

MODULE DESCRIPTOR

Module Title

Drug Dosage Form and Design

Reference	PLM341	Version	1
Created	June 2023	SCQF Level	SCQF 11
Approved	July 2023	SCQF Points	30
Amended	October 2022	ECTS Points	15

Aims of Module

To enable the student to develop a detailed understanding of the design of dosage forms, taking into account the preclinical and clinical aspects of medicine development, within a quality framework and in the context of a variety of clinical indications and patient groups.

Learning Outcomes for Module

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

- 1 Demonstrate a critical understanding of the application of pharmaceuticals in the design of dosage forms.
- 2 Have a detailed understanding of the pre-clinical and clinical development process required and the underpinning quality framework which supports such development.
- 3 Demonstrate a critical understanding of the biopharmaceutical concepts surrounding the development of medicines.

Indicative Module Content

Topics include the processes underpinning the development of dosage forms such as liquids, suspensions, emulsions, topicals, parenterals, suppositories, tablets and capsules. In addition the pre-clinical and clinical considerations of medicine development will be covered including preclinical testing (an overview of ADME and DMPK studies) and the stages of clinical trials, together with aspects of quality systems which apply to dosage form development, including cGMP, GLP and GCP. The biopharmaceutical basis for the development of medicines including the Noyes-Whitney equation and how physiology affects drug absorption, physicochemical and dosage form factors which affect bioavailability and dosage regimes for a range of patients at all stages of life from paediatrics to geriatrics.

Module Delivery

The module will be delivered using lectures and coursework supported with tutorials.

Indicative Student Workload	Full Time	Part Time
Contact Hours	76	N/A
Non-Contact Hours	224	N/A
Placement/Work-Based Learning Experience [Notional] Hours	N/A	N/A
TOTAL	300	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: Practical Exam Weighting: 50% Outcomes Assessed: 1
 Description: A presentation of the development of medicines laboratory work.

Component 2

Type: Coursework Weighting: 50% Outcomes Assessed: 2, 3
 Description: A written assignment

MODULE PERFORMANCE DESCRIPTOR

Explanatory Text

Component 1 (PE1) and Component 2 (CW1) are equally weighted. 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:						
		A	B	C	D	E	F	NS
Coursework:	A	A	A	B	B	C	E	
	B	A	B	B	C	C	E	
	C	B	B	C	C	D	E	
	D	B	C	C	D	D	E	
	E	C	C	D	D	E	E	
	F	E	E	E	E	E	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.(ed.), Taylor, K. (2017)'Aulton's pharmaceuticals - the design and manufacture of medicines', 5th edition, Churchill Livingstone, Elsevier.
- 2 Jones, D. (2016). 'Pharmaceuticals - dosage form and design'. Fasttrack, 2nd edition, Pharmaceutical Press.
- 3 Denton, P., Rostron, C. (2013). 'Pharmaceuticals - the science of medicine design', Oxford University Press.
- 4 Medicine and Health products Regulatory Agency (MHRA) (2022). 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors?', GB MHRA.