COMMONWEALTH OF AUSTRALIA

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Warning

CHARLES DARWIN UNIVERSITY

Family Name	
Given Names	
Student Number	
Teaching Period	Semester 2, 2016

FINAL EXAMINATION	**DURATION**
PHA302 – Applied Pharmaceutics	Reading Time: **10** minutes Writing Time: **120** minutes

INSTRUCTIONS TO CANDIDATES

Answer questions in the spaces provided on this exam paper.

There are two sections for this paper.

Section A, Time: 48 minutes. Answer **ALL** multiple choice questions.

Section B, Time: 72 minutes. Answer **ALL** short answer questions.

EXAM CONDITIONS

You may begin writing from the commencement of the examination session. The reading time indicated above is provided as a guide only.

This is a CLOSED BOOK examination

Any non-programmable calculator is permitted

No handwritten notes are permitted

Hard copy, unannotated English translation dictionary only

ADDITIONAL AUTHORISED MATERIALS	**EXAMINATION MATERIALS TO BE SUPPLIED**
No additional printed material is permitted	1 x Scrap Paper

THIS EXAMINATION IS PRINTED DOUBLE-SIDED.

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SECTION A

INSTRUCTIONS FOR QUESTIONS 1 - 48

Answer all questions by circling your answer ("A" to "E") for each question.
Each question is worth 1 mark and has only one correct response.
This section is worth 40% (48 marks) of the examination.

***** END OF SECTION A *****

Section B continues on the next page.

SECTION B

INSTRUCTIONS FOR QUESTIONS 49 - 58

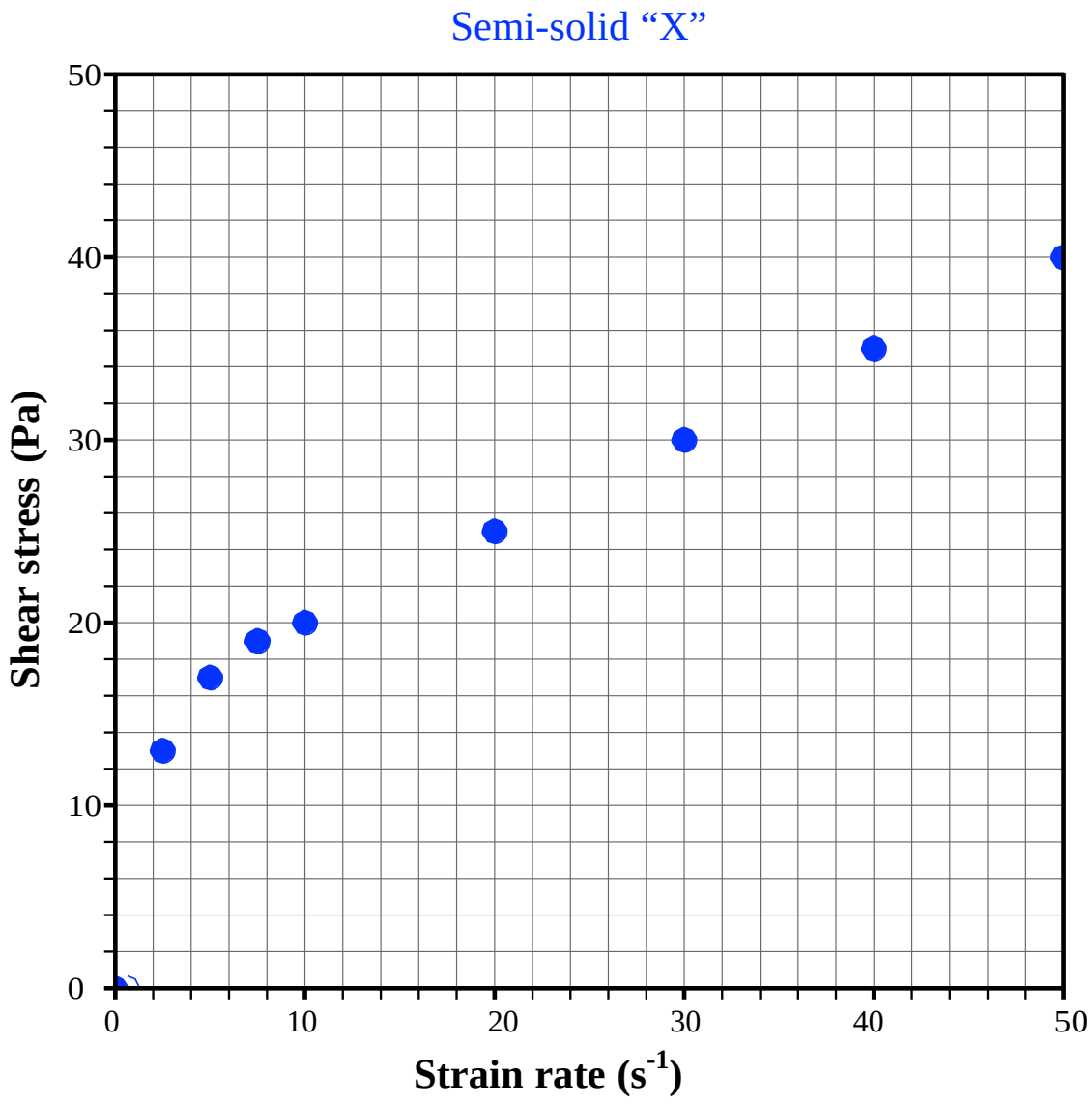
Answer all questions in the space provided on this examination paper. Each question specifies the number of marks for the question and, where appropriate, sub-questions. Follow the instructions given in each question.

This section is worth 60% (72 marks) of the examination.

Question 49 [6 Marks]

Answer BOTH parts:

This question concerns the up-curve of the rheogram for semisolid material X shown below:



(a) Sketch the up-curve using the data points provided and, showing your method on the graph, hence estimate:

Bingham died stress: f =

Actual yield stress: a =

[3 Marks]

(b) Showing your working, calculate the "coefficient of plastic viscosity" for semisolid material X.

[3 Marks]

Coefficient of plastic viscosity, U = _____

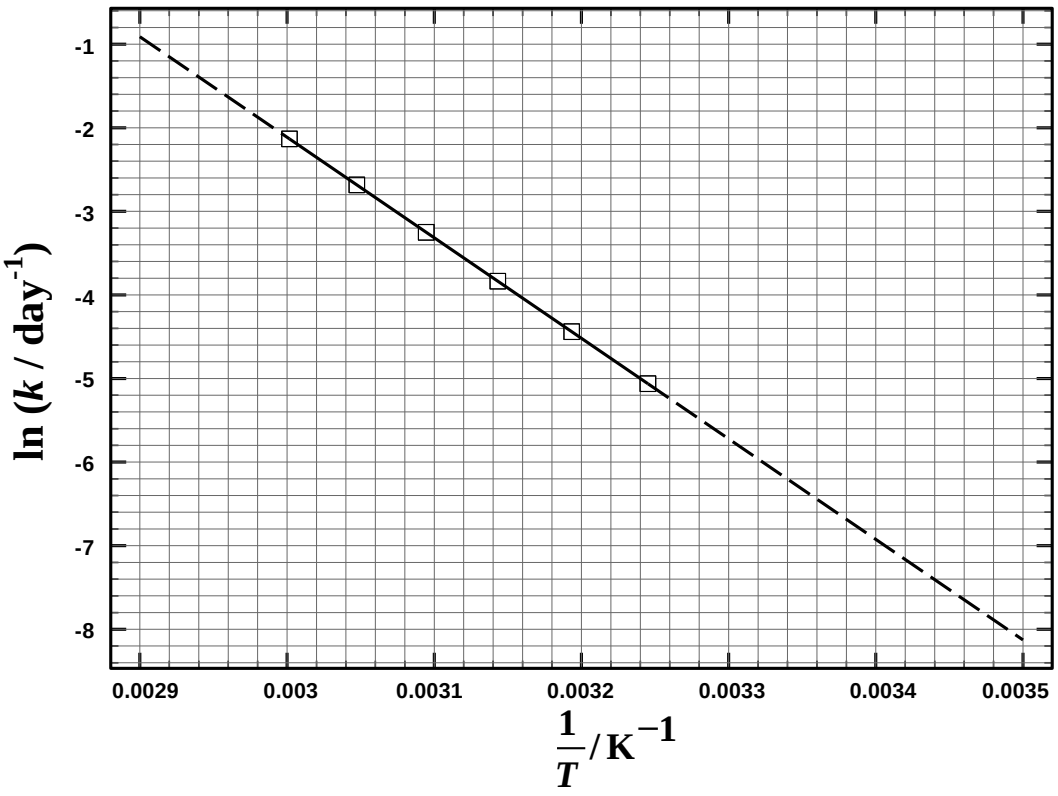
Question 50 [13 Marks]

