COURSE DATA

Data Subject

Code	34082
Name	Pharmaceutical Technology I
Cycle	Grade
ECTS Credits	12.0
Academic year	2017 - 2018

Study (s)

Degree	Center	Acad. year	Period
1201 - Degree in Pharmacy	Faculty of Pharmacy and Food Sciences	4	Annual
1211 - D.D. in Pharmacy-Human Nutrition and Dietetics	Faculty of Pharmacy and Food Sciences	4	Annual

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
NACHER ALONSO, AMPARO	134 - Pharmacy and Pharmaceutical Technology

SUMMARY

Active molecules can not be directly administered into the human body, they have to be conditioned in a formulation (dosage form) that includes different excipient substances. Common pharmaceutical dosage forms are tablets, capsules, injections. A medicament is a dosage form conditioned in its final container. Medicaments are usually produced at industrial level and can be presented in different dosage forms, with different compositions, depending on the patient group that is going to use them. Some particular situations require an individualized presentation of the drug, previously prescribed by doctors, and prepared by the pharmacist.

Medicines elaboration obeys to quality criteria in order to guarantee that the products obtained are safe, effective and stable.

The subject Pharmaceutical Technology I covers the basic physico-chemical principles of stability and properties of solids and liquid systems, aspects of preformulation that have to be considered to obtain pharmaceutical dosage forms of high quality, as well as the different procedures and methods that can be used to prepare oral pharmaceutical dosage forms that have the criteria aforementioned.

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 Physical-Chemistry, Biopharmaceutics and Pharmacokinetics.

OUTCOMES

1201 - Degree in Pharmacy

- 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- knowledge of the physicochemical and bio-pharmaceutic properties of the active principle ingredient and excipients as well as the possible interactions.
- Pharmacy and Pharmaceutical Technology - knowledge of the stability of the active principle ingredient and pharmaceutical dosage forms as well as the study methods.
- Pharmacy and Pharmaceutical Technology knowledge of the basic operations and technological processes related with the production and control of drugs.
- To be able to identify the factors that influence the absorption and disposition of drugs depending on their route of administration

LEARNING OUTCOMES

- Proper use of the scientific terms of the matter.
- Relate the concepts studied in Pharmaceutical Technology with those from other subjects
- Knowledge of the factors conditioning drug efficacy and stability
- Knowledge of the different excipient groups (characteristics and functions) required in oral dosage forms
- Knowledge of the methods that can be used for obtaining oral dosage forms
- Selection of dosage forms depending on pathologies and population groups

- Selection of the methods and elaboration processes of oral dosage forms according to the active molecule properties and objectives of the formulation
- Knowledge of quality controls required during the elaboration process (for intermediate products and processes) and on final products.
- Packaging and conditioning material required depending on the pharmaceutical dosage form. Quality controls applicable.
- Understanding of publications of the subject.

DESCRIPTION OF CONTENTS

1. Introduction

1. Introduction to Pharmaceutical Technology. Concept and objectives of the matter. Contents structure. Important definitions. Especial medicaments. Homeopathic formulations. References
2. Pharmaceutical dosage forms design and optimization: preformulation. Dosage forms. General considerations. Technological, physico-chemical and biopharmaceutical aspects. Compatibility studies (active drug-excipients). Dosage forms optimization. Parameters to evaluate
3. Drug delivery studies. Relevance of drug delivery. Methods in dissolution tests. Dissolution rate. Kinetical models. Dissolution parameters. in vitro- in vivo correlations

