

Course Unit	Pharmaceutical biotechnology	Field of study	Biology and biochemistry/Manufacturing Industries
Bachelor in	Biology and Biotechnology	School	School of Agriculture
Academic Year	2019/2020	Year of study	2
Type	Semestral	Semester	2
Workload (hours)	162	Contact hours	T 30 TP - PL 30 TC - S - E - OT 4 O -
Level	1-2	ECTS credits	6.0
Code	9029-510-2201-00-19		

T - Lectures; TP - Lectures and problem-solving; PL - Problem-solving, project or laboratory; TC - Fieldwork; S - Seminar; E - Placement; OT - Tutorial; O - Other

Name(s) of lecturer(s) Maria João Almeida Coelho Sousa

#### Learning outcomes and competences

At the end of the course unit the learner is expected to be able to:

1. To know the basic principles of pharmacokinetics and pharmacodynamic.
2. To evaluate the toxicity of drugs.
3. To classify the existent pharmaceutical formulations.
4. To understanding the controlled-release systems.
5. To identify the biotechnological products used as drugs.
6. To recognize and apply the biotechnological methods and techniques in the development of biopharmaceuticals.
7. To know the regulatory and bioethical issues associated to biopharmaceuticals.

#### Prerequisites

Before the course unit the learner is expected to be able to:  
To have knowledge in biology, chemistry and biochemistry

#### Course contents

Fundamentals of pharmacology. Fundamentals of pharmaceutical technology. Biotechnological products used as drugs. Development of biopharmaceuticals. Drug delivery systems. Regulation good practices and bioethics.

#### Course contents (extended version)

1. I. Fundamentals of pharmacology
  - General action mechanisms of drugs.
  - Pharmacokinetics and Pharmacodynamics. Drugs toxicity.
2. II. Fundamentals of pharmaceutical technology
  - Types of formulations and excipient.
  - Microparticles and nanoparticles. Microencapsulations.
  - Liposomes and other related structures. Controlled-release systems.
3. III. Biotechnological products used as drugs
  - Oligonucleotides, hematopoietic growth factors, interferon and interleukins, insulin, growth hormone
  - Clotting factors, clonal antibodies, DNAase I human, follicle-stimulating hormone, vaccines.
4. IV. Development of biopharmaceuticals
  - Biotechnological methods. Combinatorial biosynthesis, molecular biotechnology, bioinformatics
  - Extracts/isolates from natural products, chromatographic methods for the purification of bioproducts
  - Gene therapy. Drug delivery systems.
  - Regulation and bioethics.

#### Recommended reading

1. Golan D. ; Tashjian A. ; Armstrong E. ; Armstrong A. In Principles of Pharmacology-The Pathophysiologic Basis of Drug Therapy; 2nd Ed, L. Williams & Wilkins, USA; 2007 (ISBN978-1-60831-270-2)
2. Gad, S. C. ; In Pharmaceutical Manufacturing Handbook: Production and Processes; 1st Edition, John Wiley & Sons; New Jersey; USA; 2008 (ISBN 978-0-470-25958-0).
3. Crommelin, D. J. A. ; Sindelar, R. D. ; Meibohm B. In Pharmaceutical Biotechnology: Fundamentals and Applications; 3rd Edition; Informa Healthcare; New York; USA; 2008 (ISBN 978-1420044379).
4. Walsh, G. ; In Pharmaceutical Biotechnology: Concepts and Applications; 2nd Edition; John Wiley & Sons; Chischester; England; 2007 (ISBN 978-0-470-01245-1).
5. Walsh, G. ; In Biopharmaceuticals - Biochemistry and Biotechnology; 2nd Edition; John Wiley & Sons; Chischester; England; 2003 (ISBN 0-470-84327-6).

#### Teaching and learning methods

Theoretical classes: lectures of theoretical contents. Practical laboratorial classes: Execution of experimental protocols. Each practical class is introduced by an oral exposition of the thematic, illustrated with practical examples and questions to the students in order to promote discussion.

#### Assessment methods

- Alternative 1 - (Regular, Student Worker) (Final, Supplementary, Special)
  - Reports and Guides - 10% (Practical component)
  - Intermediate Written Test - 30% (Practical component all Modules of the evaluation with elementary character, minimum mark 9, 5)
  - Final Written Exam - 60% (components. Minimum approval mark 9, 5)

#### Language of instruction

1. Portuguese
2. English

#### Electronic validation

Maria João Almeida Coelho Sousa	Anabela Rodrigues Lourenço Martins	Joaquina Teresa Gaudêncio Dias	Maria José Miranda Arabolaza
09-11-2019	19-12-2019	06-01-2020	06-01-2020