Teaching guide

IDENTIFICATION DETAILS

Degree:	Pharmacy
Scope	Pharmacy
Faculty/School:	Experimental Sciences
Course:	INDUSTRIAL PHARMACY
Type:	Compulsory
ECTS credits:	3
Year:	4
Code:	2559
Teaching period:	Eighth semester
Subject:	Pharmaceutical Technology
Module:	Pharmacy and Technology
Teaching type:	Classroom-based
Language:	Spanish
Total number of student study hours:	75

SUBJECT DESCRIPTION

In this course, we want to address a series of knowledge that is basic in the daily operation of a pharmaceutical laboratory, and that, assuming the knowledge derived from the subject of Pharmaceutical Technology, complete it with a knowledge of how a laboratory is designed and with what criteria should be established the processes to be addressed in each of its areas.

The criteria with which the different departments of a laboratory are designed are explained: Production, Quality Control, Warehouses, Engineering and Maintenance, etc. In-depth knowledge of the facilities and services that must be provided to the laboratory so that all equipment and processes can function properly. In addition, the

validation processes of facilities, equipment, processes and cleaning that will be carried out there are addressed. Production Management topics are covered, such as Production Planning. Calculation of equipment requirements. Calculation of personnel requirements. Nowadays, this series of knowledge is considered basic in the industry and is intended to introduce the student to a practical vision of today's modern laboratory.

GOAL

The objective of this course is that the student, apart from knowing how drugs are manufactured, knows the design requirements of the different areas of a laboratory according to the standards of correct manufacturing and how these influence the productivity, quality and safety of the drugs they manufacture. The student with the knowledge acquired must present a report in which he designs a laboratory and, given manufacturing needs, can follow the steps of designing departments, calculating the needs of equipment and people and validating facilities, equipment and processes as they are carried out in the current pharmaceutical industry.

PRIOR KNOWLEDGE

Knowledge of Pharmaceutical Technology I and II

COURSE SYLLABUS

THEORETICAL PROGRAM: 1. Industrial drug manufacturing: the pharmaceutical laboratory. Design of a pharmaceutical plant. Buildings. Distribution. Organization. Warehouses. Types. General and special areas. Production. Design of facilities and equipment. Flow of people and materials. 2. Other areas: Quality Control. Installations. Special areas. Teams. 3. The pharmaceutical laboratory. Services: Air. Environmental conditions. General aspects of air and air conditioning. Special aspects: special areas, areas of controlled humidity. 4. Services: water. Treatment. Types. Scheme of industrial facilities. 5. Services: Pressure and vacuum. Cooling, heating. Industrial steam. 6. Production Management. Planning. Batch size. Yields. Labor needs. Capabilities. 7. General concepts of validation. Master Validation Plan. Validation of equipment and production processes. Validation of non-sterile processes: manufacture of solids, semisolids and liquids. 8. Validation of sterile processes. 9. Validation of cleanings. Concept. Criteria. 10. Validation of computer systems. INTERNSHIP PROGRAM: 1.A Report will be presented that will consist of the Design of a Pharmaceutical Plant that will consist of the following headings: 1.1.- Introduction. Type of plant, choice of type of structure, pharmaceutical form to be made, etc. 1.2.- Justification for the choice of location. 1.3.-Facility design: - Description of the different departments. - Floor plans and general plans. 1.4 .- Manufacturing Process. Material flow. - Raw materials - Packaging material - Bulk or intermediate product. - Finished product. 1.5.- Flow of people. - Access to different departments. - Production personnel changes of clothing. 1.6.- Calculation of equipment and personnel needed for manufacturing. - Number of people per department - No. of equipment per department. 1.7 .- Air conditioning. - Air treatment - Filtration (Clean areas). - Overpressures. 1.8.- Water System. - Types of water - Treatments. 1.9.- Other types of services used. - Steam - Compressed air - Others. 1.10.- Master Validation Plan - Validation of installations - Validation of equipment - Validation of processes - Validation of cleaning - Validation of computer systems

EDUCATION ACTIVITIES

DETAIL OF THE TEACHING METHODOLOGY OF THE SUBJECT DESCRIPTION OF ATTENDANCE 1.- MASTER CLASS (2 AFP2): The teacher will present the theoretical aspects of the subject, for this purpose, supporting teaching materials will be used (photocopied documents that will be distributed in class or digitized that will be disseminated through the student portal). Acquisition of knowledge; prioritizes the transmission of knowledge by the teacher, requiring the student to prepare for prior preparation or subsequent study. 2.- EXERCISE AND PROBLEM CLASSES (4 AFP4): Practical classes consist of the preparation of a laboratory design report. Classes will be held on exercises and problems that help in the elaboration of the memory, in which students will have to prepare under the direction of the teacher, in order to present the results orally and submit them to debate.
In working groups, students will solve problems and questions derived from the theoretical contents presented in the master classes. In some cases, the work will be solved in the classroom while in others, the students will have solved the problems and issues that will be raised in the classroom. The application of knowledge and the ability to gather, interpret and judge relevant information and data are sought. It prioritizes the participation of students in the reasoned interpretation of the knowledge and sources of the study area, with the coordination of the teacher. 3.TUTORING (6 AFP6): Students will have time allotted for personalized tutoring to answer their particular questions. The tutoring schedule can be consulted in the degree coordinator and will be informed by the teacher at the beginning of the course.
DESCRIPTION OF NON-ATTENDANCE Reading and analysis of the bibliography. Consultation of documents distributed through the student portal. Preparation and preparation of work and exercises. Exam preparation.

