Roll No. | | | | | | | | | | | | | Total No. of Pages : 02

Total No. of Questions : 13

B.Pharmacy (Sem.-8)

PHARMACEUTICAL PRODUCT DEVELOPMENT

Subject Code : BP-813 ET

M.Code : 79776

Date of Examination : 15-07-22

Time : 3 Hrs. Max. Marks : 75

INSTRUCTIONS TO CANDIDATES :

1. **SECTION-A is COMPULSORY consisting of TEN questions carrying TWO marks each.**
2. **SECTION-B contains THREE questions carrying TEN marks each and student has to attempt any TWO questions.**
3. **SECTION-C contains NINE questions carrying FIVE marks each and student has to attempt any SEVEN questions.**

SECTION-A

1. Write briefly :

a) Breakthrough products

b) Direct compression

c) Critical process parameters.

d) Disintegration of effervescent tablets.

e) Flash test

f) Full forms of ICH and SUPAC.

g) Level 1 changes.

h) F1 and F2 factors.

i) Tweens

j) Hardness.

SECTION-B

2. Discuss in detail the cyclodextrins and their application in pharmaceutical product development.

3. Enumerate different computer assisted techniques of QBD and discuss factorial design in detail.

4. Discuss the dissolution apparatus I and II along with testing of uncoated tablets mentioned in different pharmacopeias from regulatory point of view.

SECTION-C

5. Explain the significance of new product development.

6. Discuss quality control test of ointments or creams.

7. Discuss the propellents as excipient in aerosols.

8. Which excipients are used for formulation of niosomes, explain?

9. Discuss bracketing and matrixing designs for stability testing of drug substances and drug products.

10. Discuss the labeling requirement on packages according to WHO.

11. Discuss the regulatory aspect of preformulation studies.

12. Discuss the quality assurance aspect of packaging from regulatory point of view.

13. Discuss the solvents and solubilization.

NOTE : Disclosure of Identity by writing Mobile No. or Making of passing request on any page of Answer Sheet will lead to UMC against the Student.