AMENDMENTS AND CHANGES TO THE CURRICULUM IN THE EDUCAIONAL DISCIPLINE

«Standardization of Drugs»
for the specialty 1-79 01 08 Pharmacy

2022/2023 academic year

Amendments and changes	Basis/Reason
1. Changes have been introduced into the thematic plan and educational discipline curricular chart (Appendix № 1 and 2 respectively)	Educational Plan for 2022/2023 academic year
2. The list of literature recommended for 2022-2023 academic year has been updated (Appendix №3).	Department meeting of 27.06.2022, protocol # 13.

The curriculum is revised and approved at the department meeting
Pharmaceutical Chemistry (protocol # 13 of 27.06.2022)

Head of the Pharmaceutical
Chemistry department
Ph.D., associate professor _____ R.I.Lukashou

APPROVED
Dean of the Medical Faculty
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Ph.D., associate professor _____ O.S.Ishutin

Annex *No. 1*

THEMATIC PLAN

Section (topic) name	Number of hours of auditory lessons	
	lections	laboratory
1. Standardization as a basis for the formation of quality assurance and control systems		3
2. Quality assurance and quality control of medicinal products in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice	2	3
3. Quality assurance and quality control of medicinal products in the wholesale distribution in accordance with the requirements of Good Distribution Practice		3
4. Quality assurance and quality control of medicinal products in retail sales in accordance with the requirements of Good Pharmacy Practice	2	3
5. The system of state institutions providing quality control of medicinal products in the Republic of Belarus		3
6. Quality control of medicinal products in accredited testing laboratories	2	3
7. Quality control of medicinal products of commercial production		3
8. Intra-pharmacy quality control of medicinal products		3
9. Pharmaceutical inspections	2	3
10. Statistical processing of chemical experiment results		3
11. Development and validation of analytical procedures	2	6
12. Methodology for the development of original and generic drug products	2	3
13. Models for assessing the safety and efficacy of medicinal products at the stage of non-clinical studies		3
14. Modern approaches to conducting clinical trials and evaluating the equivalence of drug products	2	3
15. Development of pharmacopoeial monographs and normative documents on quality	2	3
16. Procedure for registration of medicinal products in the Republic of Belarus		3
17. Formation of a registration dossier for a medicinal product in the format of a common technical document (CTD)	2	6
Total hours	**18**	**57**

Annex *No. 2*

EDUCATIONAL AND METHODOLOGICAL CARD OF THE EDUCATIONAL DISCIPLINE «STANDARDIZATION OF DRUGS»

Section (topic) number	Section (topic) name	Number of hours of auditory lessons			Student's independent work	Forms of knowledge control
		lectures	controlled independent work (CIW)	laboratory		
1	Standardization as a basis for the formation of quality assurance and control systems			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
2	Quality assurance and quality control of medicinal products in pharmaceutical production in accordance with the requirements of Good Manufacturing Practice	1,33	0,67	3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
3	Quality assurance and quality control of medicinal products in the wholesale distribution in accordance with the requirements of Good Distribution Practice			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
4	Quality assurance and quality control of medicinal products in retail sales in accordance with the requirements of Good Pharmacy Practice	1,33	0,67	3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
5	The system of state institutions providing quality control of medicinal products in the Republic of Belarus			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
6	Quality control of medicinal products in accredited testing laboratories	1,33	0,67	3	6	Interviews, electronic tests, reports on laboratory work with their oral defense
7	Quality control of medicinal products of commercial production	1,33	0,67	3	6	Interviews, electronic tests, reports on laboratory work with their oral defense

8	Intra-pharmacy quality control of medicinal products			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense, situational tasks
9	Pharmaceutical inspections			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense, situational tasks
10	Statistical processing of chemical experiment results			3	6	Interviews, electronic tests, reports on laboratory work with their oral defense, situational tasks
11	Development and validation of analytical procedures	1,33	0,67	6	6	Interviews, electronic tests, reports on laboratory work with their oral defense, situational tasks
12	Methodology for the development of original and generic drug products	1,33	0,67	3	5	Interviews, electronic tests, reports on laboratory work with their oral defense
13	Models for assessing the safety and efficacy of medicinal products at the stage of non-clinical studies			3	5	Interviews, electronic tests, reports on laboratory work with their oral defense
14	Modern approaches to conducting clinical trials and evaluating the equivalence of drug products	1,33	0,67	3	5	Interviews, electronic tests, reports on laboratory work with their oral defense
15	Development of pharmacopoeial monographs and normative documents on quality	1,33	0,67	3	5	Interviews, electronic tests, reports on laboratory work with their oral defense
16	Procedure for registration of medicinal products in the Republic of Belarus			3	5	Interviews, electronic tests, reports on laboratory work with their oral defense
17	Formation of a registration dossier for a medicinal product in the format of a common technical document (CTD)	1,33	0,67	6	5	Interviews, electronic tests, reports on laboratory work with their oral defense, situational tasks