Exam Seat No:_____ **Enrollment No:**_____

C.U.SHAH UNIVERSITY

WADHWAN CITY

University (Winter) Examination -2013

Course Name :M.Pharm Sem-I **Subject Name: - Fundamental of Formulation and Product Development**

Duration :- 3:00 Hours **Date : 10/01/2014**

Instructions:-

(1) Attempt all Questions of both sections in same answer book / Supplementary.
(2) Use of Programmable calculator & any other electronic instrument is prohibited.
(3) Instructions written on main answer Book are strictly to be obeyed.
(4) Draw neat diagrams & figures (If necessary) at right places.
(5) Assume suitable & Perfect data if needed.

SECTION-I

Q-1 Answer the following short questions. (7)

1. Define Partition Coefficient
2. The Sweetning agent cum diluents commonly used in chewable tablet formulation is_____
3. What is HLB Scale?
4. Gel Property of CARBOPOL is affected by_____
5. If thepka of Phenobarbitone is 7.4 , what fraction of the drug would be ionized at pH 8.4?
6. Emdex and Celutab are used as _____
7. Avicel is Chemically_____

Q-2(a) What is Preformulation ? How it can be characterized? What is the preformulation data report and explain its contents in detail. (5)

(b) What do you mean by co-processed excipients? Explain with example (5)

(c) Write a note on mechanisms of biodegradation of materials. (4)

OR

Q-2 (a)What do you mean by intrinsic solubility? Explain Inclusion complexation technique. Discuss importance of beta-cyclodextrin utility number and derive the equation. (5)

(b) Write a detailed account on polymeric excipients for controlled release applications. (5)

(C) Write a brief note on techniques to estimate log P value (4)

Q-3(a) Define Polymorphism and pseudo-polymorphism.Enlist the methods to identify polymorphism.Comment on dissolution behavior and stability of polymorphs. (7)

(b)What is solubility? How solubility is predicted mathematically? Discuss the use of salt formation, surfactants and clatharates in solubilization of poorly soluble drugs. (7)

OR

Q-3(a)"Bioavailability of poorly soluble APIs is Challenging to formulation scientist " Discuss physical and chemical modifications of APIs and use of excipients to solve this problem. (7)

(b) Discuss safety and regulatory issues of excipients in formulation development. What is compatibility issue regarding excipients ? Describe in detail Three major types of Compatibility issues. (7)

SECTION-II

Q-4 Answer the following Short Questions **(7)**

1.Write full form of ICH

2. According to USP , Apparatus I is_____ and Apparatus II is_____

3.According to ICH guidline, for new drug products-solid oral: general Case, Accelerated stability study is carried out at a temperature of_____ and relative humidity of _____

4.According to ICH guideline Q1B, the sample should be exposed to light providing an overall illumination of not less than _____million lux hours.

5.The Specific ICH guideline _____ under Q1 describes the detail evaluation of stability data.

6.According to BCS, class II drugs exhibits_____ solubility and _____ permeability.

7.To carry out dissolution testing of transdermal patch, the temperature of dissolution medium should be st at _____degree C.

Q-5(a) Write a note on Biopharmaceutics Classification System and its emphasis in dosage form development. (5)

(b) Describe the equipment related factors affecting results of dissolution testing (5)

(c) Explan Bio-relevant media and Dissolution mimicking (4)

OR

Q-5(a) Discuss Accelerated stability study and its correlation with real time stability study (5)

(b) Discuss the requirements related to stability testing with emphasizing atrixing/Bracketing technique. (5)

(C) Write the importance of Documentation and records in GMP. (4)

Q-6(a) What is Photostability study? How it is Performed? Explain regulatory requirements for the same. (7)

(b) Write a detail note on major hurdles and challenges associated with herbal product development. (7)

OR

Q-6(a) Explain the process related factors affecting stability of solid dosage forms and give the way for stabilization (7)

(b) What is the significance of dissolution testing? Describe dissolution test for unconventional and novel dosage forms. (7)

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