Accelerated stability testing is based upon the Arrhenius equations:

$$k = Ae^{-\frac{E_a}{RT}}$$

where R = 8.314 J K^{-1} mol^{-1}

This is employed throughout the pharmaceutical industry. Constructing an Arrhenius plot for new solid formulation subject to hydrolysis results in the following:



(a) Given 0 °C = 273.15 K, calculate $\frac{1}{T}$ at 25 °C and hence determine ln(*k*) (marking your method on the graph above) and the first-order rate constant *k*. [2 Marks]

calculation of 1/T

Ln(*k*) = _____ show your method on the graph

k = _____ include the units

(b) Given the equation for first order decay is:

$$C_t = C_0 e^{-kt}$$

where k = first-order rate constant

Showing your working, confirm that the half life of first-order kinetics is

$$t_{½} = \frac{Ln\ (2)}{k}$$

and hence calculate the half life of the formulation at 25°C. [3 Marks]

Derivation:

The half life of the formulation at 25 °C is _____

(c) Assuming the shelf life of the formulation is the time to 5 % degradation (95 % of original activity), showing your working, calculate the shelf life of the formulation at 25°C in days. [3 Marks]

(d) Calculate the gradient of the graph and hence the activation energy for the degradation reaction. [3 Marks]

(e) State whether the Ahrennius equation projection of shelf life is reliable for this drug and outline two (2) reasons why this is the case: [2 Marks]

Valid?

Reason 1

Reason 2

Question 51 [6 Marks]

List THREE (3) physicochemical properties of a drug that must be considered when developing a formulation for nasal delivery. Explain the importance of each.

