

MEDICAL UNIVESRITY – PLOVDIV
FACULTY OF PHARMACY
DEPARTMENT OF PHARMACEUTICAL SCIENCES

SYLLABUS

in

PHARMACEUTICAL TECHNOLOGY
PART I

Approved by the Department Council - Protocol № 10/18.10.2024

Confirmed by the Faculty Council - Protocol № 09/13.11.2024

PHARMACEUTICAL TECHNOLOGY

PART I

Syllabus

Discipline	Final exam/ semester	According to the Faculty of Pharmacy curriculum of MU-Plovdiv Academic hours				ECTS	Academic hours in semester			
		V semester		VI semester						
		Auditorium	Lectures	Practices	Non-auditorium		L	P	L	P
Pharmaceutical technology I	VI	210	60	150	217	14,2	30	75	30	75

DISCIPLINE:

Pharmaceutical technology part I

TYPE OF DISCIPLINE ACCORDING TO THE UNIFORM STATE REQUIREMENTS:

Compulsory

LEVEL OF QUALIFICATION:

MPharm

FORMS OF TRAINING:

Lectures, practicals, self-training

YEAR OF TRAINING:

III course

DURATION OF TRAINING:

Two semesters

ACADEMIC HOURS:

60 hours lectures, 150 hours practicals

TECHNICAL EQUIPMENT APPLIED IN THE TRAINING:

Multimedia presentations, discussions, individual tasks, preparation of papers

FORMS OF EVALUATION:**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).

EVALUATION CRITERIA:

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.

SEMESTER EXAM:

Yes (written and oral examination)

STATE EXAM:

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

LECTURER:

Professor from the department of Pharmaceutical sciences.

DEPARTMENT:

Pharmaceutical Sciences

ANNOTATION

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.

BASIC AIMS OF THE DISCIPLINE

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.

SYLLABUS FOR LECTURES

III course, V semester

№	TOPIC	HOURS	DATE
1.	Pharmaceutical technology. Subject and historical development.	2 h.	
2.	Biopharmacy. Basic concepts.	2 h.	
3.	Stability of the pharmaceutical products.	2 h.	
4.	Pharmaceutical packaging.	2 h.	
5.	Pharmaceutical production. Good manufacturing practice.	2 h.	
6.	Powders (Pulveres).	2 h.	
7.	Dissolving and solubility.	2 h.	
8.	Liquid dosage forms for oral administration. Molecular solutions.	2 h.	
9.	Syrups. Mixtures.	2 h.	
10.	Colloidal solutions. Solutions of macromolecular substances.	2 h.	
11.	Phytoproducts.	2 h.	
12.	Extraction theory. Extraction methods.	2 h.	
13.	Aqueous extracts from herbal drugs.	2 h.	
14.	Ethanol-water extracts from herbal drugs. Other extracts.	2 h.	
15.	Preparation of phytoproducts.	2 h.	

TOTAL: 30 h.

SYLLABUS FOR LECTURES

III course, VI semester

№	TOPIC	HOURS	DATE
1.	Emulsions.	2 h.	
2.	Emulsifiers.	2 h.	
3.	Suspensions.	2 h.	
4.	Dosage forms for dermal application.	2 h.	
5.	Semi-solid formulations for dermal application.	2 h.	
6.	Excipients (bases) for semi-solid formulations for dermal application.	2 h.	
7.	Creams.	2 h.	
8.	Pastes.	2 h.	
9.	Gels.	2 h.	
10.	Rectal dosage forms.	2 h.	
11.	Rectal suppositories.	2 h.	
12.	Preparation of rectal suppositories.	2 h.	
13.	Vaginal dosage forms.	2 h.	
14.	Vaginal globules.	2 h.	
15.	Aerosols.	2 h.	

TOTAL: 30 h.

