; amaliy ko‘nikmalarni mustaqil ravishda bajara olishi (sifati va belgilangan soni jihatdan) va kompetensiyalarni egallashi, ammo bir oz kamchiliklar bilan; modul dasturida tavsiya qilingan asosiy adabiyotlarni o‘zlashtirishi; o‘rganilayotgan modul bo‘yicha konsepsiyalar va yo‘nalishlar mohiyatini anglay olishi va ularga tanqidiy baho berishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda yaxshi darajaga ega bo‘lishi lozim;		
60-70	D	Qoniqar li – sust natija, qo‘pol kamchi liklar bilan	davlat ta’lim standartlari (talablari) doirasida etarli bilim hajmiga ega bo‘lishi; terminologiyani ishlatishi, savollarga javoblarni to‘g‘ri bayon qilishi, lekin bunda ayrim xatolarga yo‘l qo‘yishi; amaliy ko‘nikmalarni (sifati va belgilangan soni jihatdan) mustaqil ammo hatoliklar bilan to‘liq bajara olishi; kompetensiyalarni mustaqil, ammo hatoliklar bilan egallashi; pedagog xodim yordami bilan standart vaziyatlarni xorijiy tilde hal eta olishi; amaliy mashg‘ulotlarda pedagog xodim rahbarligida qatnashishi, vazifalarni	3	Qoni-Qarli

			bajarishda etarli madaniyat darajasiga ega bo‘lishi lozim;		
55-59	E	"o‘rta" – minimal natijaga teng	davlat ta’lim standartlari (talablari) doirasida qoniqarli bilim hajmiga ega bo‘lishi; terminologiyani ishlatishi, savollarga javoblarni to‘g‘ri bayon qilishi, lekin bunda ayrim qo‘pol xatolarga yo‘l qo‘yishi; javob berishga yoki ayrim maxsus ko‘nikmalarni namoyish qilishda qiynalganda va hatolarga yo‘l qo‘yganda, modul bo‘yicha asosiy tushunchaga ega ekanligini namoyish etishi; kompetensiyalarni mustaqil emas va hatoliklar bilan egallashi; modulining umumiy tushunchalari bo‘yicha qisman bilimga ega bo‘lishi va uni standart (namunaviy) vaziyatlarni hal etishda qo‘llay olishi; pedagog xodim yordami bilan standart vaziyatlarni hal eta olishi;		
31-54	FX	Qoniqar-siz – minimal daraja-dagi bilimlarn i olish uchun qo‘shimc ha musta qil o‘zlash tirishi zarur	davlat ta’lim standartlari (talablari) doirasida faqat ayrim fragmentar bilimlarga ega bo‘lsa; terminlarni ishlata olmasa yoki javob berishda jiddiy mantiqiy xatolarga yo‘l qo‘ysa; amaliy mashg‘ulotlarda passiv qatnashib, vazifalar bajarish madaniyatining past darajasiga ega bo‘lsa; amaliy ko‘nikmalarga va kompetensiyalarga ega bo‘lmasa, o‘z xatolarini hatto pedagog xodim tavsiyalari yordamida ham to‘g‘rilay olmasa.	2	Qoni-qarsiz
0-30	F	mutloq qoniqar-siz – to‘liq qayta o‘zlash tirishi lozim	davlat ta’lim standartlari (talablari) doirasida faqat ayrim fragmentar bilimlarga ham ega emas; terminlarni ishlata olmasa yoki javob berishda jiddiy va qo‘pol xatolarga yo‘l qo‘ysa yoki umuman javob bermasa; amaliy ko‘nikmalarga va kompetensiyalarga ega bo‘lmasa, o‘z xatolarini hatto pedagog xodim tavsiyalari yordamida ham to‘g‘rilay olmasa		

Semestr yakunida talaba egallagan bilim, ko’nikma va malakalari yozma nazorat ishi asosida baholanadi.

TMIni baholash mezonlari

Magistratura bosqichi talabasining mustaqil ishi o‘quv izlanish mavzulari bo‘yicha referat, slaydlar, prezentatsiyalar, internet ma’lumotlar to‘plami, testlar tuzish va boshqalar bo‘lishi mumkin. Mustaqil ish mavzulari mashg‘ulotlarni olib boruvchi o‘qituvchilar tomonidan muntazam nazorat qilinib, dars uchun ajratilgan baholarga qo‘shib boriladi.
Talabalarning mustaqil ishi maksimal 100 ball bilan baholanadi:

a'lo	“5”	86-100%
yaxshi	“4”	71-85%
qoniqarli	“3”	56-70%
qoniqarsiz	“2”	55 dan past

Mustaqil ishlarni baholashda quyidagi mezonlardan foydalaniladi:

