DANYLO HALYTSKY LVIV NATIONAL MEDICAL UNIVERSITY

Department of Drug Technology and Biopharmaceutics

APPROVED
The first vice-rector on
scientific and pedagogical work,
assoc.prof. I.I. Solonynko
_____
_____ 2023

EDUCATIONAL PROGRAM
on discipline
«GOOD PRACTICES IN PHARMACEUTICS»

for training specialists of the second (master's) degree of higher education
of the specialty 226 Pharmacy, industrial pharmacy
of the specialization 226.01 Pharmacy
of the branch of study 22 Health care
for the 5th year students of Faculty of Pharmacy
of the full-time and part-time forms of education
MC 33

Discussed and approved
at the methodical meeting of
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Head of the department
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Introduction

The program of study of the discipline "Good Practices in Pharmaceutics" was constructed in accordance with the Standard of higher education of the second (master's) level of knowledge 22 "Health Care" specialty 226 "Pharmacy, industrial pharmacy" of the educational program of Master of Pharmacy.

Discipline description (abstract)

The discipline "Good Practices in Pharmaceutics" belongs to the cycle of the disciplines of professionally-oriented training of specialists in the specialty "Pharmacy, Industrial Pharmacy" and includes one content module.

The program of the discipline "Good Practices in Pharmaceutics" is made in accordance with the Standard of Higher Education of Ukraine for the specialty "Pharmacy, Industrial Pharmacy".

The subject "Good Practices in Pharmaceutics" involves the formation of students' theoretical knowledge on drug development, preclinical and clinical studies, preparation of registration dossier, requirements of Good Manufacturing Practice for the industrial manufacture of medicinal products, compliance with the principles of storage of medicinal products during manufacture and sale, proper pharmaceutical care during dispensing a drug product to a patient.

Structure of the academic discipline	Hours				Academic year / semester	Types of control
	Total, h / credits	Class hours		Self-directed learning		
		Lectures	Laboratory classes			
Good practices in pharmaceutics	90/3	8	30	52	5/IX	credit

The subject of the study of the discipline is the methodology of pharmaceutical development, parts of the quality assurance system of medicines, including the requirements of the Guidelines of Good Practices in Pharmaceutics for each stage of the life cycle of a medicinal product.

Interdisciplinary links:

- the discipline related to drug technology, biopharmacy, organization and economics of pharmacy, pharmaceutical chemistry, and clinical pharmacy;
- the discipline lays the foundations for the training of future specialists, promotes the formation of pharmaceutical thinking;
- together with other pharmaceutical disciplines and social sciences, the discipline plays an important role in providing special training for professional activities.

1. The purpose and objectives of the discipline

1.1. **The purpose of teaching** the discipline "Good Practices in Pharmaceutics" is to master a set of professional competencies on the requirements of the Guidelines of Good Practices in Pharmaceutics for each stage of the life cycle of a drug product by the higher pharmaceutical education students.

1.2. **The main tasks** of studying the discipline "Good practices in Pharmaceutics" are:

- formation knowledge, skills and practical skills, ways of thinking about ensuring and functioning of the quality assurance system of medicines at all stages of the life cycle, taking into account the requirements of Good Practices in Pharmaceutics in students of higher pharmaceutica education l;
- providing a theoretical basis for the study of other disciplines of the curriculum (biopharmacy, pharmaceutical biotechnology);

- creation of an educational base that determines the professional competence and general erudition of the Master of Pharmacy;
- ensuring the ability of the future graduates to successfully conduct professional and further educational activities.

1.3 Competences and learning outcomes, the formation of which is facilitated by the discipline (relationship with the normative content of training of students, formulated in terms of learning outcomes in the Standard).

According to the Standard of Higher Education, the discipline provides gaining the following ***competencies*** – ***general and professional***.

General:

CG01. The ability for abstract thinking, analysis and synthesis.
CG02. Knowledge and understanding of the subject area; understanding of professional activity.
CG03. The ability to communicate in the national language both orally and in writing.
CG04. The ability to communicate in a foreign language (mainly English) at a level that ensures effective professional activity.
CG05. The ability to evaluate and ensure the quality of the work performed.
CG06. The ability to work in a team.
CG07. The ability to exercise one's rights and responsibilities as a member of society; awareness of the value of a civil (free democratic) society and the need for its sustainable development, the rule of law, the rights and freedoms of a person and a citizen in Ukraine.
CG08. The ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of pharmacy development, its place in the general system of knowledge about nature and society and in the development of society, technics and technology, to use various types and forms of physical activity for active rest and leading a healthy lifestyle.
CG09. The ability to use information and communication technologies.

