Total No. of Questions : 6]

SEAT No. :

P1995

[Total No. of Pages : 2

[5145]-507
T.Y. B.Pharm.
ACTIVE PHARMACEUTICAL INGREDIENTS 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 book.***
2) ***Neat diagrams must be drawn wherever necessary.***
3) ***Figures to the right indicate full marks.***
4) ***All questions are compulsory.***

SECTION - I

Q1) What is esterification?What are different types of esterification? Describe manufacturing process of any one API by esterification process. **[10]**

OR

What is nitration? Discuss various nitrating agents. Describe manufacture of any one API by nitration process. **[10]**

Q2) Answer the following (Any Five): **[15]**

a) Define Active Pharmaceutical Ingredient, Bulk drug and Fine Chemical with example of each.

b) Define and give significance of Dehydrating Value of Sulphuric acid (D.V.S).

c) Enlist and describe reducing agents used in amination by reduction.

d) Enlist alkylating agents with examples.

e) Enlist various methods of resolution of racemates of APIs, describe one in detail.

f) What is ICH? What is significance of various ICH guidelines for API manufacturing?

g) What is polymorphism? Give its significance in API.

P.T.O.

Q3) Write Short notes on (Any Two): **[10]**

a) Outline the following with reference to the Q7 guideline of API manufacturing:

i) Process Equipment

ii) Quality Management

b) Asymmetric synthesis of Active Pharmaceutical Ingredients.

c) Methods of preparation of Polymorphs.

d) CMC document and its significance.

SECTION - II

Q4) Attempt any one question: **[10]**

What is a Material safety data sheet? Justify its significance and give a brief description of the contents of a Material Safety Data sheet.

OR

Discuss the process variable in API manufacturing and their effect on product quality and yield. **[10]**

Q5) Attempt any five: **[15]**

a) Discuss with suitable Flow chart the manufacturing process of Atenolol.

b) Enlist the characteristics of ideal reagent for preparation of API.

c) Enlist tools for purification and product isolation. Discuss any one in brief.

d) Explain types of health hazard in API manufacturing.

e) Discuss physical characteristics of solvents for scale-up.

f) Write down the basic differences between expedient route and optimal/ cost effective route.

g) What is work-up in API manufacturing?

Q6) Write short notes on (Any Two): **[10]**

a) Manufacturing procedures and scale-up techniques for Ranitidine.

b) Strategies for route selection in API manufacturing.

c) Design of environment friendly processes.

d) IPCs in API manufacturing.