FACULTY OF CHEMISTRY AND CHEMICAL TECHNOLOGY
CHAIR OF CHEMISTRY AND TECHNOLOGY OF ORGANIC MATTERS, NATURAL COMPOUNDS AND POLYMERS

FINAL EXAM PROGRAM

for the discipline "TPLF 3303 - Technology of production of dosage forms"
on the educational program "6B07201-Pharmaceutical Manufacturing Technology"

Almaty 2023 y.

The final exam program was compiled by the Senior Teacher of the Department of Chemistry and Technology of Organic Substances, Natural Compounds and Polymers, PhD Shevchenko A.S.

Considered and recommended at a meeting of the Department of Chemistry and Technology of Organic Substances, Natural Compounds and Polymers, Protocol № and date of Department Meeting: № 12 from 07.02.2023 y.

Head department _____ Irmukhametova G.S.
(signature)

Introduction

Format: Online, oral exam
Platform: Microsoft Teams
Link: Link on online conference

The process of passing an oral exam by a student involves the automatic creation of an examination ticket, to which the student must answer orally by the examination committee. During the oral examination, video recording is mandatory.

Exam control

The teacher or the examination committee:

- makes a video recording of the exam;
- saves the video of the exam within 3 months from the day of the end of the session.

Duration

The preparation time is decided by the examiner or the examination committee. The response time is decided by the examiners or the examination committee. It is recommended 15-20 to answer all questions on the ticket.

1. The exam is held on schedule.
2. Students and the teacher must know in advance the date and time of the exam.
3. It is obligatory to place in the IS Univer the document "Final exam in the discipline".
4. The chairman of the examination committee and the students are connected by video link in advance before the start of the exam.
5. The chairman of the examination committee includes a VIDEO RECORDING of the exam.
6. Students at the beginning of the exam according to the schedule get access to the tickets generated by the Univer IS in their univer.kaznu.kz accounts.
7. A student does not have the right to open a ticket until an individual invitation by the commission for the examination. Only at the request of the commission, the student logs into the account in the is Univer, and opens his ticket under video recording.
8. The student, summoned by the members of the commission, confirms his identity, demonstrates his ticket in IS Univer, and after preparation for a period of time established by the teacher or the commission, answers the questions of the ticket.
9. During the student's response, other group members can go into standby mode (turn off the cameras but not leave the videoconferencing service).
10. After the commission accepts the student's answer, he can leave the video conference room.
11. The video recording is turned off only at the end of the exam, when the answers of all examinees have been accepted.
12. Within 48 hours, the points scored by students are put on the attestation sheet.

Topics for which assignments will be compiled

1. Pharmaceutical technology as a science. Modern theoretical concept of pharmaceutical technology. The structure of pharmaceutical technology as an academic discipline, its sections.
2. Medicines. Classification. Medicines: poisonous, potent and general list.
3. Excipients. Meaning, classification: depending on the origin, chemical structure, by purpose. The main groups of excipients.
4. Dosage form. Definition. Classification. Requirements for dosage forms.
5. Technology of dosage forms. Goals and objectives. State regulation, value and directions of regulation. Biopharmacy. Pharmaceutical factors. Organization of production in the conditions of industrial enterprises and pharmacies. Product quality assurance. GMP, VFS,

FS, FSP rules. Official and mainline recipes. Technological regulations, orders of the Ministry of Health of the Russian Federation, instructions for the manufacture and quality control of medicines.

6. Production of powders according to individual prescriptions in pharmacies. Basic rules for mixing ingredients. Powders with potent and toxic substances. Powders with coloring, difficult to grind substances, with extracts, semi-finished products, etc.

7. Production of powders for injections, powders for wounds and burns surfaces, powders with antimicrobial substances, for administration into cavities, as well as for newborns and children under 1 under aseptic conditions years, etc.

8. Evaluation of the quality of powders: uniformity, dosing accuracy, flowability, etc. Dosing, packing and packaging of powders. Conditions and terms of storage of powders. Features of the design and labeling of powders with poisonous and narcotic substances.

9. Technological schemes for obtaining ointments of various types. Preparing the basics. Methods of administering medicinal substances in the form of ointments.

10. Basics depending on their physicochemical properties, quantitative content and method of production of ointments.

11. Technology of pastes.

12. Liniment. Classifications depending on the type of medium and dispersed system. Technological schemes for the production of liniments.

13. Production of suppositories according to individual prescriptions: manual formation, pouring into molds, pressing.

14. Solvents used in the technology of liquid dosage forms. Classification. Requirements for them. Purified water. Characteristic. Normative documentation governing the production, use and quality. Modern methods of obtaining: Apparatus for obtaining purified water. Conditions of storage and use of water. Quality control.

