Syllabus for Good Practices in Pharmaceutics

1. General information	
Faculty	Pharmacy
Educational program	22 Healthcare, 226 Pharmacy, 2nd (master's) level of higher education, full-time study
Educational discipline, code	Good Practices in Pharmaceutics, OK 46 http://new.meduniv.lviv.ua/
Department	Department of Drug Technology and Biopharmaceutics; 79010, Lviv, Pekarska str.,75, (032) 276-85-84, (032) 276-85-98, Kaf_biopharm@ meduniv.lviv.ua
Head of the depratment	Bilous Svitlana Bohdanivna, DSci, prof. svitlana.bilous@gmail.com
Academic year	V course
Semester	1 semester
Type of discipline	obligatory
Educators	Hudz N.I., DSci, prof., natali_gudz@ukr.net Yezerska O.I., PhD, assoc.prof., o.yezerska@gmail.com Strus O.Ye., DSci, assoc.prof., oxana.strus@ukr.net Bilous S.B., DSci, prof., svitlana.bilous@gmail.com Vashchenko O.O, PhD, assoc.prof., o_vashchenko@ukr.net
Erasmus	Yes
Person responsible for syllabus	Hudz N.I., DSci, assoc.prof., natali_gudz@ukr.net
Number of credits ECTS	3
Number of hours	Total - 30 h
Language of instruction	English
Information on consultations	Consultations are provided in accordance with the schedule of consultations by the responsible educators

2. A brief review of subject "Good Practices in Pharmaceutics"

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 (GMP) for the industrial manufacture of medicinal products, compliance with the principles of the storage of medicinal products during manufacture and sale, proper pharmaceutical care during dispensing a drug product to a patient, etc.

3. Purpose and objectives of subject "Good Practices in Pharmaceutics"

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.

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 pharmaceutical education;
- 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.

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

In accordance with the requirements of the Standard, the discipline provides students with the acquisition of the

following competencies:

A) integral competencies (IC):

- the ability to solve typical and complex specialized tasks and practical problems in the professional pharmaceutical activity using the provisions, theories, and methods of basic, chemical, technological, biomedical and socio-economic sciences; integrate knowledge and solve complex issues, formulate judgments on insufficient or limited information; clearly and unambiguously bring their conclusions and knowledge, reasonably substantiating them, to a professional and non-professional audience.

B) general competencies (GC):

GC 1. Ability to act socially responsibly and civic consciously.
GC 2. Ability to apply knowledge in practical situations.
GC 3. The desire to preserve the environment.
GC 4. Ability to abstract thinking, analysis, and synthesis, to learnng and being modernly trained.
GC 5. Ability to show initiative and entrepreneurship.
GC 6. Knowledge and understanding of the subject area and understanding of the professional activity.
GC 7. Ability to adaptation and acting in a new situation.
GC 8. Ability to communicate in the state language both in oral and written form, ability to communicate in a foreign language (mainly the English lanquage) at the level that ensures effective professional activity.
GC 9. Skills in the use of information and communication technologies.
GC 10. Ability to choose communication strategy, ability to work in a team and with experts in other fields of knowledge/types of economic activity.
GC 11. Ability to assess and ensure the quality of work performed.
GC 12. Ability to conduct research at the appropriate level.
GC 13. Ability to exercise their rights and responsibilities as a member of society, to realize the values of civil (free democratic) society and the need for its sustainable development, the rule of law, human and civil rights, and freedoms in Ukraine.
GC 14. Ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of the development of the subject area, its place in the general system of knowledge about nature and society, and in the development of society, techniques and technologies, use different types and forms physical activity for rest and a healthy lifestyle.

b) Special (professional) competencies (PC):

PC 1. Ability to conduct health education among the population with the purpose of the prevention of common diseases, dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to the treatment of these diseases in accordance with their medical and biological characteristics and microbiological features.
PC 2. Ability to provide advice on prescription and over-the-counter drugs and other products of the pharmacy range; pharmaceutical care during the selection and sale of over-the-counter drugs by assessing the risk/benefit, compatibility, indications and contraindications based on the health status of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of medicinal products and other pharmaceutical products.
PC 7. Ability to ensure proper storage of medicines and other products of the pharmacy range in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities.
PC 8. Ability to organize the activities of pharmacies in order to provide the population, health care facilities with medicines and other products of the pharmacy range and implement appropriate reporting and accounting systems (management, statistical, accounting and financial) in accordance with the requirements of the National Medical Policy, Good Pharmacy Practice (GPP) and to carry out commodity analysis, administrative record-keeping taking into account organizational and legal norms of the pharmaceutical legislation.
PC 12. Ability to use in professional activities knowledge of regulations, legislation of Ukraine, and recommendations of Good Pharmaceutical Practices.
PC 13. Ability to demonstrate and apply in practice communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations and values, ethical standards of professional conduct and responsibility in accordance with the Code of Ethics for Pharmaceutical Workers of Ukraine and WHO guidelines.
PC 14. Ability to carry out the production activities of pharmacies for the preparation of medicinal products in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP).
PC 15. Ability to organize and participate in the production of medicines in pharmaceutical companies, including the selection and justification of the process, equipment and premises with the appropriate development and design of the necessary documentation in accordance with the requirements of Good Manufacturing Practice (GMP); ability to determine the stability of medicinal products.
PC 16. Ability to organize and conduct the procurement of medicinal plant raw materials in accordance with the rules of Good Agricultural and Collection Practice for herbal starting materials (GACP), as a guarantee of the

quality of medicinal plant raw materials and medicines based on it. Ability to predict and calculate ways to solve the problem of conservation and protection of thickets of wild medicinal plants in accordance with current legislation.
PC 18. Ability to develop and implement a quality management system for pharmaceutical companies in accordance with the requirements of current Standards, to conduct quality audits and risk management for the quality of pharmaceutical products.
PC 21. Ability to organize and participate in the development of medicines.
PC 22. Ability to create registration documents or conduct their examination, which contain, in particular, materials of pharmaceutical development, technological process, pre-clinical research, clinical trials; to develop regulatory documents on the circulation of medicines