2. Pharmaceutical Systems: basic principles

4. Powders: characterization. Particle size: statistical diameters. Size distribution curves. Granulometric analysis. Particle shape: determination. Specific surface and porosity.
5. Powder rheology. Factors conditioning flux properties of powders. Evaluation of powder properties
6. Pharmaceutical solvents. Water for pharmaceutical products and uses. Classification and specifications. Methods for obtaining different kinds of water. Controls. Storage and distribution. Other solvents used in pharmaceutical products.
7. Solutions. Disperse systems. Classification. Ideal and non ideal solutions. Solubility. Factors conditioning solubility and dissolution rate.
8. Hydro-solubilization of drugs. Methods to increase water solubility of drugs: pH control, co-solvents, complexes, ciclodextrines, micelle solubilization, solid dispersions, other methods.
9. Heterogeneous disperse systems: physico-chemical basis. Interface phenomena. DLVO theory. Disperse systems stabilization. Rheology of disperse systems.
10. Colloids. Definition. Classification. Kinetic, optic and electric properties. Formulation: critical aspects. Stability. Hydrocolloids: types and pharmaceutical uses.
11. Suspensions. Concept and applications. Formulation. Physical stability. Compounding of suspensions. Characterization and controls.
12. Emulsions. Definition and classification. Emulsifying agents: classification, properties and uses. Stability: creaming, sedimentation, coalescence. Compounding. Equipments: emulsifiers and homogenizers. Multiple emulsions. Microemulsions. Characterization and controls. Applications

3. Fundamental operations in compounding

13. Pulverization. Size reduction. Relevance and objectives. Fundamentals of the process. Energy calculations. Equipments for size reduction: types and factors for selection.
14. Size separation. Sieving: range of uses. Sedimentation: fundamentals. Elutriation. Apparatus and efficacy.
15. Mixing. Mixing of powders. Types of mixtures: random and ordered mixtures. Mechanisms of mixing. Mechanisms of segregation. Degree of mixing. Sampling and homogeneity control. Mixing equipments: types and selection criteria. Semisolid mixing equipments.
16. Filtration. Concept and objectives. Mechanisms of filtration. Theoretical aspects. Filters and coadjutants. Filters characterization. Filtration equipment. Control of the process. Other techniques to separate solids from liquids.
17. Desiccation. Drying: concept and objectives. Psychometric. Mechanisms of solids desiccation. Desiccation kinetics. Conduction, convection and radiation for desiccation. Equipments for solid drying.
18. Microencapsulation. Concept and objectives. Materials for microencapsulation. Microencapsulation techniques. Microcapsules characterization. Encapsulation efficacy. Pharmaceutical applications of microencapsulation. Assays and controls.

4. Stability

19. Drug stability I. Relevance of stability in the therapeutical activity of drugs. Parameters that condition stability. Physical alterations. Chemical alterations. Biological alterations. Preservatives.
20. Drug stability II. Drug stability in solution: Kinetics of chemical degradation. Arrhenius equation. Accelerated inestability studies. Preserving controls (real time stability). Period of validity and expiration date. Drug stability in the solid state. Kinetics of degradation. Influence of temperature and humidity: theory of layer moist. Decomposition in the presence of water vapour. Biopharmaceutical expiration.
21. Drug stability III. Harmonization of the stability studies. ICH guidelines for the realization of stability studies of new drugs and pharmaceuticals. Batch selection. Test procedures. Specifications. Storage Conditions

5. Oral pharmaceutical dosage forms

22. Liquid pharmaceutical forms for oral administration. Generalities and biopharmaceutical aspects. Solutions, suspensions, emulsions: formulation, compounding, tests and controls. Powders for extemporaneous preparation of solutions or oral suspensions, tests.
23. Excipients for solid oral dosage forms. Excipients: diluents, adsorbents, binding agents, glidants, lubricants, disintegrating agents, moistening agents and others. Direct compression excipients.
24. Granules. Granulation objectives. Wet and dry granulation. Extrusion and spheronizing; other techniques. Criteria to choose excipients in granulation. Rheological properties of granules. Granules resistance and friability. Types of granules. Assays.
25. Capsules. Shells: Materials and manufacture. Soft and shelled capsules: materials, compounding and elaboration methods. Dosing systems for powders: bench-scale and industrial-scale filling. Complementary processes: closing, impression, sealing. Assays and controls.
26. Tablets. General characteristics. Processes of tablet production. Physics of compression. Properties of compressed tablets. Eccentric press and rotary tablet press. Problems during compression: adjusting

and scale transposition. Controls during compression: assays and controls on tablets.
27. Special tablets. Effervescent tablets. Soluble and dispersable tablets. Buccal and sublingual tablets. Multilayer tablets. Excipient selection and compounding. Assays and controls.
28. Coating. Objectives. Coating techniques: Sugar, press and film coating. Materials and process details. Functional coatings: objectives and materials. Assays and controls.
29. Modified release dosage forms . Advantages and inconveniences. Systems available to control delivery. Assays and controls.