SYLLABUS FOR PRACTICALS

III course, V semester

№	TOPIC	HOURS	DATE
1.	Introduction. Requirements for working in the laboratories of Pharmaceutical technology.	5 h.	
2.	Powders. Complex powders.	5 h.	
3.	Powders. Preparation of powders.	5 h.	
4.	Powders. Incompatibilities.	5 h.	
5.	Colloquium – powders.	5 h.	
6.	Liquid dosage forms.	5 h.	
7.	Syrups. Mixtures with solid and liquid soluble drugs.	5 h.	
8.	Increasing the solubility of slightly soluble drugs.	5 h.	
9.	Mixtures. Complex prescriptions.	5 h.	
10.	Colloidal solutions. Solutions of macromolecular substances.	5 h.	
11.	Phytoproducts. Infusions and decoctions.	5 h.	
12.	Phytoproducts. Aromatic waters.	5 h.	
13.	Phytoproducts. Tinctures.	5 h.	
14.	Phytoproducts. Extracts.	5 h.	
15.	Colloquium – liquid dosage forms and phytoproducts.	5 h.	

TOTAL: 75 h.

SYLLABUS FOR PRACTICALS

III course, VI semester

№	TOPIC	HOURS	DATE
1.	Emulsions – I.	5 h.	
2.	Emulsions – II.	5 h.	
3.	Suspensions	5 h.	
4.	Liquid dosage forms for dermal application.	5 h.	
5.	Colloquium – emulsions and suspensions.	5 h.	
6.	Semi-solid formulations – ointments.	5 h.	
7.	Semi-solid formulations – ointments-suspensions and pastes.	5 h.	
8.	Semi-solid formulations – creams.	5 h.	
9.	Gels.	5 h.	
10.	Colloquium – semi-solid formulations for dermal application.	5 h.	
11.	Suppositories. Preparation of suppositories – I.	5 h.	
12.	Suppositories. Preparation of suppositories – II.	5 h.	
13.	Vaginal globules. Preparation of globules	5 h.	
14.	Rectal suppositories and vaginal globules – individual tasks.	5 h.	
15.	Colloquium – suppositories and globules.	5 h.	

TOTAL: 75 h.

LECTURES – THESES

LECTURE № 1 – 2 hours

PHARMACEUTICAL TECHNOLOGY. SUBJECT AND HISTORICAL DEVELOPMENT

1. Pharmaceutical technology.
2. Subject and historical development of pharmaceutical technology.
3. Basic terms in pharmaceutical technology (active substance, excipient, dosage form, pharmaceutical product, generic product, packaging).
4. Basic normative documents. Pharmacopoeia.
5. Classification of the dosage forms – according to the type of disperse system and according to the route of administration.

LECTURE № 2 – 2 hours

BIOPHARMACY. BASIC CONCEPTS

1. Biopharmacy – basic concepts.
2. Pharmaceutical and biological availability.
3. Factors affecting bioavailability.
4. Pharmaceutically, biologically and therapeutically equivalent medicinal products.

LECTURE № 3 – 2 hours

STABILITY OF THE PHARMACEUTICAL PRODUCTS

1. Stability of medicinal products.
2. Types of stability (physical, chemical and microbiological).
3. Factors that affect stability.
4. Technological approaches for stabilization.
5. Shelf life.

LECTURE № 4 – 2 hours

PHARMACEUTICAL PACKAGING.

1. Packaging of dosage forms.
2. Pharmacopoeial requirements for packaging materials.
3. Types of packaging and materials for packaging.

LECTURE № 5 – 2 hours

PHARMACEUTICAL PRODUCTION. GOOD MANUFACTURING PRACTICE

1. Good Manufacturing Practice (GMP).
2. Basic GMP requirements.
3. Elements of GMP (personnel, rooms, equipment, production, quality control, documentation).

LECTURE № 6 – 2 hours

POWDERS (PULVERES)

1. Definition and classification.
2. Basic technological operations (drying, grinding, sieving, mixing).
3. Preparation of simple and complex powders.

4. Incompatibility and instability of powders.
5. Individual cases in the preparation of powders.
6. Control tests and their determination.

LECTURE № 7 – 2 hours

DISSOLVING AND SOLUBILITY

1. Dissolution – essence of the process.
2. Solubility. Factors affecting solubility.
3. Dissolution rate and degree.
4. Factors influencing the dissolution process.
5. Methods for increasing solubility (co-dissolution, complexation, hydrotropia, micelle solubilization).

