COURSE DATA

Data Subject	
Code	34084
Name	Pharmaceutical Technology II
Cycle	Grade
ECTS Credits	6.0
Academic year	2018 - 2019

Study (s)

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Faculty of Pharmacy and Food Sciences	5	First term
1211 - D.D. in Pharmacy-Human Nutrition and Dietetics	Faculty of Pharmacy and Food Sciences	5	First term

Subject-matter

Degree	Subject-matter	Character
1201 - Degree in Pharmacy	16 - Pharmaceutical technology	Obligatory
1211 - D.D. in Pharmacy-Human Nutrition and Dietetics	1 - Asignaturas obligatorias del PDG Farmacia-Nutrición Humana y Dietética	Obligatory

Coordination

Name	Department
MELERO ZAERA, ANA	134 - Pharmacy and Pharmaceutical Technology

SUMMARY

The student through this course will learn the theoretical background and acquire practical skills that will enable the design, development and control of dosage forms intended for administration other than the oral route.

This implies the theoretical and practical knowledge of the main operations involved in the manufacture of such forms, excipients to be used, controls to accomplish and procedures to ensure the quality of the dosages forms produced.

The study will cover both conventional and modified release dosage forms. It will also include the packaging material and its peculiarities.

PREVIOUS KNOWLEDGE

Relationship to other subjects of the same degree

There are no specified enrollment restrictions with other subjects of the curriculum.

Other requirements

Knowledge of Pharmaceutical Technology I, Biopharmaceutics and Pharmacokinetics and Physical-Chemistry is required.

OUTCOMES

1201 - Degree in Pharmacy

- To develop communication and information skills, both oral and written, to deal with patients and other health professionals in the center where they carry out their professional activity. To promote the capacity of work and collaboration in multidisciplinary teams and those related to other health professionals.
- Pharmacy and Pharmaceutical Technology - Design, optimization and elaboration of pharmaceutical dosage forms guaranteeing their quality, including formulation and drugs quality control, drugs compounding and large scale compounding.
- Pharmacy and Pharmaceutical Technology Usage of the quality control of sanitary, dermo-pharmaceutical and cosmetic products and conditioning materials.
- Pharmacy and Pharmaceutical Technology- knowledge of the physicochemical and bio-pharmaceutic properties of the active principle ingredient and excipients as well as the possible interactions.
- To be able to identify the factors that influence the absorption and disposition of drugs depending on their route of administration

LEARNING OUTCOMES

The student will acquire knowledge of:

- Basic operations and technological processes for the preparation and control of sterile dosage forms, as well as the factors that influence the quality

- Methods for the design, optimization and development of dosage forms intended for administration by routes other than oral, ensuring quality for industrially manufactured drugs, individual formulations and officinal preparations.

- Biopharmaceutical Implications of the physical-chemical properties of active ingredients and excipients, as well as possible interactions between them.

The student will acquire during the course the following skills:

- Management of documentation on excipients and active ingredients
- Management of equipment and operations needed for drug development
- Application of the computer-aided simulation methodology in various stages of drug development,
- Analysis of problems of development, their solution and proposed operating alternatives.

DESCRIPTION OF CONTENTS

1. Parenteral and ophthalmic dosage forms

1. Key concepts on sterilization and sterile environment work
2. Lyophilization: rationale, development and control of key processes
3. General characteristics of parenteral preparations
4. Injection of small and large volume: technology requirements and biopharmaceutical constraints
5. Dosage forms for ophthalmic administration: general characteristics and suitability for therapeutic target.

2. Dosage forms to be administered to the lung and mucosae

6. Sprays and other preparations for inhalation: biopharmaceutical considerations. Devices. Preparation technology and excipients.
7. Nasal dosage forms and otologic application: biopharmaceutical considerations. Preparation technology and excipients.
8. Rectal dosage form: biopharmaceutical considerations. Preparation technology and excipients. Packaging material.
9. Dosage forms of vaginal administration, urethral and uterine biopharmaceutical considerations. Preparation technology and excipients.

3. Dosage forms to be administered on the skin

10. Semi-solid preparations: type of excipients, physical-chemical properties and stability controls and requirements. Formulation of emulsions and microemulsions. Preparation of patches. Industrial and pilot plant facilities. Selection of dosage forms.
11. Pharmaceutical forms intended application on the skin with purpose topical and systemic as a vehicle. Biofarmacèutiques considerations. Packaging material.

