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MASTER OF PHARMACY & M. PHARM. CLINICAL PHARM. & PHARM. PRACTICE EXAMINATION 2017

(1ST SEMESTER)

Pharmaceutical Pre-formulation and Product Development

Time : 3 hours Full Marks : 100

Answer any five questions.

Answer all parts of a question in one place.

1a) How will you proceed to select excipients during development of tablet dosage form?

b) Why size distribution of granules should be standardized during development stage of tablet dosage form?

c) Discuss the effects of different processing and formulation factors on size and size distribution of granules. 10+4+6=20

2 a) Write the importance of determining the aqueous solubility of a new drug molecule during pre-formulation stage.

b) Describe Phase Solubility method for the determination of solubility of a drug.

c) Write an expression to relate solubility of a drug with ideal solubility and activity coefficient in water. Based on this expression, discuss the different approaches to improve aqueous solubility of drugs.

d) Keeping the pharmacophore unaltered, introduction of polar/ionizable groups may increase the aqueous solubility of a drug- Discuss with examples.

e) Lowering of M.P. by suitable substitution may increase the aqueous solubility of a drug- Explain with examples. How does the position of substituents affect the solubility? 2+3+5+5+5=20

3 a) Distinguish between Core flow and Mass flow of granules through a hopper.

b) How do the formulation and processing factors affect the flow rate of granules through a hopper?

c) Mention the forces involved in agglomeration of powders and formation of granules during preparation by wet granulation method.

d) Discuss the different factors which should be standardized to obtain reproducible strength and friability of granules. 4+6+2+8=20

4. Discuss the most relevant factors which must be considered from an in-vivo perspective during designing an in-vitro dissolution test method. 20

5 a) Explain the different stages of tablet compression.

b) Do you think that original particle size of a granule may affect the tablet strength? Explain with Heckel equation.

c) Describe ICH guidelines for general stability study of active substances and for active substances which are to be stored in refrigerator. 5+5+10=20

6 a) What informations are obtained from pKa value of an ionizable drug?

b) How will you determine pKa value of a drug which is poorly soluble and does not contain any chromphore?

c) The choice of product formulation will dictate the selection of suitable salt of a new drug- Discuss with examples.

d) Using HPLC, how will you determine Impurity Index and Homogeneity Index of a drug?

2+4+12+2=20

7. Discuss the following:

a) Solid state stability study, b) ICH classification of solvents, c) Different types of hydrates and their identification, d) Effect of log P on ADME of drugs. 6+3+6+5=20

8. Describe in details Caco-2 cell culture technique to determine permeability coefficient and mechanism of transport of a new drug candidate across the biological membrane. 20