

MEDICAL UNIVESRITY - PLOVDIV
FACULTY OF PHARMACY
DEPARTMENT OF PHARMACEUTICAL SCIENCES

SYLLABUS

in

PHARMACEUTICAL TECHNOLOGY II

Accepted by Department counsel Prot. № 07/14.07.2021

Approved by the Faculty counsel of the Faculty of Pharmacy Prot. № 08/16.09.2021

**MEDICAL UNIVERSITY - PLOVDIV
FACULTY OF PHARMACY**

Course name:

Pharmaceutical technology II

Course type according to Unitary State Requirements:

Compulsory

Acquired degree:

MPharm

Education forms:

Lectures, practicals, self-training

Duration of study:

Two semesters

Chorarium:

60 hours lectures, 150 hours practicals

Teaching resources:

Multimedia presentations, discussions, individual tasks, preparation of papers

Assessment forms::

1. Current assessment during the semesters:

- entry test before each practical exercise to assess the readiness of the students to participate in the lesson;
- colloquium after each practical thematic module;
- assessment of individual tasks.

2. Semester exam:

- practical exam;
- theoretical exam (written and oral form).

Formation of the final exam mark:

An average mark is formed on the basis of the grades from the current assessments during the semesters, the practical exam and the theoretical exam.

State exam:

Yes (written and oral exam together with Pharmaceutical technology I and Biopharmacy).

Chief lecturer:

Professor from the department of Pharmaceutical sciences.

ANOTATION

Pharmaceutical technology is the science that studies the theoretical foundations and practical methods for the preparation of pharmaceutical formulations.

The drug substances, which are used in the pharmaceutical practice, are chemically defined compounds or products of plant or animal origin, obtained after extraction. Processing these drugs into formulations involves suitable technological operations that are determined according to their physical, chemical and pharmacological properties.

It is the right choice of technological operations and the proper route of administration of the formulation that allow the main purpose of the pharmaceutical technology to be accomplished – development of pharmaceutical formulations that ensure quality, appropriate biopharmaceutical characteristics and maximum effectiveness of therapy.

AIM AND TASKS

Providing basic knowledge on the concepts related to the development and formulation of conventional dosage forms and innovative drug delivery systems through:

- introducing the pharmaceutical terminology and the main normative documents - pharmacopoeias, books, manuals;
- studying the main technological operations and approaches for preparation of dosage forms;
- studying the requirements to the main groups of dosage forms (granules, tablets, capsules, solutions for injection and infusion, eye drops, etc.);
- providing knowledge and forming practical skills for the preparation, control, storage and dispensing of various dosage forms (for oral, parenteral and ocular use);
- providing knowledge about the indicators for quality control of the individual groups of dosage forms and the methods for their determination.

EXPECTED RESULTS

After completing the course, students must:

- have basic knowledge and skills for the development, production and quality control of final pharmaceutical products;
- be able independently, in the laboratory of the pharmacy store, to prepare and dispense by individual prescriptions extemporaneous dosage forms from different groups (solid dosage forms, parenteral forms, ophthalmic forms, etc.);
- know and apply the rules for storage and dispensing medicines;
- be able to dispense prescription drugs after checking the dose and dosage;
- understand the influence of various factors in the development of dosage forms and the concept of quality assurance in their preparation;
- have knowledge to independently deal with and solve problems that have arisen during the preparation of the dosage form;
- have acquired the ability to seek and critically analyze information related to a problem.

