

ЗАТВЕРДЖЕНО
на засіданні кафедри,
протокол № 1
від "31" серпня 2021 р.

**Thematic plan of independent work
in the subject "Standardization of drugs"
for 5th year students of the Faculty of Pharmacy
for the 9th semester of the 2021/2022 academic year**

№	Topic	Hours
1.	Law of Ukraine "On Medicinal Products"	4
2.	Production of medicines. State quality control of medicines. Implementation of drugs	4
3.	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification".	4
4.	WHO strategy in the system of ensuring (guaranteeing) the quality of medicines. Principles and rules of GMP EU and GMP WHO and rules of GMP RIS and GMP WHO.	4
5.	Strategy of Ukraine in the system of quality assurance of medicines.	4
6.	State Pharmacopoeia of Ukraine. Terms.	4
7.	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control.	4
8.	Requirements for quality control: principles, general requirements.	4
9.	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions.	4
10.	Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine.	4
11.	Regulatory and technical documentation governing the quality of medicines. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	4
12.	Documentation requirements. Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Anglo products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	4
13.	Production requirements: principles, general requirements. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	2
14.	Validation. Requirements for finished products. Research of technological indicators and analysis of multicomponent liquid dosage forms manufactured in pharmacies according to doctors' prescriptions	2
Total		52