Total No. of Questions :6]

SEAT No. :

P1456

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[5049]-507

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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