APPROVED

PHAR S8018: Pharmaceutical Analysis and Validation

Module Details

Module Code:	PHAR S8018
Full Title:	Pharmaceutical Analysis and Validation APPROVED
Valid From::	Semester 1 - 2018/19 (September 2018)
Language of Instruction:	
Duration:	1 Semester
Credits::	10
Module Owner::	Sinead Loughran
Departments:	Unknown
Module Description:	The aims of this module are to • introduce and survey the applicability of novel and emerging spectroscopic, mass spectrometry, capillary electrophoresis and nanoscience techniques. • to increase student's confidence in undertaking biochemical and chemical analysis, to become independent in designing and executing experiments and to provide good quality presentations of their findings. • to introduce the principles of qualification and validation of equipment and methods used for the manufacture of medicinal products.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Summarise the fundamental theoretical basis of advanced analytical science techniques for physical, chemical and biochemical analysis and manipulation.
MLO2	Interpret experimentally-derived data from advanced analytical techniques.
MLO3	Operate a range of analytical instrumentation and report data electronically using an electronic laboratory notebook.
MLO4	Compare and contrast advanced analytical techniques and qualitative and quantitative methods for the analysis and manipulation of different sample types.
MLO5	Combine theoretical knowledge and technical skills gained in the laboratory to present a portfolio tailored to an analytical science job description.
MLO6	Discuss how method and equipment validation complements good manufacturing practice and appreciate the regulatory requirements of method and equipment validation.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is strongly recommended before enrolment in this module. You may enrol in this module if you have not acquired the recommended learning but you will have considerable difficulty in passing (i.e. achieving the learning outcomes of) the module. While the prior learning is expressed as named DkIT module(s) it also allows for learning (in another module or modules) which is equivalent to the learning specified in the named module(s).*
No recommendations listed

Module Indicative Content
Capillary Electrophoresis The general principles of capillary zone electrophoresis including sample addition, detection of separated components and the electro-endosmotic effect and its consequences; useful additives to the separation medium and their specific applications
Nanoscience/Nanotechnology Fundamental principles of nanotechnology, importance of size, properties of nanoparticles, carbon nanostructures, quantum dots, medical applications of nanotechnology. Scanning electron microscopy, atomic force microscopy and scanning tunneling microscopy as techniques in nanoscience.
Infra Red The interaction of infrared radiation with molecules; the infrared spectrum and its interpretation. Key features of IR instruments including sample preparation.
Mass Spectrometry Methods of ion production in mass spectrometry, the generation of MS spectra and their interpretation. GCMS and LCMS hyphenated techniques
Method and Equipment Validation Examination of the process of method and equipment validation as regulated by FDA or other regulatory authorities. Guidelines (ICH) for validation of analytical procedures. Principles of qualification and validation which are applicable to the equipment used for the manufacture of medicinal products. Preparation of user requirement specification (URS), installation qualification (IQ), operational qualification (OQ) and performance qualification (PQ) protocols. Regulatory basis for validation and harmonisation of regulatory requirements.
Learning and Teaching Methods Teaching methods will comprise blended delivery of lectures, online contact and practical sessions with an emphasis on deep learning in a student-centred learning approach. A variety of face-to-face and eLearning techniques will be deployed including in-class demonstrations, problem-based learning, peer assisted learning, self assessment and use of multi-media (animations, videos, podcasts, eAssessments, virtual eLabs and recorded lectures).
Virtual Learning Environment The DkIT Virtual Learning Environment (Moodle) page for this module will be used as a repository for lecture material, past exam papers, video links, online resource links, online quizzes, feedback, peer-reviewed articles as well as documents pertaining to practical lab sessions (Material Safety Data Sheets).
Electronic Laboratory Notebook Students will be introduced to an emerging tool in industry for lab data and documentation management which will be used for reporting laboratory practicals in place of the standard hard copy notebook. The ELN is a web-based product enabling the user to easily create, store, share and manage their research data. Students will be able to store and retrieve any type of documents, including Images, GraphPad Prism and MS-Office, enter rich text, spreadsheets, mathematical formulae, chemical structures, share entries or entire notebooks in small group work, capture electronic "signatures" for approvals. The use of the ELN is inherently environmentally friendly as it replaces traditionally paper-intensive documentation and storage and adopting the ELN represents a sustainable approach to reporting (operates on all platforms including iPhone/smartphone).
Laboratory Practical Sessions The following list is designed to serve as an illustration of possible practical exercises which would illustrate key concepts and techniques: Investigation of aspects of infra-red spectroscopy, Analysis of liquids by IR using NaCl plates, Preparation of a Nujol Mull for IR Analysis, Investigation of reproducibility of film technique in IR, Qualitative IR for isomers, Quantitative determination using Capillary Electrophoresis, Improving CE separation, Comparison of CE and HPLC techniques for drug analysis, Synthesis of gold nanoparticles and analysis via Scanning electron microscopy.

