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

Max. Marks: 15 M **CLOSED BOOK**
Date 10-05-2022 **Duration: 70 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; questions not attempted in order or parts of a question not attempted together will not be checked.

Q1. Complete the following statements— [0.5M*5= 2.5M]

1) The clean room specification for carrying out Lyophilization operation is----------?
2) The key consideration during the preparation, transfer, and filling operations of an emulsion based parenteral product should be----------
3) Omniflex® rubber stopper consists of a coating of ---------- and ----------.
4) Tyvek uniforms are worn by the personnel working in aseptic manufacturing facilities because----------
5) Contact plates differ from settle plates in that----------

Q2. What is the most suitable sterilization technique for the following- [0.5M*3= 1.5M]

1) Glass vials
2) Rubber closures
3) Plastic tubings

Q3. NewGEN Pharma Ltd. is planning to launch a generic version of Doxil® in the market. What are the key characterization tests that it requires to undertake to ensure a bioequivalent and therapeutically equivalent product to Doxil? [4M]

Q4. How will you select the most appropriate method that can provide maximum assurance of sterility for an oil based vitamin formulation? [3M]

Q5. Compare the advantages and limitations of prefilled syringes and cartridges as packaging devices for the injectable products. [2M]

Q6. Discuss the different types of SVPs available commercially. [2M]

XXXXXXXXX

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

Max. Marks: 25 **OPEN BOOK**
Date 10-05-2022 **Duration: 110 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; questions not attempted in order or parts of a question not attempted together will not be checked.

Q1. Why does small scale manufacturing of parenteral products mainly rely on presterilized components and equipments? [2M]

Q2. Discuss at least 03 specific reasons to support the fact that, "It is very challenging to establish pharmaceutical equivalence in complex injectables." [3M]

Q3. Answer for following regarding Lyophilization--- [2M]

a) Sublimation can occur at any pressure including atmospheric pressure if ice vapor pressure in less than 4.5 torr then why do we evacuate in product chambers of lyophilizers?
b) What is the role of a pressure measuring gauge in lyophilizer?

Q4. What is the correlation between Z value and D value in sterilization cycles, explain with a suitable example? [2 M]

Q5. Discuss the approaches employed for Sterilization Cycle Development. [3M]

Q6. Personnel plays a key role in maintaining the sterilization in an aseptic processing unit. What type of training is giving to the personnel employed in aseptic manufacturing operations? How is it ensured that the personnel have been appropriately trained and is now capable of carrying out the manufacturing operations independently? [2+3M]

Q7. As a formulation scientist, you are assigned the task of designing a parenteral formulation of a peptide (isoelectric point 4.2) based therapeutic for a chronic ailment, diabetes, which requires multiple injections. The peptide contains L-asparagine and L-glutamine and methionine amino acids and possesses a half-life of 4-6 min. [3+2+1+2 M]

a) Design a suitable parenteral dosage form for the said peptide and enlist the excipients required for this formulation
b) Describe briefly the unit operations (step wise) for the large scale manufacturing of this product
c) If lyophilization is required for such a product, whether you would prefer amorphous or crystalline bulking agents?
d) Suggest a suitable packaging for the dosage form.

XXXXXXXXX