

01.06.2017

Total No. of printed pages = 4

PY 134201

Roll No. of candidate

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2017

M. Pharm 2nd Semester End-Term Examination

**DOSAGE FORM DESIGN AND
PRODUCT DEVELOPMENT**

Full Marks – 100 Pass Marks – 35 Time – Three hours

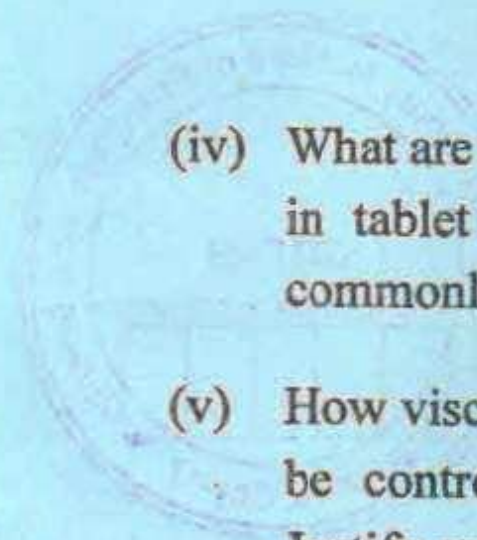
The figures in the margin indicate full marks
for the questions.

1. Answer the following questions (any *ten*) :

3×10=30

- (i) State and mention existence of pressurized package dosage form. Write the advantages of this system over other dosage form.
- (ii) Write the function of actuators used in aerosol system. Enlist the different types of actuators along with their uses.
- (iii) Mention and discuss different steps of sugar coating.

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- (iv) What are the functions of opaquant-extendors in tablet coating ? Give the examples of commonly used opaquants in tablet coating.
- (v) How viscosity of oral liquid formulation can be controlled during the manufacturing ? Justify your answer with suitable examples.
- (vi) Write the chemical structure and salient features of Aspartame.
- (vii) Specify the space requirements for a pilot plant organization.
- (viii) Write in details about the checklist of GMP items that should be part of scale-up or process introduction.
- (ix) Differentiate Nebulizers with DPIs and MDIs.
- (x) Write the stability requirements of DPIs as per International Conference on Harmonization.
- (xi) Write the significance of microbial air testing in parenteral dosage form development.
- (xii) Discuss co-solvency and solubilization with examples.

2. Answer the following questions (any *eight*) :

5×8=40

- (i) Explain the desirable rheological attributes of pharmaceutical suspension and emulsion.
- (ii) Discuss in details the preparation of master manufacturing procedures as per pilot plant scale up techniques.
- (iii) What are the components of aerosol package? Write notes on manufacture of aerosol containers.
- (iv) How will you ensure the proper performance and safety during use and storage of "pressurized package" ? Justify your answer.
- (v) What are the challenges in production of DPIs ? Discuss different secondary processing techniques for manufacturing of stable DPIs.
- (vi) Discuss the recent advances in formulation and manufacturing aspects of oral liquid formulation.
- (vii) What is parenteral admixture and incompatibility ? Write in brief about fluid dynamics of IV control system.
- (viii) Discuss in brief about the recent technologies of taste masking for bitter pharmaceuticals.

- (ix) Give a brief resume about classic optimization and evolutionary operation. What approach is taken in a Canonical type of optimization ?
- (x) Give a detail note on dermatological vehicles and terms used to explain rheological behaviour.

3. Answer the following questions (any *three*) :

$$3 \times 10 = 30$$

- (i) Describe the essential requirements in a pilot plant scale up unit and various functions of a pilot plant team. $6+4=10$
- (ii) Discuss in details the large scale manufacturing and optimization process of soft gelatin capsule. $6+4=10$
- (iii) Discuss different types of packaging system of DPIs. Write about the performance and regulatory requirements for DPIs. $2+4+4=10$
- (iv) Write notes on any *two* : $5 \times 2 = 10$
- (a) Rotary press
- (b) Specialized coatings
- (c) 3^2 factorial design.