BIRLA INSTITUTE OF TECHNOLOGY & SCIENCE, PILANI
Comprehensive Examination (Close book)
DOSAGE FORM DESIGN PHA G632 SEM II 2022-2023

Max. Marks: 40 **Duration: 180 min** **Date:16.05.2023**

Answer all the subparts of a question together. If any, the answers of parts of the same question should be written together. Each question should be answered on a new page.

Q. 1: A drug X is available in the form of a tablet dosage form and is recommended to be administered orally, three times daily, with food for 60 days. The drug substance has low solubility across the physiological pH. If a dose is missed, it is recommended to take the missed dose as soon as possible, together with food. However, if it is within 3 hours of the next scheduled dose, skip the missed dose and continue treatment as prescribed. Based on the data available for the drug X tablet dosage form, explain the following

a. What is the effect of food on the C_{max}, T_{max} and AUC of the drug X after oral administration of the tablet?
b. Why should the missed dose be skipped if it is within 3 hours of the next scheduled dose?
c. What is the effect of food if the drug X is formulated in the form of an oral solution?
d. In your opinion, is there any limitation of the present therapy? If yes, suggest a suitable alternative dosage form/delivery strategy with appropriate justification.

[8]

Q.2: Elaborate on general considerations involved in the parenteral delivery of therapeutic proteins and peptides. Describe various approaches for subcutaneous controlled delivery of proteins and peptides with suitable examples. [4+4=8]

Q 3: Explain limiting factors for nasal drug delivery. Describe various devices used for nasal drug delivery. Which is the most efficient nasal drug delivery method in your opinion and why? [3+3+2=8]

Q 4: Describe different vaccine delivery systems with the route of administration. Which is the most efficient strategy for vaccine delivery in your opinion and why? (8)

Q 5: Describe limiting factors for transdermal drug delivery. Explain various physical approaches that breach the stratum corneum for transdermal drug delivery [8]

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