4. Controlled release strategies and targeting

12. The process of release from pharmaceutical forms. Mechanisms and control parameters. Biopharmaceutical considerations. Factors involved. Strategies to control release dosage forms designed to routes other than oral.

13. Targeting of drugs. Advantages and disadvantages. Biopharmaceutical considerations. Problems and solutions provided by the pharmaceutical technology. Packaging materials. Stability.

5. Quality in the pharmaceutical industry

14. Drug packaging . Primary and secondary packaging. Packaging materials . Packaging operations. Quality management of packaging materials.

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	30,00	100
Laboratory practices	16,00	100
Seminars	5,00	100
Computer classroom practice	4,00	100
Tutorials	3,00	100
Development of group work	5,00	0
Development of individual work	10,00	0
Study and independent work	65,00	0
Preparing lectures	5,00	0
Resolution of online questionnaires	5,00	0
TOTAL	**148,00**	

TEACHING METHODOLOGY

The fundamental concepts, and the physico-chemical and biopharmaceutical bases on the subjects treated will be taught by the teacher in the form of a master's lesson, in face-to-face classes. In each thematic block, the methodology of problem solving will be used to promote the decision making about the appropriateness and peculiarities of different formulations. Finally, at the end of the study of each one of the blocs, several practical situations that will be presented, will be solved in the seminars by the students. The tutorials will be used to supervise and dynamize these works. Emphasis will be placed on the use of TICs. At the end of each theoretical block an online reinforcement control will be carried out to promote the continued study of the subject. The questions will be true / false or multiple answer. The participation will be optional and will be evaluated in the final marks.

The laboratory practices will consist of 16 hours in which will be studied and elaborated forms and pharmaceutical operations, as well as the handling of the legal documentation in compounding. The teaching methodology will be the problem solving. To be able to participate in the practices a previous minimum knowledge will be required, which will be available to students through the virtual classroom. The control of this knowledge will be done through an online test, which can be repeated until the necessary knowledge is obtained.

The computer classroom practices will focus on mathematical aspects of the different kinetics of transfer and penetration of pharmaceutical forms of administration on the skin.

EVALUATION

The use of the different activities will be evaluated by written tests. 75% of the final mark will correspond to the evaluation of theoretical knowledge and seminars and the complementary documentation imparted through the TICs. Participation in the continuous evaluation is optional, but will account for 10% of the final mark. 15% of the total mark will correspond to the practical activities presented of the laboratory sessions (10%) and the exercises presented in the computer practices (5%). Appart from the subject contents, considerations such as the ability to work in teams, progress in the use of language characteristic of matter and critical spirit, among others will be taken into account.

It is an essential requirement to be able to approve the subject in the first call, to have participated in at least 80% of the programmed activities. To pass the subject, each part must be passed separately.

According to the Pharmacy CAT guidelines (14 May 2012), those students who do not present themselves to the theory test at the first call, but have participated and have a note in any of the teaching activities carried out (seminars, tutorials) will be qualified as non-presented, but if they still do not take part in the theory test, the final mark that will appear in the second call will take into account the grades obtained in the different activities and, consequently, may appear as a fail.

REFERENCES

Basic

- Aulton M
  Farmacia: la ciencia del diseño de las formas farmacéuticas
  Elsevier, 2004

- Vila Jato, J.L.
  Tecnología Farmacéutica. Vol I y II: aspectos fundamentales de los sistemas farmacéuticos y operaciones básicas.
  Ed. Síntesis, 1997.
- Lachman L, Lieberman H. Kanig J.
  The Theory and Practice of Industrial Pharmacy.
  Ed. Lea and Febiger. Filadelfia.

Additional

- M.J. Rathbone, J. Hadgraft, M. S. Roberts and M. E. Lane Eds.
  Modified-Release Drug Delivery Technology. Vol 1 and 2
  Drugs and the pharmaceutical sciences. Vol 183 and 184.
  Informa Healthcare, 2008
- Fielder Encyclopedia of Excipients for Pharamceuticals, Cosmetics and Related Areas, 6th Edition, vol 1 y 2
  Editio Cantor Verlag, 2007
- Sarfaraz K. Niazi, Ed
  Handbook of Pharmaceutical Manufacturing Formulations.
  Vol 6. Sterile Products
  Vol 4. Semisolid Products
  CRC Press, 2004