

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 Schimid 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.