№	Baho	Baholash sifatlari
1	86-100% **“5” a'lo**	1. Og’zaki va yozma nutqda grammatika va leksikani 86-100% to’g’ri va xatosiz ishlatsa; 2.Tarjimalarni a’lo darajada qila olsa; 3. Mavzuga bog’liq qisqacha xulosani 86-100% tog’ri yoza olsa; 4. Mavzu bo’yicha a’lo taqdimot tayyorlasa
2	70- 85% **“4” yaxshi**	1. Og’zaki va yozma nutqda grammatika va leksikani 71- 85% ni to’g’ri va xatosiz ishlatsa; 2. Tarjima qilishda 1-2 ta orfografik va 1-2 ta grammatik xatoga yo’l qo’ysa; 3. Mavzuga bog’liq qisqacha xulosani 71- 85% to’g’ri yoza olsa; 4. Mavzu bo’yicha yaxshi taqdimot tayyorlasa
3	56-70% **“3”qoniqarli**	1. Og’zaki va yozma nutqda grammatika va leksikani 56-70% ni to’g’ri va xatosiz ishlatsa; 2. Tarjima qilishda 3-4 ta orfografik va 3-4 ta grammatik xatoga yo’l qo’ysa; 3. Mavzuga bog’liq qisqacha xulosani 56 - 70% to’g’ri yoza olsa; 4. Mavzu bo’yicha qoniqarli taqdimot tayyorlasa
4	55 dan past **“2” qoniqarsiz**	Belgilangan topshiriqlarni bajarmasa -55 dan past

Oraliq Nazorat

“Amaliy xorijiy til (ingliz tili)” fani bo‘yicha ON semestrda 1 marta o‘tkaziladi va 100 ball bilan baholanadi. Oraliq baholash kafedra majlisi qarori bilan yozma ish, test, og‘zaki suhbat shakllarida yoki ularning kombinatsiyalarida o‘tkazilishi mumkin.

ON baholash mezonlari

O‘zlashtirish bali % da	Baho
86-100%	a’lo “5”
71-85%	yaxshi “4”
56 - 70%	qoniqarli “3”
55 % dan kam	qoniqarsiz “2”

Yakuniy nazorat (YN)

Yakuniy nazoratga kredit ajratilmaydi, lekin o’tkazilishi majburiy. Bunda talabalarning kompetensiyalarni, amaliy ko‘nikmalarni egallash darajasi va nazariy bilimlari tekshiriladi. Yakuniy nazorat yozma ravishda semester oxirida o’tkaziladi. Maksimal ball 100, o‘tish bali 55 ball.

Yakuniy baholash mezoni:

YN ga “ Amaliy xorijiy til” modulini muvaffaqiyatli yakunlagan hamda JN, ON va TMI dan

ijobiy bahoga ega bo`lgan talabalar qo`yiladi. Yakuniy baholash mezoni: agar talaba berilgan topshiriqning 86–100% ga to`g`ri javob yozgan bo'lsa 5 baho; 2) agar talaba berilgan topshiriqning 71– 85 % ga to`g`ri javob yozgan bo'lsa 4 baho; 3) agar talaba berilgan topshiriqning 56 - 70 % ga to`g`ri javob yozgan bo'lsa 3 baho; 4) 55 % dan past – 2“ qoniqarsiz” baho qo'yiladi.

JN, ON va TMI ga ajratilgan umumiy baholarning har biridan saralash balini to`plagan talabaga YN da ishtirok etish huquqi beriladi.

YN Ilmiy Kengash qaroriga binoan yozma ish, test yoki og'zaki shaklda o'tkaziladi.

JN, ON va YN turlarida modulni o`zlashtira olmagan yoki uzrli sabablar bilan nazorat turlarida ishtirok eta olmagan talabalarga quyidagi tartibda qayta nazoratdan o`tishga ruxsat beriladi:

- qoldirilgan amaliy mashg`ulot kelgusi darsga qadar guruh o`qituvchisiga qayta topshirish va maslahat kunida topshiriladi. 3 ta mashg`ulotni qoldirgan talaba Magistratura bo'limi boshlig'i ruxsati bilan qayta topshiradi.

- akademik qarzdor talabalarga semestr tugaganidan keyin Magistratura bo'limi boshlig'i ruxsatnomasi asosida qayta o`zlashtirish uchun – 2 hafta muddat beriladi. Shu muddat davomida o`zlashtira olmagan talaba belgilangan tartibda rektorning buyrug`i bilan talabalar safidan chetlashtiriladi (birinchi kurs talabalariga o`quv yili yakunlari bo`yicha amalga oshirish maqsadga muvofiqdir).