CURRICULUM

Course	Exams	Hours			Hours for the semester	
	Semester	Total	Lectures	Practicals	VII	VIII
Pharmaceutical technology II	VIII	210	60	150	30/75	30/75

SYLLABUS FOR LECTURES

IV course, VII semester

№	TOPIC	HOURS	DATE
1.	Physical properties of powders. Bulk and rheological characteristics.	2 h.	
2.	Granules.	2 h.	
3.	Technology of granulation.	2 h.	
4.	Theoretical foundations of granulation. Basic granulation apparatus.	2 h.	
5.	Tablets.	2 h.	
6.	Excipients for tablets – I.	2 h.	
7.	Excipients for tablets – II.	2 h.	
8.	Tablet compression methods.	2 h.	
9.	Tablet presses. Control tests for tablets.	2 h.	
10.	Coated tablets – sugar-coated tablets.	2 h.	
11.	Coated tablets – film-coated tablets.	2 h.	
12.	Capsules. Hard gelatin capsules.	2 h.	
13.	Capsules. Soft gelatin capsules.	2 h.	
14.	Dosage forms with modified drug release.	2 h.	
15.	Diffusion controlled systems. Membrane (reservoir) systems.	2 h.	

TOTAL: 30 h.

SYLLABUS FOR LECTURES

IV course, VIII semester

№	TOPIC	HOURS	DATE
1.	Diffusion controlled systems. Monolithic (matrix) systems.	2 h.	
2.	Bioerosion systems. Osmotically controlled systems. Chemical systems.	2 h.	
3.	Microparticles.	2 h.	
4.	Nano-sized formulations.	2 h.	
5.	Parenteral dosage forms.	2 h.	
6.	Requirements of the Good Manufacturing Practice (GMP) in the production of sterile formulations.	2 h.	
7.	Sterilization. Physical methods for sterilization.	2 h.	
8.	Sterilization. Mechanical and chemical methods for sterilization.	2 h.	
9.	Apyrogenicity, tonicity and purity of parenteral solutions.	2 h.	
10.	Stability of parenteral dosage forms.	2 h.	
11.	Content of the parenteral dosage forms.	2 h.	
12.	Technological scheme for preparation of parenteral dosage forms.	2 h.	
13.	Solutions for intravenous infusion. Solutions and concentrates for hemodialysis.	2 h.	
14.	Ophthalmic dosage forms.	2 h.	
15.	Technology for preparation of ophthalmic dosage forms. Corneal absorption.	2 h.	

TOTAL: 30 h.

SYLLABUS FOR PRACTICALS

IV course, VII semester

№	TOPIC	HOURS	DATE
1.	Powders and granules – seminar.	5 h.	
2.	Studying the rheological characteristics of powders. Approaches to improve powder flowability.	5 h.	
3.	Preparation of different types of granules.	5 h.	
4.	Tablets – seminar.	5 h.	
5.	Preparation of tablets – I.	5 h.	
6.	Preparation of tablets – II.	5 h.	
7.	Colloquium on granules and uncoated tablets.	5 h.	
8.	Coated tablets, tablets with modified drug release, gelatin capsules – seminar.	5 h.	
9.	Preparation of coated tablets.	5 h.	
10.	Preparation of gastro-resistant tablets.	5 h.	
11.	Preparation of tablets with modified drug release – I.	5 h.	
12.	Preparation of tablets with modified drug release – II.	5 h.	
13.	Preparation of gelatin capsules.	5 h.	
14.	Preparation of microcapsules and microspheres.	5 h.	
15.	Colloquium on coated tablets, tablets with modified drug release and capsules.	5 h.	

TOTAL: 75 h.

SYLLABUS FOR PRACTICALS

IV course, VIII semester

№	TOPIC	HOURS	DATE
1.	Parenteral dosage forms - seminar.	5 h.	
2.	Studying the hydrolytic resistance of glass as a packaging material for parenteral dosage forms.	5 h.	
3.	Expressing the concentration of solutions for injection.	5 h.	
4.	Preparation of solutions for injection with isotonic concentration and isotonicization of hypotonic solutions.	5 h.	
5.	Stabilization of solutions for injection with susceptible to hydrolysis and oxidation drugs.	5 h.	
6.	Preparation of solutions for injection with non-aqueous solvents.	5 h.	
7.	Colloquium on solutions for injection.	5 h.	
8.	Solutions for intravenous infusion – seminar.	5 h.	
9.	Expressing the concentration of solutions for intravenous infusion.	5 h.	
10.	Preparation of solutions for intravenous infusion.	5 h.	
11.	Preparation of solutions and concentrates for hemodialysis.	5 h.	
12.	Ophthalmic dosage forms – seminar.	5 h.	
13.	Preparation of eyedrops – I.	5 h.	
14.	Preparation of eyedrops – II.	5 h.	
15.	Colloquium on solutions for intravenous infusion and ophthalmic dosage forms.	5 h.	

TOTAL: 75 h.

LECTURES – THESES

LECTURE № 1 – 2 hours

PHYSICAL PROPERTIES OF POWDERS. BULK AND RHEOLOGICAL CHARACTERISTICS

1. Properties of the individual powder particles (shape, surface, size distribution).
2. Basic methods for determining the particle size.
3. Bulk characteristics of powders (arrangement of particles, powder volume, density, porosity).
4. Rheology of powders (flowability of powders).
5. Methods for studying the powder flowability.
6. Approaches for improving the powder flowability.

LECTURE № 2 – 2 hours

GRANULES

1. Definition and characteristics.
2. Classification of granules.
3. Prerequisites for granulation.
4. Composition of the granules. Characteristics and representatives of the different groups of excipients.

LECTURE № 3 – 2 hours

TECHNOLOGY OF GRANULATION

1. Technology of preparing granules.
2. Dry granulation method - briquetting. Stages of granulation. Apparatus.
3. Wet granulation method. Main steps.
4. Packaging and control.

LECTURE № 4 – 2 hours

THEORETICAL FOUNDATIONS OF GRANULATION. BASIC GRANULATION APPARATUS.

1. Mechanism of wet granulation (mechanism of particle bonding, mechanism of granular growth).
2. Apparatus for wet granulation (mixer granulators, high-speed mixer-granulators, granulator type "fluidized bed", etc.).

LECTURE № 5 – 2 hours

TABLETS

1. Definition, general characteristics and classification of tablets.
2. Advantages and disadvantages.
3. Characteristics of the individual groups of tablets.

LECTURE № 6 – 2 hours

EXCIPIENTS FOR TABLETS – I

1. Main groups of excipients for tablets (diluents, binders, disintegrants, glidants, lubricants, coloring and flavoring agents).
2. Diluents.
3. Binders.
4. Disintegrants.
5. Mechanism of tablet disintegration.

LECTURE № 7 – 2 hours

EXCIPIENTS FOR TABLETS – II

1. Glidants (hydrophobic, hydrophilic).
2. Lubricants.
3. Coloring and flavoring agents.
4. Combined excipients for tablets.

LECTURE № 8 – 2 hours

TABLET COMPRESSION METHODS

1. Direct compression (with and without excipients).
2. Advantages and disadvantages.
3. Compression after granulation (dry and wet).
4. Mechanism of tablet compression.

LECTURE № 9 – 2 hours

TABLET PRESSES. CONTROL TESTS FOR TABLETS

1. Types of tablet presses.
2. Operating principle.
3. Control tests for tablets.

LECTURE № 10 – 2 hours

COATED TABLETS – SUGAR-COATED TABLETS

1. Definition and classification.
2. Prerequisites for coating, advantages and disadvantages.
3. Sugar coating.
4. Steps of sugar coating.
5. Coating materials.

LECTURE № 11 – 2 hours

COATED TABLETS – FILM-COATED TABLETS

1. Film coating - obtaining tablets with a thin film.
2. Steps of film-coating.
3. Composition of the film-coating (film excipients, plasticizers, colorants).
4. Mechanism of the film formation.
5. Coating equipment.
6. Compression coating.
7. Control tests for coated tablets.