4. Prerequisites of subject Good Practices in Pharmaceutics

Subject "Good Practices in Pharmaceutics":
a) is based on learning by students the main requirements of Guides related with pharmaceutical development Good laboratory practice (GLP); Good clinical practice (GCP), good regulatory practice (GRP), Good manufacturing practice (GMP), Good Storage Practice (GSP), Good Distribution practice (GDP), Good pharmacy practice (GPP), etc.
b) contributes to forming the basic knowledge and gaining the practical skills for further learning of such disciplines as biopharmacy, pharmaceutical biotechnology, "Methodology of research on drug technology on the topic of master's thesis", which involves the integration of teaching with these disciplines and the impact on the formation of skills to apply knowledge of Good Practices in pharmacutics" in further education and professional activities of Masters of pharmacy.
c) gives the foundations for the professional training of future specialists, and promotes the formation of pharmaceutical and technical thinking.

5. Program learning outcomes

List of learning outcomes

Content of learning outcomes (results)

PLR 1. To carry out professional activities in social interaction based on humanistic and ethical principles; to identify future professional activities as socially significant for human health.
PLR 2. To apply knowledge of general and professional disciplines in professional activities.
PLR 3. To adhere to the norms of the sanitary and hygienic regime and safety requirements during professional activities.
PLR 4. To ddemonstrate the ability to independently search, analyze and synthesize information from various sources and use these results to solve typical and complex specialized tasks of professional activity.
PLR 5. To present professional activities and personal qualities in the pharmaceutical labor market; to formulate the purposes of own activity taking into account public and industrial interests.
PLR 6. To argue information for decision-making, to be responsible for them in standard and non-standard professional situations; to adhere to the principles of deontology and ethics in professional activities.
PLR 7. To perform professional activities using creative methods and approaches.
PLR 8. To carry out professional communication in the state language, use the skills of oral communication in a foreign language, analyzing texts of professional orientation and translate foreign language information sources.
PLR 9. To carry out professional activities using information technology, "Information databases", navigation systems, Internet resources, software, and other information and communication technologies.
PLR 10. To adhere to the norms of communication in professional interaction with colleagues, management, consumers, work effectively in a team.
PLR 11. To use methods for assessing indicators of performance quality; to identify reserves to increase labor efficiency.
PLR 12. To analyze the information obtained as a result of scientific research, to summarize, systematize and use this information in professional activities.
PRR 13. To carry out sanitary-educational work in professional activity in case of outbreaks of infectious, viral and parasitic diseases.
PRR 14. To determine the advantages and disadvantages of medicinal products of different pharmacological groups, taking into account their chemical, physicochemical, biopharmaceutical, pharmacokinetic, and pharmacodynamic features. To recommend to consumers over-the-counter medicines and other products of the pharmacy range with the provision of counseling and pharmaceutical care.
PLR 16. To determine the factors influencing the processes of absorption, distribution, deposition, metabolism, and excretion of the drug products and due to the state and features of the human body and physicochemical

properties of drug products.
PLR 19. To forecast and determine the impact of environmental factors on the quality of medicines and consumer characteristics of other products of the pharmacy range during their storage.
PLR 24. To plan and implement professional activity on the basis of normative legal acts of Ukraine and recommendations of Good Pharmaceutical Practices.
PLR 25. To promote health, including disease prevention, rational administration of medicines. To perform your professional duties in good faith, to be adherent with the law on the promotion and advertising of medicines. To possess psychological communication skills to achieve trust and mutual understanding with colleagues, doctors, patients, consumers.
PLR 26. To choose rational technology, to make medicines in various dosage forms according to prescriptions of doctors and orders of medical institutions, to dispense them. To perform technological operations, namely weigh, measure, dose a variety of drugs by weight and volume, etc. To develop and draw up technological documentation for the manufacture of medicines in pharmacies.
PLR 27. To substantiate the technology and organize the manufacture of medicines at pharmaceutical enterprises and draw up technological documentation for the production of medicines at pharmaceutical enterprises.
PLR 28. To organize and conduct rational procurement of medicinal plant raw materials. Develop and implement measures for the protection, reproduction and rational use of wild species of medicinal plants.
PLR 30. To ensure quality control of medicines and document its results. To manage quality risks at all stages of the life cycle of medicines.
PLR 33. To develop medicines in accordance with modern requirements.
PLR 34. To understand the essence of drawing up registration documents for medicines and conducting their examination

6. Mode and scope of the practical training

Forma of the dicsipline	Full-time study	
Type of activity	**Number of hours**	**Number of groups**
lectures	8	6-7
practical, seminars	30	
independent	52	

7. Topics and content of the practical training

Learning outcome code	The content of the learning outcome	Link to the matrix code competences
Kn-1	To know one's social and public rights and responsibilities	PLR-1
Ab-1	To form one's civic consciousness, to be able to act in accordance with it	
GC-1	Ability to act socially responsibly and civic consciously	
AR-1	To be responsible for one's civic position and activity	
Kn-2	To know the methods of implementing knowledge in solving practical problems	PLR-2
Ab-2	To be able to use professional knowledge to solve practical situations	
GC-2	Ability to apply knowledge in practical situations	
AR-2	To be responsible for the timeliness of decisions	
Kn-3	To know the problems of environmental protection, trequirements of the sanitary and hygienic regime and conditions of labor protection	PLR-3
Ab-3	To be able to form the requirements for the preservation of the environment, compliance with the sanitary and hygienic regime and labor protection conditions; interpret the requirements of laws and regulations on labor protection; draw conclusions about the presence of harmful factors during the performance of professional duties; to ensure the safety of pharmaceutical staff	
GC-3	Striving to preserve the environment	
AR-3	To be responsible for the implementation of environmental measures within its competence	
Kn-4	To know the current trends in the industry and analyze them	PLR-4
Ab-4	To be able to analyze professional information, make informed decisions, acquire modern knowledge	
GC-4	Ability to abstract thinking, analysis and synthesis; ability to learn and be modern	