Foydalanilgan adabiyotlar ro'yxati

Asosiy adabiyotlar:

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3. New Inside Out. Sue Kay and Vaughan Jones. Macmillan, 2014.
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Internet saytlari

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2. www.englishtrairing.ru
3. www.lingua.ru
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5. www.onestopenglish.com
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TESTS

I can see Amanda. _____ is waiting for the New York plane.
A) I B) She C) His D) He
2. The clerk is speaking to the women. He is talking to _____ .
A) them B) they C) him D) he
3. I haven't got the keys. Father has got _____ .
A) him B) her C) it D) them
4. Can you see those boys and _____ father?
A) they B) them C) their D) him
5. Today _____ weather is very hot.
A) a B) an C) the D)_
6. He is Mrs. Taylor's _____ husband.
A) a B)_ C) the D) an
7. Butterflies are _____ insects.
A) a B) an C) the D) them
8. Is a bee _____ insect?
A) a B) an C) _ D) the
9. I'll wait for you half _____ hour.
A) _ B) an C) a D) the
10. I haven't got _____ paint.
A) any B) some C) _ D) many
11. We are late. The teacher will get angry with _____ .
A) we B) they C) us D) I
12. My father is _____ engineer.
A) a B) the C)_ D) an
13. This is not my bicycle. It is my _____ bicycle.
A) _ B) father C) father' D) father's
14. Cats can wash _____ paws and fur.
A) they B) is C) its D) their
15. There is some milk. I'd like to drink _____ .
A) they B) it C) them D) its
16. Terry is talking to two _____ .
A) women B) woman C) woman's D) women's
17. All the _____ are following the man.
A) policeman B) woman C) dog D) children
18. There are many _____ on the shelf.
A) paper B) magazines C) book D) dust
19. I can see a lot of _____ outside the building.
A) person B) man C) people D) child
20. There is a lot of ice in _____ refrigerator.
A) a B) _ C) an D) the
21. Give me two _____ cake, please.
A) piece B) pieces C) slice D) pieces of
22. _____ students are looking for their ball.

A) That B) Those C) This D) They
23. Please hand me _____ dictionary.
A) that B) these C) it D) them
24. A: Is this your suitcase?
B: No, _____ is my suitcase.
A) that B) these C) it D) they
25. Bill and Jack are going to _____ house.
A) they B) their C) them D) his
26. My brother and I are hungry. _____ are thirsty too.
A) They B) He C) We D) Us
27. Take Janet and Anna to _____ rooms.
A) her B) them C) they D) their
28. Father is calling Ali and me. He wants _____ .
A) we B) us C) them D) him
29. Serpil dropped some books, so I picked _____ up for her.
A) them B) it C) its D) they
30. The boys are holding up _____ hands.
A) their B) there C) they D) them
31. Seda and I washed _____ hands.
A) us B) our C) ours D) we
32. Look at that house. All _____ windows are broken.
A) their B) his C) it D) its
33. The sea is dirty. There is oil on _____ .
A) them B) they C) it D) her
34. The girls can go home. They have finished _____ work.
A) its B) ours C) hers D) their
35. Do you want those shoes? I don't want _____ .
A) them B) they C) him D) its
36. We called Allan. He came to _____ .
A) our B) us C) we D) ours
37. Look at these books. Are _____ yours?
A) they B) them C) this D) that
38. We went to _____ seaside and played on the beach.
A) a B) the C) an D) _
39. Many tourists visit _____ Turkey.
A) a B) the C) an D) _
40. There is only _____ water in the glass. Please give me some more.
A) many B) much C) a few D) a little
41. There were not _____ people at the market yesterday.
A) many B) much C) a few D) a little
42. I put _____ sugar on the fruit. I do not like sugar very much.
A) many B) much C) a few D) a little
43. We can all get on the bus. There are only _____ passengers on it now.
A) many B) much C) a few D) a little
44. The policeman is holding the _____ right arm.
A) robber B) robber's C) robbers D) robbers'

45. It was my _____ watch.
A) grandfathers B) of grandfather
C) grandfather's D) grandfather
46. I can see the _____ bicycles.
A) boys' B) boys C) boy D) of the boys
47. I checked the answers. Two of _____ were wrong.
A) it B) its C) them D) they
48. The postman gave me two letters, so I gave _____ to my mother.
A) them B) its C) they D) it
49. The army lost the battle because _____ was not strong.
A) they B) them C) it D) its
50. My parents are coming. I'll open the door for _____ .
A) they B) them C) him D) her
51. Is this radio _____ ?
A) to you B) of you C) you D) yours
52. Give that ball to Tom and me. It _____ .
A) is mine B) is ours C) is theirs D) is our
53. We washed _____ and then had our dinner.
A) myself B) himself C) herself D) ourselves
54. You must learn to defend _____ , Tom.
A) yourself B) yourselves C) himself D) ourselves
55. I cut _____ on that piece of wire.
A) himself B) myself C) oneself D) herself
56. I saw the girls, so I spoke to _____ .
A) she B) her C) they D) them
57. You can have these books. _____ are too hard for me.
A) It B) They C) Its D) There
58. The rope was not very strong, so we did not use _____ .
A) them B) its C) they D) it
59. The policeman spoke to my sister and me. He told _____ about the bridge.
A) us B) he C) I D) we
The bananas were not ripe, so we did not buy _____ .
A) it B) its C) them D) they
61. Please open the window. I can't reach _____ .
A) him B) her C) them D) it
62. My father listened to the news. He was very pleased with _____.
A) they B) them C) it D) its
63. Can you tell me _____ best way to the station?
A) a B) an C) the D) _
64. She works as _____ clerk in a very large bank.
A) a B) an C) the D)_
65. Cyprus is _____ island in the Mediterranean.
A) a B) _ C) the D) an
66. There is _____ excellent film on television this evening.
A) a B) __ C) the D) an