LECTURE № 8 – 2 hours

LIQUID DOSAGE FORMS FOR ORAL ADMINISTRATION. MOLECULAR SOLUTIONS

1. Classification of liquid dosage forms for oral administration.
2. Solvents and carriers for liquid dosage forms.
3. Molecular solutions.
4. Technological scheme for preparation.
5. Filtration. Filtration methods and apparatus.
6. Control tests.

LECTURE № 9 – 2 hours

SYRUPS. MIXTURES

1. Syrups. Classification.
2. Technological scheme for preparation and control.
3. Mixtures – characteristics.
4. Technological scheme for preparation of the mixtures.
5. Incompatibilities in mixtures.
6. Control tests.

LECTURE № 10 – 2 hours

COLLOIDAL SOLUTIONS. SOLUTIONS OF MACROMOLECULAR SUBSTANCES

1. Colloidal solutions. General characteristics and classification.
2. Technological scheme for preparation and control.
3. Properties and stability of colloidal systems.
4. Solutions of macromolecular substances. Characteristics.
5. Classification of macromolecular substances.
6. Application of macromolecular substances as carriers and stabilizers of dispersed systems.

LECTURE № 11 – 2 hours

PHYTOPRODUCTS

1. General characteristics and classification of phytoproducts.
2. Phytoproducts obtained from fresh plants (juices, syrups, alcoholates, homeopathic primary tinctures).
3. Phytoproducts derived from herbal drugs (herbal teas and powders).

LECTURE № 12 – 2 hours

EXTRACTION THEORY. EXTRACTION METHODS

1. Extraction from herbal drugs.
2. Main factors influencing the extraction process.
3. Approaches to increase the efficiency of extraction of biologically active substances.
4. Maceration – characteristics. Advantages and disadvantages. Types.
5. Percolation – characteristics, steps. Advantages and disadvantages.
6. Other extraction methods.

LECTURE № 13 – 2 hours

AQUEOUS EXTRACTS FROM HERBAL DRUGS

1. Definition. Classification.
2. Infusions (infusa) – preparation, requirements, application.
3. Decoctions (Decocta) – preparation, requirements, application.
4. Aromatic waters – classification, methods for preparing natural and artificial aromatic waters.

LECTURE № 14 – 2 hours

ETHANOL-WATER EXTRACTS FROM HERBAL DRUGS. OTHER EXTRACTS

1. Tinctures – characteristics and classification.
2. Methods for preparation. Control.
3. Extracts – characteristics and classification.
4. Methods for preparing liquid, soft and dry extracts. Control.
5. Oil extracts.
6. Maximum purified phytoproducts.
7. Chemically pure substances.

LECTURE № 15 – 2 hours

PREPARATION OF PHYTOPRODUCTS

1. Standardization of the source material. Pharmacopoeial indicators.
2. Sterilization of herbal drugs.
3. Grinding and screening of herbal drugs.
4. Extraction from herbal drugs.
5. Purifying and concentrating the extract.
6. Drying of extracts.
7. Control and standardization of phytoproducts.

LECTURE № 16 – 2 hours

EMULSIONS

1. General characteristics and classifications.
2. Advantages and disadvantages.
3. Physical stability of emulsions. Factors affecting stability.
4. Composition of emulsions.
5. Preparation and control.

LECTURE № 17 – 2 hours

EMULSIFIERS

1. Classification and representatives.
2. Pseudoemulsifiers – principle of action, advantages and disadvantages.
3. True emulsifiers. Characteristics and representatives.
4. Hydrophilic – lipophilic balance.
5. Methods for determination.

LECTURE № 18 – 2 hours

SUSPENSIONS

1. General characteristics and classifications
2. Advantages and disadvantages.
3. Physical stability of suspensions. Factors affecting stability.
4. Stabilization of suspensions.
5. Preparation of suspensions and control.
6. Biopharmaceutical aspects of liquid dosage forms for oral administration.

LECTURE № 19 – 2 hours

DOSAGE FORMS FOR DERMAL APPLICATION

1. Classification.
2. Liquid dosage forms for dermal application (solutions, liniments, lotions).
3. Nasal drops and ear drops.
4. Penetration and percutaneous absorption.
5. Factors affecting percutaneous absorption.

LECTURE № 20 – 2 hours

SEMI-SOLID FORMULATIONS FOR DERMAL APPLICATION

1. Classification.
2. Characteristics of the different groups of semi-solid forms (ointments, creams, gels, pastes, patches).
3. Technological approaches for their preparation.
4. Biopharmaceutical characteristics. Control.

LECTURE № 21 – 2 hours

EXCIPIENTS (BASES) FOR SEMI-SOLID FORMULATIONS FOR DERMAL APPLICATION

1. Requirements for the bases.
2. Types of bases.
3. Bases for ointments (hydrophobic, hydrophilic, water-emulsifying).
4. Advantages and disadvantages.
5. Preparation of ointments. Control.

LECTURE № 22 – 2 hours

CREAMS

1. Bases for creams. Classification.
2. Lipophilic and hydrophilic creams.
3. Preparation technology.
4. Control.

LECTURE № 23 – 2 hours

PASTES

1. Definition and general characteristics.
2. Bases for pastes.
3. Preparation technology.
4. Control.

LECTURE № 24 – 2 hours

GELS

1. Definition and classification.
2. Gel bases.
3. Hydrogels. Gelling agents for hydrogels.
4. Oleogels. Gelling agents for oleogels.
5. Preparation technology.
6. Control.

LECTURE № 25 – 2 hours

RECTAL DOSAGE FORMS

1. Classification.
2. Rectal route of administration. Biopharmaceutical aspects.
3. Rectal absorption. Factors affecting absorption.
4. Advantages and disadvantages of the rectal route of drug administration.

LECTURE № 26 – 2 hours

RECTAL SUPPOSITORIES

1. Rectal suppositories. Characteristics.
2. Classification.
3. Suppository bases – requirements. Classification, representatives.
4. Advantages and disadvantages of commonly used bases.

LECTURE № 27 – 2 hours

PREPARATION OF RECTAL SUPPOSITORIES

1. Manual modeling.
2. Preparation by casting.
3. Packaging and storage of suppositories.
4. Control indicators – pharmacopoeial and non-pharmacopoeial.

LECTURE № 28 – 2 hours

VAGINAL DOSAGE FORMS

1. General characteristics.
2. Classification.
3. Vaginal absorption.
4. Biopharmaceutical aspects of the vaginal route of drug administration.

LECTURE № 29 – 2 hours

VAGINAL GLOBULES

1. Preparation of vaginal globules.
2. Requirements for vaginal globule bases.
3. Control indicators.
4. Storage.

LECTURE № 30 – 2 hours

AEROSOLS

1. Definition. Advantages and disadvantages.
2. Composition of aerosols.
3. Types of aerosol systems.
4. Liquefied and compressed gases.
5. Technology of aerosol production.
6. Packaging and control.

PRACTICALS – THESES

PRACTICAL № 1 – 5 hours

INTRODUCTION. REQUIREMENTS FOR WORKING IN THE LABORATORIES OF PHARMACEUTICAL TECHNOLOGY

1. Introduction (seminar).
2. Requirements for working in the laboratories of pharmaceutical technology.
3. Basic terms, used in pharmaceutical technology - drug substance, excipient, dosage form.
4. The medical prescription as a document.
5. Dose and dosage.
6. Packaging and the required text on it.
7. Pharmaceutical calculations. Examples.

PRACTICAL № 2 – 5 hours

POWDERS. COMPLEX POWDERS

1. Complex powders.
2. Dose and dosage.
3. Technological operations.
4. Technological scheme for preparation of powders.
5. Individual cases and incompatibilities in powders (theoretical basis).
6. Control.
7. Practical tasks.

PRACTICAL № 3 – 5 hours

POWDERS. PREPARATION OF POWDERS

1. Powders with potent drugs.
2. Triturated powders.
3. Inclusion of volatile substances, extracts, coloring agents.
4. Practical tasks.

PRACTICAL № 4 – 5 hours

POWDERS. INCOMPATIBILITIES

1. Incompatibilities in powders.
2. Instability of powders.
3. Humidifying mixtures.
4. Eutectic mixtures.
5. Practical tasks.

PRACTICAL № 5 – 5 hours

COLLOQUIUM - POWDERS

Current assessment of the students knowledge in the module "Powders".

PRACTICAL № 6 – 5 hours
LIQUID DOSAGE FORMS

1. Basic principles of preparation of solutions.
2. Dosage for liquid formulations.
3. Expressing concentration.
4. Molecular solutions with more than one substance.
5. Preparation of solutions by diluting concentrates.
6. Control.

PRACTICAL № 7 – 5 hours
SYRUPS. MIXTURES WITH SOLID AND LIQUID SOLUBLE DRUGS

1. Sugar syrup (Sirupus Simplex).
2. Medicinal syrups.
3. Mixtures with liquid and solid soluble drugs.
4. Inclusion of tinctures and extracts.
5. Taste correction.
6. Possible incompatibilities and their prevention.
7. Control.
8. Practical tasks.

PRACTICAL № 8 – 5 hours
INCREASING THE SOLUBILITY OF SLIGHTLY SOLUBLE DRUGS

1. Increasing the solubility of slightly soluble drugs:
 - 1.1. by inorganic complexes - iodine/potassium iodide;
 - 1.2. by replacing the solvent - replacing part of the water with a hydrophilic co-solvent;
 - 1.3. by micellar solubilization with surfactants - Twin 20, Twin 80.

PRACTICAL № 9 – 5 hours
MIXTURES. COMPLEX PRESCRIPTIONS

1. Mixtures with potential incompatibility between the drug substances and/or the excipients.
2. Preparation of mixtures, avoiding potential incompatibilities:
 - 2.1. selection of an appropriate drug;
 - 2.2. increase of the solvent;
 - 2.3. preparation of two separate mixtures, etc.
3. Individual tasks.

PRACTICAL № 10 – 5 hours
COLLOIDAL SOLUTIONS. SOLUTIONS OF MACROMOLECULAR SUBSTANCES

1. Colloidal solutions.
2. Preparation technology.
3. Storage requirements.
4. Preparation of solutions with different concentration of Collargol, Protargol.
5. Solutions of macromolecular substances.
6. Preparation of solutions of starch, gum arabic, gelatin, methylcellulose and others.

PRACTICAL № 11 – 5 hours

PHYTOPRODUCTS. INFUSIONS AND DECOCTIONS

1. Herbal materials. Methods for standardization, qualitative and quantitative indicators.
2. Preparation of infusions.
3. Preparation of decoctions.
4. Preparation of liquid dosage forms with aqueous extracts.
5. Practical tasks.

PRACTICAL № 12 – 5 hours

PHYTOPRODUCTS. AROMATIC WATERS

1. Natural aromatic waters.
2. Artificial aromatic waters.
3. Determination of the aromatic water type.
4. Aromatic alcohols.
5. Control.
6. Practical tasks.

PRACTICAL № 13 – 5 hours

PHYTOPRODUCTS. TINCTURES

1. Preparation of tinctures:
 - 1.1. maceration;
 - 1.2. percolation;
 - 1.3. dissolving extracts;
 - 1.4. control.
2. Practical tasks.

PRACTICAL № 14 – 5 hours

PHYTOPRODUCTS. EXTRACTS

1. Preparation of extracts:
 - 1.1. preparation of liquid extracts;
 - 1.2. preparation of soft extracts;
 - 1.3. preparation of dry extracts.
2. Control.
3. Practical tasks.

PRACTICAL № 15 – 5 hours

COLLOQUIUM - LIQUID DOSAGE FORMS AND PHYTOPRODUCTS

Current assessment of the students knowledge in the modules "Liquid dosage forms" and "Phytoproducts".

PRACTICAL № 16 – 5 hours

EMULSIONS – I

1. Definition and composition.
2. Types of emulsions.
3. Emulsifiers.
4. Technological operations in the preparation of emulsions.
5. Preparation of the following types of emulsions:
 - 5.1. Seed (natural) emulsion;
 - 5.2. O/W type emulsion with pseudoemulsifier arabic gum;
 - 5.3. W/O emulsion.

PRACTICAL № 17 – 5 hours

EMULSIONS – II

1. Emulsifiers – hydrophilic-lipophilic balance.
2. Representatives and classification.
3. Mixed emulsifiers.
4. Inclusion of a drug, which is water or oil soluble.

