PHARMACEUTICAL TECHNOLOGY

1. Information about the program

1.1.	UNIVERSITY: "GRIGORE T. POPA" UNIVERSITY OF MEDICINE AND PHARMACY OF IAŞI
1.2.	FACULTY: PHARMACY SCHOOL / DEPARTMENT: PHARMACEUTICAL SCIENCES II
1.3.	SUBJECT: PHARMACEUTICAL TECHNOLOGY
1.4.	STUDY FIELD: HEALTH
1.5.	STUDY CYCLE: UNDERGRADUATE
1.6.	STUDY PROGRAMME: PHARMACY

2. Subject data

2.1.	SUBJECT: PHARMACEUTICAL TECHNOLOGY						
2.2.	Module leader: Prof. Lacramioara Ochiuz,PhD; Assoc. Prof. Carmen Gafițanu, PhD;						
2.3.	Seminar leader: Prof. Lacramioara Ochiuz,PhD; Assoc. Prof. Carmen Gafițanu, PhD; Assoc. Prof. Grațiela Popa, PhD; Lecturer Andreea Crețeanu, PhD, Assist. Magdalena Bârsan, PhD; Asist. Iliuta Cretan, PhD; Assist. Alexandra Bujor, PhD student, Assis. Sha'at Mousa, PhD student						
2.4. Year of study	IV	2.5. Semester in which is taught	I/II	2.6. Evaluation type	E1/E2	2.7. Subject status	Compulsory

3. Duration of the course (hours per semester)

3.1.Number of hours / week	6 (1st sem) 6 (2nd sem)	3.2.Number of hours / week	2 (1st sem) 2 (2nd sem)	3.3.Seminar / lab	4 (1st sem) 4 (2nd sem)
3.4.Total number of learning hours	84 (1st sem) 84 (2nd sem)	3.5.Total number of learning hours	28(1st sem) 28 (2nd sem)	3.6. seminar / lab	56 (1st sem) 56 (2nd sem)

3.7.Distribution of activities in the course (1st sem/ 2nd sem)	hours
Study based on the manual, printed course, bibliography and notes	50/40
Additional research in the library, on specialized e-platforms and field study	5/3
Preparation for seminars, practical courses, portfolios and essays	10/6
Tutoring	-
Assessment	26/20
Other activities	-
3.8. Number of hours of individual study	65/49
3.9. Number of hours per semester	175/125
3.10. Number of ECTS	7/5

4. Previous Knowledge (if applicable)

4.1. course related	Pharmaceutical propedeutics, Medical and Pharmaceutical Terminology, Pharmacology.
4.2. skill related	-

5. Requirements (if applicable)

5.1. course conditions	Projector.
5.2. seminar / laboratory conditions	Glaasware and laboratory equipment for pharmaceutical substances, containers of different formulations conditioning.

6. Specific Skills Acquired

Professional skills displayed by knowledge and skills	• Design, formulation, preparation and conditioning of sterile dosage forms (injections, infusions, eye, serums and vaccines, radiopharmaceuticals) and extractive. • Storage, preservation, distribution of sterile dosage forms (injections, infusions, eye, serums and vaccines, radiopharmaceuticals) and extractive. • Design, formulation, preparation and packaging of medicines, food supplements, cosmetics and other health products. • Storage, preservation, distribution of medicines, food supplements, cosmetics and other health products. • Using theoretical knowledge to solve specific problems qualifications.
Transversal skills (role skills, professional and personal skills)	• Problem solving and decision making. • Using the concepts in new contexts. • Open for lifelong learning. • Ability to work in team.

7. Course Objectives (confirmed by the grid of specific skills acquired)

7.1. General Objective	- Understanding of the modern, theoretical and practical concepts regarding the influence of physico-chemical, technological, pharmacological and biological factors on formulation, development, packing, quality control and bioavailability evaluation of extractive and sterile pharmaceutical dosage forms. - Knowledge of pharmaceutical dosage forms as heterogeneous dispersions: emulsions, suspensions, aerosols, ointments, transdermal therapeutical systems and suppositories.
7.2. Specific Objectives	- Knowledge extractive dosage forms and sterile dosage forms: injections, infusions and eye washes; formulation, preparation technology, quality conditions and control, packaging, storage and method of administration. - Pharmaceutical dosage forms as heterogeneous dispersions: Colloidal solutions, emulsions, suspensions, aerosols, ointments, suppositories. Formulation, conditioning devices, industrial manufacturing, quality control. -Knowledge of FRX specifications.

8. Contents

8.1. Course	Teaching methods	Observations
1nd Semester		
1. Extractive pharmaceutical forms. General concepts. Advantages and disadvantages. Formulation. The nature and humidity of vegetable product. The wetting of vegetable product. The size reduction of vegetable product. The nature of solvent. The ratio vegetable product/solvent for aqueous extractive solutions. The influence of pH value on the extraction process. The influence of stirring, temperature and duration of the extraction process. Maceration – examples; Infusion – examples; Decoction – examples; Digestion. Tinctures – definition, classification, manufacturing and examples according to 10th Romanian Pharmacopeia; Pharmaceutical extracts – definition, classification, manufacturing and examples according to 10th Romanian Pharmacopeia	Lecture; powerpoint presentation; projector	5 hours
2. Injectable pharmaceutical forms.Definition and classification. The advantages and disadvantages of parenteral pharmaceutical forms. Methods of sterilization – classification, methods of sterilization according to 10th Romanian Pharmacopeia. Aseptic preparation of sterile products. Absence of insoluble particles, apyrogenity, isotonicity, isohydry; quality conditions of pharmaceutical substances for injectable products. Quality conditions of solvent for parenterals. Distilled water; Oleum Helianti; Anhydrous solvents for injectable medicines. Additives and adjuvants for injectable medicines. Production rooms for manufacturing injectable products.Primary pharmaceutical containers – glass: compositions, types of glass. Pharmaceutical glass ampoules: types, quality conditions and capacity. The quality control and preparation of ampoules. Plastomers pharmaceutical containers. Elastomers – quality control and preparation of rubber closures. Vial and bag plastomers pharmaceutical containers – quality conditions and control. Aqueous injectable solutions. The phases of the manufacturing process – delivery of raw materials, weighing, dissolution, filtration, filling, sealing (vials, ampoules), sterilization, visual inspection, packaging, labeling and storage. Modern ways for prolongation of action injectable product. Depot pharmaceutical dosage forms – classification. Oily and viscous injectable solutions, injectable emulsions, injectable suspensions, tablets and implants. Stability of injectable medicine. Bioavailability of injectable medicine 3. Perfusions. Definition and classification, differences from injectable solutions. Primary pharmaceutical containers – control and preparation of glass bottle. Elastomers. Vial and bag plastomers pharmaceutical containers –properties. Perfusions manufacturing – the phases of the manufacturing process. Rooms for manufacturing. Perfusion which ensure the hydro-ionic balance examples; perfusions for stabilization of the acid – basic balance examples; energetic perfusions – examples; perfusions that substitute plasma examples; perfusions for		12 hours 4 hours

total and partial parenteral nutrition 4. Ophtalmic pharmaceutical dosage forms. Definition and classification. Ophtalmic route. Advantages and disadvantages. Sterility, isotonicity, isohydry, tolerance and contact time prolongation of eye drops.Formulation, drug substances, vehicles, viscous agents, preservatives for eye drops. Rooms for pharmacy manufacturing. Containers type for eye drops packaging. Viscous ophthalmic solutions, oily ophthalmic solutions. Phases of manufacturing process of ophthalmic solutions in pharmacy and industry. Ophthalmic suspensions. Ocular baths. Bioavailability of eye drops 5.Sera and vaccines. Definition, classification, manufacturing and uses 6. Radiopharmaceutical dosage forms. Definition, classification, manufacturing and uses	Lecture; powerpoint presentation; projector	4 hours 0.5 hours 0.5 hours
2nd Semester		
1. Pharmaceutical dosage forms as heterogeneous dispersions. Colloidal solutions (lipophil and hydrophil) - mucilages- preparation and quality control. The rheology of fluids and ointments pharmaceutical dosage forms	Lecture; powerpoint presentation; projector	4 hours
2. Emulsions. Classification, formulation, ingredients. Emulsifiers: classification, mechanisms of action. Manufacturing technology of emulsions; industrial equipment, quality control, examples of emulsions for internal and external use 3. Suspensions. Classification; flocculated and unflocculated suspensions Formulation of suspensions: ingredients, suspending agents- classification, mechanisms. Manufacturing technology, industrial equipment, conditioning, quality control. Dried suspensions 4. Aerosols. Formulation, conditioning devices, industrial manufacturing, quality control 5. Ointments. Mechanism of skin permeation and factors influencing absorption of pharmaceutical substances from ointments. Formulation of ointments. Excipients for ointments- ointment bases; manufacturing technology and equipment, conditioning of ointments. Rheology control, cutaneous tolerance, release of pharmaceutical substances from ointments 6. Transdermal therapeutical systems. Drug release from transdermal therapeutical systems 7. Suppositories. Formulation, suppository bases, other ingredients. Manufacturing technology, characteristic, quality control, conditioning		5 hours 5 hours 2 hours 6 hours 2 hours 4 hours
Bibliography 1. Michael AE. *Pharmaceutics – the science of dosage form design.* Livingston, 2010. 2. Allen LV, Popovici NG, Ansel HC. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. New York: Ed. Lippincott Williams & Wilkins, 2011. 3. *** *Remington – The Science and Practice of Pharmacy*, 21st Edition. New York: Ed. Lippincott Williams & Wilkins, 2011.		
8.2. Seminar / Practical lessons	**Teaching Methods**	**Observations**
1st Semester		

1. Extractive pharmaceutical forms. Aqueous extractive solutions; decoctions; tinctures; pharmaceuticals extracts 1.1. Extractive pharmaceutical forms. Formulation, raw materials, manufacturing process. Solutiones extractivae aquosae – 10th Romanian Pharmacopeia – Lini semen and Altheae radix macerates. Chamomillae flos and Tiliae flos infusion. Magistral formulas – examples 1.2. Valerian, Pectoral Species, Digitalae and Ipeca infusions. Magistral formulas – examples 1.3. Chinae cortex and Primulae radix decoctions. Tincturae – 10th Romanian Pharmacopeia. Tinctures prepared by maceration – Tinctura Aurantii pericarpii, Tinctura Opii; Tinctures prepared by percolation - Tinctura Aconiti, Tinctura Belladonnae, Tinctura Menthae 1.4. Tinctures prepared by dissolution, dilution and mixing –Tinctura Balsamum Tolutanum, Tinctura Anticholerina. Extracta – 10th Romanian Pharmacopeia. Pharmaceutical extracts – exemples: Extractum Frangulae Fluidum, Extractum Valerianae Spissum, Extractum Belladonnae Siccum. Ticiverol®, Romazulan®. Magistral formulas – exam		14 hours
2. Sterile pharmaceutical dosage forms. Injectable solutions 2.1. Sterile pharmaceutical dosage forms. Injectabilia – 10th Romanian Pharmacopeia. Formulation, raw materials, manufacturing rooms, pharmaceutical containers. Injectable solution of Natrii Chloridum 2.2. Injectable solutions – the phases of manufacturing process. Injectable solutions of – Calcii Chloridum, Magnesii Sulfas, Calcii Bromidum, Calcii Gluconas and Glucosum 2.3. Injectable solutions of – Atropinii Sulfas, Procaini Hydrochloridum, Papaverini Hydrochloridum, Epinephrini Hydrochloridum, Morphini Hydrochloridum, Acidum Ascorbicum, Riboflavin Phosphate and Phytomenadione 2.4. Injectable solutions of – Phenobarbital, Progesterone, Sodium Citrate, Digoxin. Sterile suspensions and powders – Hydrocortisone Injectable Suspension, Penicilina G, Moldamin®, Calcii Glutamate	Essays, books of practical work.	14 hours
3. Sterile pharmaceutical dosage forms. Perfusion solutions 3.1. Perfusions. Infundibilia – 10th Romanian Pharmacopeia. Formulation, raw materials, pharmaceutical containers. Manufacturing rooms and the phases of manufacturing process. Perfusion which ensure the hydro-ionic balance of human body – perfusion of Natrii Chloridum, Kalii Chloridum and Natrii Chloridum, Ringer' s solution 3.2. Perfusions for stabilization of the acid – basic balance: Arginini Hydrochloridum, Natrii Hydrogenocarbonas, Natrii Lactatis, Natrii Chloridum compounded with Natrii Lactates,		12 hours

Tromethamol 3.3. Energetic perfusions of – Glucosum, Fructosum, Sorbitolum. Intralipide. Drug perfusions – Manitolum, Metronidazolum, Tinidazolum. Perfusions that substitute plasma – Dextrans; Solutions for peritoneal dialysis and hemodialysis 4. Sterile pharmaceutical dosage forms. Ophtalmic solutions 4.1. Ophtalmic dosage forms. Oculoguttae – 10th Romanian Pharmacopeia. Formulations, raw materials, manufacturing rooms and the phases of manufacturing process in pharmacy and industry, containers. Eyes drops of: Resorcinolum, Atropini Sufate, Pilocarnini Nitrate, Argenti Nitrate. Doseatropine®, Mydrum®, Timoptic® 4.2. Eye drops of Zinc Sulfate, Eye drops with antibiotics: Chloramfenicol, Ampicillin Sodium, Neomycin Sulfate, Bacitracin, Polimixin B, Rifampicin, Sificetina®, Gentosept® 4.3. Eye drops with vasoconstrictor drug substances – Efedrinum Hydrochoricum, Proculin®; with anesthetics, vitamins. Eye drops for diagnosis, eye drops of Argint' colloid salts. Wash ophthalmic solutions. Powders for eye drops – Indocollyre. Viscous ophthalmic solutions. Artificial tears; Contact lens solutions, Lacrisifi®	Essays, books of practical work.	16 hours
2nd Semester		
1. Labour protection. Lyophobic colloidal dispersions with colloidal silver salts. Colloidal dispersions in water with cationic dyes 2. Hydrophilic colloidal dispersions in water with different polymers such as: acacia gum, tragacanth, methylcellulose, sodium carboxymethylcellulose, polyvinyl alcohol, polyvidone, carbomer, sodium alginate 3. The rheology of hydrophilic colloidal dispersions. Emulsions. Emulsions for oral administration – emulsion with liquid paraffin, emusion with castor oil, emulsion with sunflower oil (FRX)		4 ore 4 ore 4 ore
4. Emulsions for external use – emulsions for nasal mucosa, topical emulsions. Quality assurance and control of emulsions 5. Suspensions. Suspensions for oral administration – with long-acting drugs such as phenobarbital; suspension with terpin hydrate, barium sulfate 6. Suspensions for oral administration with antacid active substances. Reconstitutable suspensiones. Quality assurance for reconstitutable suspensions 7. Suspensions for external use – with sulphur, zinc oxyde, talc. Quality assurance and control for suspensions 8. Ointments. Fats and fixed oil bases. Absorption bases. Emulsifying bases (FRX) 9. Water-soluble bases (FRX) 10. Different types of oitmens. Quality assurance and control for ointments 11. Sterile ointments – Ophtalmic ointments; ointments	Essays, books of practical work.	4 ore 4 ore 4 ore 4 ore 4 ore 4 ore 4 ore

with antimicrobial. Ointments for mucosal sufaces 12. Cosmetic ointments. Transdermal delivery system 13. Suppositories. Method of manufacture by hand molding 14. Suppositories. Method of manufacture by authomatic machine (pour molding). Quality assurance and control for suppositories	Essays, books of practical work.	4 ore 4 ore 4 ore

Bibliografie / Bibliography

1. Michael AE. *Pharmaceutics – the science of dosage form design.* Livingston, 2010.
2. Allen LV, Popovici NG, Ansel HC. *Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems*. New York: Ed. Lippincott Williams & Wilkins, 2011.
3. *** *Remington – The Science and Practice of Pharmacy*, 21st Edition. New York: Ed. Lippincott Williams & Wilkins, 2011.

9. The agreement between the course contents and the expectations of the representatives of the epistemic communities, professional associations and employers in the field related to the program

Updating the analytical program in order to gain theoretical and practical knowledge necessary to achieve modern formulations used in current treatments, both at the level of industrial and magistral.

10.Assessment

Activity	10.1. Assessment criteria	10.2. Assessment methods	10.3. Percentage of the final grade
10.4. Course	Answers to written examination.	Written exam (final examination)	50%
10.5. Seminar / Practical lessons	Periodic testing by control papers.	Written papers	10%
	Final answers to practical laboratory work.	Examination	40%
Minimal standard of proficiency			
• Promotion with minimum 5.			