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 DISCIPLINE
Pharmaceutical Manufacturing technology

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 practice " **Manufacturing technology**" is an integral appendix to the working program of the practice " **Manufacturing technology**". 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. Preparatory Section 2. Work in the pill and capsule shop Section 3. Work in the injection and infusion solutions shop Section 4. Work in the soft dosage forms shop Section 5. Work of the OCC, CL and BL. Section 6. Work of the research center	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. Preparatory Section 2. Work in the pill and capsule shop Section 3. Work in the injection and infusion solutions shop Section 4. Work in the soft dosage forms shop Section 5. Work of the OCC, CL and BL. Section 6. Work of the research center	Tests, interview
GPC-6 ability to understand the principles of modern information technologies and use them to solve problems of professional activity	Entry, Current, Mid-term	Section 1. Preparatory Section 2. Work in the pill and capsule shop Section 3. Work in the injection and infusion solutions shop Section 4. Work in the soft dosage forms shop Section 5. Work of the OCC, CL and BL.	Tests, interview

		Section 6. Work of the research center	
PC-7 implementation of operations related to the technological process in the production of medicines, and their control	Entry, Current, Mid-term	Section 1. Preparatory Section 2. Work in the pill and capsule shop Section 3. Work in the injection and infusion solutions shop Section 4. Work in the soft dosage forms shop Section 5. Work of the OCC, CL and BL. Section 6. Work of the research center	Tests, interview
PC-11. Able to take part in measures to ensure the quality of medicines in industrial production	Entry, Current, Mid-term	Section 1. Preparatory Section 2. Work in the pill and capsule shop Section 3. Work in the injection and infusion solutions shop Section 4. Work in the soft dosage forms shop Section 5. Work of the OCC, CL and BL. Section 6. Work of the research center	Tests, interview

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 the assessment of the competencies *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 an exam

5.1 The list of control tasks and other materials necessary for the assessment of knowledge, skills and work experience

5.1.1. Questions for the practice exam «Manufacturing Technology»

1. Organization of the production of finished medicines (GLS) at pharmaceutical enterprises, the shop principle of the organization of production. Technological process, its types and components (stage, operation). Basic terms and concepts of industrial production.
2. The principle of operation of grinding machines: for medium and fine grinding (root cutters, grass cutters, roller crushers, impact-centrifugal mills, excelsior, hammer mills); for fine grinding (ball and rod drum mills); for ultra-fine grinding (jet and vibration).
3. Methods of separation of crushed material. Characteristics of sieve separation, material and types of meshes. Standards and numbering of sieves. Design features and principle of operation of mechanized sieves (swinging, rotational-vibrating, vibrating). Triboelectric phenomena during sieving. Separation of particles depending on the rate of their deposition in an aqueous medium and separation by separation.
4. Mixing of powdered medicinal substances and crushed vegetable raw materials. The principle of operation of mixers with a rotating body, rotating blades, centrifugal mixers.
5. Tablets as a dosage form. Determination of physico-chemical and technological properties of powders used in the production of tablets.
6. Groups of excipients used in the manufacture of tablets, their nature, purpose; substances belonging to each group, their regulated quantity.
7. Theoretical foundations of tableting. Dosing accuracy, mechanical strength and disintegration of tablets. Factors affecting these characteristics of tablets.
8. Technology of tablets by granulation (wet and dry), direct pressing and molding of masses (trituration tablets).
9. The principle of operation of tablet machines and their comparative characteristics (crank, rotary). Press tool (matrix, punches) and its characteristics.

10. Methods of coating tablets with shells: coated, film, pressed. The purpose of various types of coatings.
11. Evaluation of the quality of tablets. The method of determination, the devices used.
12. Packaging of tablets. The principle of operation of automatic machines used for packaging tablets in contour cell packaging, in contour cell-free packaging, in glass vials.
13. Granules. Technological scheme of production, quality assessment. Dragees. Technological scheme of production, quality assessment.
14. Capsules as a dosage form. Characteristics, types of gelatin capsules, advantages of encapsulated preparations. Characteristics of excipients used for the manufacture of capsules. Requirements of GF XIII for capsules.
15. Capsule technology using various methods of immersion, pressing, drip. The equipment used for this purpose.
16. Methods of separation of liquid heterogeneous systems: settling, filtration, centrifugation. The principle of operation of the equipment used.
17. Suspensions and emulsions. Definition, stages of the technological process. Methods of preparation of suspensions and emulsions in industrial production, the principle of operation of the equipment used.
18. Definition of ointments as a dosage form, their classification. Classification and types of bases for ointments. ND requirements for ointments.
19. Technological stages of preparation of ointments. Equipment used at the stages of preparatory work, introduction of medicinal substances into the base, homogenization and packing of ointments.
20. Definition, classification of patches as a dosage form. The technology of a simple lead patch, rubber patches, liquid patches. The principle of operation of the equipment used. Technology of mustard plasters.
21. Medical pencils as a dosage form. Their characteristics, methods of obtaining, quality assessment. The technology of pencils obtained by pouring.
22. The technology of suppositories in industrial production, the principle of operation of the equipment used.
23. Describe the main technological factors affecting the extraction process technological properties of raw materials and process parameters that can be regulated (the degree and nature of grinding of raw materials, the nature of the extractant, temperature, concentration difference and hydrodynamic conditions, duration of extraction).
24. Extracts as a dosage form. Classification of extracts depending on the consistency and the extractant used. Technology of liquid extracts.
25. Methods for obtaining liquid extracts percolation, repercolation and its modification, countercurrent extraction in a battery of extractors, continuous countercurrent extraction with the movement of raw materials and extractant, accelerated fractional maceration by countercurrent type.
26. Dosage forms for injection. Characteristics, requirements for them. Requirements for premises, personnel, equipment. Classes of cleanliness of the premises.
27. Medical glass, its composition, production, main quality indicators. Brands of glass. The influence of glass on the quality of solutions and their stability.
28. Stages of ampoule manufacturing: obtaining the dart, its calibration, washing and drying the dart. Dart washing methods, their advantages and disadvantages. The device of the production line for washing and drying the dart.
29. Preparation of ampoules for filling. Opening of ampoules on prefixes to glass-forming machines and on semi-automatic machines of belt and rotary type. Annealing of ampoules.
30. Washing of internal and external surfaces of ampoules. Methods of washing ampoules, the principle of operation and design features of the equipment used. Drying and sterilization of ampoules. Evaluation of the quality of ampoules.
31. Solvents used for the preparation of injection solutions, the requirements for them. Obtaining water for injection, methods of preliminary purification of drinking water. The principle of operation of aquadistillators. Storage of water for injection in the factory. Assessment of water quality for injection

32. Demineralized water. Methods of production: ion exchange, methods of separation through a membrane. Non-aqueous solvents and co-solvents. Characteristics, requirements for them, their advantages and disadvantages.
33. Stages of technology of solutions for injection in the factory. Requirements for medicinal substances. Filtration of solutions for injection. Requirements for filters and filter materials, types of filtration. Deep and surface filtration.
34. Methods of sterilization of injection solutions thermal, filtration, radiation, chemical. The possibility of using these methods depending on the properties of medicinal substances. Determination of the tightness of ampoules and vials after sterilization.
35. Rectal dosage forms in industrial production.
36. Aerosols as a dosage form and their classification: inhalation, for external use, film-forming.
37. The device and the principle of operation of the aerosol can. Classification, characteristics, nomenclature of propellants. Technological stages of aerosol packaging production.

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*

6. Criteria for evaluating learning outcomes

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"

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Date "14" December 2022