Professional:

PC1. The ability to integrate knowledge and solve complex pharmacy/industrial pharmacy problems in broad or multidisciplinary contexts.
PC2. The ability to collect, interpret and apply data necessary for professional activity, research and implementation of innovative projects in the field of pharmacy.
PC3. The ability to solve pharmacy problems in new or unfamiliar environments in the presence of incomplete or limited information, taking into account aspects of social and ethical responsibility.
PC4. The ability to clearly and unambiguously convey one's own knowledge, conclusions and arguments in the field of pharmacy to specialists and non-specialists, in particular to people who are studying.
PC5. The ability to demonstrate and apply communication skills and fundamental principles of pharmaceutical ethics and deontology in practical activities
PC6. The ability to develop and implement a quality management system for pharmaceutical enterprises in accordance with the requirements of current Standards, to conduct quality audits and risk management for the quality of pharmaceutical products.
PC7. The ability to carry out sanitary and educational work among the population for the purpose of prevention of common, dangerous infectious, viral and parasitic diseases, promotion of timely detection and support of adherence to the treatment of these diseases according to their medical-biological characteristics and microbiological features.
PC8. The ability to provide rational use and counseling regarding prescription and non-prescription medicines and other products of the pharmacy assortment, to provide pharmaceutical care during the selection and dispense of medicines by assessing the risk/benefit ratio, compatibility, taking into account their biopharmaceutical, pharmacokinetic, pharmacodynamic and physical-chemical and chemical features, indications/contraindications for use, guided by data on the health status of a particular patient.

PC12. The ability to ensure proper storage of medicines and other products of the pharmacy assortment in accordance with their physical and chemical properties and the rules of Good Storage Practice in health care institutions.
PC16. The ability to organize and carry out the production activities of pharmacies for the formulaion of medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of medical-preventive institutions, including the justification of technology and the selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice.
PC17. The ability to carry out pharmaceutical development, to determine the stability of medicinal products and to participate in the production of medicinal products in the conditions of pharmaceutical enterprises in accordance with the requirements of Good Manufacturing Practice with the appropriate development and preparation of the necessary documentation.
PC19. The ability to organize and carry out quality control of medicinal products in accordance with the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; to carry out standardization of medicinal products in accordance with current requirements; to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PC20. The ability to develop and evaluate methods of quality control of medicinal products, including active pharmaceutical ingredients, medicinal plant raw materials and excipients using physical, chemical, physical-chemical, biological, microbiological and pharmaco-technological control methods.

Matrix of competencies

No.	Competency	Knowledge	Skill	Communication	Autonomy and responsibility
	General competencies				
1	CG01		S2		
2	CG02	K1	S1		
3	CG03			C1	
4	CG04			C1	
5	CG05	K1	S1, S2, S3	C1	AR1, AR2, AR3
6	CG06		S3	C1	AR1, AR2
7	CG07		S1, S2, S3	C1	AR1, AR2, AR3
8	CG08		S1, S2, S3	C1	AR1, AR2, AR3
9	CG09		S1		AR1
Professional competencies					
1	PC01	K1	S1, S2		AR1, AR2
2	PC02	K1	S1		AR3
3	PC03	K1	S1, S2, S3	C1	AR1, AR2, AR3
4	PC4	K1	S1, S2, S3	C1	AR1, AR2, AR3
5	PC5	K1	S1, S2, S3	C1	AR1, AR2, AR3
6	PC6	K1	S1, S2, S3	C1	AR1, AR2, AR3
7	PC7	K1	S1, S2, S3	C1	AR1, AR2, AR3
8	PC8	K1	S1, S2, S3	C1	AR1, AR2
9	PC12	K1	S1, S2		AR1, AR2
10	PC16	K1	S1, S2, S3	C1	AR1, AR2
11	PC17	K1	S1, S2		AR1, AR2, AR3
12	PC19	K1	S1, S2, S3	C1	AR1, AR2
13	PC20	K1	S1, S2, S3	C1	AR1, AR2, AR3

Program learning outcomes (PLO), the formation of which is facilitated by the academic discipline:

