**PMY8111 Section A Question 3**

**PLEASE STATE YOUR FIVE DIGIT ANONYMOUS CODE:**

1. In 1975, Chien et al. published a research article entitled 'Controlled Drug Release from Polymeric Delivery Devices III: In *Vitro-In Vivo* Correlation for Intravaginal Release of Ethynodiol Diacetate from Silicone Devices in Rabbits'. In that study, female rabbits (n=40) were implanted with silicone vaginal rings containing ethynodiol diacetate for up to 8weeks. In an effort to establish an *in vitro*-*in vivo* correlation, Chien and his co-authors produced the following graph, showing the correlation between the plasma concentration (*CB*) of norethindrone (the major metabolite of ethynodiol diacetate) and the *in vitro* release rate (*Q*/*t*; referred to as 'flux' in the figure caption) at various time points.

Chart, scatter chart

Description automatically generated

***Figure 1.***

1. What level of *in vitro*-*in vivo* correlation (IVIVC) do the data in the figure represent? Give a reason for your answer.

[10%]

1. Across how many time points were the *in vivo* and *in vitro* data collected?

[10%]

The article also includes the following graph, showing *in vitro* cumulative drug release (Q) versus the square root of time for a silicone elastomer ring device initially containing 30 mg ethynodiol diacetate.

Chart, line chart

Description automatically generated

1. Based on the data presented in this *in vitro* release graph, comment on the type (i.e., the design) of the vaginal ring that was tested.

[20%]

1. How might you change the formulation to increase the rate of release of ethynodiol diacetate?

[10%]

1. With reference to a specific example you have studied, outline the experimental techniques that can be used to investigate microbial penetration across microneedle-punctured skin.

[50%]

Please write your answer between the lines above and below this sentence (you may delete this text)

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Marks awarded for this question: