



**PAK-1612040701080400** Seat No. \_\_\_\_\_

**M. P. M. (Sem. VIII) Examination**

**August - 2020**

**Pharmaceutical Analysis - VI**

*(Theory)*

Time : 3 Hours]

[Total Marks : 80

- Instructions :**
- (1) Answer and tie up both the sections separately.
  - (2) Figure to the right indicates marks.
  - (3) Answer three (03) questions from each section.
  - (4) Question one (01) and question five (05) are compulsory.
  - (5) Draw neat and clean diagrams as required.

**SECTION - I**

- 1** Explain the following terms with suitable example : **14**  
(Any Seven)

- (a) Why pharmaceutical quality is important?
- (b) What is calibration? How can you calibrate an instrument? Give example.
- (c) Give the full name of QbD and PAT.
- (d) What is design space? What is its significance in pharmaceutical development?
- (e) How qualification and validation are different?
- (f) What are the objectives of GMP and GPP?
- (g) What are the objectives of patent? Give example.
- (h) What is the full name of ICH and 21 CFR?
- (i) Give the name of regulatory agencies of US and India.
- (j) Comment: The role of QC is more important than QA.

- 2** Answer the following questions :

- (a) What is the difference between QA and QC? **7**  
Discuss their role in pharma industry with suitable example.
- (b) Whether IPQC testing is better or finished product **6**  
testing is better? Discuss with suitable example.

- 3** Answer the following questions :
- (a) What is TQM? Give objective, advantage, and disadvantages of TQM. **7**
  - (b) Discuss: The role of TQM in quality management system with example. **6**

- 4** Answer the following questions :
- (a) What is GLP? Discuss in detail. **7**
  - (b) Discuss the Good Pharmacy Practice in detail. **6**

## **SECTION - II**

- 5** Answer the following questions : (Any **Two**) **14**
- (a) Discuss different elements of QbD with example.
  - (b) What is PAT? Give its principle and applications in pharma industry.
  - (c) Write an informative note: Good Clinical Practice

- 6** Answer the following questions :
- (a) What is intellectual property? Enlist and discuss in detail. **7**
  - (b) What is the objective of GMP? Discuss its role in pharma quality management. **6**

- 7** Answer the following questions :
- (a) What is ICH? Give its brief history and discuss its role in recent pharma world. **7**
  - (b) Write a note: Six sigma **6**

- 8** Answer the following questions :
- (a) What is the role of PCT and WIPO? Discuss Indian scenario of patent. **7**
  - (b) Discuss the role of ISO 9000 and ISO 14000 quality standards in pharma. **6**