PLO1. To possess specialized conceptual knowledge in the field of pharmacy and related fields, taking into account modern scientific achievements, and to be able to apply them in professional activities.
PLO3. To possess specialized knowledge and abilities/skills for solving professional problems and tasks, including for the purpose of improving knowledge and procedures in the field of pharmacy.
PLO4. To communicate freely in the national and English languages orally and in writing to discuss professional problems and results of activities, for presentation of scientific research and innovative projects.
PLO5. To assess and to ensure the quality and efficiency of activities in the field of pharmacy in standard and non-standard situations; to adhere to the principles of deontology and ethics in professional activity.
PLO7. To analyze the necessary information on the development and production of medicinal products, using professional literature, patents, databases and other sources; to systematize, analyze and evaluate it, in particular, using statistical analysis.
PLO8. To develop and to implement innovative projects in the field of pharmacy, as well as related interdisciplinary projects taking into account technical, social, economic, ethical, legal and environmental aspects.
PLO9. To formulate, to argument, to convey clearly and concretely to specialists and non-specialists, including studetns, information based on own knowledge and professional experience, the main trends in the development of world pharmacy and related industries.
PL10. To carry out sanitary and educational work among the population for the purpose of prevention and in case of outbreaks of dangerous infectious, viral and parasitic diseases.
PLO11. To determine the advantages and disadvantages of medicinal products of natural and synthetic origin of various pharmacological groups, taking into account their chemical, physical-chemical, biopharmaceutical, pharmacokinetic and pharmacodynamic features and the type of dosage form. To recommend medicinal products and other products of the pharmacy assortment with the provision of advisory assistance and pharmaceutical care.
PLO13. To record cases of side effects of medicinal products of natural and synthetic origin; to evaluate factors that can affect the processes of absorption, distribution, deposition, metabolism and excretion of medicines and are determined by the condition and characteristics of the human body and the pharmaceutical characteristics of medicines.
PLO15. To predict and to determine the influence of environmental factors on the quality and consumer characteristics of medicines and other products of the pharmacy assortment, organize their storage in accordance with their physical and chemical properties and the rules of Good Storage Practices.
PLO19. To develop technological documentation for the manufacture of medicinal products, to choose a rational technology, to produce medicinal products in various dosage forms according to the prescriptions of doctors and the requirements (orders) of treatment-prevention institutions, to prepare them for release.
PLO20. To carry out pharmaceutical development of medicinal products of natural and synthetic origin in the industrial conditions.
PLO22. To ensure and implement quality control of medicinal products and document its results; to issue quality certificates and analysis certificates taking into account the requirements of the current edition of the State Pharmacopoeia of Ukraine, quality control methods, technological instructions, etc.; to take measures to prevent the distribution of low-quality, falsified and unregistered medicinal products.
PLO23. To determine the main chemical and pharmaceutical characteristics of medicinal products; to choose and/or develop quality control methods for the purpose of their standardization using physical, chemical, physical-chemical, biological, microbiological and pharmacotechnological methods in accordance with current requirements.
PLO26. To plan and implement professional activities on the basis of normative legal acts of Ukraine and recommendations of proper pharmaceutical practices.

PLO27. To contribute to the preservation of health, in particular the prevention of diseases, the rational prescription and use of medicinal products.

2. Information volume of the discipline

The study of the discipline is allocated 3 ECTS credits - 90 hours.

Content module 1. Good practices in pharmacy as a as a basis for ensuring the quality, effectiveness and safety of medicines.

3. The structure of the discipline

Topic	Lectures	Laboratory classes	Self-directed learning	Individual work
Unit 1. Content module 1. Good practices in pharmacy as a basis for ensuring the quality, effectiveness and safety of medicines				
Topic 1. Quality Assurance of drug products at all their phases of lifecycle. Standards of Good practices.		2	6	Preparation and analysis of a review of scientific literature, normative-legal and normative-technical documents
Topic 2. General approaches of Pharmaceutical Development. The requirements for the research of pharmaceutical development of liquid and semisolid dosage forms.	1	2	6	
Topic 3. The requirements for research of Pharmaceutical development of solid drug products, transdermal patches, metered dose inhalers and dry powders inhalers.	2	2	2	
Topic 4. The rules of GLP (Good laboratory practice). The requirements for the conduct of preclinical studies in dependence on type of dosage form. Clinical trials. The purpose, basic principles and requirements of Good Clinical Practice (GCP).		2		
Topic 5. The requirements to the determination of generic products equivalence. The principles of referring generic drug products to the waiver category. Bioequivalence. Biosimilars.	2	2		
Topic 6. The authorization of drug products in Europe. Normative documents regulating authorization of drug products. Structure of registration dossier.		2	6	
Topic 7. The requirements of Good Manufacturing Practices (GMP) for Quality Management and personnel, premises and equipment.	0.5	2	6	
Topic 8. The requirements of GMP for production. The types of documentation. The form and content of standard operating procedures, Manufacturing Formulae, Processing, Packaging and Testing Instructions.	0.5	2	6	
Topic 9. The requirements of GMP for contract manufacture and analysis, complaints and product recall. Changes in registration documents, classification of changes, their expertise.	0.5	2		
Topic 10. The requirements of Good Manufacturing Practice for biological medicinal products.		2	3	
Topic 11. The requirements of Good Manufacturing Practice for herbal medicinal products.	0.5	2	3	
Topic 12. The requirements of Good Storage Practice (GSP).	0.5	2	2	
Topic 13. The requirements of Good Distribution Practice (GDP).	0.5	2	2	
Topic 14. The regulations and principles of Good Pharmacy Practice (GPP).	0.5	2	2	
Topic 15. The requirements of GPP for the compounding of drug products in pharmacies.	0.5	2	4	
Total (hours) 90 hours / 3 credits ECTS	**8**	**30**	**52**	
Final control				**Credit**