67. In England there is a saying. “_____ apple a day keeps the doctor away”. This means that apples keep you healthy.
A) An B) A C) The D)_
68. It is going to rain. I must buy _____ umbrella quickly.
A) an B) a C) the D) __
69. _____ other day I had a letter from my friend.
A) A B) An C) _ D) The
70. They enjoyed _____ at the party.
A) himself B) themselves C) them D) __
71. My friend cut _____ when she was cooking.
A) myself B) himself C) herself D) her
72. Help _____ to some more coffee.
A) yourself B) myself C) you D) yours
73. I taught _____ to play the guitar. I’ve never had lessons.
A) me B) myself C) himself D) herself
74. The cow hurt _____ when it tried to get through the fence.
A) himself B) herself C) itself D) themselves
75. That machine is automatic. It runs by _____ .
A) itself B) it C) themselves D) herself
76. She is wearing _____ unusual dress .
A) a B)_ C) the D) an
77. The car was traveling at more than 90 miles _____ hour when the accident happened.
A) an B) a C) _ D) the
78. It’s _____ time for us to go home.
A) _ B) a C) the D) an
79. This cake was made with _____ butter so it should be good.
A) a B) _ C) the D) an
80. His parents and _____ went to a concert last weekend.
A) me B) our C) mine D) us
81. I enjoyed _____ vacation. Did you enjoy _____ too ?
A) me
/yours B) my/yourself C) mine/yours D) my/yours
82. _____ of the children is sick today.
A) One B) Fewer C) Many D) Some
83. Everyone is responsible for _____ own composition.
A) his B) their C) nobody’s D) all their
84. I asked her _____ was on the phone.
A) which B) who C) whom D) whomever
85. I don’t have _____ petrol in my car.
A) some B) no C) any D) lots of
86. He knows _____ about sports.
A) nothing B) anything C) at all D) something
87. The children ran screaming into _____ own rooms.
A) his B) they’re C) their D) its
88. _____ of us are staying home.
A) Some B) A little C) Couples D) Much

89. There is _____ food in the house.
A) none B) some C) no D) any
90. Misfortunes like that aren't _____ fault.
A) each B) anybody C) no one's D) anybody's
91. This test is for students _____ native language is not English.
A) that B) whose C) of whom D) which
92. Please lend me _____ dollar.
A) a B) an C) any D) a few
93. Her mother wants _____ to wash the dishes.
A) she B) her C) hers D) she herself
94. Each of the children _____ given a box of chocolate.
A) was B) were C) are D) aren't
95. Everyone _____ in the room now.
A) are B) is C) were D) weren't
96. Everybody in the classroom _____ sleepy.
A) is B) has C) are D) weren't
97. They were here, but they have gone back to _____ apartment.
A) they're B) theirs C) hers D) their
98. A couple of the players _____ leaving now.
A) is B) are C) was D) were
99. All the businessmen _____ staying at the hotel.
A) isn't B) was C) is D) are
100. A: Whose coat it that?
B : It's _____ .
A) my daughter's B) of my daughter
C) to my daughter D) of my daughter's

O‘ZBEKISTON RESPUBLIKASI SOG‘LIQNI SAQLASH VAZIRLIGI

TOSHKENT FARMATSEVTIKA INSTITUTI

O’ZBEK TILI VA ADABIYOTI KAFEDRASI

“TASDIQLAYMAN”
Toshkent farmatsevtika instituti
O`quv ishlari bo`yicha prorektor
Z.A.Yuldashev_____
2021 yil “_____” _____

“AMALIY XORIJIY TIL” MODULI BO’YICHA

MAGISTRATURA BOSQICHI

1 KURS TALABALARINING

O‘ZLASHTIRISH KO‘RSATKICHINI

NAZORAT QILISH NAMUNAVIY

MEZONI

TOSHKENT – 2021

Ushbu baholash me'zoni Toshkent farmatsevtika instituti rektori tomonidan 2020 yil 6 noyabrda tasdiqlangan Toshkent farmatsevtika institutida o'qitishning kredit-modul tizimi bo'yicha talabalar bilimini nazorat qilish tartibi va baholash mezonlari to'g'risidagi nizomiga asosan ishlab chiqilgan.

UMUMIY QOIDALAR

Magistratura bosqichi 1 kurs talabalari bilimini nazorat qilish va baholashdan maqsad ta'lim sifatini boshqarish orqali yuqori malakali, raqobatbardosh, zamonaviy xalqaro standartlarga javob bera oladigan farmatsevtika sohasi uchun yetuk kadrlarni tayyorlash hamda talabalarni mustaqil ta'lim olish, ta'lim sifatini boshqargan holda farmatsevtikaning tegishli sohalarida bilim va ko'nikmalarini rivojlantirishdan iborat.

