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

CALENDAR-THEMATIC PLAN

laboratory classes on the subject "Standardization of drugs"

for 5th year students of the Faculty of Pharmacy for the 9th semester 2021-2022 academic year

№	Topic	Hours	Group / Date			
			1-2	3-4	5	6 7
1.	Law of Ukraine "On Medicinal Products"	2	03.09	01.09	06.09	01.09 07.09
2.	Production of medicines. State quality control of medicines. Implementation of drugs	2	10.09	08.09	13.09	08.09 14.09
3.	Decree of the Cabinet of Ministers of Ukraine "On standardization and certification". Study of pharmaco-technological indicators, purity, identity and quantitative content of the medicinal substance "Angro" "Calcii gluconas pro injectionibus" and its compliance with the Pharmacopoeial article of SPU 1 ed.	2	17.09	15.09	20.09	15.09 21.09
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. Study of pharmaco-technological indicators, purity, identity and quantitative content of the drug substance "Angro" "Acidum ascorbinicum" and "Thiamini hydrobromidum aut hydrochloridum" and its compliance with the Pharmacopoeial article of the SPU 1 ed.	2	24.09	22.09	27.09	22.09 28.09
5.	Strategy of Ukraine in the system of quality assurance of medicines. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Analgini 0.5" and its compliance with the Pharmacopoeial article developed by the manufacturer	2	01.10	29.09	04.10	29.09 05.10
6.	State Pharmacopoeia of Ukraine. Terms. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Streptocidi 0.3" and its compliance with the Pharmacopoeial article developed by the manufacturer	2	08.10	06.10	11.10	06.10 12.10
7.	Requirements for quality management, principles of quality assurance, good manufacturing practice, quality control. Study of pharmaco-technological parameters, purity, identity and quantitative content of the medicinal product "Tabulettae Furacilini 0.02 ad usum externum" and its compliance with analytical regulatory documentation (AND)	2	15.10	13.10	18.10	13.10 19.10
8.	Requirements for quality control: principles, general requirements. Study of pharmaco-technological parameters, purity, identity and quantitative content of the drug "Sol. Calcii chloridi 10% pro injectionibus ”and its compliance with the Pharmacopoeial article developed by the manufacturer	2	22.10	20.10	25.10	20.10 26.10
9.	Requirements for premises, equipment, personnel, documentation, sampling. Control of medicines in Ukraine in modern conditions. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Novocaini 0.5% per injection bus ”and“ Sol. Acidi nicotinici 1% pro injectionibus "and compliance with its analytical regulatory documentation (AND)	2	29.10	27.10	01.11	27.10 02.11

10.	Validation of analytical methods and tests. System of Pharmacopoeial standard samples of the State Pharmacopoeia of Ukraine. Study of pharmaco-technological parameters, purity, identity and quantitative content of drugs "Sol. Euphylylini 2.4% per injection bus ”and“ Sol. Papaverini hydrochloridi 2% pro injectionibus ”and its temporary Pharmacopoeial article developed by the manufacturer	2	05.11	03.11	08.11	03.11 09.11
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	2	12.11	10.11	15.11	10.11 16.11
12.	Documentation requirements. Principles, general requirements. Regulatory documentation for intermediate products, semi-finished products and Angro products. Research of technological indicators and analysis of multicomponent powder dosage forms manufactured in pharmacies according to doctors' prescriptions	2	19.11	17.11	22.11	17.11 23.11
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	26.11	24.11	29.11	24.11 30.11
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	03.12	01.12	06.12	01.12 07.12
15.	Final control.	2	10.12	08.12	13.12	08.12 14.12
	Total	**30 hours**				