4. Thematic plan of lectures

No.	Topic	Hours
1	General principles of pharmaceutical development. The features of the pharmaceutical development of liquid, semi-solid, solid and sterile dosage forms	2
2	Generic drug products and biosimilars. The requirements for the assessment of the equivalence of generic preparations. The principles and criteria for referring generic drug products to the waiver category. Bioequivalence	2
3	Good Manufacturing Practice (GMP) as a basis of quality assurance of drug products. The requirements of GMP for production. The types of documents, their form, content, general principles of writing	2
4	The requirements of Good pharmacy practice (GPP) for the preparation of drug products in pharmacies. Interconnection of Good Distribution Practice (GDP), Good Distribution Practice (GDP), Good practice of pharmacovigilance and GPP	2

5.Thematic plan of laboratory classes

No.	Topic	Hours
1.	Quality Assurance of drug products at all phases of their lifecycle. Standards of Good practices	2
2.	General approaches to the pharmaceutical development. The requirements for the research on pharmaceutical development of liquid and semi-solid dosage forms	2
3.	The requirements for the research on the pharmaceutical development of solid dosage forms, transdermal patches, pressurized metered-dose preparations for inhalation and dry powders for inhalation	2
4.	The requirements for the conduct of preclinical studies of medicinal products. The rules of Good laboratory practice (GLP). Clinical trials of drug products. Good Clinical Practice (GCP). The purpose, basic principles and requirements of GCP	2
5.	The requirements for the assessment of generic preparations equivalence. The principles and criteria for referring generic drug products to the waiver category. Bioequivalence. Biosimilars	2
6.	Good Regulatory Practice. Normative documents regulating the authorization of drug products in Europe. The structure of registration dossier	2
7.	The requirements of Good Manufacturing Practices (GMP) for quality management and personnel, premises and equipment	2
8.	The requirements of GMP for production. The types of documentation. The form and content of standard operating procedures, Manufacturing Formulae, Processing, Packaging and Testing Instructions	2
9.	The requirements of GMP for contract manufacture and analysis, complaints and product recall. Changes in registration documents, classification of changes, their expertise	2
10.	The requirements of GMP for biological medicinal products	2
11.	The requirements of GMP for herbal medicinal products	2
12.	The requirements of Good Storage Practice (GSP)	2
13.	The requirements of Good Distribution Practice (GDP)	2
14.	The regulations and principles of Good Pharmacy Practice (GPP)	2
15.	The requirements of GPP for the preparation of drug products in pharmacies	2
	Total	30

6. Thematic plan of individual work

No.	Topic	Hours	Type of control
1	Acquaintance with the basic terms of guidelines: ICH Harmonised Tripartite Guideline Pharmaceutical Development Q8, Directive 2001/83/EC of the European Parliament and the Council of 6 November 2001, Guide to Good Manufacturing Practice for Medicinal Products of Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme	6	Current control during laboratory classes
2	The requirements for the research on pharmaceutical development of sterile dosage forms	6	

3	The requirement for the research on pharmaceutical development of drug products for oral administration	6	
4	Acquaintance with the structure of registration file in the format of Common Technical Document. The requirements for the chemical, pharmaceutical and biological documentation in format of Common Technical Document	6	
5	Acquaintance with the nomenclature of excipients used for production and preparation of drug products. General requirements for excipients	6	
6	The requirements for the manufacture of sterile medicinal products	6	
7	The requirements for the manufacture of radiopharmaceuticals and medicinal gases	6	
8	The current requirements for distribution and retailing of medicinal products	6	
9	The requirements for the production of drug products in pharmacies in The European Union	4	
	Total:	**52**	

7. Individual tasks

Not provided by the curriculum.

8. Teaching methods: explanatory-illustrated (multimedia lectures with the elements of communication discussion with applicants for higher education), reproductive, research, part-search (independent search work, work with literature).

The following teaching methods are used:

• *verbal* - story, explanation, conversation, instruction, lecture, discussion;

• *visual* - demonstration of films, visual equipment (small mechanization), illustrations, materials, demonstration of operations and processes of drug production in pharmacies and industrial enterprises;

• *practical methods* - laboratory and practical work;

• *inductive methods* - generalization of the results of observations and experiments.