BAHOLASH MEZONINING ASOSIY VAZIFALARI QUYIDAGILARDAN IBORAT:

a) o'quv materialining talabalar tomonidan tizimli ravishda va belgilangan muddatlarda o'zlashtirilishini tashkil etish va tahlil qwilish;

b) talabalarda mustaqil ishlash ko'nikmalarini rivojlantirish, a[borot resurslari manbalaridan samarali foydalanishni tashkil etish;

d) talabalar bilimini holis va adolatli baholash hamda uning natijalarini o'z vaqtida ma'lum qilish;

e) talabalarning o'quv rejasi doirasida kompleks hamda uzluksiz tayyorligini ta'minlash;

f) o'quv jarayonining tashkiliy ishlarini kompyuterlashtirishga (raqamlashtirishga) sharoit yaratish.

Talabalarning modul bo`yicha o`zlashtirishini baholash o`quv yili davomida muntazam ravishda olib boriladi va quyidagi turlar orqali amalga oshiriladi, "Tibbiyotda xorijiy til" moduli bo'yicha talabalar bilimini nazorat qilish va baholash tizimi quyidagicha belgilandi:

- joriy nazorat (JN; mustaqil ta'limni qamrab olgan holda);
- oraliq nazorat (ON);
- yakuniy nazorat (YN).

"Amaliy xorijiy til" moduli bo`yicha talabaning semestr davomida o`zlashtirish ko`rsatkichi baholashning reyting tizimi asosida ballarda aks ettiriladi va amaliy mashg`ulotning ikkinchi darsidan baholanadi.

Har bir nazorat turi unga ajratilgan maksimal ballning 100 % idan kelib chiqqan holda baholanadi.

Modulga ajratilgan kreditlar nazorat turlari bo'yicha quyidagicha taqsimlanadi:

Joriy nazorat uchun 2 kredit quiydagicha taqsimlanadi:

1 semestr - 2 kredit

Izoh: 2 semestrda mashg'ulotlar rejalashtirilmagan.

Talaba xar bir bo'limdan belgilangan kreditlarni to'plagandan keyingina yakuniy nazoratga kiritiladi.

Talabalarning modul bo`yicha o`zlashtirishini baholashda quyidagi namunaviy mezonlardan foydalaniladi:

Baholash usullari	**Testlar, yozma ishlar, og'zaki so'rov**
"A" 86 - 100 ball - a'lo natija; minimal xatoliklar bilan	- modul dasturining barcha bo'limlari bo'yicha tizimli, to'la va chuqur bilimga ega bo'lishi, zarur dalillar bilan asoslantirishi; - ilmiy terminologiyadan aniq, o'z o'rnida foydalanishi, savollarga javobni mantiqan - olgan bilimini amalda qo'llay oladi - fanning mohiyatini tushunadi, biladi, ifodalay oladi, aytib beradi hamda fan bo'yicha tasavvurga ega bo`ladi - xorijiy tilda eshitish, yozish, o'qish va gapirish ko'nikmalari a'lo shakllangan bo'ladi; - tez va xatosiz o`qiydi; - yozishda 1 ta orfografik xatoga yo`l qo`yadi, - o`tilgan mavzuni tahlil qiladi va qo`llaydi, umumlashtiradi, - darsda faol qatnashadi; - uy vazifasini xatosiz bajaradi

“B” 81 - 85 ball - juda yaxshi; ayrim xatoliklar bilan	- xorijiy tilda eshitish, yozish, o’qish va gapirish ko’nikmalari shakllangan bo’ladi; talaba mustaqil mushohada yuritadi, olgan bilimini amalda qo‘llay oladi – fanning mohiyatni tushunadi, biladi, ifodalay oladi, aytib beradi hamda fan bo‘yicha tasavvurga ega bo’ladi; - so`zlarni o`qishda 1,2 ta xatoga yo`l qo`yadi; - yozishda 1,2 ta orfografik xatoga yo`l qo`yadi va1 yo 2 ta so`zni bilmaydi; -o`tilgan mavzuni tushunadi va darsda faol qatnashadi -uy vazifasini 1 ta yo 2 ta xato bilan bajaradi
“C” 71 - 80 ball - yaxshi; sezilarli xatoliklar bilan	-xorijiy tilda eshitish, yozish, o’qish va gapirish ko’nikmalari qoniqarli shakllangan bo’ladi; talaba olgan bilimini amalda qo‘llay oladi fanning mohiyatni tushunadi, ifodalashga harakat qiladi hamda fan bo‘yicha tasavvurga ega deb topilganda - so`zlarni o`qishda 3-4 ta xatoga yo`l qo`yadi, - yozishda 3-4 ta orfografik xatoga yo`l qo`yadi - 2-3 ta so`zni bilmaydi, - o`tilgan mavzuni tushunadi va biladi, darsda sust qatnashadi. uy vazifasini bajarishda 2-3 ta xatoga yo’l qo`yadi
“D” 60 - 70 ball - qoniqarli; sust natija qo’pol kamchiliklar bilan	talaba fan dasturini o‘zlashtirmagan fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi deb topilganda - talaba uy vazifasini bajarib kelgan, lekin mavzu bo`yicha savollarga javob bera olmaydi.
“E” 55 - 59 ball - o’rta; minimal natijaga ega	talaba fan dasturini o‘zlashtirmagan fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi deb topilganda - talaba uy vazifasini bajarib kelgan, lekin mavzu bo`yicha savollarga javob bera olmaydi.
“FX” 31 - 54 ball - qoniqarsiz; minimal baholanadi	– talaba fan dasturini o‘zlashtirmagan – fanning (mavzuning) mohiyatini tushunmaydi hamda fan bo‘yicha tasavvurga ega emas, mustaqil fikrlay olmaydi – talaba uy vazifasini bajarmagan, mavzu bo`yicha savollarga javob bera olmaydi.
“F” 0 - 30 ball - mutloq qoniqarsiz; to’liq qayta o’zlashtirilishi lozim	– talaba fan dasturini umuman o‘zlashtirmagan – fanning (mavzuning) mohiyatini umuman tushunmaydi hamda fan bo‘yicha umuman tasavvurga ega emas, mustaqil fikrlay olmaydi – talaba uy vazifasini bajarmagan, mavzu bo`yicha savollarga umuman javob bera olmaydi.