DISTRIBUTION OF WORK TIME

TEACHER-LED TRAINING ACTIVITIES	INDIVIDUAL WORK
34 Horas	41 Horas

Cross Skills

To nurture an attitude of intellectual curiosity and a quest for truth in all areas of life.

LEARNING RESULTS

Know the basic operations and technological processes related to the development and control of medicines.

SPECIFIC LEARNING RESULTS

It develops basic knowledge about industrial drug manufacturing; design of pharmaceutical plants; validation of equipment, processes, cleaning; production management and expresses them in the prepared memory.

Design a laboratory with the following departments:
- Warehouse
- Production
- Quality Control
- Offices
- Maintenance

With:
a) definition of facilities
b) Definition of equipment
c) Definition of processes
d) Calculation of needs. Labor and equipment.
e) Capacity calculation
f) Validation of equipment, systems, processes and cleaning.

and it expresses them in the elaborated memory.

Demonstrates the ability to work independently, to locate up-to-date information on the subjects of study and to apply the knowledge acquired to practice.

LEARNING APPRAISAL SYSTEM

EVALUATION ACTIVITIES The exams will be face-to-face. DAILY ACTIVITIES AND EXERCISES (SE2:10%): Daily tasks and exercises will be developed by the student. ORDINARY FINAL EXAM (SE1:60%): The evaluation system will be continuous. In addition, the student will take a final written exam of the subject. The grades will be kept until the 2nd call. PRACTICAL EXAM (SE 3:25%) The practice exam will be the evaluation of the report of a laboratory that you must submit. In the grade of the ordinary call, the report must have been approved to count the other evaluations. PARAMETERS TO BE EVALUATED (PERCENTAGE): -Attendance to theoretical classes and attitude in class (SE 4:5%): To pass, it is necessary to attend a minimum of 80% of face-to-face classes, as well as to deliver 80% of the proposed activities and exercises. To pass the course, it is necessary to have obtained a minimum of 5 points on average between class work, the final exam and the memory. ALTERNATIVE EVALUATION SYSTEM, intended for repeat students who do not take advantage of the ordinary evaluation system because they cannot attend classes on a regular basis. Students in second or subsequent enrollment must contact the teacher to request to take advantage of this system. EXTRAORDINARY EXAM: The student who does not pass the subject in the ordinary call must take the final exam of the extraordinary call. The extraordinary practical exam will take place on the same day as the theory exam presenting the new report, if it were suspended in the ordinary call. In the qualification of the extraordinary call, the percentages established in the continuous evaluation will be applied. Students who enroll for the second or more times in a subject should contact the teacher to find out about the specific evaluation criteria in their case. The evaluation system in this extraordinary exam will be as follows: - Written test: 50% - Final work: 50% NOTE: Plagiarism, as well as the use of illegitimate means in evaluation tests, will be sanctioned in accordance with those established in the Evaluation Regulations and the University's Coexistence Regulations.

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ETHICAL AND RESPONSIBLE USE OF ARTIFICIAL INTELLIGENCE

1.- The use of any Artificial Intelligence (AI) system or service shall be determined by the lecturer, and may only be used in the manner and under the conditions indicated by them. In all cases, its use must comply with the following principles:
a) The use of AI systems or services must be accompanied by critical reflection on the part of the student regarding their impact and/or limitations in the development of the assigned task or project.
b) The selection of AI systems or services must be justified, explaining their advantages over other tools or methods of obtaining information. The chosen model and the version of AI used must be described in as much detail as possible.
c) The student must appropriately cite the use of AI systems or services, specifying the parts of the work where they were used and describing the creative process followed. The use of citation formats and usage examples may be consulted on the Library website(https://www.ufv.es/gestion-de-la-informacion_biblioteca/).
d) The results obtained through AI systems or services must always be verified. As the author, the student is responsible for their work and for the legitimacy of the sources used.
2.- In all cases, the use of AI systems or services must always respect the principles of responsible and ethical use upheld by the university, as outlined in the Guide for the Responsible Use of Artificial Intelligence in Studies at UFV. Additionally, the lecturer may request other types of individual commitments from the student when deemed necessary.
3.- Without prejudice to the above, in cases of doubt regarding the ethical and responsible use of any AI system or service, the lecturer may require an oral presentation of any assignment or partial submission. This oral evaluation shall take precedence over any other form of assessment outlined in the Teaching Guide. In this oral defense, the student must demonstrate knowledge of the subject, justify their decisions, and explain the development of their work.

BIBLIOGRAPHY AND OTHER RESOURCES

Basic

SALAZAR MACIÁN RAMÓN INDUSTRIAL VALIDATION 1999