The preference is given to active and interactive methods and multimedia learning (multimedia lectures, educational films).

The types of educational activities of students according to the curriculum are:

a) lectures; b) laboratory classes; c) independent work of students (VTS).

The lecture course will cover the teaching of the most important topics related to the requirements of Good Practices.

The laboratory classes of the discipline are conducted on the basis of theoretical principles of pharmaceutical development, drug technology, preclinical study and clinical trials of drugs, determining the equivalence of generic drugs and biosimilars, modern requirements for dosage forms, knowledge of properties of drug substances and excipients, basic requirements for Good Manufacturing Practice of medicines, including biological, herbal medicines, sterile medicines, Good Distribution Practices, Good Storage Practices, Good Pharmacy Practices, Good Pharmacovigilance Practices. In the laboratory classes, students acquire knowledge, skills, and abilities to work with Guidelines for Pharmaceutical Development, Good Laboratory Practice, Good Clinical Practice, Good Manufacturing Practice, Good Storage Practice, Good Distribution Practice, Good Pharmacy Practice and other good practices. The classes include elements of research work.

The basis of laboratory classes is independent work of students. To deepen the theoretical knowledge, an oral consideration of certain issues is recommended to be conducted in the form of a discussion.

In the process of conducting laboratory tasks, students must follow the rules of safety, instruction in which is conducted in the first laboratory lesson and supervised by teachers in each lesson.

Laboratory classes include:

• consideration of theoretical issues;

• watching educational videos;

• elaboration of the main provisions of the Guidelines;

• analysis and interpretation of the obtained results.

In laboratory classes, it is recommended to fill out a diary in the form of protocols, which record the processing.

Plan and organizational structure of laboratory classes
on the discipline "Good Practices in Pharmaceutics"

No.	Key stages of laboratory class, their functions	Methods of control and training	Materials for methodological support	Duration, min
1. The preparatory stage				

1.	The organization of lesson			1-3
2.	Formulation of learning objectives		Actuality of theme The aim of the lesson	3-5
3.	Control of initial level of knowledge, skills and abilities	Frontal oral examination Individual oral examination	Control oral questions	15-20
2. The basic stage				
4.	Formation of professional abilities and skills: 1. Be able to use the normative documents of Ukraine and the EU to achieve the objectives 2. Be able to select and to justify the excipients for different dosage forms for pharmaceutical development stage	Practical use of normative documentation and Internet resources Professional training to perform the practical tasks	Normative documents, schemes, tables, situation tasks, structural logic and technological schemes, State Pharmacopoeia of Ukraine and the EU, guidelines on quality, samples of drug products	40-50
3. The final stage				
5.	Monitoring and updating the knowledge and practical skills	Individual control of decisions of situation tasks Monitoring of the results of practical work (check of protocols of the lesson) Test control	Tests to control the level of assimilation of the material	15-20
6.	Conclusions from the lesson			3-5
7.	Homework: theme, literature		Oriented algorithms for individual work with literature	1-3

9. Forms of control . Forms of control are current and final control.

10. The current control of the students is carried out at each laboratory class, in accordance with specific goals. Current control includes oral examination; test control; inspection and acceptance of protocols of practical work.
Control of theoretical training is carried out by performing tests and situational tasks.
During laboratory classes students fill the reports where they record the topic of the lesson, describe all the work performed according to the tasks and make the conclusions.
Self-directed learning of students is evaluated during the current control of theme on the appropriate lesson.
Final control is a credit.

11. Evaluation of current educational activity of student

In evaluating the assimilation of each theme for current educational activity the student score for the 4-point (traditional) scale taking into account the approved evaluation criteria. This takes into account all types of work, provided the curriculum. The student must obtain an assessment of each topic. Exhibited the traditional assessment scale are converted into points.

The highest number of points, assigned to students for the current educational activity – 200 points.

Minimum sum of points which student can get for current activity for the admission for the discipline is 120 points.