	learned	
AR-4	To be responsible for the timely acquisition of modern knowledge	
Kn-5	To know the laws and trends of modern economic development	PLR-5
Ab-5	To be able to apply knowledge to the modern development of an enterprise	
GC-5	Ability to show initiative and entrepreneurship	
AR-5	To be responsible for the activity goals	
Kn-6	To know the structure and features of professional activity	PLR-6
Ab-6	To be able to perform professional activity that requires updating and integration of knowledge	
GC-6	Knowledge and understanding of the subject area and understanding of the profession	
AR-6	To be responsible for professional development with a high level of autonomy	
Kn-7	To know the elements of industrial and social adaptation; factors of successful adaptation to the new environment	PLR -7
Ab-7	To be able to form an effective strategy of personal adaptation to new conditions	
GC-7	Ability to adaptation and action in a new situation	
AR-7	To be responsible for making decisions	
Kn-8	To have perfect knowledge of the native language and basic knowledge of a foreign language	PLR -8
Ab-8	To be able to apply knowledge of the native language in oral and writing form.	
GC-8	Ability to communicate in the state language both orally and in writing, in a foreign language (mostly the English language) at a level that ensures effective professional activity	
AR-8	To be responsible for fluency in the native language, development of professional knowledge	
Kn-9	To have deep knowledge in the field of information and communication technologies used in professional activities	PLR -9
Ab-9	To be able to use information and communication technologies in the professional field that requires updating and integration of knowledge	
GC-9	Information and communication technology skills	
AR-9	To be responsible for professional development knowledge and skills	
Kn-10	To know the tactics and strategies of communication, laws, and ways of communicative behavior	PLR -10
Ab-10	To be able to choose ways and strategies of communication to ensure effective teamwork	
GC-10	Ability to choose communication strategies, ability to work in a team and with experts in other fields of knowledge / types of economic activity	
AR-10	To be responsible for the choice and tactics of communication	
Kn-11	To know the assessment methods of the quality of activities	PLR -11
Ab-11	To be able to ensure the quality of professional work	
GC-11	Ability to evaluate and ensure the quality of work performed	
AR-11	To be responsible for the quality of work	
Kn-12	To know the components of the health care system, planning and evaluation of scientific research	PLR -12
Ab-12	To search for scientific sources of information; to make a choice of methods of carrying out scientific research; to use methods of mathematical analysis and modeling, theoretical and experimental research in pharmacy	
GC-12	Ability to conduct research at the appropriate level	
AR-12	To be responsible for the development and implementation of planned projects	
Kn-13	To know the rights and responsibilities of members of society and values of civil democratic society	PLR -1
Ab-13	To apply their rights and responsibilities in practice, taking into account the values of civil society	
GC-13	Ability to exercise their rights and responsibilities as a member of society, to realize the values of civil (free democratic) society and the need for its sustainable	

	development, the rule of law, human and civil rights and freedoms in Ukraine	
AR-13	To be responsible for their actions in the civil society	
Kn-14	To know the moral, cultural, scientific values and achievements of society based on understanding the history and patterns of pharmacy, its place in the general system of knowledge about nature and society and in the development of society, technology types and forms of physical activity for active recreation and a healthy lifestyle	PLR -2
Ab-14	To use moral, cultural, scientific values and achievements of society based on understanding the history and regularities of the development of pharmacy in practical activity	
GC-14	Ability to preserve and multiply moral, cultural, scientific values and achievements of society based on understanding the history and patterns of development of the subject area (pharmacy), its place in the general system of knowledge about nature and society and in the development of society, technique and technology, to use different types and forms of motor activity for active recreation and healthy living lifestyle	
AR-14	To be responsible for the observance of moral, cultural and scientific values	
Kn-15	To know the clinical and pharmaceutical characteristics of dosage forms for the treatment of patients with dangerous infectious and parasitic diseases; principles of compiling pharmaceutical information and creation information products.	
Ab-15	To organize scientific and practical seminars for medical staff and lectures for the population on the rational administration of medicinal products, medicinal plant raw materials, the harmfulness of drugs and strong active drug abuse, measures for the prevention drug dependence; To compile information messages for doctors and junior pharmacy specialists about new medicinal products and new indications for the use of known medicinal products, data from automated information systems, etc.	
SC-1	Ability to conduct health education work among the population in order to prevent common diseases, prevent dangerous infectious, viral and parasitic diseases, as well as to facilitate the timely detection and maintenance of adherence to the treatment of these diseases in accordance with their medical, biological and microbiological features	
AR-15	To be responsible for the quality and timeliness of preventive and anti-epidemic measures	
Kn-16	To know: - symptoms and syndromes, variants of the development of diseases for which the use of over-the-counter drugs is possible; - regulatory documents governing dispensing over-the-counter and prescription drugs; - types of action and routes of drug administration; - pharmacokinetic and biopharmaceutical factors influencing the choice of the dosage form; - methods of using modern transdermal, inhalation, oral, dosage forms; -deontological aspects of the pharmacist-patient relationship; - chemical structure medicines; - new dosage forms of prolonged action; - therapeutic systems of delivery of medicines; - characteristics of types of action and routes of drug administration; - bioequivalence of medicinal products and the principles of their clinical study; - features of innovative medicinal products , generics, and biosimilars; • - requirements for the equivalence of generic drug products and biosimilars	PLR-14
Ab-16	To provide information on the regime, periods and requirements for storage of various drug products using knowledge of chemical and physicochemical properties; - provide information about compatibility, indications and	

