Appendix to the working program

Federal State Budgetary Educational Institution of Higher Education
"Privolzhsky Research Medical University"
Ministry of Health of the Russian Federation

BANK OF ASSESSMENT TOOLS FOR PRACTICE

PRACTICE ON QUALITY CONTROL OF DRUGS

Training program (specialty): 33.05.01 PHARMACY

Department: Pharmaceutical Chemistry and Pharmacognosy

Mode of study: full-time

Nizhniy Novgorod
2022

1. Bank of assessment tools for the current monitoring of academic performance, mid-term assessment of students in the practice

This Bank of Assessment Tools (BAT) for the discipline " PRACTICE ON QUALITY CONTROL OF DRUGS " is an integral appendix to the working program of the discipline " PRACTICE ON QUALITY CONTROL OF DRUGS ". All the details of the approval submitted in the WPD for this discipline apply to this BAT.

2. List of assessment tools

The following assessment tools are used to determine the quality of mastering the academic material by students in the practice:

No	Assessment tool	Brief description of the assessment tool	Presentation of the assessment tool in the BAT
1	Test	A system of standardized tasks that allows you to automate the procedure of measuring the level of knowledge and skills of a student	Bank of test tasks
2	Interview	A tool of control organized as a special conversation between the teacher and the student on topics related to the discipline being studied, and designed to clarify the amount of knowledge of the student on a specific section, topic, problem, etc.	Questions on topics/sections of the discipline

3. A list of competencies indicating the stages of their formation in the process of mastering the educational program and the types of evaluation tools

Code and formulation of competence*	Stage of competence formation	Controlled sections of the discipline	Assessment tools
UC-1. ability to carry out critical analysis of problem situations based on a systematic approach, develop an action strategy	Entry, Current, Mid-term	Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	Tests, interview
GPC-1 Ability to use basic biological, physico-chemical, chemical, mathematical methods for the development, research and examination of medicines, manufacturing of medicines	Entry, Current, Mid-term	Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	Tests, interview
GPC 3 ability to carry out professional activities taking into account specific economic, environmental, social factors within the framework of the regulatory framework of the sphere of circulation of medicines	Entry, Current, Mid-term	Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	Tests, interview

GPC -6 ability to understand the principles of modern information technologies and use them to solve professional tasks		Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	
PC-4. ability to participate in monitoring the quality, effectiveness and safety of medicinal products and medicinal plant raw	Entry, Current, Mid-term	Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	Tests, interview
PC-7 implementation of operations related to the technological process in the production of medicines, and their control		Section 1. Theoretical training Section 2. Preparatory stage Section 3. Production stage Section 4. Final stage	

4. The content of the assessment tools of entry, current control

Entry /current control is carried out by the discipline teacher when conducting classes in the form of: tests.

4.1. Tests for assessing the competencies *of the UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC-7* are presented on the PIMU Educational Portal:

https://sdo.pimunn.net/course/view.php?id=1763

5. The content of the assessment tools of mid-term assessment

Mid-term assessment is carried out in the form of a differentiated credit

5.1 List of control tasks and other materials required to assess knowledge, skills and work experience

5.1.1. Questions for the practice assessment *PRACTICE ON QUALITY CONTROL OF DRUGS*

1. Principles of organization of the state system of quality control, effectiveness and safety of medicines in the Russian Federation.
2. Structure and functions of the Department of State Quality Control of Medicines and Medical Equipment of the Ministry of Health of the Russian Federation.
3. Structure and functions of the Scientific Center for Expertise and State Control of Medicines of the Ministry of Health of the Russian Federation.
4. Principles of organization of quality control of industrial medicinal products in the Russian Federation. State control (preliminary, subsequent selective, inspection, arbitration). Types of in-house control (entrance, operational, acceptance). GMP industry standard (OST 42-510-98).
5. The system of certification of medicines in the Russian Federation. Certification Center of the Ministry of Health of the Russian Federation, territorial certification bodies, control (testing) laboratories.
6. Standardization of medicines in the Russian Federation. Types of state quality standards for medicinal products: general pharmacopoeial article(OFS), pharmacopoeial article (FS), enterprise pharmacopoeial article (FSP). State Pharmacopoeia of the Russian Federation.
7. The problem of falsification of medicines and ways to solve it. Sources and classification of low-quality and counterfeit products
8. Structure, features and scope of regulatory documentation (FS, OFS, FSP, ND of the manufacturer)
9. The main quality criteria of a pharmaceutical substance. General pharmacopoeial methods of analysis.
10. Quality control of medicines manufactured in pharmacies. Main tasks and functions of territorial control and analytical laboratories.
11. Quality control of medicines manufactured in pharmacies. Analytical service of

pharmacies (control and analytical office, control and analytical desk). The main responsibilities of a pharmacist-analyst.

12. Quality control of medicines manufactured in pharmacies. Intra-apical control (organoleptic, written, vacation control, questionnaire, physical, chemical rapid analysis).

13. The concept of technological and specific impurities, the principles of normalization of their content.

14. Pharmaceutical analysis. Tasks and directions of pharmaceutical analysis (pharmacopoeial analysis, intra-pharmacy control, biopharmaceutical research).

15. Pharmaceutical analysis. Basic physical methods for establishing the authenticity of medicinal substances (determination of the melting temperature range, distillation temperature limit, density, viscosity, solubility).

16. Pharmaceutical analysis. Basic chemical methods for establishing the authenticity of inorganic medicinal substances (cation and anion deposition reactions, oxidation-reduction reactions, microcrystalloscopy).