Calculating the number of points is based on evaluations received by traditional scale while learning the discipline during the semester, by calculating the arithmetic average (AA), rounded to two decimal places. The resulting value is converted into points by multi-points scale as follows:

X=(AA*200)/5

Conversion of the average score for current activity in multi-points scale shown in Table 1:

Conversion of the average score for current activity in multi-point scale

4-points scale	200-points scale		4-points scale	200-points scale		4-points scale	200-points scale		4-points scale	200-points scale
5	200		4.45	178		3.92	157		3.37	135
4.97	199		4.42	177		3.89	156		3.35	134
4.95	198		4.4	176		3.87	155		3.32	133
4.92	197		4.37	175		3.84	154		3.3	132
4.9	196		4.35	174		3.82	153		3.27	131
4.87	195		4.32	173		3.79	152		3.25	130
4.85	194		4.3	172		3.77	151		3.22	129
4.82	193		4.27	171		3.74	150		3.2	128
4.8	192		4.24	170		3.72	149		3.17	127
4.77	191		4.22	169		3.7	148		3.15	126
4.75	190		4.19	168		3.67	147		3.12	125
4.72	189		4.17	167		3.65	146		3.1	124
4.7	188		4.14	166		3.62	145		3.07	123
4.67	187		4.12	165		3.57	143		3.02	121
4.65	186		4.09	164		3.55	142		3	120
4.62	185		4.07	163		3.52	141		less than 3	not enough
4.6	184		4.04	162		3.5	140			
4.57	183		4.02	161		3.47	139			
4.52	181		3.99	160		3.45	138			
4.5	180		3.97	159		3.42	137			
4.47	179		3.94	158		3.4	136			

Evaluation of the discipline "God practices in pharmaceutics" is based on current educational activities and expressed by 2-points scale "passed" or "not passed". To be admitted a student must obtain for current educational activity score of at least 60% of the maximum amount of points for the discipline (120 points).

Points for the discipline are converted regardless both in scale ECTS, and a 4-point scale. Points from ECTS-scale are not converted to 4-point scale and conversely.

Points of students studying for one specialty, based on the number of points gained of the discipline, are ranged on ECTS-scale as follows:

Point by ECTS	Statistical index
A	The best 10% of students
B	The following 25% of students
C	The following 30% of students
D	The following 25% of students
E	The last 10% of students

Methodical support

Methodical materials for teachers and students - lectures, guidelines for laboratory classes and self-directed training of students according to units, guidelines on quality.

LIST OF QUESTIONS TO BE CONSIDERED AT THE FINAL (CURRENT) CONTROL

1. The stages of the life cycle of drug products.
2. Classification of drug products by their nature and by the technological process of manufacturing of active substances.
3. Physico-chemical parameters of the active pharmaceutical ingredients (API) influencing the bioavailability of the drug product.
4. The solubility of the active pharmaceutical ingredients, the classification of API according to the solubility by State Pharmacopoeia.
5. Lipophilicity of the API, the classification of active substances by lipophilicity.
6. The particle size of the API, their effect on the bioavailability of the drug.
7. Chirality of substances, influence on the bioavailability of drug products.
8. General requirements for the choice of excipients. Classification of excipients by functional purpose. List of excipients must be indicated on the packaging of drug products.
9. The excess of active ingredient, the definition; classification of excesses.

10. General requirements of State Pharmacopoeia for containers and rubber closure systems.
11. Basic principles of introduction of antimicrobial preservatives to semi-solid and liquid dosage forms during the pharmaceutical development.
12. Factors affecting the antimicrobial activity of preservatives. Classification of preservatives.
13. Classification of the antioxidants by the principle of action.
14. Features of pharmaceutical development of liquid drug products for oral use.
15. Features of pharmaceutical development of liquid drug products for parenteral use.
16. Features of pharmaceutical development of drug products for peritoneal dialysis and hemodialysis.
17. Features of pharmaceutical development of tablets.
18. Features of pharmaceutical development of capsuls.
19. Purpose the "Dissolution" test in pharmaceutical development. Apparatuses used in the "dissolution" test.
20. Features of "Dissolution" test for dosage forms with traditional, delayed and prolonged release.
21. Classification and functions of excipients used in the manufacture of tablets according to European Pharmacopoeia.
22. Features of pharmaceutical development of transdermal patches.
23. Classification of drug products for inhalation use. General characteristics of powders for inhalation. Features of pharmaceutical development of metered dose inhalers, powders for inhalation.
24. Propellants, their general characteristics, classification, advantages and disadvantages.
25. Features of biological medicinal products. Features of vaccine development for prevention of Kovid 19.
26. Features of herbal medicines.
27. Classification of sterile drugs.
28. Types of sterilization
29. Pharmaceutical development, definition, main objects, purpose and main stages
30. Types of preclinical trials of drug products.
31. Classification of substances by toxicity.
32. Basic requirements of GLP for the personnel, premises and equipment.
33. Description of the phases of clinical trials.
34. Basic principles and requirements of GCP.
35. Biopharmaceutical system of active pharmaceutical ingredients classification.
36. Methods used to prove interchangeability (equivalence) of drug products.
37. The term "Bioequivalence", its definition. Factors that determine necessity of bioequivalence studies for reproduced drugs. Methods of determination of generic products equivalence.
38. Pharmaceutically equivalent drug products. Pharmaceutically alternative drug products. Examples of pharmaceutically equivalent and pharmaceutically alternative drug products.
39. Drugs for which bioequivalence studies should be conducted.
40. Basic requirements for comparative in vitro studies.
41. The concept of biosimilars.
42. Waiver (biowaiver), main indicators for its obtaining.
43. Types of applications for registration of drug products in Ukraine.
44. The structure of the registration dossier.
45. Basic requirements for registration materials. Requirements for the labeling of drug products.
46. Classification of changes. Changes relating to technological process.
47. The procedure for making changes to the materials in the registration dossier.
48. Types of changes to registration materials that require comparison of dissolution profiles.
49. Basic conditions of the test "Dissolution" to establish similarity of dissolution profiles of solid drug products for oral use.
50. Conditions of expertise similarity of dissolution profiles.
51. Basic provisions and requirements of GMP.
52. General requirements for the personnel. Key personnel functions.
53. The responsibilities of Head of Production and Head of Quality control according to the rules of Good Manufacturing Practice.
54. General requirements of Good Manufacturing Practice for premises. GMP requirements for the production areas, storage areas, quality control areas.
55. The basic requirements of Good Manufacturing Practice for the clean area.
56. Classification of ancillary facilities. GMP requirements for ancillary areas.
57. Specific requirements for premises in the manufacture of antibiotics and hormones. Specific features of drug production based on Penicillin and live microorganisms. Features of production of pesticides and herbicides.
58. The basic requirements of Good Manufacturing Practice for the technological process.
59. Measures to prevent cross-contamination.
60. Types of validation of the process.