Ma’ruzalar rejalashtirilmagan.

JN baholashda Magistratura bosqichi talabasining mashg‘ulotda qatnashishi hisobga olinadi.

Joriy nazorat (JN)

Joriy nazoratda talabaning modul mavzulari bo‘yicha bilim, amaliy ko‘nikma va kompetensiyalarni egallash darajasini aniqlash va baholab borish ko‘zda tutiladi. Moduli bo‘yicha JN og‘zaki, testlari, tarqatma materiallari bilan ishlash, vaziyatli matnlar, uyga berilgan vazifalarni tekshirish va shu kabi boshqa shakllarda o‘tkazilishi mumkin.

Baholashda talabaning bilim darajasi, amaliy mashg‘ulot materiallarini o‘zlashtirishi va ta’limning interaktiv usullarida ishtirokining faollik darajasi, shuningdek, amaliy bilim va

ko‘nikmalarni o‘zlashtirish darajasi, kompetensiyalarni egallash (ya’ni nazariy, analitik va amaliy yondoshuvlar) hisobga olinadi.

Joriy nazorat semestr davomida ikkinchi mashg’ulotdan oxirgi mashg’ulotga qadar har bir mashg’ulotda, ishchi fan dasturining tegishli bo’limi tugaganidan keyin talabaning bilim va amaliy ko’nikmalarini baholash maqsadida o’quv mashg’ulotlari davomida o’tkaziladi.

Maksimal ball 100, o‘tish bali 55 ball.

Modul bo‘yicha talaba reytingi quyidagicha aniqlanadi:

Ball	**ECTS baho**	**ECTS ning ta’rifi**		**Baho**	**Ta’rifi**
86-100	A	"a’lo" – a’lo natija, minimal hatolik lar bilan	Modul dasturining barcha bo‘limlari bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi; terminologiyadan (shu jumladan, ilmiy, xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; muammoli savollarni aniqlashi, o‘z qarashlarini xorijiy tilda asoslab bera olishi; modulning tayanch tushunchalarini bilishi va uni qisqa vaqt ichida echishda samarali qo‘llay olishi; nostandart vaziyatlarda muammolarni mustaqil va ijodiy hal qila olish qobiliyatini ko‘rsata olishi; amaliy ko‘nikmalarni mustaqil ravishda to‘liq bajara olishi (sifati va belgilangan soni jihatdan) va kompetensiyalarni to‘liq egallashi; amaliy masalalarni qisqa, asoslangan va ratsional ravishda hal etishi; modul dasturida tavsiya etilgan asosiy va qo‘shimcha adabiyotlarni to‘liq va chuqur o‘zlashtirishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda yuqori madaniyat darajasiga ega bo‘lishi lozim;	5	a’lo
81-85	B	"juda yaxshi" – o‘rtadan yuqori natija, ayrim hatolik lar bilan	modul dasturining barcha bo‘limlari bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi; terminologiyadan (xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; modulning tayanch tushunchalarini bilishi, qisqa vaqt ichida kasbiy vazifalarni qo‘yish hamda hal qilishda undan unumli foydalanishi;	4	Yaxshi