6. Laboratory practices

PRACTICE 1. BASIC OPERATIONS: SIZE REDUCTION AND MIXING OF POWDERY SOLIDS

PRACTICE 2. GRANULATION AND ANALYSIS OF THE CHARACTERISTICS OF GRANULATES
2.1. Preparation of granulates
2.2. Particle size analysis
2.3. Rheological study: flow capacity

PRACTICE 3. HETEROGENEOUS DISPERSE SYSTEMS
3.1. Suspensions. Wetting and flocculation principles
3.2. Emulsions. Calculation of HLB

PRACTICE 4. MANUFACTURE AND CONTROL OF TABLETS
4.1. Preparation of granules for compression
4.2. Compression process
4.3. On-site controls
4.4. Finished product testing
a) Uniformity of dosage units: mass variation
b) Uniformity of content of active ingredient
c) Friability test (abrasion resistance) of uncoated tablets
d) Mechanical strength resistance of tablets
4.5. Dissolution test for solid dosage forms

PRACTICE 5. PREPARATION AND CONTROL OF HARD GELATIN CAPSULES
5.1. Hard capsule preparation
5.2. Controls. Uniformity of dosage units: mass variation
5.3. Gastro-resistant coating
5.4. Gastro-resistance efficacy test

PRACTICE 6. MICROENCAPSULATION
6.1. MICROENCAPSULATION by simple coacervation
6.2. MICROENCAPSULATION by complex coacervation

PRACTICE 7. SOLUTIONS
7.1. SIMPLE SUCROSE SYRUP
7.2. Controls: determination of the density of the simple syrup

PRACTICE 8. CHEMICAL STABILITY IN SOLUTION. INFLUENCE OF pH AND TEMPERATURE.

7. Computer practices

DISSOLUTION RATE TESTING

PRACTICE 1. First- order and cube root law dissolution kinetics
PRACTICE 2. Comparison of dissolution profiles
PRACTICE 3. Selection and adjustment of the kinetic model

WORKLOAD

ACTIVITY	Hours	% To be attended
Theory classes	60,00	100
Laboratory practices	28,00	100
Seminars	10,00	100
Computer classroom practice	7,00	100
Tutorials	6,00	100
Study and independent work	100,00	0
Readings supplementary material	15,00	0
Preparing lectures	25,00	0
Preparation of practical classes and problem	20,00	0
Resolution of case studies	20,00	0
TOTAL	**291,00**	

TEACHING METHODOLOGY

Theory classes.- Attending classes aimed at the presentation by the teacher of the most important concepts and contents of each unit in order for the student to acquire the knowledge related to the subject. Student participation will be encouraged.

Tutorials.- Students will attend tutorials in reduced groups. In these, the teacher will evaluate the learning process of students in a global way. Equally, tutorials will serve to resolve all the doubts that have arisen along the classes and will guide students on the methods of work more useful for the resolution of the problems they may have. The teacher can raise questions and specific problems according to the needs of the students.

Classroom practical classes: seminars.- The seminars will be used to enhance teamwork and improve oral presentation, by conducting theoretical or practical works to supplement the skills acquired in the theory classes, and also to design another complementary activities of different types (resolution of case studies,

management of scientific literature, discussion of current issues).

Laboratory practices.- Practical classes are designed to consolidate the theoretical knowledge, by means of its practical application. The teacher will present the aims, inform about the proper material handling, will supervise that the work is properly done and will help the interpretation of the results.

Computer classroom practice.- The activities will be carried out in computer classrooms. These practices are related to the resolution of practical cases by using computer systems. They are intended to complement and/or consolidate the theoretical knowledge, by means of its practical application.