61. The requirements of Good Manufacturing Practice for starting materials. Marking of initial raw materials.
62. GMP requirements for the packaging operation, packaging materials, printed packaging materials.
63. GMP requirements for processing of rejected products and returned products.
64. General requirements for manufacture of sterile drug products according to GMP rules.
65. General requirements for manufacture of drug products from plant materials according to GMP rules.
66. General requirements for manufacture of liquid and semi-solid drug products according to GMP rules.
67. Structure of Dossier for Sites of manufacture.
68. Types of manufacturing documents. General requirements of Good Manufacturing Practice for compilation documentation of technological process.
69. Types of specifications. The content of specifications for raw materials, packaging materials, intermediate and in bulk products, finished products.
70. The content production of master formula, technological instructions, packaging instructions, protocols of production series, protocols of packaging series.
71. Protocols of distribution, their content and purpose.
72. Contract manufacture and analysis. The basic principle of the work under contract. Responsibilities of the Contract Giver. Responsibilities of the Contract Acceptor.
73. Requirements for laboratories performing quality control of drug products under the contract.
74. Requirements of GMP to handling and investigating complaints. The main reasons for the recall of products from a pharmacy.
75. Requirements of current license conditions for drug production.
76. Compounding of extemporaneous drug products according to GPP requirements.
77. Dispensing of drug products. Over-the-counter (OTC) drug products.
78. Counselling patients about prescribed medicines.
79. Requirements of current license conditions for the retail sale of drug products.
80. Structure of pharmacists' counseling protocols for OTC drug products.
81. Distribution protocols, their content and purpose.
82. Types of activities that can be performed under contract. The basic principle of contract work.
83. Responsibilities of the Customer and the Contractor in the production and control of the contract.
84. Requirements for laboratories that perform quality control work on contract drugs.
85. Requirements of Good Manufacturing Practice for handling complaints.
86. The main reasons for the recall of products from the pharmacy network.
87. Requirements of Good Manufacturing Practice for product recall.
88. Requirements for Good Manufacturing Practice for self-inspections.
89. Requirements of current Licensing Conditions for the production of medicinal products.
90. Legal documents of Ukraine and EU, which regulate the storage of drug products..
91. Basic requirements for Good Distribution Practice for personnel and documentation, premises and equipment,
92. The responsibilities of distributors. Requirements of current license conditions for the wholesale of drug products.
93. Responsibilities of distributors to serve the public in accordance with the requirements of the "Guidelines. Medicines. Good distribution practice. ST-N MOZU 42.5.0: 2008 ».
94. Requirements of current Licensing Conditions for wholesale trade in medicinal products.
95. The concept of good pharmacy practice. The main practical areas of good pharmacy practice.
96. Rules for the release of medicines from pharmacies. Over-the-counter dispensing of medicines from pharmacies.
97. Code of Ethics of pharmaceutical workers of Ukraine, its structure.
98. Requirements of current Licensing Conditions for retail trade in medicinal products.
99. The structure of the protocols of the pharmacist (pharmacist) when dispensing over-the-counter drugs. Features of the release of drugs to patients with Kovid-19.
100. Structure of the Guidelines for Good Pharmacovigilance Practice.

