

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Semester 1 Examinations 2012/2013

Module Title: Formulation

Module Code: CHEI7001

School: Biological Sciences

Programme Title: Bachelor of Science (Honours) in Pharmaceutical Biotechnology – Year 3
Bachelor of Science in Good Manufacturing Practice – Year 3
Bachelor of Science in Food Science & Technology – Year 3
Bachelor of Science (Honours) in Nutrition & Health Science – Year 3

Programme Code: SPHBI_8_Y3
SGMPE_7_Y3
SFSTE_7_Y3
SNHSC_8_Y3

External Examiner(s): Ms B. Whelan, Dr S. Fitzpatrick
Internal Examiner(s): Ms Caroline O’Sullivan, Dr. Sandra Lenihan

Instructions: Answer **FOUR** questions. All questions carry equal marks

Duration: 2 Hours

Sitting: Winter 2012

Requirements for this examination: Calculator

Note to Candidates: Please check the Programme Title and the Module Title to ensure that you have received the correct examination paper.
If in doubt please contact an Invigilator.

- Q1. (a)** List the **FOUR** API classes and give an example of a drug from each class. (4 marks)
- (b)** List **SEVEN** factors that affect the drug presentation to the body? (7 marks)
- (c)** 'Possible routes of drug entry for systemic administration can be divided into two classes-*enteral* or *parental*'. Write a note on the fate of drugs *in vivo* under these two classifications. (14 marks)
- (25 marks)**

Q2.

- (a)** What is the difference between Drug Encapsulation and Drug Entrapment? (5 marks)
- (b)** Write a note on Biodegradable Polymers under the following headings:
- (i) synthetic versus natural polymers,
 - (ii) degradation mechanisms,
 - (iii) factors that affect the biodegradation and
 - (iv) methods of studying polymer degradation.
- (20 marks)
- (25 marks)**

Q3.

- (a)** Solid state properties have a key role in drug formulations. Discuss the impact of crystals in terms of shape and size. (5 marks)
- (b)** Determine the mode for the following Magnesium Stearate data:

Sieve Size (um)	Mass of sample retained on sieve (mg)
300	7.5
250	13.5
212	52.3
150	12.8
106	10.3
53	1.1
27	1.5
Pan	1.0

(12 marks)

- (c)** Write a note on shelf life determination. (8 marks)
- (25 marks)**

Q4.

- (a) Outline a model for Dissolution. A schematic can be used to support your answer. (16 marks)
- (b) Chemical Stability is vital to pre-formulation studies. Discuss covering the following topics;
- i) reaction kinetics,
 - ii) degradation products and
 - iii) photochemical degradation. (9 marks)
- (25 marks)**

Q5

- (a) List the benefits of an accelerated stability programme. (7 marks)
- (b) Discuss the dissolution profile of sustained release dosages. (6 marks)
- (c) Water for Injections is a major ingredient in Formulations. Identify **FIVE** key physiochemical tests to be executed to ensure WFI is of high quality. (5 marks)
- (d) What is Granulation and why do we granulate? (7 marks)
- (25 marks)**