ЗАТВЕРДЖЕНО
на засіданні кафедри,
протокол №_1_
від “31” _серпня_ 2021 р.

CALENDAR-THEMATIC PLAN

lectures on the subject "Standardization of drugs"
for 5th year students of the Faculty of Pharmacy
for the 9th semester of the 2021/2022 academic year

№	Date	Groups	Topic
1	09.09 01.09	1-5 6-7	Standardization of medicines. Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Compilation of mandatory principles, norms and rules, called "GMP" - "Good manufacturing practice". Quality certification system Medicines for International Trade developed by the World Health Organization (WHO) European Community (EU) Commission Directives of 1991. EU GMP and GMP WHO principles and rules and GMP RIS and GMP WHO rules EU Commission Directives 91/356 / EEC and 91/412 / EEC Functions performing GMP rules, Ukrainian quality assurance system for medicines, Law of Ukraine "On Medicinal Products" Competent management bodies in the field of creation, production, quality control and sale of medicines in Ukraine.
2	23.09 08.09	1-5 6	Strategy of Ukraine in the system of quality assurance of medicines. Guidelines "Manufacture of medicines. Appropriate rules and quality control" are developed in accordance with the legislation of Ukraine, the State Standardization System of Ukraine, the rules of GMP WHO and the EU, their characteristics, objectives, scope and significance. State Pharmacopoeia of Ukraine - concept, content, construction. The main principles on which the State Pharmacopoeia of Ukraine is based. Terms. Format of general and separate articles of the State Pharmacopoeia of Ukraine. Monographs of the State Pharmacopoeia of Ukraine on medicinal substances.
3	07.10 15.09	1-5 6	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Requirements for quality control: principles, general requirements. Good laboratory practice in quality control. Requirements for premises, equipment, personnel, documentation, sampling. Requirements for testing, control of raw materials, intermediates and materials, finished products. Control of medicines in Ukraine in modern conditions. Current state and prospects of development of biological methods of drug control.

4	21.10 22.09	1-5 6	Validation of analytical methods and tests. Standard samples. Basic provisions, procedure for development, certification, approval, registration and application. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Regulatory and technical documentation governing the quality of medicines. Temporary Pharmacopoeial Article (TFS), Pharmacopoeial Article (FS), their requirements for the quality of substances, injectable drugs, eye drops, tablet drugs, capsules, suppositories, ointments, aerosols, granules, oily solutions, tinctures and liquid extracts and sorbents. Requirements for documentation, principles, general requirements, required documentation. Specifications, specifications for raw materials and semi-finished products, for packaging materials. Regulatory documentation for intermediate products, semi-finished products and "angro" products. Specifications for finished products. Technological regulations, their categories. Contents of technological regulations. Production and technological instructions. Production requirements: principles, general requirements. Prevention of cross-contamination during production. Validation. Requirements for raw materials, for technological processes of manufacturing intermediate products, for packaging materials, for packaging and labeling processes. Requirements for finished products. Product complaints and recalls: principles, cases in which mandatory product recalls are required, procedure for recalling defective or potentially defective products.
Total		**8 hours**	