Exam Code(s)  3EV2 and 3BS9
Exam(s)  Third Science Examination
Module Code(s)  CH327
Module(s)  Validation and Industrial Chemistry

Paper No.
Repeat Paper

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Instructions:  Answer 2 questions from each section (4 questions in total)
Use separate books for each section

3BS9 Students answer questions from sections A and B only
3EV2 Students answer questions from sections B and C only
All questions will be marked equally

Duration  2 hours
No. of Pages  5
Department(s)  Chemistry
Course Co-ordinator(s)  Dr. L. F. Jones

Requirements:
MCQ
Handout
Statistical Tables
Graph Paper
Log Graph Paper
Other Material
Please use separate answer books for each section

**Section A**

1. With respect to the pharmaceutical industry explain the term Process Analytical Technology (PAT) and discuss its origin and objectives from the viewpoint of manufacturers and regulators.

   [25 marks]

2. With respect to the manufacturing of pharmaceuticals, biopharmaceuticals and medical devices, discuss in good detail the following headings:

   (a) Validation

   [11 marks]

   (b) The Validation Master Plan (VMP) and its aims and benefits

   [14 marks]

3. **Answer all parts**

   In terms of cleaning validation discuss the following headings:

   (a) Validation Protocol Documentation

   [5 marks]

   (b) Equipment to be cleaned

   [5 marks]

   (c) Personnel responsibilities

   [5 marks]

   (d) Sampling methods

   [5 marks]

   (e) Record keeping

   [5 marks]

4. **Answer all parts**

   (a) Describe a medical device that may be used in the treatment of damaged heart valves? In your answer give the classification of the device and explain the reasons for this classification?

   [10 marks]

   (b) Give a brief description of one heart condition that can be treated with a cardiac rhythm management (CRM) medical device? In your answer describe how the device is used to treat the disease.

   [10 marks]

   (c) Why might an investigational device exemption (IDE) be required prior to obtaining U.S approval for either of the examples given in part (a) and (b) of this question?

   [5 marks]
Section B

5. Answer all parts

(a) Aluminium occurs as bauxite, which contains aluminium oxide with impurities mainly of iron oxide and silica. Outline how bauxite is processed to give pure aluminium oxide, showing clearly the chemical basis for the method.

[7 marks]

(b) Aluminium is produced by electrolysis of purified aluminium oxide. State briefly the necessary conditions used and sketch and label the cell used. Give the reaction at each electrode.

[8 marks]

(c) Describe the advantages and disadvantages of homogeneous and heterogeneous catalysis and the reactor types that suit each type of catalyst.

[10 marks]

6. Answer all parts

(a) Outline the Monsanto process for the production of acetic acid.

[8 marks]

(b) What is an olefin metathesis reaction?

[4 marks]

(c) Sketch the mechanism of an alkene metathesis reaction.

[4 marks]

(d) Which typical metals are used in metathesis catalysts?

[4 marks]

(e) Draw the chemical structure of the Grubs 1st. and 2nd. Generation metathesis catalysts.

[5 marks]
Section C

7. Answer all parts

(a) Explain in detail the fate of a sample molecule as it is passed through a mass spectrometer. Use diagrams in your explanations to describe each step.

[10 marks]

(b) The electron impact ionisation spectrum of propanoic acid (CH₃CH₂COOH) is given below. Account for the major peaks in the spectrum (only those indicated) and draw a suggested fragmentation mechanism for propanoic acid that leads to the formation of the respective ions. Comment on the relative intensities of the main four peaks.

[10 marks]

(c) Calculate the resolution that is required to determine the mass to charge signals for the following two molecules: (i) C₆H₁₂ (84.0939 amu) and (ii) C₅H₈O (84.0575 amu).

[5 marks]
8. Answer all parts

(a) Draw a schematic of a typical gas chromatography setup.

[4 marks]

(b) Explain the fundamental theory of chromatography using column chromatography as an example. In your answer use and define the following terms: mobile phase, stationary phase, adsorption chromatography, partition chromatography, retention time, polarity, affinity, theoretical plates, plate heights and band spreading.

[10 marks]

(c) Explain the concept of theoretical plates in chromatography.

[6 marks]

(d) The retention time of a solute X is 105s. The peak width at half-height is 2.15s and the column length is 15m. Calculate the number of plates and the plate heights.

[5 marks]

9. Answer all parts

(a) Kramer’s formula $\lambda_v = \frac{hc}{U}$, $I_M = k_i ZU^2$ is used to describe what concept? Illustrate your answer with appropriate diagrams. Explain each term in the equation.

[12 marks]

(b) Explain the concept of intensity enhancement and describe its impact on quantitative XRF measurements.

[8 marks]

(c) Name five (5) advantages of the XRF technique.

[5 marks]