LECTURE № 12 – 2 hours

CAPSULES. HARD GELATIN CAPSULES

1. Characteristics and types.
2. Composition of the capsules.
3. Hard gelatin capsules.
4. Excipients for the preparation of capsules.
5. Technology for preparation of hard gelatin capsules.
6. Hard gelatin capsule fillers.

LECTURE № 13 – 2 hours

CAPSULES. SOFT GELATIN CAPSULES

1. Characteristics, advantages and disadvantages.
2. Composition of soft gelatin capsules.
3. Preparation of soft gelatin capsules.
4. Packaging and storage.
5. Control of the capsules.

LECTURE № 14 – 2 hours

DOSAGE FORMS WITH MODIFIED DRUG RELEASE

1. General characteristics.
2. Prerequisites for the development of dosage forms with modified drug release.
3. Advantages and disadvantages.
4. Classification (physical and chemical systems).
5. Physical systems. Technological approaches to prolong the drug release on the principle of decreasing the dissolution rate.

LECTURE № 15 – 2 hours

DIFUSION CONTROLLED SYSTEMS. MEMBRANE (RESERVOIR) SYSTEMS

1. Technological approaches to prolong the drug release on the principle of delayed diffusion.
2. Types of diffusion-controlled systems.
3. Reservoir (membrane) physical systems (with a dense membrane and with a porous membrane).
4. Factors, which influence the drug release.

LECTURE № 16 – 2 hours

DIFUSION CONTROLLED SYSTEMS. MONOLITHIC (MATRIX) SYSTEMS

1. Monolithic physical systems.
2. Hydrophobic monolithic systems (with dissolved or suspended drug substance, porous systems).
3. Hydrophilic (hydrogel and hydrocolloid) systems.

LECTURE № 17 – 2 hours

BIOEROSION SYSTEMS. OSMOTICALLY CONTROLLED SYSTEMS. CHEMICAL SYSTEMS

1. Bioerosion (biodegradable) systems.
2. Osmotically controlled systems.

3. Hydrostatically controlled systems.
4. Chemical systems (immobilized systems, prodrugs).

LECTURE № 18 – 2 hours

MICROPARTICLES

1. Definition and types (microspheres and microcapsules).
2. Advantages and disadvantages.
3. Methods for preparation of microparticles (physicochemical, physical and chemical methods).

LECTURE № 19 – 2 hours

NANO-SIZED FORMULATIONS

1. General characteristics and classification.
2. Lipid nanosized carriers (liposomes, solid lipid nanoparticles, nanoemulsions).
3. Liposomes - advantages and disadvantages. Methods for preparation of liposomes.
4. Polymer nanoparticles. Methods for preparation and characterization.

LECTURE № 20 – 2 hours

PARENTERAL DOSAGE FORMS

1. General characteristics of parenteral forms.
2. Advantages and disadvantages of the parenteral route of administration.
3. Routes of parenteral administration.
4. Classification of the parenteral dosage forms.
5. Basic requirements for parenteral forms.

LECTURE № 21 – 2 hours

REQUIREMENTS OF THE GOOD MANUFACTURING PRACTICE (GMP) IN THE PRODUCTION OF STERILE FORMULATIONS

1. Clean rooms for sterile manufacturing.
2. Types of clean rooms.
3. Requirements for the clean rooms.
4. Staff requirements.
5. Aseptic method for preparation.

LECTURE № 22 – 2 hours

STERILIZATION. PHYSICAL METHODS FOR STERILIZATION

1. Heat sterilization (dry heat sterilization, wet heat sterilization, tindalization, pasteurization).
2. Kinetics of microbial destruction.
3. Sterilization with ionizing rays (UV rays, gamma and beta- (cathode) rays).

LECTURE № 23 – 2 hours

STERILIZATION. MECHANICAL AND CHEMICAL METHODS FOR STERILIZATION

1. Bacterial filtration. Principle.
2. Types of bacterial filters.
3. Chemical methods for sterilization.
4. Sterilization with antimicrobial agents (preservatives), requirements for preservatives.