REFERENCES

1. Biopharmaceutics. Lectures for English students of the speciality «Pharmacy»: a handbook for the out-of-class work of students / A.I. Tikhonov, T.G. Yarnych, A.B. Yuryeva, L.N. Podorozhna, S.S. Zuykina; Edited by A.I. Tikhonov.- Kharkiv: NUPh; Original, 2011.-140 p.
2. Biopharmaceutics. Tutorials: Practical course for English students of the speciality «Pharmacy» / A.I. Tikhonov, Ye. Ye. Bogutskaya, T.G. Yarnych, A.M. Kotenko, O.A. Garkavtseva; Edited by A.I. Tikhonov.- Kharkiv: NUPh; Original, 2011.-80 p.
3. British Pharmacopoeia. – London, 2009.
4. COMMISSION DIRECTIVE 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (Text with EEA relevance). Available at: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm.
5. Directive 2001/83/ of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Available at: https://eur-lex.europa.eu/legal-content/en/ALL/?uri=CELEX%3A32001L0083.
6. Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version) (Text with EEA relevance). Available at: http://eur-lex.europa.eu/eli/dir/2004/9/oj.
7. European Pharmacopoeia, 5-rd ed. 2006.
8. Encyclopedia of Pharmaceutical Technology. Edition Third.- Edited by James Swarbrick.- 2006.- 4370 p. // http: // informahealthcare.com.
9. ICH Harmonised tripartite Guideline. Guideline for Good Clinical Practice E6(R1). Available at: http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.
10. Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use (Text with EEA relevance) (2013/C 343/01). Available at: http://ec.europa.eu/health/human-use/good_distribution_practice/index_en.htm.
11. Guidance for industry. ANDAs: Pharmaceutical Solid Polymorphism. Chemistry, Manufacturing, And Control Information // http: www.fda.gov.
12. Guideline on the investigation of bioequivalence. - European Medicines Agency, 2010. – 27 p. Available at: http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_001278.jsp&mid=.
13. Guidance for Industry Q8 Pharmaceutical Development.- ICH.- May 2006. Available at: https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q8_R1/Step4/Q8_R2_Guideline.pdf.
14. Guidance for Industry S2B Genotoxicity: A Standard Battery for Genotoxicity Testing of Pharmaceuticals Available at: https://www.fda.gov/downloads/drugs/guidancecomplianceregulatoryinformation/guidances/ucm074929.pdf.
15. Guide for industry to non-sterile Semisolid Dosage Forms “Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Release Testing and In vivo Bioequivalence Documentation” // U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research. May 1997. Available at: https://www.fda.gov/downloads/drugs/guidances/ucm070930.pdf.
16. Guide for industry to Immediate Release Solid Oral Dosage Forms “Scale-Up and Postapproval Changes: Chemistry, Manufacturing, and Controls; In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation”// U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research. Nov. 1995. Available at: http://www.gmp-compliance.org/guidemgr/files/1-6-8.PDF.
17. Guide for industry to CMC Postapproval Manufacturing Changes to be Documented in Annual Reports // U.S. Department of Health and Human Services. Food and Drug Administration. Center for Drug Evaluation and Research. March 2014 /

18. Pharmaceutical Preformulation and Formulation. A Practical Guide from Candidate Drug Selection to Commercial Dosage Form. Edited by Mark Gibson. -2004.-596 p.
19. The United States Pharmacopoeia, 30-th ed., NF.25, 2007.
20. Good laboratory practice for nonclinical laboratory studies section in the Code of Federal Regulations (CFR) (58 CFR). Available at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58.
21. PIC/S Guide to Good Distribution practice for medicinal products. Available at: http://www.gmp-compliance.org/guidemgr/files/PICS/PE-011-1-PICS-GDP-GUIDE.PDF.
22. PIC/S Guide to Good Manufacturing Practice. Available at: https://picscheme.org/en/publications?tri=gmp.
23. WHO Guide to Good Storage Practices for pharmaceuticals. Available at: http://www.gmp-compliance.org/guidemgr/files/GUIDEGOODSTORAGEPRACTICESTRS908ANNEX9 (1).PDF.
24. Joint FIP/WHO Guidelines on GPP: Standards for quality of pharmacy services. Avaolable at: https://www.fip.org/www/uploads/database_file.php?id=331&table_id= .
25. Resolution CM/ResAP (2011) 1 on quality and safety assurance requirements for medicinal products prepared in pharmacies for the special needs of patients (Adopted by the Committee of Ministers on 19 January 2011 at the 1103rd meeting of the Ministers' Deputies).