			standart vaziyatlarda muammolarni o‘quv dasturi doirasida mustaqil hal qila olishi; modul dasturida tavsiya qilingan asosiy adabiyotlarni o‘zlashtirishi; o‘rganilayotgan modul bo‘yicha konsepsiyalar va yo‘nalishlar mohiyatini anglay olishi va ularga tanqidiy baho berishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda juda yaxshi madaniyat darajasiga ega bo‘lishi lozim;		
71-80	C	"yaxsh" – o‘rtacha natija, sezilarli hatolik lar bilan	modul dasturining bo‘yicha tizimli, to‘la va chuqur bilimga ega bo‘lishi, zarur dalillar bilan asoslay olishi, ammo bir oz kamchiliklar bilan; terminologiyadan (xorijiy tilda) aniq, o‘z o‘rnida foydalanishi, savollarga javobni mantiqan to‘g‘ri, stilistik savodli ravishda ifodalashi; o‘z fikrini isbotlashda yoki boshqa nazariy materialni bayon qilishda yuzaga kelgan noaniqliklarni mustaqil bartaraf eta olishi; modulning tayanch tushunchalarini bilishi, qisqa vaqt ichida kasbiy vazifalarni qo‘yish hamda hal qilishda undan unumli foydalanishi; amaliy ko‘nikmalarni mustaqil ravishda bajara olishi (sifati va belgilangan soni jihatdan) va kompetensiyalarni egallashi, ammo bir oz kamchiliklar bilan; modul dasturida tavsiya qilingan asosiy adabiyotlarni o‘zlashtirishi; o‘rganilayotgan modul bo‘yicha konsepsiyalar va yo‘nalishlar mohiyatini anglay olishi va ularga tanqidiy baho berishi; amaliy mashg‘ulotlarda butun semestr mobaynida ijodiy va mustaqil qatnashishi, guruhli muhokamalarda faol bo‘lishi, vazifalarni bajarishda yaxshi darajaga ega bo‘lishi lozim;		
60-70	D	Qoniqar li – sust natija, qo‘pol kamchi liklar bilan	davlat ta’lim standartlari (talablari) doirasida etarli bilim hajmiga ega bo‘lishi; terminologiyani ishlatishi, savollarga javoblarni to‘g‘ri bayon qilishi, lekin bunda ayrim xatolarga yo‘l qo‘yishi; amaliy ko‘nikmalarni (sifati va belgilangan soni jihatdan) mustaqil ammo hatoliklar bilan to‘liq bajara olishi;	3	Qoni-Qarli

			kompetensiyalarni mustaqil, ammo hatoliklar bilan egallashi; pedagog xodim yordami bilan standart vaziyatlarni xorijiy tilde hal eta olishi; amaliy mashg‘ulotlarda pedagog xodim rahbarligida qatnashishi, vazifalarni bajarishda etarli madaniyat darajasiga ega bo‘lishi lozim;		
55-59	E	"o‘rta" – minimal natijaga teng	davlat ta’lim standartlari (talablari) doirasida qoniqarli bilim hajmiga ega bo‘lishi; terminologiyani ishlatishi, savollarga javoblarni to‘g‘ri bayon qilishi, lekin bunda ayrim qo‘pol xatolarga yo‘l qo‘yishi; javob berishga yoki ayrim maxsus ko‘nikmalarni namoyish qilishda qiynalganda va hatolarga yo‘l qo‘yganda, modul bo‘yicha asosiy tushunchaga ega ekanligini namoyish etishi; kompetensiyalarni mustaqil emas va hatoliklar bilan egallashi; modulining umumiy tushunchalari bo‘yicha qisman bilimga ega bo‘lishi va uni standart (namunaviy) vaziyatlarni hal etishda qo‘llay olishi; pedagog xodim yordami bilan standart vaziyatlarni hal eta olishi;		
31-54	FX	Qoniqar-siz – minimal daraja-dagi bilimlarn i olish uchun qo‘shimc ha musta qil o‘zlash tirishi zarur	davlat ta’lim standartlari (talablari) doirasida faqat ayrim fragmentar bilimlarga ega bo‘lsa; terminlarni ishlata olmasa yoki javob berishda jiddiy mantiqiy xatolarga yo‘l qo‘ysa; amaliy mashg‘ulotlarda passiv qatnashib, vazifalar bajarish madaniyatining past darajasiga ega bo‘lsa; amaliy ko‘nikmalarga va kompetensiyalarga ega bo‘lmasa, o‘z xatolarini hatto pedagog xodim tavsiyalari yordamida ham to‘g‘rilay olmasa.	2	Qoni-qarsiz
0-30	F	mutloq qoniqar-siz – to‘liq qayta o‘zlash tirishi lozim	davlat ta’lim standartlari (talablari) doirasida faqat ayrim fragmentar bilimlarga ham ega emas; terminlarni ishlata olmasa yoki javob berishda jiddiy va qo‘pol xatolarga yo‘l qo‘ysa yoki umuman javob bermasa; amaliy ko‘nikmalarga va kompetensiyalarga ega bo‘lmasa, o‘z xatolarini hatto pedagog xodim		

			tavsiyalari yordamida ham to‘g‘rilay olmasa		

Semestr yakunida talaba egallagan bilim, ko’nikma va malakalari yozma ish asosida nazorat qilinadi.

TMIni baholash mezonlari

Magistratura bosqichi talabasining mustaqil ishi o‘quv izlanish mavzulari bo‘yicha referat, slaydlar, prezentatsiyalar, internet ma’lumotlar to‘plami, testlar tuzish va boshqalar bo‘lishi mumkin. Mustaqil ish mavzulari mashg‘ulotlarni olib boruvchi o‘qituvchilar tomonidan muntazam nazorat qilinib, dars uchun ajratilgan baholarga qo‘shib boriladi.

