

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Semester 1 Examinations 2011/2012

Module Title: Formulation

Module Code: CHEI7001

School: Biological Sciences

Programme Title: BSc in Good Manufacturing Practice
BSc in Food Science & Technology
BSc (Hons) in Nutrition & Health Science
BSc (Hons) in Pharmaceutical Biotechnology

Programme Code: SGMPE_7_Y3
SFSTE_7_Y3
SNHSC_8_Y3
SPHBI_8_Y3

External Examiner(s): Ms B. Whelan, Dr S. Fitzpatrick, Dr A. Gallagher, Dr J. Bird

Internal Examiner(s): Ms Caroline O'Sullivan

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

Duration: 2 Hours

Sitting: Winter 2011

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)** Define excipients. Give three examples and outline their function. (5 marks)
- (b)** Write a brief note on available pharmaceutical dosage forms. (10 marks)
- (c)** Write a brief note on routes of pharmaceutical administration delivery. (10 marks)
- (25 marks)**

- Q2. (a)** List the five techniques used to produce entrapment and encapsulation of the drug within a polymer. (5 marks)
- (b)** Write a note on biodegradable polymers under the following headings: drug delivery systems, entrapment and encapsulation, degradation mechanisms, factors that accelerate degradation (20 marks)
- (25 marks)**

- Q3. (a)** Solid state properties have a key role in formulations. Outline the impact of the surface area of a particle. (4 marks)
- (b)** Summarise the regulatory requirements in using excipients in formulations. (8 marks)
- (c)** Collate a frequency distribution curve for the following Starch data and determine the mode:

Sieve Size (μm)	Mass of sample retained on sieve (mg)
1000	4.5
710	10.2
500	21.3
250	31.5
150	15.7
100	11.2
53	4.4
Pan	1.2

(13 marks)
(25 marks)

- Q4.** (a) Define Dissolution (3 marks)
- (b) Describe the Dissolution process in detail. Schematics can be used to support your answer. (17 marks)
- (c) Sketch the key features of a Basket Dissolution Apparatus. (5 marks)
- (25 marks)**
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- Q5.** (a) Summarise the importance of shelf life determination. (6 marks)
- (b) Define hygroscopicity and outline what drug properties can it effect. (6 marks)
- (c) Discuss the dissolution profiles of sustained release dosages. (8 marks)
- (d) “Water for Injections” (WFI) is a major ingredient in Formulations. Identify four key physiochemical tests to be executed to ensure WFI is of high quality. (5 marks)
- (25 marks)**