M PHARMACY FIRST YEAR FIRST SEMESTER EXAMINATION 2018

SUBJECT: PHARMACEUTICAL PREFORMULATION PRODUCT DEVELOPMENT

Time 3 hours **Full marks: 100**

Answer any **five** *questions*

Group A

Answer at least two question from each group

1. Write down the significances of preformulation investigation of drug-excipients compatibility tests. Write about various methods to investigate various preformulation tests, including such compatibility tests.

4+16 = 20

2. Describe various physicochemical and biopharmaceutical methods to evaluate TDDS film. 20

3. Write about how you will develop vesicular drug delivery system. 20

4. Describe a method to develop virus based drug delivery system. 20

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Group-B

Answer at least any two questions from this Group

Q.5.a) What are the pre formulation studies associated with new API 10

b) Define the following terms:

i)Patent Clauses ii)NIS iii) FOI iv) BCS 4+2+2+2

Q.6.a) What is the solvent system selected for Log P determination? Give justification of the solvent system and outcome of the study. 2+2+2

b) Why forced degradation studies are carried out for API and dosage forms? Write the conditions as per ICH guidelines. 4+4

c) What are the stages of product development for tablet dosage form using approved new API? 6

Q.7.a) What is Pivotal batch? Explain critical parameters for BE studies adopted for pivotal batch. 6

b) What is validation master plan? How you proceed for validation exercise of pivotal batches? 2+4

c) What is IVIVC? How it is significant for bio-waiver decision and it's application for BCS? 2+1+3

d) Explain F-1 and F-2 test in relation to dissolution study 2