Посветени на хуманността
МЕДИЦИНСКИ УНИВЕРСИТЕТ – ПЛОВДИВ
4002 Пловдив, бул. Васил Априлов № 15А

Dedicated to humanity
MEDICAL UNIVERSITY – PLOVDIV
15A, Vasil Aprilov Blvd., 4002 Plovdiv, Bulgaria

www.mu-plovdiv.bg

Катедра по фармацевтични науки
4002 Пловдив, ул. Братя Бъкстон № 120
email: pharm.sciences@ff.mu-plovdiv.bg

Department of Pharmaceutical Sciences
120, Bratya Bakston St., 4002 Plovdiv, Bulgaria
email: pharm.sciences@ff.mu-plovdiv.bg

SYLLABUS

for the state exam

in "Pharmaceutical technology and biopharmacy"

1. Pharmaceutical powder formulations. Properties of powder particles. Incompatibility and instability. Technological and biopharmaceutical evaluation. Control.
2. Granules. Preparation methods. Theoretical foundations of granulation. Excipients. Characteristics and control.
3. Tablets. Methods for tablet compression. Mechanism of tablet compression. Excipients used for tablets and biopharmaceutical aspects for their selection.
4. Tablets. Classification of tablets. Tablet presses. Influence of pharmaceutical factors on the biopharmaceutical characteristics of tablets.
5. Coated tablets. Reasons for coating. Excipients. Technology. Control.
6. Capsules. Classification. Technology and biopharmaceutical evaluation. Control.
7. Technological and biopharmaceutical evaluation of solid dosage forms – tablets, coated tablets and capsules.
8. Liquid oral drug formulations – solutions. Methods for enhancing drug solubility. Biopharmaceutical characterization.
9. Liquid oral drug formulations – emulsions. Composition, classification, stability, excipients. Technological and biopharmaceutical evaluation.
10. Liquid oral drug formulations – suspensions. Technological approaches for their stabilization. Excipients. Taste correction. Biopharmaceutical characterization.
11. Semi-solid drug formulations for cutaneous application. Classification. Excipients (bases) for semi-solid drug formulations. Percutaneous absorption.
12. Semi-solid drug formulations for cutaneous application – preparation of different types dispersed systems. Technological and biopharmaceutical evaluation. Stabilization. Control.
13. Rectal drug formulations. Classification. Rectal absorption. Bases for suppositories. Preparation of suppositories – technological and biopharmaceutical aspects. Control.
14. Vaginal drug formulations. Vaginal pessaries. Technological and biopharmaceutical evaluation. Control.
15. Parenteral dosage forms. Classification. Routes of parenteral administration. Containers for parenteral drug formulations. Requirements for container materials. Possible interactions.
16. Methods for sterilization. Aseptic production – requirements.
17. Injections – solutions, emulsions, suspensions, powders. Requirements. Solvents. Technology. Control.

18. Solutions for IV infusion. Solutions for total parenteral nutrition. Tonicity and osmolarity. Technological requirements. Control.

19. Ophthalmic formulations. Characteristics. Corneal absorption – biopharmaceutical aspects. Approaches for improving bioavalability. Technological approaches to meet the requirements. Stabilization. Control.

20. Herbal drug preparations. Classification. Standardization of herbal drugs. Extraction methods. Characteristics of the methods. Theory of extraction.

21. Tinctures and extracts. Preparation methods. Standardization and control.

22. Modified-release drug formulations. Prerequisites for their development – therapeutic and biopharmaceutical. Technological approaches for extension the drug release.

23. Modified-release drug formulations. Diffusion-controlled systems. Monolithic (matrix) physical drug delivery systems.

24. Modified-release drug formulations. Diffusion-controlled systems. Reservoir (membrane) physical drug delivery systems.

25. Modified-release drug formulations. Bioerosive systems. Osmotically driven systems. Chemical systems.

26. Microcapsules and microspheres. Methods for preparation. Technological and biopharmaceutical characterization.

27. Liposomes. Technology. Biopharmaceutical characteristics.

28. Nanoparticles. Technological and biopharmaceutical characterization.

29. Stability. Factors influencing instability processes. Types of stability.

30. Stability, respectively instability, of drug substances and drug formulations. Shelf life of drug products. Methods for stability evaluation and shelf life prediction.

31. Biopharmaceutical control. Pharmacopoeial apparatuses for *in vitro* testing. Principle of operation and construction. Pharmaceutical availability.

32. Biopharmaceutical control. Pharmacopoeial and non-pharmacopoeial criteria for the evaluation of the dissolution result. Factor of similarity. Pharmaceutically, biologically, and therapeutically equivalent products.

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ASSOC. PROF. BISSERA PILICHEVA, PHD
Head of Department of Pharmaceutical Sciences