	contraindications to the use of drug products taking into account their biopharmaceutical, pharmacokinetic and pharmacodynamic properties; - to provide comparative characteristics of original (innovative) drug products (brands) and their copies (generic drug products), guided by the data of clinical and pharmacological research, pharmacoeconomic indicators and information database on drug products to justify the optimal choice of a drug product	
SC-2	Ability to provide the advice on prescription and over-the-counter drugs and other pharmaceutical products; pharmaceutical care in the selection and implementation of over-the-counter drugs by assessing the risk/benefit, compatibility, indications and contraindications based on data on the health of a particular patient, taking into account biopharmaceutical, pharmacokinetic, pharmacodynamic and physicochemical characteristics of the drug and other pharmaceutical products	
AR-16	To be responsible for the implementation of pharmaceutical care during dispensing over-the-counter drug products; for the validity of management of decisions to improve the quality of pharmaceutical care	
Kn-17	To know: - classification of medicinal products and dosage forms; - physicochemical properties of medicinal substances; - types of containers, closures, and packaging materials used in medicine and pharmacy; - orders of the Ministry of Health of Ukraine on the organization of storage of various groups of medicinal products and medical devices in pharmacies ; - general requirements for the storage of medicines; - rules of the storage of medicinal substances with different physicochemical properties; - stability and shelf life of medicinal products	PLR-24
AB-17	To provide conditions of the storage of medicines to prevent adverse effects; to anticipate the possible influence of storage conditions on the quality of pharmaceutical products, medicinal plant raw materials and medical devices; to control the conditions of the storage of raw materials at pharmaceutical enterprises; to determine the stability of medicines and medical devices during storage for the established shelf-life	
SC-7	Ability to ensure proper storage of medicines and other pharmaceutical products in accordance with their physicochemical properties and the rules of Good Storage Practice (GSP) in health care facilities	
AR-17	To be responsible for the storage of medicines and medical devices in accordance with Good Storage Practice (GSP) in healthcare facilities	
Kn-18	To know the legal framework of Ukraine for business activities and principles of organizing the work of pharmacies, pharmaceutical companies, and their structural units	PLR-24
AB-18	To make commercial agreements, agreements on cooperation with business partners and to carry out constant work with clients according to the concluded agreements, to control performance of contractual obligations by suppliers of production, raw materials and materials	
SC-8	Ability to organize the activities of pharmacies to provide the population and health care facilities with medicines and other products of the pharmacy range and to implement appropriate reporting and accounting systems (management, statistical, accounting, and financial) in accordance with the requirements of National Medical Policy, Good Pharmacy Practice (GPP) and carry out commodity analysis, administrative record-keeping, taking into account the organizational and legal norms of pharmaceutical legislation	
AR-18	To be responsible for performing the recommendations of Good Pharmacy Practice (GPP)	
Kn-19	To know basics of the system of law and pharmaceutical legislation; principal mechanisms of the state regulation of pharmaceutical activity; legal and ethical	PLR-24

	norms of pharmaceutical activity	
Ab-19	To use normative-legal acts regulating pharmaceutical activity in Ukraine and abroad; to monitor and determine changes and amendments in the domestic pharmaceutical legislation; to form relations with patients and doctors in order to meet the ethical criteria of the WHO and the principles of Good Pharmacy Practice (GPP) to promote medicinal products on the market, minimize abuse and misuse of medicinal products	
SC-12	Ability to use the knowledge of regulations, legislation of Ukraine and pharmaceutical practices in the professional activities	
AR-19	To be responsible for high-quality and timely use of normative documents in professional activity	
Kn-20	To use communication skills, fundamental principles of pharmaceutical ethics and deontology	PLR-10
AB-20	To know communication skills, fundamental principles of pharmaceutical ethics and deontology	
SC-13	Ability to demonstrate and apply in the practice communication skills, fundamental principles of pharmaceutical ethics and deontology, based on moral obligations, values, ethical standards of professional conduct and responsibility in accordance with the Code of Ethics of Pharmaceutical Workers of Ukraine and WHO guidelines	
AR-20	To be responsible for qualitative communication	
Kn-21	To know pharmacy technology of pharmaceutical products; stability and shelf life of medicines; determination of the influence of the nature of excipients on the therapeutic efficacy of pharmaceutical products by "*in vitro*" and "*in vivo*" methods; requirements of regulatory documents (orders, guidelines, etc.) on the design and rules of the development of technological documentation	PLR-26
AB-21	To characterize dosage forms by types of dispersed systems, method of administration, place of action, physical state; to take into account the physicochemical properties of active substances and excipients; to stabilize pharmaceuticals taking into account biological, physicochemical, technological properties of active and excipients and use of necessary reagents; to make technological schemes and instructions for the manufacture of drugs "in stock" in the pharmacy	
SC-14	Ability to organize and carry out the production activities of pharmacies for the preparation of medicinal products in various dosage forms on prescriptions and orders of medical institutions, including justification of technology and selection of auxiliary materials in accordance with the rules of Good Pharmacy Practice (GPP)	
AR-21	To be responsible for the extemporaneous preparation of medicinal products	
Kn-22	To know industrial technology of medicinal products; requirements of GMP and other Good Practices for the manufacture of medicinal products, including the development and design of documentation (protocols, production formula, reports, technological instructions, etc.)	
AB-22	Обирати оптимальну технологію лікарських форм, використовуючи необхідне обладнання; To choose the optimal technology of dosage forms, appropriate equipment; to develop documentation related to the technological process, consideration of complaints and product recalls, self-inspections, etc.	
SC-15	Ability to organize and participate in the manufacture of medicines in the context of pharmaceutical companies, including the selection and justification of the technological process, equipment and premises with the appropriate development and design of the necessary documentation in accordance with the requirements of Good Manufacturing Practice (GMP). To determine the stability of medicinal products	PLR-27
AR-22	To be responsible for the compliance with Good Manufacturing Practice (GMP)	