EVALUATION

	Evaluation system	Evaluation criteria	% calificat
Theory evaluation	Written exam: Short questions, multiple choice questions and problems solving	-Precise answers -Clear concepts -Consistent reasoning -Proper presentation	80
Laboratory practices evaluation	Written exam: short questions and problems solving Control of assistance	A: -Teamwork and participative attitude -Skill in laboratory work -Work with order and cleanliness -Proper disposal of waste- B: -Successful completion of practice -Reflective attitude to the results -Order and clarity in the resolution of the practice -Mandatory attendance at all sessions	15
Computer practices evaluation	Written exam: short questions and problems solving Control of assistance	- Teamwork and participative attitude - Successful completion of practice -Reflective attitude to the results -Order and clarity in the resolution of the practice -Mandatory attendance at all sessions	3

Practical classes (seminars) evaluation	Control of assistance		2

Theory evaluation system: written exam.

At the end of the first semester an exam corresponding to the explained matter will take place. If the obtained mark is equal to or greater than 5, it is considered that the matter has been approved in the academic year. This grade is saved until July.

At the end of the second semester, an exam corresponding to the explained matter in this period of time will take place for those students who have passed the first exam. Total matter of the course (final exam) will take place for those students who had not passed the first exam, had not attended or are interested in improving the obtained mark.

The final grade will be that obtained in the final exam or the average of the two parts exam, as long as the mark of each part is equal to or greater than 5.

Practices evaluation system

Laboratory practices: Mandatory attendance at all practical sessions, a written exam of the practices will take place. 5 % of the final laboratory practices mark will correspond to the criteria specified at the A section in laboratory practices evaluation, and 95 % to the those specified at the B section.

Computer classroom practices: Mandatory attendance at all practical sessions, a written exam of the practices will take place.

If a student fails the laboratory and/or computer practices exam, which is performed at the end of the practical sessions, the new practical exam will be on June and/or July final exam (two opportunities per academic year). This exam will be convened and evaluated by the responsible teachers.

If the obtained mark in each of the practices (laboratory and computer) is equal to or greater than 5, it is considered that the matter has been approved in the academic year.

When the subject is suspended, the grade obtained in the block of practices can be maintained during the subsequent academic year.

Practical classes (seminars) evaluation

Mandatory attendance at the 80% of the practical classes in order to obtain the 2% in the final grade of the subject.

When a student does not submit to the theory exam at the first regular call for the academic year but has been evaluated in any of the rest educational activities (laboratory practice, informatics practices, tutorials,...) the qualification report will be not attended. However, if in the second call, the student does not attend the theory exam, the qualification report will be failed, and the numerical will be calculated according to the percentages allocated to each of the activities carried out. In summary: in second call not

attended will qualify only students who had not attended any of the activities integrating the subject.

REFERENCES

Basic

- Vila Jato, J.L. Tecnología Farmacéutica.Vol I: aspectos fundamentales de los sistemas farmacéuticos y operaciones básicas. Ed. Síntesis, 1997
- Vila Jato, J.L. Tecnología Farmacéutica.Vol II: Formas Farmacéuticas. Ed.síntesis 1997
- Aulton M.E. La ciencia del diseño de las formas farmacéuticas. Ed. Elsevier, 2004
- Martínez Pacheco R. Tratado de tecnología Farmacéutica. Vol I: sistemas farmacéuticos. Ed. Síntesis, 2016
- Martínez Pacheco R. Tratado de tecnología Farmacéutica. Vol II: operaciones básicas. Ed. Síntesis, 2016
- Lozano M. Manual de Tecnología Farmacéutica. Ed. Elsevier, 2012

Additional

- Lachman L Lieberman H. Kanig J. The theory and Practice of Industrial Pharmacy. Ed. Lea and Febiger. Filadelfia, 1995
- Real Farmacopea Española
- Formulario Nacional. Ministerio de Sanidad y Consumo. AGEMED, 2007.
- Swarbrick J., Boylan JC. Encyclopedia of Pharmaceutical Technology. Marcel Dekker Inc, New York (1989-2004)