Talabalarning mustaqil ishi maksimal 100 ball bilan baholanadi:

a'lo	“5”	86-100%
yaxshi	“4”	71-85%
qoniqarli	“3”	56-70%
qoniqarsiz	“2”	55 dan past

Mustaqil ishlarni baholashda quyidagi mezonlardan foydalaniladi:

№	Baho	Baholash sifatlari
1	86-100% **“5” a'lo**	1. Og’zaki va yozma nutqda grammatika va leksikani 86-100% to’g’ri va xatosiz ishlatsa; 2.Tarjimalarni a’lo darajada qila olsa; 3. Mavzuga bog’liq qisqacha xulosani 86-100% tog’ri yoza olsa; 4. Mavzu bo’yicha a’lo taqdimot tayyorlasa
2	70- 85% **“4” yaxshi**	1. Og’zaki va yozma nutqda grammatika va leksikani 71- 85% ni to’g’ri va xatosiz ishlatsa; 2. Tarjima qilishda 1-2 ta orfografik va 1-2 ta grammatik xatoga yo’l qo’ysa; 3. Mavzuga bog’liq qisqacha xulosani 71- 85% to’g’ri yoza olsa; 4. Mavzu bo’yicha yaxshi taqdimot tayyorlasa
3	56-70% **“3”qoniqarli**	1. Og’zaki va yozma nutqda grammatika va leksikani 56-70% ni to’g’ri va xatosiz ishlatsa; 2. Tarjima qilishda 3-4 ta orfografik va 3-4 ta grammatik xatoga yo’l qo’ysa; 3. Mavzuga bog’liq qisqacha xulosani 56 - 70% to’g’ri yoza olsa; 4. Mavzu bo’yicha qoniqarli taqdimot tayyorlasa
4	55 dan past **“2” qoniqarsiz**	Belgilangan topshiriqlarni bajarmasa -55 dan past

Oraliq Nazorat

“Amaliy xorijiy til (ingliz tili)” fani bo‘yicha ON semestrda 1 marta o‘tkaziladi va 100 ball bilan baholanadi. Oraliq baholash kafedra majlisi qarori bilan yozma ish, test, og‘zaki suhbat shakllarida yoki ularning kombinatsiyalarida o‘tkazilishi mumkin.

ON baholash mezonlari

O‘zlashtirish bali % da	Baho
86-100%	a’lo “5”
71-85%	yaxshi “4”
56 - 70%	qoniqarli “3”
55 % dan kam	qoniqarsiz “2”

Yakuniy nazorat (YN)

Yakuniy nazoratga kredit ajratilmaydi, lekin o’tkazilishi majburiy. Bunda talabalarning kompetensiyalarni, amaliy ko‘nikmalarni egallash darajasi va nazariy bilimlari tekshiriladi. Yakuniy nazorat semester oxirida rejalashtirilgan. Maksimal ball 100, o‘tish bali 55 ball.

Yakuniy baholash mezoni:

YN ga “ Amaliy xorijiy til” modulini muvaffaqiyatli yakunlagan hamda JN, ON va TMI dan ijobiy bahoga ega bo`lgan talabalar qo`yiladi. Yakuniy baholash mezoni: agar talaba 30 savoldan iborat bo’lgan testning 86–100% ga to`g`ri javob bersa 5 baho; 2) agar talaba 30 savoldan iborat bo’lgan testning 71– 85 % ga to`g`ri javob bersa 4 baho; 3) agar talaba 30 savoldan iborat bo’lgan testning 56 - 70 % ga to’g’ri javob bersa 3 baho; 4) 55 % dan past – 2“ qoniqarsiz” baho qo’yiladi.

JN, ON va TMI ga ajratilgan umumiy baholarning har biridan saralash balini to`plagan talabaga YN ga ishtirok etishga huquq beriladi.

YN o`tkazish shakli – yozma ish, test yoki og’zaki sinov Ilmiy Kengash qarori bilan belgilanadi.

JN, ON va YN turlarida modulni o`zlashtira olmagan yoki uzrli sabablar bilan nazorat turlarida ishtirok eta olmagan talabalarga quyidagi tartibda qayta nazoratdan o`tishga ruxsat beriladi:

- qoldirilgan amaliy mashg`ulot kelgusi darsga qadar guruh o`qituvchisiga qayta topshirish va maslahat kunida topshiriladi. 3 ta mashg`ulotni qoldirgan talaba Magistratura bo’limi boshlig’i ruxsati bilan qayta topshiradi.

- akademik qarzdor talabalarga semestr tugaganidan keyin Magistratura bo’limi boshlig’i ruxsatnomasi asosida qayta o`zlashtirish uchun – 2 hafta muddat beriladi. Shu muddat davomida o`zlashtira olmagan talaba belgilangan tartibda rektorning buyrug`i bilan talabalar safidan chetlashtiriladi (birinchi kurs talabalariga o`quv yili yakunlari bo`yicha amalga oshirish maqsadga muvofiqdir).

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