Kn-23	To know: - characteristics of medicinal plants and raw materials that contain different groups of biologically active substances; - Latin names of medicinal plants and plant raw materials; - terminology, chemical and botanical nomenclature, plant taxonomy, the morphology of vegetative and generative organs; - physico-chemical properties of the main groups of biologically active substances in medicinal plant materials; - optimal time of the procurement of plant raw materials; - periodicity of exploitation of thickets of medicinal plants	PLR-28
AB-23	To determine the appropriate times and methods of procurement, drying and storage of medicinal plant raw materials in accordance with list 2, depending on the chemical composition and dynamics of accumulation of biologically active substances in medicinal plant raw materials	
SC 16	Ability to organize and procure medicinal plant raw materials in accordance with the rules of Good Agricultural and Collection Practice for herbal starting materials (GACP) as a guarantee of the quality of medicinal plant raw materials and medicinal products based on it. Ability to predict and calculate ways to solve the problem of conservation and protection of thickets of wild medicinal plants, in accordance with current legislation	
AB-23	To be responsible for the compliance of the GACP rules	
Kn-24	To know the principles of quality management system in pharmaceutical companies	PLR-30
AB-24	To be able to use the principles of quality management in the organization of quality management system, its support and audits	
SC-18	Ability to develop and implement quality management system for pharmaceutical companies in accordance with the requirements of current Standards, perform quality audits, and risk management for the quality of pharmaceutical products	
AR-24	To be responsible for the organization and support of quality management system	
Kn-25	To know requirements of regulatory documents (orders, guidelines, etc.) for the development of medicines; methodology of drug development; theoretical foundations of drug technology; functional purpose of excipients of different groups; risk management during pharmaceutical development and principles of selection of packaging materials	PLR-33
AB-25	To be able to select excipients (stabilizers, emulsifiers, prolongators, ointments and suppositories, fillers for tablets, etc.) for the manufacture of various dosage forms; choose the optimal composition, technological process and packaging materials for medicinal products of industrial manufacture	
SC-21	Ability to organize and participate in the development of medicines	
AR-25	To be responsible for compliance with pharmaceutical development requirements	
Kn-26	To know the structure of the registration dossier; requirements for the design of materials for pharmaceutical development, preclinical studies, technological process and clinical trials	PLR-34
AB-26	Ability to form registration documents or conduct their examination, which contain, in particular, materials of pharmaceutical development, technological process, pre-clinical research, clinical trials; to develop legal documents on the circulation of medicines	
SC-22	Ability to form registration documents or conduct their examination	
AR-26	Responsibility for the quality of filling in registration documents and their examination	

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Code of type of classes	**Topic**	**Essence of learning**	**Kod of the result of learning**	**Teacher**
L-1 *2 h*	General principles of pharmaceutical development. The	Pharmaceutical development, definition, purpose, main objects and main stages. Physico-chemical parameters of the drug substance that affect the	*Kn – 1–14, 25, 26;* *Ab – 1–14, 25, 26;*	Hudz N.I., Strus O.Ye., Vashchenko O.O, Yezerska O.I.,

	features of the pharmaceutical development of liquid, semi-solid, solid and sterile dosage forms	bioavailability of the drug (solubility, lipophilicity, particle size, chirality of substances, etc.). Principles of selection of excipients. Classification of excipients by functional purpose. Overages of active substance, the definition of the term; classification of pverages. Principles of the development of composition and technology of liquid, solid, soft and sterile medicines	*GC – 1–14, SC 21, 22; AR* – 1–14, 25, 26	Bilous S.B.
L-2 2 h	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	Regulatory documents governing the establishment of equivalence of generic and biotechnological drug products. Features of methods for establishing the equivalence and similarity of biotechnological drug products	*Kn– 1–14, 16; AB – 1–14, 16; GC – 1–14, SC 2; AR* – 1–14, 16	
L-3 2 h	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	Basic statements of Good Manufacturing Practice. Requirements for the technological process. Features of the documentation for the technological process	Kn – 1–14, 22–24; AB – 1–14, 22–24; GC – 1–14, SC 15, 16, 18; AR – 1–14, 22–24	
L-4 2 h	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	Key statements of Good Distribution Practice, Good Storage Practice, Good Pharmacy Practice and Good Pharmacovigilance Practice	*Kn– 1–17; AB – 1–17; GC– 1–14; SC 1, 2, 7 AR* – 1–17	
P-1 2 h	Quality Assurance of drug products at all their phases of lifecycle. Standards of Good practices	The main stages of the life cycle of a medicinal product. The concept of quality, safety, and efficacy of the drug. Pharmaceutical development, definition. State registration of medicines and re-registration, their differences. Wholesale and retail trade by medicines, their differences. Post-registration supervision, its tasks. Regulatory documents governing the circulation of medicines in Ukraine.	*Kn – 1–14, 17-19, 23; AB – 1–14, 17-19, 23; GC – 1–14, SC 7, 8, 12, 16; AR* – 1–14, 17-19, 23	Hudz N.I., Strus O.Ye., Vashchenko O.O, Yezerska O.I., Bilous S.B.
P-2 2 h	General approaches of Pharmaceutical Development. The requirements for the research of pharmaceutical development of liquid and semisolid dosage forms.	Pharmaceutical development, definition, purpose, main objects, and stages. Physico-chemical parameters of the drug substance that affect the bioavailability of the drug product (solubility, lyophilicity, particle size, the chirality of substances, etc.). The overage of active substance, the definition of the term; classification of overages. General requirements of the State Pharmacopeia of Ukraine for containers and rubber seals. Classification of liquid dosage forms by type of dispersed system.	*Kn– 1–14, 25; AB – 1–14, 25; GC – 1–14, SC 21; AR* – 1–14, 25	

