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MODULE DESCRIPTOR

Module Title

Medicinal Analysis And Aseptic Control

Reference	PH3131	Version	4
Created	May 2019	SCQF Level	SCQF 9
Approved	March 2013	SCQF Points	30
Amended	August 2019	ECTS Points	15

Aims of Module

To develop knowledge and understanding of the principles and concepts of methods to assure quality of medicines for patients through aseptic manipulation, quality assurance, and the qualitative and quantitative analysis of medicinal products.

Learning Outcomes for Module

On completion of this module, students are expected to be able to:

1	Appraise the major qualitative and quantitative analytical techniques used for the quality assurance of medicinal products.
2	Generate, apply, document and interpret data from instrumental techniques in both quantitative and qualitative analysis of medicinal products.
3	Apply the principles of clean room design, operation and working practices.
4	Apply the principles of the preparation, supply and testing of aseptically prepared sterile products including the design, manufacture and production of radiopharmaceuticals.

Indicative Module Content

The application of instrumental and aseptic techniques in the preparation and quality assurance of medicinal products. Topics include: purpose of pharmacopoeial, pharmaceutical and biopharmaceutical analyses; characterisation, evaluation and selection of assay methods; drug assays and structure elucidation by UV, IR, Raman, fluorescence, atomic spectroscopy, NMR and MS; drug quality and quantity by UV, fluorescence, TLC, GLC and HPLC; the design and operation of clean work areas; methods of manufacture and testing sterile products, aseptic preparation and supply processes, including cold chain; the production of radiopharmaceuticals; Quality Assurance systems for manufacturing, preparing and supply of medicines; the role of Good Manufacturing Practice (GMP) and Quality Control (QC) in the manufacture of sterile products.

Module Delivery

Lectures, coursework sessions (including laboratory work, tutorials, workshops) and input from industrial and hospital pharmacists, directed study.

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Indicative Student Workload	Full Time	Part Time
Contact Hours	94	N/A
Non-Contact Hours	206	N/A
Placement/Work-Based Learning Experience [Notional] Hours	N/A	N/A
TOTAL	300	N/A
Actual Placement hours for professional, statutory or regulatory body		

ASSESSMENT PLAN

If a major/minor model is used and box is ticked, % weightings below are indicative only.

Component 1

Type:	Examination	Weighting:	80%	Outcomes Assessed:	1, 3, 4
Description:	2 hour written examination				

Component 2

Type:	Coursework	Weighting:	20%	Outcomes Assessed:	2
Description:	Lab report on a practical experiment				

MODULE PERFORMANCE DESCRIPTOR

Explanatory Text

To pass this module, the student MUST achieve a module Grade of Grade D or better and a minimum mark of 40% in C1 and C2.

Module Grade	Minimum Requirements to achieve Module Grade:
A	When 80% of the mark for C1 added to 20% of the mark for C2 is 70% or more.
B	When 80% of the mark for C1 added to 20% of the mark for C2 is 60-69%.
C	When 80% of the mark for C1 added to 20% of the mark for C2 is 50-59%.
D	When 80% of the mark for C1 added to 20% of the mark for C2 is 40-49%.
E	When 80% of the mark for C1 added to 20% of the mark for C2 is 35% or more but less than 40% in C1 and/or C2.
F	When 80% of the mark for C1 added to 20% of the mark for C2 is 35% or less.
NS	Non-submission of work by published deadline or non-attendance for examination

Module Requirements

Prerequisites for Module	Successful completion of MPharm stage 2.
Corequisites for module	None.
Precluded Modules	None.

INDICATIVE BIBLIOGRAPHY

1	WATSON, D., Pharmaceutical Analysis. Current Edition. London: Churchill Livingstone.
2	WILLIAMS, D.H. and FLEMING, I., Spectroscopic Methods in Organic Chemistry. Current Edition. London: McGraw-Hill.
3	HM STATIONERY OFFICE, British Pharmacopoeia. London: HMSO and via web-site.
4	WINFIELD, A.J., REES, J. and SMITH, I. Pharmaceutical Practice. Current Edition. London: Elsevier Science.
5	BEANEY, A.M. Quality Assurance of Aseptic Preparation Services. Current Edition. London: Pharmaceutical Press.