5. Gas sterilization.
6. Validation of the sterilization process.

LECTURE № 24 – 2 hours

APYROGENICITY, TONICITY AND PURITY OF PARENTERAL SOLUTIONS

1. Pyrogenic substances - nature, types.
2. Bacterial endotoxins. Structure of endotoxins. Clinical significance.
3. Depyrogenization. Methods.
4. Detection of pyrogens and endotoxins (biological test, limulus amoebocyte lysate test).
5. Tonicity of injection solutions. Methods for tonicity evaluation.
6. Purity. Tests for purity.

LECTURE № 25 – 2 hours

STABILITY OF PARENTERAL DOSAGE FORMS

1. Stability and stabilization of parenteral dosage forms.
2. Preparation of solutions with susceptible to oxidation drugs.
3. Stabilization of solution with susceptible to hydrolysis drugs.
4. Parameters for assessment and verification of stability.

LECTURE № 26 – 2 hours

CONTENT OF THE PARENTERAL DOSAGE FORMS

1. Liquid carriers/solvents (water for injections, non-aqueous carriers).
2. Solvent requirements for parenteral solutions.
3. Solubility enhancers.
4. Isotonizing agents.
5. Buffers.
6. Antioxidants and chelating agents.
7. Antimicrobial agents (preservatives).

LECTURE № 27 – 2 hours

TECHNOLOGICAL SCHEME FOR PREPARATION OF PARENTERAL DOSAGE FORMS

1. Basic technological operations.
2. Preparation of packaging - ampoules, containers, stoppers.
3. Requirements for packaging materials for parenteral forms.
4. Preparation of parenteral solutions (dissolution, filtration, filling, sterilization).
5. Control of the solutions before dispensing.
6. Adding drug substances in solutions for infusion.

LECTURE № 28 – 2 hours

SOLUTIONS FOR INTRAVENOUS INFUSION. SOLUTIONS AND CONCENTRATES FOR HEMODIALYSIS

1. Classification of the solutions for infusion.
2. Solutions for blood transfusion and volume replacement.
3. Solutions for total parenteral nutrition
4. Concentrates for hemodialysis. Principle of hemodialysis as a method for blood purification.

LECTURE № 29 – 2 hours

OPHTHALMIC DOSAGE FORMS

1. Anatomical and physiological characteristics of the eye.
2. Classification of the ophthalmic dosage forms.
3. Requirements for ophthalmic dosage forms (sterility, stability, purity, isotonicity).
4. Composition of the ophthalmic dosage forms (solvents, buffers, isotonicizing agents, viscosity enhancers, preservatives, antioxidants).

LECTURE № 30 – 2 hours

**TECHNOLOGY FOR PREPARATION OF OPHTHALMIC DOSAGE FORMS.
CORNEAL ABSORPTION**

1. Technological scheme for preparation of ophthalmic dosage forms.
2. Filling and packaging.
3. Control tests.
4. Corneal absorption and biopharmaceutical approaches to improve the absorption.

PRACTICALS – THESES

PRACTICAL № 1 – 5 hours

POWDERS AND GRANULES – SEMINAR

1. Composition of the granules and representatives of the different groups of excipients.
2. Granulation methods - dry and wet granulation.
3. Rheological parameters of powders and granules.
4. Approaches to improve the flowability of powders.

PRACTICAL № 2 – 5 hours

STUDYING THE RHEOLOGICAL CHARACTERISTICS OF POWDERS. APPROACHES TO IMPROVE POWDER FLOWABILITY

1. Evaluation of the rheological characteristics of powders with poor flowability.
2. Improving the rheological properties using glidants.
3. Improving the rheological properties through granulation.
4. Evaluation of the rheological characteristics of the obtained granules.

PRACTICAL № 3 – 5 hours

PREPARATION OF DIFFERENT TYPES OF GRANULES

1. Preparation of effervescent granules.
2. Preparation of granules for oral liquids.
3. Preparation of sugar granules.
4. Control of the granules.

