

MODULE DESCRIPTOR

Module Title

Advanced Pharmaceutical Analysis and Quality Control

Reference	PLM340	Version	1
Created	June 2023	SCQF Level	SCQF 11
Approved	July 2023	SCQF Points	15
Amended	June 2022	ECTS Points	7.5

Aims of Module

To enable students to evaluate, problem solve and develop skills in a range of advanced analytical techniques for the analysis of drugs and medicines. To enable students to understand and evaluate quality assurance and control systems for medicine manufacture.

Learning Outcomes for Module

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

- 1 Critically understand the principles and applications of advanced analytical techniques for the determination of a drug or medicine.
- 2 Make informed decisions on a range of practical problems concerning analytical sample preparation.
- 3 Evaluate an appropriate quality assurance and control system for medicine manufacture.

Indicative Module Content

Pharmaceutical drug/medicine analysis, use of pharmaceutical monographs for the analysis of formulated preparations, extraction methods. Advanced analytical techniques include: liquid chromatography, gas chromatography, mass spectrometry, fluorescence spectroscopy, (derivative) ultra-violet spectroscopy, infrared spectroscopy. Quality assurance: Principles, procedures, test methods, records, reporting, data management, auditing and sampling; laboratory accreditation and accreditation regimes; standards GLP and GMP.

Module Delivery

The module will be delivered by lectures, tutorials and laboratory workshops.

Indicative Student Workload	Full Time	Part Time
Contact Hours	30	N/A
Non-Contact Hours	120	N/A
Placement/Work-Based Learning Experience [Notional] Hours	N/A	N/A
TOTAL	150	N/A
<i>Actual Placement hours for professional, statutory or regulatory body</i>		

ASSESSMENT PLAN

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

Component 1

Type: Coursework Weighting: 60% Outcomes Assessed: 1, 3
 Description: Written report critically evaluating quality control standards for a given medicine.

Component 2

Type: Practical Exam Weighting: 40% Outcomes Assessed: 2
 Description: Practical assessment of laboratory based skills

MODULE PERFORMANCE DESCRIPTOR

Explanatory Text

Component 1 (CW1) is weighted as 60% and Component 2 (PE1) as 40%. A minimum module grade of D is required to pass the module. Non-submission of either component will result in an NS grade.

		Practical Exam:						NS
		A	B	C	D	E	F	
Coursework:	A	A	A	B	B	B	E	
	B	B	B	B	C	C	E	
	C	B	C	C	C	D	E	
	D	C	C	D	D	D	E	
	E	D	D	D	E	E	E	
	F	E	E	E	E	F	F	
	NS	Non-submission of work by published deadline or non-attendance for examination						

Module Requirements

Prerequisites for Module	None, in addition to course entry requirements.
Corequisites for module	None.
Precluded Modules	None.

INDICATIVE BIBLIOGRAPHY

- 1 Aulton, M.E. (2017). 'Pharmaceutics - the design and manufacture of medicines', 5th edition, Churchill Livingstone, Elsevier.
- 2 Khar, R.K. (2017). 'Lachman's/Lieberman's: the theory and practice of industrial pharmacy', 4th edition, CBS Publishers.
- 3 Prichard, E. (2007). 'Quality assurance in analytical chemistry', Wiley.
- 4 Skoog, D.A., Holler, F.J., Crouch, S.R. (2018). 'Principles of instrumental analysis', 7th edition, Brooks Cole.
- 5 Watson, D.G. (2016) 'Pharmaceutical analysis - a textbook for pharmacy students and pharmaceutical chemists', 4th edition, Churchill Livingstone, Elsevier.
- 6 Medicine and Health products Regulatory Agency (MHRA) (2022). 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors?', GB MHRA.