17. Pharmaceutical analysis. Basic chemical methods for establishing the authenticity of organic medicinal substances (functional analysis).

18. Pharmaceutical analysis. Methods for testing medicinal products for impurities of inorganic ions.

19. Pharmaceutical analysis. Methods for determining arsenic admixture in medicinal products (Gutzeit and Bugo-Thiele methods).

20. Pharmaceutical analysis. Basic methods for determining the acidity, alkalinity and pH of the medium.

21. Pharmaceutical analysis. Physico-chemical methods of quantitative determination of medicinal substances. Optical methods (refractometry and polarimetry).

22. Pharmaceutical analysis. Gravimetric (weight) method for quantitative determination of medicinal substances. Chemical basis of the method.

23. Pharmaceutical analysis. Direct and reverse argentometry (Faience and Folgard methods). Chemical basis of the method. Calculation formulas.

24. Pharmaceutical analysis. Acid-base titration in an aqueous medium (neutralization method). Range of application of the method, main indicators. Chemical basis of the method. Calculation formulas.

25. Pharmaceutical analysis. Titration in a medium of non-aqueous solvents. Chemical basis of the method. Calculation formulas.

26. Pharmaceutical analysis. Redox titration (permanganatometry, iodometry). Chemical basis of the method. Calculation formulas.

27. Pharmaceutical analysis. Redox titration (bromatometry, cerimetry). Chemical basis of the method. Calculation formulas.

28. Pharmaceutical analysis. Complexometry. Chemical basis of the method. Metal indicators. Calculation formulas.

29. Pharmaceutical analysis. Nitritometry. Chemical basis of the method. Calculation formulas.

30. Pharmaceutical analysis. Method for determining nitrogen in organic compounds (Kjeldahl method).

31. Application of chromatographic methods in pharmaceutical analysis. Types of chromatography (adsorption, ion exchange, distribution). Chromatography on paper and in a thin layer of sorbent.

32. Optical methods of analysis. Ultraviolet spectrophotometry. Scope of the method.

33. Biological methods of drug control. Determination of specific activity, toxicity, and pyrogenicity.

34. Microbiological control of medicinal products. Microbiological purity and sterility testing.

35. Classification of dosage forms as objects of pharmaceutical analysis. Features of testing solid dosage forms (tablets) for disintegration, abrasion, solubility, determination of the

average mass.

36. Stability and shelf life of medicinal products. The main physical and chemical processes that occur during the storage of medicines.

37. Stability and shelf life of medicinal products. Methods for accelerated determination of drug stability.

38. Main tasks and features of biopharmaceutical analysis. Investigation of biotransformation of medicinal substances.

Question	Competence code (according to the WPD)
1	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
2	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
3	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
4	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
5	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
6	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
7	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
8	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
9	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
10	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
11	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
12	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
13	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
14	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
15	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
16	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
17	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
18	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
19	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
20	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
21	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
22	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
23	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
24	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
25	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
26	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
27	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
28	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
29	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
30	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
31	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
32	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
33	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
34	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
35	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
36	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
37	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*
38	*UC-1, GPC-1, GPC -3, GPC -6, PC-4, PC - 7*

6. Criteria for evaluating learning outcomes

Learning outcomes	**Assessment of competence developed**			
	unsatisfactory	**satisfactory**	**good**	**excellent**

Learning outcomes	Assessment of competence developed			
	unsatisfactory	**satisfactory**	**good**	**excellent**
Completeness of knowledge	The level of knowledge is below the minimum requirements. There were bad mistakes	The minimum acceptable level of knowledge. A lot of light mistakes were made	The level of knowledge in the volume corresponding to the training program. A few light mistakes were made	The level of knowledge in the volume corresponding to the training program, without errors
Availability of skills	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	Basic skills are demonstrated. Typical problems with light mistakes have been solved. All tasks have been completed, but not in full.	All basic skills are demonstrated. All the main tasks have been solved with light mistakes. All tasks have been completed, in full, but some of them with shortcomings	All the basic skills were demonstrated, all the main tasks were solved with some minor shortcomings, all the tasks were completed in full
Availability of skills (possession of experience)	Basic skills are not demonstrated when solving standard tasks. There were bad mistakes	There is a minimal set of skills for solving standard tasks with some shortcomings	Basic skills in solving standard tasks with some shortcomings are demonstrated	Skills in solving non-standard tasks without mistakes and shortcomings are demonstrated
Characteristics of competence formation*	The competence is not fully formed. The available knowledge and skills are not enough to solve professional tasks. Repeated training is required	The formation of competence meets the minimum requirements. The available knowledge and abilities are generally sufficient to solve professional tasks, but additional practice is required for most practical tasks	The formation of competence generally meets the requirements, but there are shortcomings. The available knowledge, skills and motivation are generally sufficient to solve professional tasks, but additional practice is required for some professional tasks	The formation of competence fully meets the requirements. The available knowledge, skills and motivation are fully sufficient to solve complex professional tasks
The level of competence formation*	Low	Below average	Intermediate	High

For testing:

Mark "5" (Excellent) - points (100-90%)
Mark"4" (Good) - points (89-80%)
Mark "3" (Satisfactory) - points (79-70%)

Less than 70% – Unsatisfactory – Mark "2"

Developer(s):
O. A. Vorobyeva, Associate Professor of the Department of Pharmaceutical Chemistry and Pharmacognosy

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