PRACTICAL № 4 – 5 hours

TABLETS – SEMINAR

1. Types of tablets - characteristics.
2. Excipients in the preparation of tablets.
3. Tablet compression methods - direct compression and compression after granulation.
4. Control tests for tablets.

PRACTICAL № 5 – 5 hours

PREPARATION OF TABLETS – I

1. Preparation of tablets by direct compression.
2. Testing the control parameters of the obtained tablets.
3. Determining the influence of the excipients and the compression force on the tablets hardness.
4. Determining the influence of the excipients on the tablets disintegration.

PRACTICAL № 6 – 5 hours

PREPARATION OF TABLETS – II

1. Preparation of tablets by compression after wet granulation.
2. Using different binders and disintegrants.
3. Testing the control parameters of the obtained tablets.

4. Evaluating the influence of the excipients on the hardness and disintegration of the tablets.

PRACTICAL № 7 – 5 hours

COLLOQUIUM ON GRANULES AND UNCOATED TABLETS

Current assessment of the theoretical knowledge and practical skills acquired by the students on granules and uncoated tablets.

PRACTICAL № 8 – 5 hours

COATED TABLETS, TABLETS WITH MODIFIED DRUG RELEASE, GELATIN CAPSULES – SEMINAR

1. Excipients for coated tablets.
2. Coating steps and apparatus.
3. Technological approaches for the preparation of tablets with modified drug release.
4. Excipients for the preparation of capsules.
5. Fillers for hard gelatin capsules.

PRACTICAL № 9 – 5 hours

PREPARATION OF COATED TABLETS

1. Preparation of tablet cores.
2. Characterization of the obtained tablet cores.
3. Film-coating of the tablet cores.
4. Testing the the control parameters of the obtained coated tablets.

PRACTICAL № 10 – 5 hours

PREPARATION OF GASTRO-RESISTANT TABLETS

1. Preparation of tablet cores for coating.
2. Coating the tablet cores with polymer, which is soluble in an alkaline pH.
3. Testing the disintegration of the obtained tablets in acidic and alkaline environment.
4. Testing the tablets hardness, friability, mass and uniformity of the mass.

PRACTICAL № 11 – 5 hours

PREPARATION OF TABLETS WITH MODIFIED DRUG RELEASE – I

1. Selecting excipients for the preparation of tablets with modified drug release.
2. Compression of model formulations of matrix systems.
3. Testing the control parameters of the obtained tablets.

PRACTICAL № 12 – 5 hours

PREPARATION OF TABLETS WITH MODIFIED DRUG RELEASE – II

1. Introducing the apparatus for dissolution testing.
2. Evaluation of the drug release from the formulated modified-release tablets and conventional tablets.
3. Presenting the drug release profiles graphically.

4. Comparing the drug release profiles from modified-release tablets and conventional tablets.

PRACTICAL № 13 – 5 hours

PREPARATION OF GELATIN CAPSULES

1. Selecting excipients for the preparation of capsules.
2. Filling hard gelatin capsules with powders.
3. Filling hard gelatin capsules with granules.
4. Testing the control parameters of the obtained capsules.

PRACTICAL № 14 – 5 hours

PREPARATION OF MICROCAPSULES AND MICROSPHERES

1. Selection of a suitable carrier and sample preparation.
2. Spray drying of the prepared samples - assessing the influence of the technological parameters.
3. Determination of the microparticles shape.
4. Determination of the yield of the obtained microstructures, drug loading and entrapment efficiency.

PRACTICAL № 15 – 5 hours

COLLOQUIUM ON COATED TABLETS, TABLETS WITH MODIFIED DRUG RELEASE AND CAPSULES.

Current assessment of the theoretical knowledge and practical skills acquired by the students on coated tablets, tablets with modified drug release and capsules.

