Total No. of Questions : 6] **SEAT No. :**

P3167 **[Total No. of Pages : 2**

[5245]-507
T.Y. B. Pharmacy (Semester - V)
API TECHNOLOGY
(2013 Pattern)

Time : 3 Hours] ***[Max. Marks : 70***

Instructions to the candidates:

1) ***Answers to the two sections should be written in separate books.***
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 Hydrolysis? Give details of Unit process of Hydrolysis. Describe Hydrolyzing agents. Describe manufacturing process of any one API by Hydrolysis process. **[10]**

OR

Give the summary or Glossary of Q7 Guidelines.

Q2) Answer the following (ANY FIVE) **[15]**

a) Define Active Pharmaceutical Ingredient, with examples.

b) Enlist various equipments used in API manufacturing.

c) Enlist and describe oxidizing agents.

d) Describe various Nitrating agents and give significance of Mixed Acids

e) Describe any one API prepared by Esterification.

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

g) Give details of Schimd Reactor.

Q3) Write Short notes on (ANY TWO) **[10]**

a) API Quality Specifications

b) Chirality and US FDA guideline

c) Nitrators used in API manufacturing

d) Any one API prepared by Oxidation with layout diagram.

P.T.O.

SECTION - II

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

What are optimal routes for scale-up of API? Discuss suitable strategies for selection of the most optimal route.

OR

Classify and discuss reactors used in API manufacturing.

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

a) Discuss solvents that are useful for scale-up.

b) Enlist techniques for API purification and discuss any one technique.

c) What is the purpose of work up in API preparation?

d) Discuss potential health hazards in API preparation.

e) Enlist the various stages in Process development.

f) What are In Process controls in API manufacturing?

g) Explain industrial manufacturing of Metformin with suitable flow charts.

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

a) Process variables in API manufacturing.

b) Work-up procedures in API manufacturing.

c) Industrial manufacturing method & flow chart of Amoxicillin trihydrate.

d) MSDS.