**Liverpool** John Moores University

| | |
|---|---|
| Title: | PHARMACEUTICAL DELIVERY SYSTEMS |
| Status: | Definitive |
| Code: | **6004DFACAP** (113299) |
| Version Start Date: | 01-08-2011 |
| Owning School/Faculty: | Pharmacy & Biomolecular Sciences |
| Teaching School/Faculty: | Pharmacy & Biomolecular Sciences |

| Team | Leader |
|---|---|
| Touraj Ehtezazi | Y |
| Imran Saleem | |
| Robert Jones | |
| Shaqil Chaudary | |

| | | | | | |
|---|---|---|---|---|---|
| **Academic Level:** | FHEQ6 | **Credit Value:** | 24.00 | **Total Delivered Hours:** | 68.00 |
| **Total Learning Hours:** | 240 | **Private Study:** | 172 | | |

**Delivery Options**
Course typically offered: Standard Year Long

| Component | Contact Hours |
|---|---|
| Lecture | 35.000 |
| Online | 2.000 |
| Practical | 24.000 |
| Seminar | 1.000 |
| Tutorial | 3.000 |

**Grading Basis:** 40 %

**Assessment Details**

| Category | Short Description | Description | Weighting (%) | Exam Duration |
|---|---|---|---|---|
| Exam | ass 1 | Ex- 3 HOURS AT END OF SEMESTER 2 | 75.0 | 3.00 |
| Practice | ass 2 | CW - PRACTICALS ON STERILE PRODUCTS | 3.8 | |
| Test | ass 4 | CW - MCQ ON PRACTICALS | 5.0 | |
| Essay | ass 5 | CW - ASSIGNMENT WRITE UP | 15.0 | |
| Practice | ass3 | CW - PRACTICAL TEST ON STERILE PRODUCT | 1.3 | |

## 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 demonstrate the concepts of semi-solid preparations and their rheology, skin and wound dressings, transdermal delivery, gene delivery, biotechnological products, and inhalation aerosols.*
*To facilitate the development of communication skills (verbal and written) as they apply to the contents 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. |
| 10 | Discuss the principles and concepts of systems used to apply drugs and dressings to the skin. |
| 11 | Discuss the principles and concepts of inhalation aerosols. |
| 12 | Manufacture simple aseptic products. |
| 13 | Recall and review in writing, accurately and concisely, the contents of the module. |
| 14 | Apply the concepts of teamwork and leadership to the manufacture of sterile products. |
| 15 | Demonstrate an understanding of current developments in gene targeting and delivery |
| 16 | Discuss pharmaceutical aspects of biotechnological 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, mechanistics and controls of: (a) moist heat sterilisation (autoclaving), (b) dry heat sterilisation, (c) filtration and (d) gaseous sterilisation. |
| 5 | Review the resistance of microorganisms to heat. |
| 6 | Demonstrate sterilising cycles for pharmaceutical products. |
| 7 | Recall steriliser design, operation, safety aspects and validation. |
| 8 | Discuss the concepts of bioburdens and overkill to sterilisation. |
| 9 | 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:

| | |
|---|---|
| assign 1 | 1 4 5 8 9 10 11 16 |
| assign 2 | 2 15 |
| assign 4 | 3 |
| assign 5 | 6 7 13 14 |

| | | |
|---|---|---|
| assign 3 | 12 | 15 |

## 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.*
*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.*
*Transdermal preparations: Skin and wound dressings, transdermal delivery.*
*Inhalation aerosols: design, construction and use, delivery of insulin, mechanism of drug lung deposition from pharmaceutical aerosols.*
*Principles of gene delivery, pharmaceutical aspects of biotechnological products, and*
*principles of semisolid rheology.*

## Learning Activities

Problem solving exercises.
Laboratory exercises: development of aseptic transfer skills.
Essay writing
Poster presentation: preparation of documentation to GMP specification. Peer review and interactive small group learning.

## References

| | |
|---|---|
| **Course Material** | Book |
| **Author** | Aulton, M.E. |
| **Publishing Year** | 2001 |
| **Title** | Pharmaceutics The Science of Dosage Form Design.' |
| **Subtitle** | |
| **Edition** | 2nd |
| **Publisher** | Churchill Livingstone |
| **ISBN** | |

| | |
|---|---|
| **Course Material** | Book |

| | |
|---|---|
| **Author** | Lieberman, H.A., Lachman, L., Schwartz, J.B. |
| **Publishing Year** | 1990 |
| **Title** | 'Pharmaceutical Dosage Forms. :Vols I and II' |
| **Subtitle** | |
| **Edition** | |
| **Publisher** | |
| **ISBN** | 0-8247-8289-5 |

| | |
|---|---|
| **Course Material** | Book |
| **Author** | Denyer, S., Baird, R |
| **Publishing Year** | 1990 |
| **Title** | 'Guide to Microbiological Control in Pharmaceuticals |
| **Subtitle** | |
| **Edition** | |
| **Publisher** | Taylor & Francis |
| **ISBN** | 0-13-372822-6 |

| | |
|---|---|
| **Course Material** | Book |
| **Author** | Sinko PJ |
| **Publishing Year** | 2006 |
| **Title** | Martin's Physical Pharmacy and Pharmaceutical Sciences |
| **Subtitle** | |
| **Edition** | |
| **Publisher** | Lippincott Williams & Wilkins |
| **ISBN** | 0-7817-5027-x |

| | |
|---|---|
| **Course Material** | Book |
| **Author** | Stephen P. Denyer , Norman A. Hodges , Sean P. Gorman |
| **Publishing Year** | 2004 |
| **Title** | Hugo and Russell's Pharmaceutical Microbiology |
| **Subtitle** | |
| **Edition** | |
| **Publisher** | WileyBlackwell |
| **ISBN** | 0632064676 |

| | |
|---|---|
| **Course Material** | Book |
| **Author** | Hans Bisgaard , Christopher O'Callaghan , Gerald C. Smaldone |
| **Publishing Year** | 2001 |
| **Title** | Drug Delivery to the Lung |
| **Subtitle** | |
| **Edition** | 1st |
| **Publisher** | Marcel Dekker Inc |
| **ISBN** | 0824705416 |

**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.