Liverpool John Moores University

Title: PHARMACEUTICAL QUALITY CONTROL

Status: Definitive

Code: **5003MCACAP** (113320)

Version Start Date: 01-08-2011

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

Team	Leader
Linda Seton	Y
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Academic Credit Total

Level: FHEQ5 Value: 12.00 Delivered 32.00

Hours:

Total Private

Learning 120 Study: 88

Hours:

Delivery Options

Course typically offered: Standard Year Long

Component	Contact Hours
Lecture	18.000
Practical	9.000
Workshop	3.000

Grading Basis: 40 %

Assessment Details

Category	Short Description	Description	Weighting (%)	Exam Duration
Exam	AS1	Examination	60.0	2.00
Report	AS3	Coursework:CLASS TEST AND OTHER ASSIGNMENTS	25.0	
Test	AS2	Coursework: Practical Exercises	15.0	

Aims

To introduce and develop the concept of pharmaceutical quality by considering the

issues of analytical testing, data evaluation and product specification.

Learning Outcomes

After completing the module the student should be able to:

- 1 Demonstrate an understanding of the principles of pharmaceutical product quality
- 2 Demonstrate a basic knowledge of instrumental & non-instrumental approaches to pharmaceutical analysis
- 3 Effectively evaluate both quantitative & qualitative data
- 4 Identify suitable sources of information on the quality of pharmaceutical products
- Develop a rational specification for the testing and release of a typical pharmaceutical product
- 6 Plan & execute a suitable programme of testing of a typical pharmaceutical product

Learning Outcomes of Assessments

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

EXAM	1	2	3	4	5
PRACTICAL REPORT	1	5			
CLASS TESTS	2	3	4	6	

Outline Syllabus

Principles of pharmaceutical quality and the role of product specification.

The role of the pharmacopoeia - BP, USP & Ph.Eur.

Principles of pharmaceutical analysis; qualitative & quantitative approaches, physical, chemical and biological techniques.

Theory and application of the following analytical techniques: Classical chemistry, spectroscopy, chromatography, physical characterisation.

Learning Activities

Lectures on specific topics. Tutorials on data evaluation, analytical method selection and pharmaceutical calculations. A series of practicals demonstrating key pharmaceutical analytical techniques.

References

Course Material	Book
Author	Department of Health
Publishing Year	2009
Title	British Pharmacopoeia

Subtitle	BP2009
Edition	
Publisher	TSO
ISBN	9780113227990

Course Material	Book
Author	Council of Europe
Publishing Year	2007
Title	European Pharmacopoeia
Subtitle	
Edition	6TH
Publisher	Council of Europe
ISBN	9789287160546

Course Material	Book
Author	Watson, D. G.
Publishing Year	2005
Title	Pharmaceutical Analysis:
Subtitle	A textbook for pharmacy students and pharmaceutical
	chemists
Edition	2nd Edition
Publisher	Elsevier Churchill Livingstone
ISBN	0443074453

Course Material	Book
Author	Cairns, D.
Publishing Year	2008
Title	Essentials of pharmaceutical chemistry
Subtitle	
Edition	3rd
Publisher	Pharmaceutical Press
ISBN	9780853697459

Course Material	Book
Author	United States Pharmacopoeial Convention
Publishing Year	2005
Title	United States Pharmacopoeia
Subtitle	USP 28 / NF 23
Edition	
Publisher	The United States Pharmacopoeial Convention Inc.
ISBN	

Course Material	Book
Author	Rowe, P.H.
Publishing Year	2007
Title	Essential Statistics for the Pharmaceutical Sciences.
Subtitle	

Edition	1st
Publisher	John Wiley & Sons.
ISBN	9780-4700-34682

Notes

This module will provide an overview of the quality control of pharmaceuticals. It will introduce the concept of product specification and the role of the pharmacopoeia. Emphasis will be placed of the theoretical principles of product quality and the rational use of selected analytical techniques to evaluate quality attributes. Practice will be given in both the generation and assessment of analytical data.