PRACTICAL № 16 – 5 hours

PARENTERAL DOSAGE FORMS – SEMINAR

1. Classification of the parenteral dosage forms.
2. Basic requirements.
3. Groups of excipients and their representatives.
4. Technological scheme for preparation.

PRACTICAL № 17 – 5 hours

STUDYING THE HYDROLYTIC RESISTANCE OF GLASS AS A PACKAGING MATERIAL FOR PARENTERAL DOSAGE FORMS.

1. Requirements for packaging materials for parenteral forms.
2. Types of glass depending on their hydrolytic stability.
3. Testing the hydrolytic stability of glass by quality methods – a potentiometric method and a method with a methyl red indicator.
4. Quantitative method for assessing the chemical resistance of glass - titration with hydrochloric acid.

PRACTICAL № 18 – 5 hours

EXPRESSING THE CONCENTRATION OF SOLUTIONS FOR INJECTION

1. Expressing the concentration of a solution.
2. Calculating isotonic concentration according to Raoult's law and Vant Hoff's law.
3. Calculating isotonic concentration using isotonic equivalent to sodium chloride.
4. Solving individual tasks.

PRACTICAL № 19 – 5 hours

PREPARATION OF SOLUTIONS FOR INJECTION WITH ISOTONIC CONCENTRATION AND ISOTONIZATION OF HYPOTONIC SOLUTIONS

1. Preparation of an isotonic solution of sodium chloride.
2. Preparation and stabilization of an isotonic glucose solution.
3. Isotonization of hypotonic solutions using an isotonic equivalent to sodium chloride.
4. Isotonization using the decrease in the freezing point temperature.

PRACTICAL № 20 – 5 hours

STABILIZATION OF SOLUTIONS FOR INJECTION WITH SUSCEPTIBLE TO HYDROLYSIS AND OXIDATION DRUGS

1. Approaches for stabilization of solutions with susceptible to oxidation drugs.
2. Preparation of an ascorbic acid solution.
3. Approaches for stabilization of solutions with susceptible to hydrolysis drugs.
4. Preparation of a solution of novocaine hydrochloride and a solution of caffeine-sodium benzoate.

PRACTICAL № 21 – 5 hours

PREPARATION OF SOLUTIONS FOR INJECTION WITH NON-AQUEOUS SOLVENTS

1. Types of non-aqueous carriers for injection solutions and requirements towards them.
2. Preparation of a camphor oil solution for injection.
3. Preparation of an oil solution of vit. D3 for injection.
4. Sterilization and control.

PRACTICAL № 22 – 5 hours

COLLOQUIUM ON SOLUTIONS FOR INJECTION

Current assessment of the theoretical knowledge and practical skills acquired by the students on solutions for injection.

PRACTICAL № 23 – 5 hours

SOLUTIONS FOR INTRAVENOUS INFUSION – SEMINAR

1. Classification of solutions for infusion.
2. Basic requirements.
3. Excipient groups and representatives.
4. Technological scheme for preparation.

PRACTICAL № 24 – 5 hours

EXPRESSING THE CONCENTRATION OF SOLUTIONS FOR INTRAVENOUS INFUSION

1. Expressing the concentration in mmol/L and mEq/L.
2. Converting the concentration of ions in the solution from mg/L to mEq/L.
3. Converting the concentration of ions in the solution from mEq/L to mg/L.
4. Solving individual tasks.

PRACTICAL № 25 – 5 hours

PREPARATION OF SOLUTIONS FOR INTRAVENOUS INFUSION

1. Preparation of a Ringer's solution.
2. Preparation of a Hartmann's solution.
3. Preparation of solutions for infusion at a given concentration of the ions in them.
4. Sterilization and control.

PRACTICAL № 26 – 5 hours

PREPARATION OF SOLUTIONS AND CONCENTRATES FOR HEMODIALYSIS

1. Hemodialysis as a method for blood purification.
2. Requirements for hemodialysis concentrates and expressing the concentration in mEq/L.
3. Preparation of a concentrate for hemodialysis.

