

Total No. of Questions :6]

SEAT No. :

P1456

[5049]-507

[Total No. of Pages :3

T.Y. B. Pharmacy

**APIT(ACTIVE PHARMACEUTICAL INGREDIENT TECHNOLOGY)
(2013 Pattern) (Semester - V)**

Time : 3 Hours]

[Max. Marks :70

Instructions to the candidates:

- 1) Answers to the two sections should be written in separate books.*
- 2) All questions are compulsory.*

SECTION-I

Q1) Attempt any one question:

[10]

- a) Define alkylation. Discuss various alkylating agents. Describe the manufacture of any one active pharmaceutical ingredient by alkylation process.

OR

- b) Define nitration. Discuss various nitrating agents. Describe the manufacture of any one active pharmaceutical ingredient by nitration.

Q2) Attempt any five:

[15]

- a) Define oxidation. Enlist various oxidising agents.
- b) Explain any two methods for characterization of polymorphs.
- c) Enlist various methods for reductive amination and discuss any one in brief.
- d) Mention the methods for resolution of racemates. Explain any one method in detail.
- e) Differentiate between unit operation and unit process.
- f) Define active pharmaceutical ingredient, bulk drug and fine chemical with example of each.
- g) Enlist significance of chivality in API industry.

P.T.O.

Q3) Attempt any two:

[10]

- a) Discuss types of hydrolysis and manufacture of an API/API intermediate by hydrolysis.
- b) Mention various approaches for asymmetric synthesis. Explain asymmetric synthesis of metoprolol.
- c) Explain the importance of polymorphism in active pharmaceutical ingredients.
- d) Outline the GMP guidelines for API (Q7a) with respect to following points.
 - i) Buildings and facilities
 - ii) Documentation and Records

SECTION-II

Q4) Attempt any one question:

[10]

- a) What are process variables in API manufacturing. Enlist the process variables and discuss them in brief.

OR

- b) What is work-up and purpose of work-up. Explain suitable techniques employed in work-up procedures in API manufacturing.

Q5) Attempt any five:

[15]

- a) Classify routes for API preparation. Enlist characteristics of cost effective routes.
- b) Discuss reactors in API manufacturing.
- c) Discuss selection of solvents based on their physical characteristics.

- d) Draw the flow chart for manufacturing of amoxicillin trihydrate.
- e) What is a MSDS.
- f) What are the techniques for API purification and isolation.
- g) Give a brief account of characteristics of ideal reagents for preparation of API.

Q6) Write short notes on (Any two):

[10]

- a) Industrial manufacturing of amlodipine with suitable flow charts.
- b) Safety and toxicity considerations for selection of reagents for API preparation.
- c) Strategies for Route selection in API manufacturing.
- d) In - process controls in API manufacturing.

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