PRACTICAL № 18 – 5 hours

SUSPENSIONS

1. Suspensions.
2. Definition, composition, physical stability.
3. Suspending agents.
4. Technological scheme for preparation.
5. Practical tasks:
 - 5.1. Suspensions of hydrophilic substances;
 - 5.2. Suspensions of hydrophobic substances.
6. Determination of sedimentation volume.
7. Practical tasks – studying the influence of different suspending agents on the sedimentation volume of the prepared suspensions.

PRACTICAL № 19 – 5 hours

LIQUID DOSAGE FORMS FOR DERMAL APPLICATION

1. Liquid dosage forms for dermal application. Classification:
 - 1.1. Liniments;
 - 1.2. Molecular solutions;
 - 1.3. Emulsions.
2. Practical tasks.

PRACTICAL № 20 – 5 hours

COLLOQUIUM - EMULSIONS AND SUSPENSIONS

Current assessment of the students knowledge in the module "Emulsions and suspensions".

PRACTICAL № 21 – 5 hours

SEMI-SOLID FORMULATIONS – OINTMENTS

1. Preparation of ointments:
 - 1.1. Hydrophobic ointments;
 - 1.2. Hydrophilic ointments.
2. Preparation of two- and multiphase disperse systems.
3. Practical tasks.

PRACTICAL № 22 – 5 hours

SEMI-SOLID FORMULATIONS - OINTMENTS-SUSPENSIONS AND PASTES

1. Definition.
2. Technological approaches for preparation.
3. Preparation of semi-solid forms with suspended drugs up to 20%.
4. Preparation of pastes with drugs over 20%.
5. Homogeneity control.

PRACTICAL № 23 – 5 hours

SEMI-SOLID FORMULATIONS – CREAMS

1. Hydrophilic creams.
2. Hydrophobic creams.
3. Emulsifiers for creams.
4. Preparation of manual formulations.
5. Practical tasks.
6. Determination of the emulsion type.

PRACTICAL № 24 – 5 hours

GELS

1. Types of gelling agents.
2. Preparation of hydrogels.
3. Preparation of oleogels.
4. Inclusion of drugs in gel carriers.
5. Practical tasks – preparation of hydrogel and oleogel.

PRACTICAL № 25 – 5 hours

COLLOQUIUM - SEMI-SOLID FORMULATIONS FOR DERMAL APPLICATION

Current assessment of the students knowledge in the module "Semi-solid formulations for dermal application".

PRACTICAL № 26 – 5 hours

SUPPOSITORIES. PREPARATION OF SUPPOSITORIES – I

1. Suppositories. Characteristics.
2. Suppository bases:
 - 2.1. Hydrophobic;
 - 2.2. Hydrophobic semi-synthetic;
 - 2.3. Hydrophilic.
3. Practical tasks – preparation of rectal suppositories.

PRACTICAL № 27 – 5 hours

SUPPOSITORIES. PREPARATION OF SUPPOSITORIES – II

1. Calculation of the amount of base for preparation of suppositories.
2. Substitution coefficient:
 - 2.1. for hydrophilic bases;
 - 2.2. for hydrophobic bases.
3. Practical tasks – preparation of suppositories by casting.
4. Calculation of the basis using the substitution coefficients of the drug substances.
5. Control – time for complete deformation, mass and uniformity of the mass.

PRACTICAL № 28 – 5 hours

VAGINAL GLOBULES. PREPARATION OF GLOBULES

1. Bases for vaginal globules:
 - 1.1. Hydrophilic;
 - 1.2. Hydrophobic.
2. Advantages and disadvantages.
3. Calculation of the amount of the base using the substitution coefficients of the drugs.
4. Practical tasks – preparation of globules.
5. Control – mass and uniformity of the mass, time for complete deformation, etc.

PRACTICAL № 29 – 5 hours

RECTAL SUPPOSITORIES AND VAGINAL GLOBULES - INDIVIDUAL TASKS

1. Preparation of rectal suppositories by casting.
2. Preparation of vaginal globules by casting – with a semi-synthetic hydrophobic base, with a PEG-base and with a gelatin-glycerin base.
3. Determination of the control parameters of one formulation, prepared by manual modeling and one formulation by casting.