1

2

3

Importance of 1

Importance of 2

Importance of 3

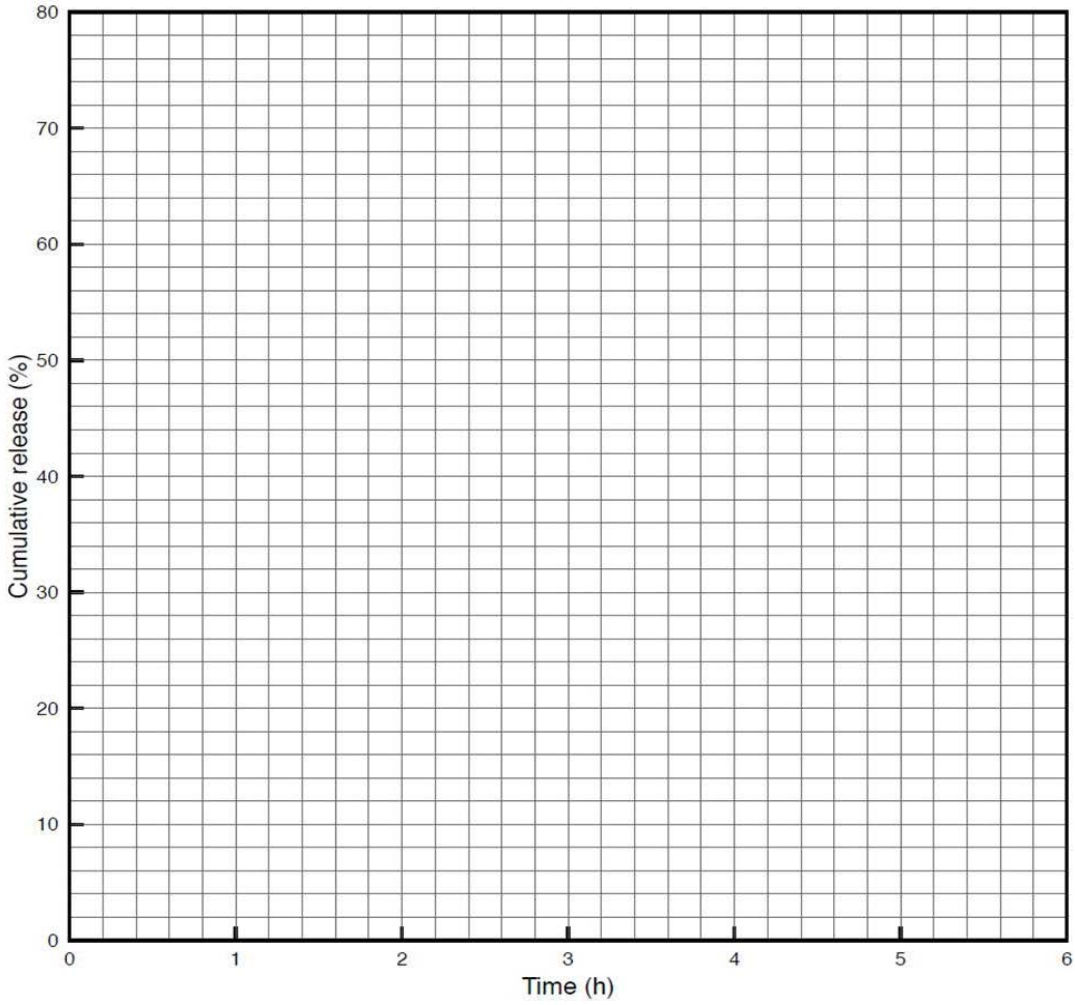
Question 52 [6 Marks]

Answer **BOTH** parts:

The release of drug from an oral formulation is given below:

Time (h)	0	1	2	4	6
Cumulative release (%)	0	8.9	22.2	48.9	75.6

(a) Complete the graph of cumulative drug release against time from the tabulated data above and, showing your method on the graph, determine the lag time of the absorption process. [5 Marks]



The estimated lag time is: _____._____ hours.

(b) State whether the device is controlled release or modified release and outline the reason for your answer: [1 Mark]

The device is: Controlled release [ ] Modified release [ ]

Because:

Question 53 [6 Marks]

Epithelia demonstrate "polarity". Explain how polarity is achieved using a suitable example.

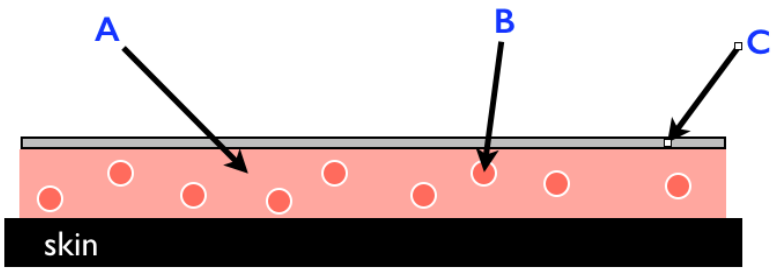
[6 Marks]

Question 54 [8 Marks]

Answer **BOTH** parts:

Below is a diagram of a membrane moderated transdermal patch.

