Birla Institute of Technology and Science, Pilani (Raj.)
Second Semester 2021-22
PHA G537: Parenteral Products Development
MID-TERM EXAMINATION

Max. Marks: 30 **OPEN BOOK**
Date 15-03-2021 **Duration: 90 Minutes**

All questions are compulsory.
Attempt all the questions in the order as given in the question paper and all the parts of a question should be attempted together.

Q1. Short question answers: [4M]

a) What is backfilling in lyophilization?
b) Role of sample thief in lyophilization?
c) Secondary drying carried out at 40°C for 6 h does not compromise the stability of heat sensitive products.
d) Why do we see a rim of dried solids adhering to the glass surface in lyophilized products?

Q2. Discuss the broad categories of solvents used to formulate solutions for parenteral dosage form. [3M]

Q3. What are the 2 techniques for preparing Sterile powders for injection, compare the two in tabular form. [1+2 M]

Q4. Match the following- [2]

Product Name	Formulation
Treanda	Polymeric implants
Propofol	Emulsion
Gliadel	Liposomes
AmBiSome	Suspension

Q5. A NCE, ANMCX567 has to be formulated as a parenteral formulation. [4+3M]

Make all suitable assumptions regarding its physicochemical properties as well as for the formulation to be designed and discuss a step-wise approach that you would follow/ all factors to be considered to develop a suitable formulation.

The first choice for dosage form is solution for IV administration in multiple doses, however, the required dose of the drug is 50mg/ml and the solubility is 20 mg/ml in water. The drug has a high Log P value and is non-ionizable. Suggest a step wise approach (with rationale) to overcome the solubility issue of the molecule to formulate it as a solution for parenteral route. Mention name of excipients if required to be used.

Q6. What should be the precautions while using the following excipients/API in a parenteral formulation and suggest a solution for the same---- [4M]

a) Ethylenediaminetetraacetic acid
b) Peptide/Protein having sulfhydryl containing amino acids
c) Polysorbates
d) Co-solvents

Q7. Lyophilization in parenterals [0.5+2+4.5M]

a. What is the significance of determining critical temperature of the bulk solution before lyophilization?
b. How to determine critical temperature?
c. Design a lyophilization recipe for a bulk solution having a critical temperature of -30°C and Glass transition temperature of -32°C. The bulk solution consists of some amorphous components as well which cannot be frozen at temperature lower than -30°C. Depict the recipe on a lyo chart also.

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