		Advantages and disadvantages of liquid dosage forms. Classification of mild medicines according to the State Pharmacopeia of Ukraine. Antimicrobial preservatives, antioxidants, features of the application. Basic principles of introducing antimicrobial preservatives into liquid, semisolid dosage forms and parenteral drug products. Classification of antioxidants by the principle of action. The use of solvents and co-solvents in liquid drug products. The use of flavorings in the composition of liquid drugs. The mechanism of action of "absorption activators" in semisolid drug products. Features of selection of packaging materials for liquid and semisolid medicines		
P-3 *2 h*	The requirements for research of Pharmaceutical development of solid drug products, transdermal patches, metered dose inhalers and dry powders inhalers.	Classification of tablets according to the State Pharmacopeia of Ukraine, quality criteria for tablets. Classification and functions of excipients according to the State Pharmacopeia of Ukraine, which are used in the manufacture of tablets and capsules. The main functional characteristics of solid dispersed systems. Types of pharmaco-technological tests in the process of pharmaceutical development of solid drugs. Appointment of the "dissolution" test in the process of pharmaceutical development. Features of the "Dissolution" test for dosage forms with traditional, delayed and prolonged release. Features of the pharmaceutical development of dosed drugs for inhalation under pressure. Propellants, their general characteristics, classification, advantages and disadvantages.	*Kn – 1–14, 25;* *AB– 1–14, 25;* *GC – 1–14, SC 21;* *AR* – 1–14, 25	
P-4 *2 h*	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).	The main tasks of a preclinical study of drug products. Requirements for preclinical studies. Guidelines for Good Laboratory Practice (GLP), its structure, scope. Requirements for GLP for premises, equipment, test systems, materials, and reagents. Requirements for the report on the research results. Regulatory documents governing the preclinical study of potential drug products in Ukraine. The purpose of toxicological, pharmacological and pharmacological safety studies. Types of toxicological studies. Classification of substances by toxicity. Clinical trials of drug products, their place in the life cycle of the drug products. Stages of regulatory regulation of experiments on humans. Regulatory documents governing the conduct of clinical trials in Ukraine. Phases of clinical trials of drug products, their purpose. Report on clinical trials of the drug product. Requirements for clinical bases and their staff for conducting clinical trials. Ethics Committee and Ethics Commissions, their functions in conducting clinical trials. Requirements for drug products that are intended for clinical trials. Principles of patient selection for clinical trials of drug products. Basic requirements of the Guidelines “Medicines. Good clinical practice. ST-N MOZU 42-7.0: 2008 ».	*Kn – 1–14, 19;* *AB– 1–14, 19;* *GC– 1–14,* *SC–12;* *AR* – 1–14, 19	
P-5 *2 h*	The requirements to the determination of generic products equivalence. The principles of referring generic drug products to the waiver	Regulatory documents governing the establishment of equivalence of generic drug products. Generic drug product, definition, characteristics. The biopharmaceutical classification system of active substances. Methods used to prove the interchangeability (equivalence) of drug products. The term "Bioequivalence", its definition.	*Kn– 1–14, 16;* *AB – 1–14, 16;* *GC – 1–14,* *SC–2;* *AR* – 1–14, 16	

	category. Bioequivalence. Biosimilars.	Pharmaceutically equivalent drug products. Pharmaceutically alternative drug products. Biopharmaceutical solubility of drug products. The degree of permeability of active substances. Soluble drug products and very soluble ones. Waver (biowaiver), the main indicator for its granting.		
P-6 *2 h*	The authorization of drug products in Europe. Normative documents regulating authorization of drug products. Structure of registration dossier.	The main legal documents governing registration (re-registration) in Ukraine. Basic requirements for registration materials. The State Expert Center, its functions. Types of applications for registration of medicines in Ukraine. Primary, preliminary and specialized examination of registration materials. The structure of the registration dossier in the format of a general technical document. Registration of generic drug products. Requirements for labeling of medicines. Registration certificate for a medicinal product, the validity period.	*Kn – 1–14, 19;* *AB – 1–14, 19;* *GC – 1–14,* *SC–12;* *AR* – 1–14, 19	
P-7 *2 год*	The requirements of Good Manufacturing Practices (GMP) for Quality Management and personnel, premises and equipment.	The quality of a drug product. Components of the quality assurance system. Quality assurance system designed for the manufacture of medicines, its guarantees. Good Manufacturing Practice, definition and scope. Basic requirements for GMP and quality control. General staff requirements. Personnel training. Management staff, its functions. Risk management for quality. Classification of premises according to the standard of GMP. General requirements for GMP for premises, production and storage areas, quality control areas and ancillary areas. Specific requirements for premises in the manufacture of antibiotics and hormones. Requirements for GMP for equipment, pipelines, drains, ventilation systems	*Kn – 1–14, 22–24;* *AB – 1–14, 22–24;* *GC – 1–14,* *SC 15, 16, 18;* *AR* – 1–14, 22–24	
P-8 *2 h*	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.	Stages of the technological process. General requirements of GMP for production. Types of the most dangerous polluting materials. Measures for the prevention of cross-contamination. Types of process validation. Requirements of GMP for raw materials, labeling of raw materials, packaging materials, packaging operations. Product control on the line during packaging. Storage of finished products in quarantine. Requirements for GMP for returned products. Types of production documents. General requirements of GMP for the preparation of process documentation. Types of specifications. The content of specifications for raw materials, packaging materials, finished products, intermediate and bulk products. Contents of production compounding, technological instructions, packing instructions, production protocols and packing of a series. List of required written methods. Issuance by the Authorized Persons of a permission for the release of finished products for sale. Distribution protocols, their content, and purpose	*Kn – 1–14, 22–24;* *AB – 1–14, 22–24;* *GC – 1–14,* *SC 15, 16, 18;* *AR* – 1–14, 22–24	
P-9 *2 h*	Topic 9. The requirements of GMP for contract manufacture and analysis, complaints and product recall. Changes in registration documents, classification of	The main reasons that determine the production and control on a contractual basis. Normative documents regulating the work under the contract. Types of activities that can be performed under the contract. The basic principle of contract work. Responsibilities of the Customer and the Contractor in the production and control of the contract. Requirements for laboratories that perform quality control of drug products on the contact base. Requirements of GMP for handling complaints. Reasons for recalling	*Kn – 1–14, 22–24;* *AB – 1–14, 22–24;* *GC – 1–14,* *SC 15, 16, 18;* AR – *1–14, 22–24*	