(a) Identify the labelled components (A-C). [3 Marks]



A _____

B _____

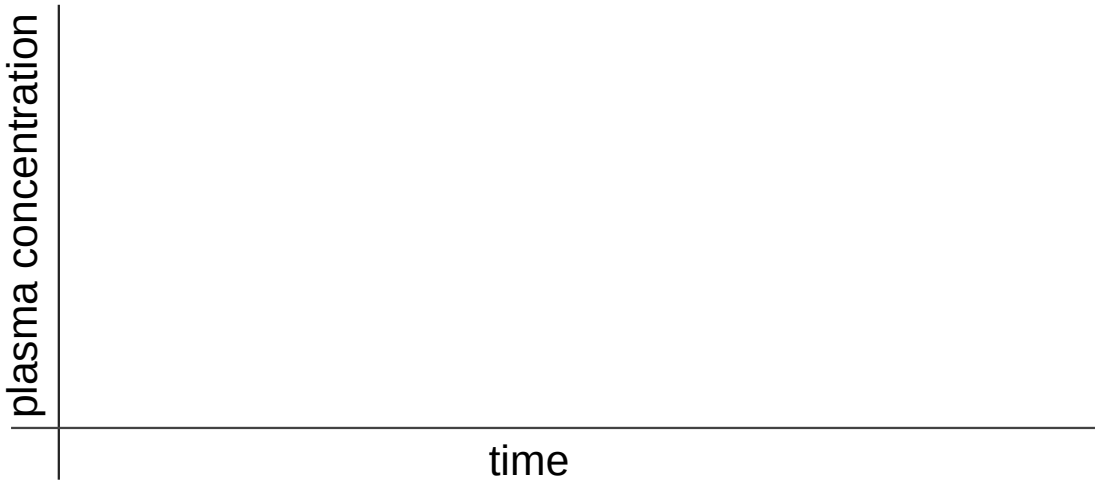
C _____

(b) Explain the nature of the rate limiting step in the absorption process and the observed absorption kinetics that result. [5 Marks]

Question 55 [10 Marks]

Answer **ALL** parts:

(a) Many formulations are either controlled release or modified release. With the aid of a suitable diagram of plasma concentration against time, define these terms and explain the difference between these formulation types. [5 Marks]

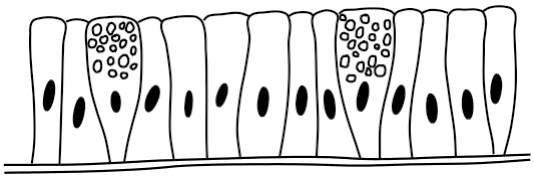


(b) MR formulations release their drug content in two aliquots or portions (referred to as *Di* and *Dm).* Explain why such a pattern of release is desirable and the rate-limiting step in the absorption of each aliquot. Explain how multiple-unit membrane devices achieve the release of components *Di* and *Dm.* [5 Marks]

Question 56 [6 Marks]

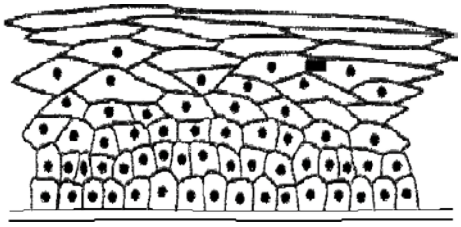
For each of the epithelia shown in the diagrams below, identify the type, function and a suitable example, explaining the purpose of any specialised cell types and appendages.

(a)



[3 Marks]

(b)



[3 Marks]

Question 57 [4 Marks]

Answer **BOTH** parts:

(a) Poor physical stability is a key issue of protein therapeutics. Outline two (2) factors that can cause physical degradation of proteins. [2 Marks]

1

2

(b) Explain one (1) formulation strategy that can be used to increase the bioavailability of protein therapeutics. [2 Marks]

Question 58 [7 Marks]

Answer **ALL** parts:

(a) Briefly explain the terms "dependent" and "independent" in relation to the filling of hard gelatin capsules. [2 Marks]

Dependent

Independent

(b) Briefly explain why conventional capsules may be less expensive to produce than an equivalent tablet. [3 Marks]

(c) List two (2) excipients that may accompany the powdered drug in a hard gelatin capsule and give an example of each. [2 Marks]

1	Example:
2	Example:

*** END OF SECTION B ***

*** END OF EXAMINATION ***