PRACTICAL № 30 – 5 hours

COLLOQUIUM - SUPPOSITORIES AND GLOBULES

Current assessment of the students knowledge in the module "Suppositories and globules".

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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 6-th 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/>

CONSPECTUS

Pharmaceutical technology part I

1. Pharmaceutical technology. Subject and historical development of pharmaceutical technology. Basic concepts and terminology used in the pharmaceutical technology. Classification of the pharmaceutical dosage forms.
2. Biopharmacy. Prerequisites for its foundation. Basic concepts. Pharmaceutical and biological availability. Main biopharmaceutical factors related to the drug substances and the dosage form and their influence on bioavailability. Pharmaceutically, biologically and therapeutically equivalent pharmaceutical products.
3. Stability, respectively instability. Shelf life of the pharmaceutical products. Factors that cause instability. Methods for stability evaluation. Technological approaches for stabilization. Examples.
4. Pharmaceutical packaging. Types of packages. Requirements.
5. Pharmaceutical powders. Classification. Technological scheme for preparation and control.
6. Individual cases in the preparation of powder formulations. Incompatibilities and instability in powders.
7. Liquid dosage forms. Biopharmaceutical characteristics and classification. Gastrointestinal absorption. Factors influencing the absorption.
8. Dissolution. Dissolution rate and degree. Factors influencing the dissolution process.
9. Methods for increasing solubility. Solubilization. Possible mechanisms of solubilization. Technological scheme.
10. Surfactants. General characteristics and classification. Application in the pharmaceutical technology.
11. Liquid dosage forms for oral administration – molecular solutions. Technological scheme and control.
12. Syrups. Technological scheme and control indicators.
13. Solutions of macromolecular substances. Characteristics. Applications in the pharmaceutical technology.
14. Colloidal solutions. Technological scheme for preparation. Control.
15. Phytoproducts. Characteristics. Classification. Standardization of herbal drugs. Pharmacopoeial methods. Grinding and screening of herbal drugs. Phytoproducts obtained from fresh plants.
16. Factors influencing the extraction process. Extraction theory.
17. Extraction methods. Maceration. Characteristics of the method. Percolation. Characteristics of the method. Other extraction methods.
18. Aqueous extracts from herbal drugs. Classification. Preparation. Aromatic waters. Methods for preparation.
19. Ethanol-water extracts. Classification. Preparation and control. Maximum purified phytoproducts.

20. Emulsions. Composition, classification, biopharmaceutical aspects. Physical stability of emulsions. Factors affecting stability. Microbiological stability of emulsions. Preparation of emulsions. Control and storage.
21. Emulsifiers – classification, representatives. Hydrophilic-lipophilic balance. Methods for determination.
22. Suspensions. Classification. Biopharmaceutical aspects. Preparation of suspensions. Control and storage. Suspending excipients. Sedimentation. Kinetics of the sedimentation process – factors.
23. Mixtures. Characteristics. Technological scheme. Taste correction. Control. Incompatibilities in mixtures.
24. Biopharmaceutical aspects of the dosage forms – powders, emulsion solutions, suspensions.
25. Liquid dosage forms for external application. Classification and characteristics.
26. Semi-solid dosage forms for dermal application. Classification. Characteristics. Percutaneous absorption. Factors affecting the percutaneous absorption. Control.
27. Bases for semi-solid formulations. Classification. Excipients for semi-solid bases and ointments. Requirements. Classification.
28. Ointments – homogeneous and heterogeneous disperse systems. Pastes. Preparation. Control.
29. Creams. Preparation. Control.
30. Gels. Characteristics. Gelling agents. Preparation. Control.
31. Suppositories. Characteristics. Classification. Preparation, control, storage.
32. Suppository bases. Classification. Requirements. Representatives.
33. Rectal absorption. Physiological factors. Biopharmaceutical aspects of rectal dosage forms.
34. Vaginal globules – general characteristics and classification. Globule preparation, control and storage. Biopharmaceutical aspects of vaginal dosage forms.
35. Aerosols. Composition. Types of aerosols. Liquefied and compressed gases. Technology. Package.