APPROVED

PHAR S8014: Pharmacopoeial Characterisation

Module Details

Module Code:	PHAR S8014
Full Title:	Pharmacopoeial Characterisation APPROVED
Valid From::	Semester 1 - 2018/19 (September 2018)
Language of Instruction:	
Duration:	1 Semester
Credits::	7.5
Module Owner::	
Departments:	Unknown
Module Description:	•To provide students with the background and understanding into the pharmaceutical characterisation of dosage forms as governed by the European /British Pharmacopoeia. •To explain the chemical, biological and physical properties that are involved in dosage form design. •To ensure that the students understand the importance and significance of stability and bioavailability of dosage forms. •To discuss the pharmacopoeia analysis methods used to monitor the quality and to ensure reproducibility of the dosage forms in the pharmaceutical industry.

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Recognise the importance of pharmaceutical drug solubility to the overall bioavailability of the drug.
MLO2	Discuss pharmaceutical preformulation studies, physicochemical properties and stability studies which are critical in dosage form design.
MLO3	Use pharmacokinetics, excipient and formulation considerations of dosage forms to investigate drug bioavailability.
MLO4	Discuss a wide variety of pharmaceutical analytical tests as governed by the European/British Pharmacopoeia.
MLO5	Examine a variety of raw materials (API) as governed by the European/British Pharmacopoeia (including analysis, pharmaceutical paperwork completion and cross-checking of paperwork) to mimic the pharmaceutical quality control set-up.

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
Pharmaceutical drug solubility Solubility importance. Biopharmaceutical Classification System (BCS). Techniques for solubility enhancement (physical and chemical modification, formulation methods and other techniques).
Pharmaceutical preformulation studies Pharmaceutical preformulation studies and the physicochemical properties of drug substances (physical description, dissolution, melting point, polymorphism, particle size, partition affinity, membrane permeability).
Pharmaceutical excipients Types of pharmaceutical excipients used in dosage forms. Effect of excipients on pharmaceutical drug bioavailability. Examination of excipient compatibility.
Pharmaceutical stability studies Drug and product stability (physical, chemical and microbiological). Objectives of stability testing. Accelerated stability testing and drug shelf-life prediction. Mechanisms of drug degradation.
Pharmaceutical drug bioavailability Ideal drug, factors influencing bioavailability, drug action phases. Pharmacokinetics. Effect of formulation factors on bioavailability.
Pharmacopoeia analysis Pharmacopoeia influence (primarily European/British pharmacopoeia). Analysis of raw materials (API) - including identification tests and limit tests. Analysis of final dosage forms - including production/on-line tests and laboratory/QC control tests
Practical The students will be given the opportunity to follow the guidelines of the European/British Pharmacopoeia to mimic the pharmaceutical quality control set up for raw materials (API) testing. This will be achieved over a number of weekly practical sessions with the following specific set up. 1st practical (testing week): The student must follow the analysis of a specific raw material as governed by the EP/BP. The student must have the ability to work within a group to complete the raw material testing paperwork while also working as an individual to complete and document correctly the results of the specific tests required. 2nd practical (checking week): The student must cross-check all the raw material testing results, analyst book reporting and instrument log paperwork completion of another students work during the 1st practical. This will give the student the opportunity to follow the quality control process for releasing a raw material including analysis, pharmaceutical paperwork completion and cross-checking of paperwork. This testing and checking process will be repeated over the course of all the practical sessions with the student learning the overall quality control process required in the pharmaceutical industry to release a raw material for use. A feedback week will be provided after the first testing and checking cycle. The practical supervisor/lecturer will give detailed feedback on the students ability to perform the testing and checking exercises set. This will include both generic feedback and individual feedback.

Module Assessment

Assessment Breakdown	%
Course Work	10.00%
Practical	40.00%
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	S1 Week 10	**Learning Outcome**	1,2
Duration in minutes	0		

Assessment Description
In class test

No Project

Practical

Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	40
Marks Out Of	0	**Pass Mark**	0
Timing	Every Week	**Learning Outcome**	5
Duration in minutes	0		

Assessment Description
Three hour practical sessions will provide the student with the opportunity to follow the guidelines of the European/British Pharmacopoeia to mimic the pharmaceutical quality control set up for raw materials (API) testing. The student will have the opportunity (over a number of practicals) to follow the quality control process for releasing a raw material including analysis, pharmaceutical paperwork completion and cross-checking of paperwork.

Final Examination

Assessment Type	Formal Exam	**% of Total Mark**	50
Marks Out Of	0	**Pass Mark**	0
Timing	End-of-Semester	**Learning Outcome**	1,2,3,4
Duration in minutes	0		

Assessment Description
End-of-Semester Final Examination

Reassessment Requirement

A repeat examination
Reassessment of this module will consist of a repeat examination. It is possible that there will also be a requirement to be reassessed in a coursework element.

Module Workload

Workload: Full Time On Campus					
Workload Type	*Contact Type*	*Workload Description*	*Frequency*	*Average Weekly Learner Workload*	*Hours*
Lecture	Contact	No Description	Every Week	2.00	2
Practical	Contact	No Description	Every Week	3.00	3
Directed Reading	Non Contact	No Description	Every Week	2.00	2
Independent Study	Non Contact	No Description	Every Week	2.00	2
				Total Weekly Learner Workload	9.00
				Total Weekly Contact Hours	5.00

This module has no Part Time On Campus workload.

Module Resources

Recommended Book Resources

Thomas, G. Medicinal Chemistry; an introduction, 2nd. Wiley, [ISBN: 9780470025987].

Gaisford, S, Saunders, M. Essentials of Pharmaceutical Preformulation, 1st. Wiley-Blackwell, [ISBN: 9780470976364].

Aulton, M.E.. Aulton's Pharmaceutics, The Science of Dosage Form Design, 3rd. Churchill Livingstone, [ISBN: 9780443101083].

Allen, L.V. , Popovich, N.G., Ansel, H.C.. (2004), Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems, 8th. Lippincott Williams and Wilkins, [ISBN: 0781746124].

Hansen, S.H, Pedersen-Bjergaard, S, Rasmussen, K.E. Introduction to Pharmaceutical Analysis, 1st. Wiley, [ISBN: 9780470661222].

Watson, D. (2005), Pharmaceutical Analysis, 2nd. Wiley, [ISBN: 044074453].

Supplementary Book Resources

Mahato, R.I, Narang, A.S. Pharmaceutical Dosage forms and Drug Delivery, 2nd. CRC Press, [ISBN: 9781439849187].

Wermuth, C. (2008), The practice of medicinal chemistry, 3rd. Academic Press, [ISBN: 9780123741943].

Kee, J., Hayes, E., McCuistion, L.. (2006), Pharmacology A nursing process approach, 5th. Elsevier, [ISBN: 9780721639277].

Dale, M.M, Haylett, D.G. (2009), Pharmacology Condensed, 2nd. Churchill Livingstone, [ISBN: 9780443067730].

This module does not have any article/paper resources

Other Resources

Website, Dr Chiara Hanlon. Lecture notes and other resources, DkIT Moodle.

Reference text (used in practicals), European Pharmacopoeia, Council of Europe.

Website, European Pharmacopoeia (European Directorate for the Quality of Medicines). www.edqm.eu.

Website, British Pharmacopoeia. www.pharmacopoeia.com.

Website, Health Products Regulatory Authority. www.HPRA.ie.

Website, US Food and Drug Administration. www.FDA.gov.

Link, Library Catalogue,
http://tinyurl.com/k683276