	changes, their expertise.	products from the retail network. Requirements of GMP for product recall. Required information to be specified in the distribution (sales) protocols of the series. Actions to be taken with recalled products. The purpose of self-inspection. Requirements for GMP for self-inspections		
P-10 *2 h*	The requirements of Good Manufacturing Practice for biological medicinal products.	Classification of biological drug products. Scope of Annex 2 of the Guidelines for GMP. The general principle of the production of biological drug products. Requirements of GMP for personnel, premises, equipment, animals, documentation, crop systems and cell banks, quality control in the production of biological drug products	*Kn – 1–14, 22–24;* *AB – 1–14, 22–24;* *GC – 1–14,* *SC 15, 16, 18;* AR – *1–14, 22–24*	
P-11 *2 h*	The requirements of Good Manufacturing Practice (GMP) for herbal medicinal products.	Good practice of cultivation and collection of raw materials of plant origin as a basis for ensuring the quality and effectiveness of herbal medicines: the main statements of the Guidelines. Application of the rules of GMP to herbal medicines	*Kn – 1–14, 22–24;* *AB – 1–14, 22–24;* *GC – 1–14,* *SC 15, 16, 18;* *AR* – 1–14, 22–24	
P-12 *2 год*	The requirements of Good Storage Practice (GSP).	Classification of storage conditions according to the State Pharmacopoeia of Ukraine. Basic requirements of GSP for the storage and transportation of pharmaceutical products. Requirements of GMP for storage areas. The requirements of the Quality Guideline 42-3.3:2004 “Medicines. Stability tests" to the stability study of drug products, formulations for labeling drugs, classification of climatic zones. Regulatory documents governing the storage and labeling of medicines in Ukraine.	*Kn – 1–14, 17, 19;* *AB – 1–14, 17, 19;* *GC – 1–14,* *SC – 7, 12;* *AR* – 1–14, 17, 19	
P-13 *2 h*	The requirements of Good Distribution Practice (GDP).	Regulatory documents governing the distribution of medicines in Ukraine. Requirements of GDP for the responsibilities of distributors for public service, quality system according to which distributors of medicinal products must operate; to personnel, documentation, premises and equipment, deliveries to customers, transportation, storage, and returning of medicines. Requirements of the License Conditions for carrying out activities on wholesale trade in medicinal products	*Kn – 1–14, 17, 19;* *AB – 1–14, 17, 19;* *GC – 1–14,* *SC – 7, 12;* *AR* – 1–14, 17, 19	
P-14 *2 h*	The regulations and principles of Good Pharmacy Practice (GPP).	The concept of GPP. The main roles and functions of pharmacists in accordance with the Guidelines for GPP. COVID-19 as a socio-medical problem. Code of ethics of pharmaceutical workers of Ukraine, its structure. Requirements of current License Terms for the retail sale of medicines	*Kn – 1–21;* *AB – 1–21;* *GC – 1–14,* *SC – 1,2, 7, 8, 12-14;* *AR* – 1–21	
P-15 *2 h*	The requirements of GPP for the compounding of drug products in pharmacies.	Preparation of extemporaneous drugs in accordance with the requirements of the Guidelines for proper drug prepparation practices in healthcare facilities.	*Kn – 1–21;* *AB – 1–21;* *GC– 1–14,* *SC – 1,2, 7, 8, 12-14;* *AR* – 1–21	
Ind-1 6 h	Acquaintance with the main terms of the Guides: "Good manufacturing practice","Pharmaceutical development","Excipient"	Mastering the basic terms and sections of the Guidelines	Kn– 1–14, 19; AB–1–14, 19; GC–1–14, SP –12; AR– 1–14, 19	
Ind-2 6 h	Requirements for research on the pharmaceutical development of sterile drugs	Study of the composition and technology of parenteral drugs of small and large volume	Kn– 1–14, 25; AB– 1–14, 25; GC– 1–14, SC 21; AR– 1–14, 25	
Ind -3 *6 h*	Requirements for research on pharmaceutical	Study of the composition and technology of parenteral drug products and drug products for oral	*Kn– 1–14, 25;* *AB – 1–14, 25;*	

	development of drug products for oral administration	administration (syrups, liquids)	*GC– 1–14, SC 21; AR* – 1–14, 25	
Ind-4 6 h	Acquaintance with the structure of the registration dossier and chemical, pharmaceutical and biological documentation	Study of the structure of the registration dossier. Relationship between the registration dossier structure and pharmaceutical development	*Kn– 1–14, 26; AB – 1–14, 26; GC – 1–14, SC 22; AR – 1–14, 26*	
Ind-5 6 h	Acquaintance with the nomenclature of excipients allowed for the manufacture of drug products and their preparation in pharmacies	Requirements for excipients. General requirements for the choice of excipients. Classification of excipients by functional purpose	*Kn – 1–14, 25; AB– 1–14, 25; GC – 1–14, SC 21;* AR *– 1–14, 25*	
Ind -6 6 h	Requirements of the rules of GMP for the manufacture of sterile medicines	Development of the main provisions of Annex 1 of the Guidelines for Good Manufacturing Practice. Principles of classification of clean rooms	Kn – 1–14, 22–24; AB – 1–14, 22–24; GC – 1–14, SC 15, 16, 18; AR – 1–14, 22–24	
Ind-7 6 h	Requirements of the rules of GMP for the manufacture of radioactive drugs, medical gases	Features of the technological process of radioactive drugs, medical gases	*Kn–1–14, 22–24; AB–1–14, 22–24; GC – 1–14, SC 15, 16, 18;* AR *– 1–14, 22–24*	
Ind-8 6 h	Requirements of current licensing requirements for wholesale and retail trade in medicines, preparation of medicines in pharmacies	Development of the provisions of the license conditions for wholesale and retail trade	*Kn – 1–14, 19; AB – 1–14, 19; GC – 1–14, SC- 12;* AR *– 1–14, 19*	
Ind-9 2 год	Requirements for pharmacy manufacturing in Ukraine and the European Union	Study of the main statements of legal provisions for the organization of pharmacy preparation in Ukraine and the EU	*Kn – 1–14, 19, 21; AB – 1–14, 19, 21; GC – 1–14, SC 12, 14;* AR *– 1–14, 19, 21*	