Module Assessment

Assessment Breakdown	%
Course Work	10.00%
Project	20.00%
Practical	20.00%
Final Examination	50.00%

Module Special Regulation

Assessments

Full Time On Campus

Course Work

Assessment Type	Continuous Assessment	**% of Total Mark**	10
Marks Out Of	0	**Pass Mark**	0
Timing	S2 Week 29	**Learning Outcome**	2
Duration in minutes	0		

Assessment Description
In class workshops will focus on interpretation, observational, scientific and categorisation skills and tools, and data from journal articles or experimentally-derived data will be provided for scrutiny. Formative assessment via classroom assessment techniques and continuous assessment via class exam.

Project

Assessment Type	Project	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	Every Week	**Learning Outcome**	4,5,6
Duration in minutes	0		

Assessment Description
Students will produce an individual portfolio of their expertise in Pharmaceutical Analysis and Validation using the ELN and will complete an self-reflection of their group teamwork experience.

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	20
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	2,3
Duration in minutes	0		

Assessment Description
In weekly 3-hour laboratory practical sessions, students will partake in instrument demonstrations and perform advanced analytical techniques by following basic operating procedures, thereby gaining hands-on experience. Assessment will comprise four individual formal laboratory reports using an ELN, a peer assessed literature review assignment, a self-assessed method development practical assignment, a standard operating procedure writing assignment.

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	50
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,2,4,6
Duration in minutes	0		

Assessment Description
End-of-Semester Final Examination

Module Workload

Workload: Full Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	Learning and Teaching Methods described in Module Content	Every Week	3.00	3
Practical	Contact	Weekly 3-hour laboratory practical sessions outlined in the Indicative Content section under Laboratory Practical Sessions	Every Week	3.00	3
Directed Reading	Non Contact	Lecture notes, Peer-reviewed papers, Textbooks, e-Resources	Every Week	5.00	5
Independent Study	Non Contact	Independent/Group study	Every Week	5.00	5
Online Contact	Contact	Online contact on Moodle; activities, discussion forums, recorded lectures	Every Week	1.00	1
				Total Weekly Learner Workload	17.00
				Total Weekly Contact Hours	7.00

This module has no Part Time On Campus workload.

Module Resources

Recommended Book Resources

Harris D C. (2012), Exploring chemical analysis, 5th. WH Freeman.

Skoog D.A., Holler F.J. and Crouch S.R.. (2017), Principles of instrumental analysis, 7th. Thomson Publ.

Harris D.C.. (2007), Quantitative chemical analysis, 7th. Freeman.

Watson D.G.. (2005), Pharmaceutical analysis, 2nd. Elsevier.

Stuart, Barbara. (2004), Infrared spectroscopy fundamentals and applications [online resource], Wiley, DkIT Ebrary Collection.

Rolf Ekman et al. (2009), Mass spectrometry [electronic resource] : instrumentation, interpretation, and applications, Wiley, DkIT Ebrary Collection.

Binns, C.. (2010), Introduction to Nanoscience and Nanotechnology [online resource], Wiley, DkIT Ebrary Collection.

Supplementary Book Resources

Luigi Mondello. (2011), Comprehensive chromatography in combination with mass spectrometry [online resource], Wiley, DkIT Ebrary Collection.

This module does not have any article/paper resources

Other Resources

Website, MicroSolv -Capillary Electrophoresis Site. http://www.microsolvtech.com/ce.asp.

Website, Mass Spectrometry,
http://www2.chemistry.msu.edu/faculty/re usch/VirtTxtJml/Spectrpy/MassSpec/masspe c1.htm#ms1

Website, Infra Red Spectroscopy,
http://www2.chemistry.msu.edu/faculty/re usch/VirtTxtJml/Spectrpy/InfraRed/infrar ed.htm#ir1

Website, Chemistry Hypermedia Project- Capillary Electrophoresis,
http://www.files.chem.vt.edu/chem-ed/cro ssref/ac-separations.html

Website, Sam Houston State University Analytical Science,
http://www.shsu.edu/~chm_tgc/sounds/soun d.html

Website, LabArchives. Electronic Laboratory Notebook,
http://www.labarchives.com

Website, ICH Harmonised Tripartite Guideline for Validation of Analytical Procedures,
https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Quality/Q2_R1/Step4/Q2_R1__Guideline.pdf

Website, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use Annex 15: Qualification and Validation,
https://ec.europa.eu/health/sites/health /files/files/eudralex/vol-4/2015-10_anne x15.pdf