15 Ethanol. Physicochemical characteristics. Alcoholimetry. Ethanol concentration: methods of its expression, methods and instruments for determination. Dilution and strengthening of aqueous-alcoholic solutions in pharmacies, their standardization. Regulatory documentation used in calculations for alcoholimetry: GF tables, tables of the State Committee for Standards. Determination of the content of anhydrous ethanol in solutions. Accounting for ethanol in pharmacies.

16. Technological schemes for obtaining solutions for internal and external use. General and particular rules in the technology of aqueous and non-aqueous solutions.

17. Calculation of a working recipe for the manufacture of a solution. Volume expansion factor. Solubility of medicinal substances. Indicators of solubility of substances in various solvents and designation of solubility in GF. Evaluation of the quality of solutions for external and internal use.

18. Preparation of aqueous solutions: solutions of oxidizing agents, moderately soluble, slightly soluble, practically insoluble substances (silver nitrate, potassium permanganate, mercury dichloride, sodium bicarbonate, osarsol, etc.). Features of the preparation of solutions with antibiotics.

19. Dilution of standard liquids: solutions of formaldehyde, hydrogen peroxide, potassium acetate, ammonia, basic aluminum acetate.

20. Features of the technology of solutions in non-aqueous solvents. Manufacturing solutions based on ethanol, glycerin, vegetable oils and vaseline, Dimexide, combined solvents.

21. Manufacturing of liquid medicinal products using a burette installation. Basic provisions "Instructions for the manufacture of liquid dosage forms in pharmacies". Burette installations and rules for their operation.

22. Concentrated solutions for a burette installation. Calculations related to strengthening and dilution of concentrated solutions. Terms and conditions of storage.

23. Making mixtures using concentrated solutions, dissolving medicinal substances prescribed in concentrations up to and more than 3%. Quality control of mixtures at the stages of manufacture and finished products.

24. True solutions of high-molecular compounds. Technological schemes for obtaining IUD solutions. The influence of the structure of the IUD on the dissolution process. Stabilization of IUD solutions.

25. Evaluation of the quality of IUD solutions: color, absence of mechanical impurities, deviations in the total volume or mass, etc. Packing of IUD solutions. Storage of IUD solutions, depending on the characteristics of their physicochemical properties. Salting out, coacervation, gelling and other processes causing changes in solutions during storage.

26 Solutions of protected colloids. Definition. Characterization of solutions of collargol, protargol, ichthyol. Technological scheme of obtaining. Features of dissolution and filtration of solutions of collargol and protargol. Assessment of the quality of solutions of protected colloids. Packaging. Marking.

27 Suspensions. Technological schemes for obtaining suspensions by various methods: dispersion, solvent replacement, salting out, chemical interaction.

28. Evaluation of the quality of suspensions: quantitative content of medicinal substances, particle size of the dispersed phase, absence of foreign mechanical impurities, delamination, resuspension, deviations in mass, microbiological purity.

29. Emulsions. Technological scheme for obtaining emulsions. Production of emulsions according to individual prescriptions.

30. Evaluation of the quality of emulsions: quantitative content of medicinal substances, particle size of the dispersed phase, absence of foreign mechanical impurities, stratification, resuspension, deviations in mass, microbiological purity. Dosing of emulsions.

31. Ophthalmic dosage forms. Characteristic. Classification. Basic requirements for ophthalmic dosage forms. Normative documents, orders, instructions, GF.

Recommended Sources for Exam Preparation

1. 1.Loyd V. Allen, A. S. Gavrilov. Pharmaceutical technology. Manufacturing of medicines: textbook. manual-M.: GEOTAR-Med / 2014 512p.

2. A. S. Gavrilov. Pharmaceutical technology. Manufacturing of medicines: textbook / - M.: GEOTAR-Media, 2010. – 618p.

3. Josep, B. V. Passet, V. Ya. Samarenko, O. B. Schennikov. Chemical technology of pharmaceutical substances: Textbook. SPt: LAN publishing House, 2016. 384 p.

4. Passet, B. V. Technology of chemical and pharmaceutical preparations and antibiotics / M: Medicine, 1977. 430 p

5. Dorofeev, V. I. Pharmaceutical industry of Russia in the conditions of transition / M.: Medicine 1995.

Internet resources:

1. Handbook
2. Pharmaceutical Dosage Forms
3. Pharmaceutics – Dosage Form and Design
4. Pharmaceutics: The Science of Dosage Form Design
5. Ansel’s Pharmaceutical Dosage Forms and Drug Delivery Systems