

Liverpool John Moores University

Title: STERILE PHARMACEUTICAL PRODUCTS
Status: Definitive
Code: **5004PHASCI** (122596)
Version Start Date: 01-08-2019

Owning School/Faculty: Pharmacy & Biomolecular Sciences
Teaching School/Faculty: Pharmacy & Biomolecular Sciences

Team	Leader
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Academic Level: FHEQ5 **Credit Value:** 20 **Total Delivered Hours:** 45
Total Learning Hours: 200 **Private Study:** 155

Delivery Options

Course typically offered: Semester 1

Component	Contact Hours
Lecture	20
Practical	18
Tutorial	1
Workshop	4

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Report	Report	Report	40	
Exam	Exam	Exam	60	2

Aims

*To describe and evaluate the formulation, preparation, manufacture and quality control of sterile products including injections and ophthalmic products.
To describe and discuss the principles and practice of sterilisation and sterilisation*

controls.

To discuss the concepts of quality assurance of sterile products

To facilitate the development of communication skills (written) as they apply to the content of the module.

Learning Outcomes

After completing the module the student should be able to:

- 1 Discuss the formulation and characteristics of formulated sterile products
- 2 Demonstrate hygienic and clean preparation, and aseptic processing.
- 3 Discuss the quality control pertinent to the sterilisation of sterile products
- 4 Discuss the mode of action, mechanistic and controls of: (a) moist heat sterilisation (autoclaving), (b) dry heat sterilisation, (c) filtration and (d) gaseous sterilisation
- 5 Discuss the concepts of bioburden and overkill to sterilisation

Learning Outcomes of Assessments

The assessment item list is assessed via the learning outcomes listed:

Sterile Dosage Forms	4	2	
Exam	3	1	5

Outline Syllabus

- 1. Discuss the formulation and characteristics of formulated sterile products*
- 2. Demonstrate hygienic and clean preparation, and aseptic processing.*
- 3. Discuss the quality control pertinent to the sterilisation of sterile products*
- 4. Discuss the mode of action, mechanistic and controls of: (a) moist heat sterilisation (autoclaving), (b) dry heat sterilisation, (c) filtration and (d) gaseous sterilisation*
- 5. Discuss the concepts of bioburden and overkill to sterilisation*

Learning Activities

- Lectures covering each topic within the module
- Practical sessions giving students first-hand experience of relevant formulation principles and sterilisation processes and practical: group project to formulate and evaluate an assigned pharmaceutical sterile product
- Workshops to support sterilisation process, formulation of sterile products and relevant quality control methods
- Tutorial to support practical group work
- Heat resistance of microorganisms (thermal death point, thermal death time, D-values, Z-values, Fo-values).
- Sterilisation processes, including theory and practice, methods, validation and design of sterilisers for: Autoclaving, Dry heat sterilisation, Ionising radiation,

Filtration, and Gaseous sterilisation.

- The concepts of bioburden, overkill and depyrogenation
- Physical, biological and chemical controls of sterilisation including sterility tests
- Aseptic processes, principles and evaluation of clean rooms and isolation units
- Cleaning and disinfection of clean manufacture and aseptic areas, including disciplines expected of personnel working in such areas
- Formulation, preparation and production of the following sterile products:
Ophthalmic products (eye ointments, eye drops, eye lotions, contact lens solutions),
Parenteral products (injections, total parenteral nutritional fluids), Water for injections, Bladder irrigations, and Dialysis solutions

Notes

The module will introduce the student to the manufacture, formulation and quality control of sterile products. The module will also describe the theory behind the sterilisation process as applied to pharmaceutical products. The module also follows the concepts provided by earlier modules in dosage form design to discuss the systems and devices which provide drug to the patient