Liverpool John Moores University

Title:	PHARMACEUTICAL STERILE PRODUCTS AND MICROBIOLOGICAL QUALITY CONTROL
Status:	Definitive
Code:	**5002DFPHAR** (113284)
Version Start Date:	01-08-2014
Owning School/Faculty:	Pharmacy & Biomolecular Sciences
Teaching School/Faculty:	Pharmacy & Biomolecular Sciences

Team	Leader
Michael Davies	Y
Imran Saleem	
Robert Jones	
Touraj Ehtezazi	
Matthew Roberts	
Shaqil Chaudary	

Academic Level:	FHEQ5	**Credit Value:**	24.00	**Total Delivered Hours:**	49.00
Total Learning Hours:	240	**Private Study:**	191		

Delivery Options
Course typically offered: Standard Year Long

Component	Contact Hours
Lecture	36.000
Practical	8.000
Workshop	2.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1	Examination	70.0	3.00
Report	AS2	CW - report based on4 labs	15.0	
Test	AS3	CW - MCQ based on practicals	15.0	

Aims

To describe and evaluate the formulation, preparation, manufacture and quality control of sterile products including injections, ophthalmic products and radiopharmaceuticals.
To describe and discuss the principles and practice of sterilisation and sterilisation controls.
To discuss the concepts of quality assurance of sterile products.
To demonstrate the concepts of semi-solid preparations and their rheology.

Learning Outcomes

After completing the module the student should be able to:

1	Discuss the formulation and manufacture of of sterile products including the processes of QC and sterilisation techniques.
2	Evaluate the methods of sterilisation and theory and limitations of disinfectants/preservatives.
3	Recall the concepts of biotechnology and radiopharmaceuticals.
4	Analyse the rheological theory of ointments, creams and semi-solids.

Learning Outcomes of Assessments

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

Exam	1	2	3	4
Lab Report	1	2		
Test	1	2		

Outline Syllabus

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
Water for injections. Radiopharmaceuticals and their preparation.
Semi-solid preparations: Formulation and rheology including deformation, elasticity, Newtonian and non-Newtonian flow.
Microbiological assay techniques for antibiotics, practical and statistical rationale.
Testing of non-sterile pharmaceuticals for contamination.
Disinfection and its dynamics, classes of disinfectant, modes of action and evaluation. Preservation and preservative efficacy tests, problems arising from

failure to preserve pharmaceuticals satisfactorily.
Biotechnology

Learning Activities

Laboratory exercises: development of aseptic transfer skills.

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.