PRACTICAL № 27 – 5 hours

OPHTHALMIC DOSAGE FORMS – SEMINAR

1. Basic and additional requirements for eyedrops.
2. Main technological stages in the preparation of eyedrops.
3. Excipients used in the preparation of ophthalmic dosage forms.
4. Control tests.

PRACTICAL № 28 – 5 hours

PREPARATION OF EYEDROPS – I

1. Preparing individual prescriptions for eyedrops.
2. Discussing the excipients involved in the preparation and their role.
3. Calculating the tonicity of the solution and, if necessary, isotonicizing.
4. Sterilization methods.

PRACTICAL № 29 – 5 hours

PREPARATION OF EYEDROPS – II

1. Characteristics of the colloidal solutions for application in the eyes.
2. Preparation of collargol solution.
3. Preparation of protargol solution.
4. Individual tasks.

PRACTICAL № 30 – 5 hours

**COLLOQUIUM ON SOLUTIONS FOR INTRAVENOUS INFUSION AND
OPHTHALMIC DOSAGE FORMS**

Current assessment of the theoretical knowledge and practical skills acquired by the students on solutions for intravenous infusion and ophthalmic dosage forms.

INFORMATION SOURCES

1. *European pharmacopoeia*, 9th edition.
2. *Applied Physical Pharmacy, Third Edition*, Mansoor Amiji, Thomas Cook, Cary Mobley, McGraw Hill
3. *Aulton's Pharmaceutics: The Design and Manufacture of Medicines*, Editors: Kevin Taylor Michael Aulton, Elsevier
4. *Pharmaceutical Dosage Forms and Drug Delivery: Revised and Expanded; 3rd Edition*, Ram I. Mahato, Ajit S. Narang, CRC Press
5. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*, Loyd Allen, Wolters Kluwer
6. *Pharmaceutical Compounding and Dispensing Second edition*, John Marriott, Keith Wilson, Christopher Langley, Dawn Belcher, Pharmaceutical press
7. *Handbook of Extemporaneous Preparation First edition*, Mark Jackson, Andrew Lowey, Pharmaceutical press
8. *The Art, Science, and Technology of Pharmaceutical Compounding 5th Edition*, Loyd Allen, American Pharmacists Association
9. *Applied Biopharmaceutics & Pharmacokinetics*, Leon Shargel, McGraw Hill
10. *Pharmaceutics – Drug Delivery and Targeting 2E*, Perrie & Rades, Pharmaceutical press
11. *Basic Statistics and Pharmaceutical Statistical Applications 3rd Edition*, James E. De Muth, CRC Press
12. *Pharmaceutical Calculations, 15th Edition*, Howard Ansel; Shelly Stockton, Wolters Kluwer
13. *Cosmetic Formulation: Principles and Practice 1st Edition*, Heather Benson, Michael Roberts, Vania Rodrigues Leite-Silva, Kenneth Walters, CRC Press
14. *Martin's Physical Pharmacy and Pharmaceutical Sciences Seventh Edition*, Patrick J.Sinko, LWW
15. *Modern Pharmaceutics, Two Volume Set 5th Edition*, Alexander Florence, Juergen Siepmann, CRC Press
16. *Physicochemical Principles of Pharmacy: In Manufacture, Formulation and Clinical Use 6th edition*, Alexander Florence; David Attwood, Pharmaceutical Press
17. *Essentials of Biopharmaceutics and Pharmacokinetics, 2/e*, Ashutosh Kar, CBS Publishers & Distributors
18. *Handbook of Pharmaceutical Excipients 8th Revised edition*, Edited by Paul Sheskey, Walter Cook, Colin G. Cable, Pharmaceutical Press
19. *Access Pharmacy*, <https://accesspharmacy.mhmedical.com/>

EXAM SYLLABUS
PHARMACEUTICAL TECHNOLOGY II

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.