8. Verification of learning outcomes

Current control

The current control is conducted at each practical lesson in accordance with specific objectives. The form of assessment of the current educational activity is standardized and includes control of theoretical training, which is carried out by means of interrogation, check of protocols on the performance of individual practical tasks and situational tasks, and also testing in the written form or on the MISA platform during distance learning. The results of the current control are an indicator of the level of students' mastery of the curriculum and the performance of independent work. For each topic the student must receive a grade on a 4-point (traditional) scale, taking into account the approved criteria

Code of the result of training	Code of a type of employment	Method of verifying learning outcomes	Criteria of crediting
Kn – 1–26; AB –1–26; GC – 1–14; SC 1,2, 7, 8, 12, 13, 14, 15, 1, 18, 21, 22 AR –1–26	L – 1–4 P – 1–15 Ind – 1–15	Evaluation of test control Protocol evaluation	2 - <50% 3 - 50-60% 4 - 70-80% 5 - 90–100%. 2 The student does not reproduce practical work, does not have a clear idea of the object of study and the necessary skills to perform practical

			work 3 - The student reproduces part of the practical work, has a vague idea of the object of study, does not have the necessary skills to perform practical work 4 - The student performs the basic provisions and tasks of practical work, shows inappropriateness during the tasks, works with the help of the teacher with the necessary materials for practical work 5 - The student independently correctly performs the tasks of practical work, independently uses sources of information and necessary materials
		Evaluation of the oral answer	2 - The student does not reproduce the study material, has a vague idea of the object of study 3 - The student has some difficulties with reproducing the basic educational material, with errors and inaccuracies gives a definition of the basic concepts and definitions of the topic 4 - The student shows knowledge and understanding of the main provisions of the study material 5 - The student has a systematic, solid knowledge within the requirements of the curriculum, consciously uses them in standard and non-standard situations. Is able to independently analyze, evaluate, summarize the mastered material

Final control		
General grading system	Participation in the work during the semester 100% on a 200-point scale	
Scales of assessment	traditional 4-point scale, multi-point (200-point) scale, ECTS rating scale	
Conditions of admission to final control	The student attended all the practical (laboratory, seminar) classes and received at least 120 points for current performance	
Type of final control	Methodology of final control	Crediting criteria
Credit	All the topics should be credited in the current control. Grades from the 4-point scale are converted into points for a multi-point (200-point) scale in accordance with the Regulation "Criteria, rules and	The maximum number of points is 200. The minimum number of points is 120

	procedures for evaluating the results of student learning activities"	

The calculation of the number of points is based on the grades obtained by the student on a 4-point (national) scale during the study of the discipline, by calculating the arithmetic mean (CA), rounded to two decimal places. The resulting value is converted into points on a multi-point scale as follows:

$$x = \frac{\text{CA} \times 200}{5}$$

9. Policy of Good Practices in Pharmaceutics

During the study of the discipline, the policy of academic integrity is ensured accordingly to the Law of Ukraine "On Education". Article 42 "Academic Integrity". URL: http://zakon0.rada.gov.ua/laws/show/2145-19/page3. Students are explained the value of acquiring new knowledge, the need to independently perform all types of work and tasks provided by the work program of the discipline.

Adherence to academic integrity by students provides:

• independent performance of educational tasks, tasks of current and final control of learning outcomes;

• links to sources of information in the case of the use of other people's ideas, developments, statements, information;

• personal presence at all lectures and practical classes, with exception of cases caused by good reasons;

• providing reliable information about the results of their own educational (scientific, creative) activities, used research methods and sources of information.

Adherence of academic integrity by pedagogical workers provides:

• provision of quality educational services;

• objective assessment of learning outcomes.

• control over the adherence of academic integrity by students;

• systematic and continuous professional development through self-development and self-improvement;

• compliance with the rules of internal regulations, labor discipline, corporate ethics;

• informing students about typical violations of academic integrity and types of responsibility.

Detection of signs of academic dishonesty in the student's work (lack of references to sources used, fabrication of sources, writing off, interference in the work of other students) is the basis for its non-crediting by the teacher, regardless of plagiarism or deception.

For violation of academic integrity, pedagogical, scientific, and pedagogical workers and students can be brought to academic responsibility.

10. Literature

Required

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.
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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

11. Equipment, material, technical, and software support of the practical training

1. Working curriculum for the discipline.
2. Multimedia support of lectures.
3. Abstracts of lectures on the discipline.
4. Methodical recommendations and developments for the teacher.
5. MISA training platform.
6. Methodical instructions for practical classes of students.
7. Test and control tasks for practical classes.
8. Methodical recommendations for laboratory classes in the discipline "Good Practices in Pharmaceutics"

for 5th year students of the Faculty of Pharmacy, specialty "Pharmacy and Industrial Pharmacy ". 9. Normative-legal and normative-technical documents related to the discipline.
12. Additional information
Responsible person for the educational process at the Department – Yakymiv O.V., PhD, assoc.prof., e-mail: olga_yakymiv@ukr.net Responsible person for the subject – Hudz N.I., DSci, assoc.prof. e-mail: natali_gudz@ukr.net The department has a student research group, the direction of which is the development of formulations, technology and research of medicines and cosmetics. Students should wear medical gowns and hats during lectures and workshops. Classes are held in the premises of the department at: Lviv, street Pekarska, 75, building of training and production pharmacy, 2nd floor

Compilers of the syllabus:
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