ZPHA C4105: Drug Stability

Module Title:	Drug Stability
Language of Instruction:	English

Credits:	5

NFQ Level:	8

Module Delivered In	1 programme(s)

Teaching & Learning Strategies:	This module will be taught in three 1-hour theory lectures and one 3-hour practical session per week. It will be delivered using a blended learning approach. Lectures will provide a structured framework to enable fulfilment of the learning outcomes. The learners will work in a supervised/unsupervised environment. Access to on-line resources will be encouraged.

Module Aim:	The aim of this module is to give students an overview of the scientific principles underpinning drug stability studies as used in the Pharma industry.

Learning Outcomes	
On successful completion of this module the learner should be able to:	
LO1	Assess the theory and application of methods for the analysis of pharmaceutical products, and the role of kinetics and the mechanism/pathway of degradation on formulation stability.
LO2	Evaluate the importance and requirements of FDA/EU regulation and compliance requirements for the analysis of related substances and for the validation of analytical methods.
LO3	Apply and evaluate analytical methods to assess the stability of pharmaceutical formulations and techniques to artificially accelerate the aging and degradation of pharmaceutical products.

Pre-requisite learning
Module Recommendations *This is prior learning (or a practical skill) that is recommended before enrolment in this module.*
No recommendations listed
Incompatible Modules *These are modules which have learning outcomes that are too similar to the learning outcomes of this module.*
No incompatible modules listed
Co-requisite Modules
No Co-requisite modules listed
Requirements *This is prior learning (or a practical skill) that is mandatory before enrolment in this module is allowed.*
No requirements listed

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Module Content & Assessment

Indicative Content
Indicative content 1. Stability indicating methods (SIM): Hydrolysis, Oxidation, Photolysis and Photo stability studies, Realistic and focussed product degradation ,Stress testing and representative sampling, Over and under stressing, Thresholds for drug degradation as percentage of total daily intake (TDI), Investigation of Out of trend (OOT) and out of Specification (OOS) results, LOD, LOQ 2. Analytical methodologies: LC, GC, Spectroscopy, NIR, Raman Spectroscopy, UV Spectroscopy and Particle size analysis, dissolution testing. Determination of stability indicating methods. 3. Stability types Physical, Microbiological, therapeutic and toxicological, Stages in life cycle from Stage 1 to on-going i.e. clinical trial follow up stability trials. Photo stability studies. Extrapolation of data to indicate stability of product. Pharmaco-kinetics. 4. Container closure systems, packaging and dosage form and their impact of stability and shelf life. Bracketing and matrixing to reduce size of stability studies. SUPAC. Statements for label information and investigation of OOS results encountered during analysis. 5. Stability of Bio molecules

Assessment Breakdown	%
Continuous Assessment	10.00%
Practical	30.00%
End of Module Formal Examination	60.00%

Special Regulation
Students must achieve a minimum grade (35%) in both the practical/CA and final examination.

Continuous Assessment

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Examination	Mid semester and end of semester examination.	1,2	10.00	n/a

No Project

Practical

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	Written laboratory reports	1,3	30.00	Every Week

End of Module Formal Examination

Assessment Type	*Assessment Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Formal Exam	End of module written assessment	1,2,3	60.00	End-of-Semester

SETU Carlow Campus reserves the right to alter the nature and timings of assessment

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Module Workload

Workload: Full Time		
Workload Type	*Frequency*	*Average Weekly Learner Workload*
Practicals	12 Weeks per Stage	3.00
Lecture	12 Weeks per Stage	3.00
Independent Learning Time	12 Weeks per Stage	4.42
	Total Hours	125.00

Module Delivered In

Programme Code	Programme	Semester	Delivery
CW_SAPHA_B	Bachelor of Science (Honours) in Pharmaceutics and Drug Formulation	7	Mandatory