APPROVED

CHEM S7013: Pharmaceutical Processing

Module Details

Module Code:	CHEM S7013
Full Title:	Pharmaceutical Processing APPROVED
Valid From::	Semester 1 - 2019/20 (June 2019)
Language of Instruction:	
Duration:	1 Semester
Credits::	7.5
Module Owner::	Noelle Cunning
Departments:	Unknown
Module Description:	•The aims of this module are to introduce the student to the current legislative and mandatory requirements for processing in the Pharmaceutical Industry and to explain to students the impact of the product's physical and chemical properties to Pharmaceutical processing. Students will also be introduced to topics which can be used to analyse and improve processing

Module Learning Outcome	
On successful completion of this module the learner will be able to:	
#	**Module Learning Outcome Description**
MLO1	Discuss the current legislative requirements associated with the Pharmaceutical product and Pharmaceutical processing
MLO2	Explain how the Pharmaceutical process can be validated in line with mandatory requirements
MLO3	Recognise how the basic chemical and physical properties of the product affect Pharmaceutical drug Processing
MLO4	Describe how kinetics, thermodynamics and PAT are applied to Pharmaceutical processing

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 process legislation Introduce legislation and mandatory requirements for processing - current EU, FDA,HPRA and ICH
Pharmaceutical Industry Introduction to the pharmaceutical industry and the requirements for GMP and Quality systems related to processing. Quality systems will include Good documentation practice (GDP), laboratory out of specification (OOS) and change management.
Pharmaceutical Process Effect of chemical and physical properties of the products (API or finished) on the process - To include: Salt formation, particle size, powder flow, kinetics and thermodynamics
Process validation Process validation and validation master plan. Introduction to concept of Process Analytical technology (PAT)
Practicals Practicals will be carried out to reflect and support the material covered in lectures. The practicals will include the determination of active ingredients in pharmaceutical preparations

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	Other	**% of Total Mark**	10
Marks Out Of	0	**Pass Mark**	0
Timing	S1 Week 6	**Learning Outcome**	1,2
Duration in minutes	0		
Assessment Description Continuous assessment			

No Project

Practical			
Assessment Type	Practical/Skills Evaluation	**% of Total Mark**	40
Marks Out Of	0	**Pass Mark**	0
Timing	n/a	**Learning Outcome**	3,4
Duration in minutes	0		
Assessment Description The practical sessions will provide the student with the opportunity to use the theory covered in formal lectures. After each practical, students will be required to submit a scientific practical report and a mark will be attributed to it by the laboratory demonstrator.			

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			

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	3.00	3
Practical	Contact	No Description	Every Week	3.00	3
Directed Reading	Non Contact	No Description	Every Week	3.00	3
Independent Study	Non Contact	No Description	Every Week	3.00	3
				Total Weekly Learner Workload	12.00
				Total Weekly Contact Hours	6.00

This module has no Part Time On Campus workload.

Module Resources

This module does not have any book resources

This module does not have any article/paper resources

Other Resources

website, Health Products regulatory authority (HPRA),
http://www.hpra.ie/

Website, Food and Drug Administration (FDA),
http://www.fda.gov/

Website, European Medicines Agency (EMA),
http://www.ema.europa.eu

website, 'International congress on harmonisation' (ICH). http://www.ich.org,
http://www.ich.org