

**CORK INSTITUTE OF TECHNOLOGY
INSTITIÚID TEICNEOLAÍOCHTA CHORCAÍ**

Autumn Examinations 2012

Module Title: Formulation

Module Code: CHEI7001

School: Biological Sciences

Programme Title: Bachelor of Science in Good Manufacturing Practice and Technology

Programme Code: SGMPE_7_Y3

**External Examiner(s): Dr Stephen Fitzpatrick, Ms Bernadette Whelan
Internal Examiner(s): Ms Caroline O' Sullivan**

Instructions: Answer FOUR questions. All questions carry equal marks

Duration: 2 Hours

Sitting: Autumn Repeat 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.

(4 marks)

(b) What is Granulation and why is this process important in Formulation?

(10 marks)

(c) Write a brief note on routes of pharmaceutical administration delivery.

(11 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) Define excipients. Give three examples and outline their function.

(4 marks)

(b) Summarise the regulatory requirements for 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)

Q5. (a) What are the factors that effect Voidage?

(5 marks)

(b) Water for Injections is a major ingredient in Formulations. Identify four key physiochemical tests to be executed to ensure WFI is of a high quality.

(5 marks)

(c) Outline the criteria for Binders.

(6 marks)

(d) Write a note on Reverse Osmosis.

(9 marks)

(25 marks)