Institute of Technology Tallaght
Institiúid Teicneolaíochta Tamhlacht

MANP H2001: Manufacturing & Process & Tech Extra Header Data

Module Delivered in

Programme Code	Programme	Semester	Delivery
TA_SMGMP_C	Certificate in Good Manufacturing Practice & Technology (Minor) Pharmaceutical GMP & Technology	3	Mandatory
TA_SGMPT_C	Higher Certificate in Science in GMP and Technology	3	Mandatory

Short Title:	Manufacturing & Process & Tech APPROVED
Full Title:	Manufacturing and Process Technology

Module Code:	MANP H2001	**NFQ Level:**	6	**ECTS Credits:**	10

Reviewed By:	JOHN BEHAN

Description:	This module aims to provide the student with an understanding of the equipment and unit processes used in pharmaceutical industry.

Learning Outcomes:

On successful completion of this module the learner will be able to

1. Describe the steps normally used in a typical drug development process from discovery to market.
2. Understand the organisation of a pharmaceutical plant and the functions of each department
3. Explain the basic operations involved in the synthesis and purification of chemicals on a large scale.
4. Demonstrate a detailed knowledge of the equipment used in a bulk pharmaceutical plant and its operation.
5. Describe the basic issues associated with scale up, yield optimisation and process safety.
6. Describe the basic operations of a Waste Treatment Plant.
7. Describe how to record data during the manufacturing process.

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Module Content & Assessment

Content
Chemical Operations in Bulk Pharmaceutical Plants: Plant Layout; Organization and functions of each department. **Drug Development Process:** From discovery to market - Research phase; Development phase – including an overview process, analytical and formulation development. **Unit Operations & Equipment: Reactors –** Types, uses, limitations, operations such as extractions, sampling, volume measurement, temperature control; scrubbing gaseous byproducts **Distillation Operations –** Simple binary, fractional, azeotropic, vacuum, steam stripping, evaporation, solvent recovery **Filtration operations & equipment;** Drying operations & equipment **Process Control;** Cleaning; Utilities. **Mixing/Agitation:** Operation & types of agitation; flow characteristics; mixing effects/product selectivity. **Bulk Pharmaceutical Manufacture** Reactor design, maintenance, control and operation: Design of reactors. Materials used in reactor construction, agitation. Heating and cooling reactor units. Fluid flow, pumps, pumping and viscosity. **Recovery and Purification of Bulk Pharmaceutical Products** Precipitation, filtration, centrifugation, cell disruption, liquid extraction, chromatography (adsorption, ion-exchange, gel-filtration, affinity and continuous chromatography), crystallization. **Introduction to Scale-Up Issues** Pilot Plant; Safety; Heat Transfer; Chemical Reaction Hazards. **Waste Treatment** Layout of a typical waste treatment plant; Primary & Secondary Treatment; Bacteria Conditions; Sludge Treatment. **Introduction to GMP:** Documentation; Manufacturing records. **Manufacture of Class I, II and III Medical Devices** Introduction to materials used in medical device manufacture. Overview of molding design and extruded medical plastic manufacturing processes. Manufacturing flow diagrams. **Medical Device Stability Testing** Review of the mechanisms adopted to assign shelf life to medical devices. **Suggested Practicals** 1. P&ID's 2. Utilities and Waste Management 3. Formulation and Filling 4. Instrumentation overview 5. Clean in Place 6. Sterilise in Place 7. Filter Integrity Tester 8. Introduction to NFF/TFF

Assessment Breakdown	%
Course Work	50%
End of Semester Formal Examination	50%

	Outcome addressed	*% of total*	*Assessment Date*
Formal End-of-Semester Examination	None	50%	Semester End

Coursework Breakdown				
Type	*Description*	*Outcome addressed*	*% of total*	*Assessment Date*
Practical/Skills Evaluation	No Description	None	35	Sem 1 End

IT Tallaght reserves the right to alter the nature and timings of assessment

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Module Workload & Resources

This course has no full time workload.

Resources
Required Book Resources
McConville 2002, *The Pilot Plant Real Book*, FHM Eng **1999, *TAC Manuals & CD Rom (Training Awareness Campaign in the Pharmaceutical Industry)*, Compupharma**
Recommended Book Resources
Concepts-Atherton & Carpenter 1999, *Process Development: Physicochemical*, Oxford Univ. Press **Kumar G. Cadamasetti 1999, *Process Chemistry in the Pharmaceutical Industry*, Marcel Dekker, Inc**