



**Катедра по технология на лекарствата
и биофармация**

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**SYLLABUS FOR THE SEMESTER EXAM
in PHARMACEUTICAL TECHNOLOGY PART II
for students in IV course for the academic year 2025/2026**

1. Physicochemical properties of powders. Properties of individual particles. Rheological properties of powders. Methods for flowability evaluation. Improving the flowability of powders. Excipients.
2. Granules. Definition. Characteristic. Types of granules. Properties and control of granules. Composition of the granules. Excipients.
3. Technology of granulation. Basic apparatus for granulation. Theoretical foundations of granulation.
4. Tablets. Definition and characteristics. Types of tablets. Advantages. Control tests for tablets – pharmacopoeial and non-pharmacopoeial.
5. Excipients used for tablet preparation - diluents, binders, disintegrants. Disintegration mechanism. Excipients improving rheological properties. Lubricants, coloring and flavoring agents.
6. Tablet compression methods. Advantages and disadvantages. Mechanism of tablet compression. Main compression steps.
7. Direct compression. Advantages and disadvantages. Main technological steps. Compression after granulation – dry and wet. Main technological steps.
8. Tablet presses. Principle of their operation.
9. Coated tablets. Film-coated tablets. Preparation technology. Excipients. Sugar-coated tablets. Production. Excipients.
10. Capsules. Characteristics. Classification. Control. Hard gelatin capsules. Excipients. Production technology. Soft gelatin capsules. Production technology.
11. Biopharmaceutical aspects of the solid dosage forms.
12. Dosage forms with modified drug release. Classification. Prerequisites for their production.
13. Diffusion controlled systems. Membrane (reservoir) systems.
14. Diffusion controlled systems. Monolithic (matrix) systems.
15. Bioerosion systems. Osmotically controlled systems. Chemical systems.
16. Microparticles.
17. Nanosized dosage forms.
18. Parenteral dosage forms – classification. Characteristics. Routes of parenteral administration. Requirements of the "Good Manufacturing Practice" in the production of sterile dosage forms. Aseptic conditions.

19. Sterilization. Physical, mechanical and chemical methods for sterilization. Preservatives. Solvents for parenteral formulations. Water for injection. Methods for preparation. Pharmacopoeial requirements.
20. Solutions for injection – basic and additional requirements. Pyrogenic substances. Bacterial endotoxins. Pharmacopoeial methods for detection of pyrogens and endotoxins.
21. Tonicity of solutions for injection – methods for determination. Isotonization – methods for calculating the isotonic concentration. Isohydricity and euhydricity. Stability of solutions for injection. Approaches for stabilization.
22. Technological scheme for preparation of solutions for injection – suspensions, emulsions and powders for injection solutions. Methods for control of mechanical impurities.
23. Solutions for infusion – characteristics and basic requirements. Classification. Infusion solutions for total parenteral nutrition. Tonicity and osmolarity of the solutions for infusion. Hemodialysis concentrates. Characteristics. Classification. Osmolarity.
24. Packaging for parenteral dosage forms – requirements for packaging materials. Potential interactions with the dosage form.
25. Control of parenteral dosage forms – pharmacopoeial and additional requirements.
26. Ophthalmic dosage forms. Anatomical and physiological characteristics of the eye. Tears and tear fluid. Corneal absorption – biopharmaceutical aspects. Approaches to increase bioavailability.
27. Ophthalmic dosage forms. Characteristics. Classification. Excipients for ophthalmic formulations. Technological scheme for preparation of eyedrops. Aseptic conditions. Filtration systems. Preparation of suspensions – particle size requirements.
28. Methods for sterilization of ophthalmic dosage forms. Preservatives – advantages and disadvantages of the most commonly used preservatives. Stability and stabilization of ophthalmic dosage forms.

Accepted by the Department Council with. Prot. № 10/28.10.2025.

Approved by: /S/

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