MCQ-014-003806 Seat No. _____

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

May / June - 2018

Pharmaceutical Analysis - VI

(Theory)

Faculty Code : 014
Subject Code : 003806

Time : **3** Hours] [Total Marks : **80**

Instruction :
(1) Answer and tie up both the sections separately.
(2) Figure to the right indicates marks.
(3) Answer the 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 term with suitable example : (any **seven**) **14**

(a) What is pharmaceutical quality ?
(b) What is the difference between QA and QC ?
(c) Explain the term: (1) TQM (2) ISO.
(d) QbD is a current need of pharma industry. Explain.
(e) Give full name of (1) GMP (2) GPP.
(f) Discuss briefly the schedule which covers GCP according to D & C act 1940.
(g) Why pharma market need to be regulated ? Explain.
(h) Name the Indian Drug Regulatory Authority.
(i) Explain 21 CFR with reference to US drug regulatory authority.
(j) Give old and new name of ICH.

2 Answer the following questions :

(a) Discuss in detail role and responsibility of QA and QC in pharma industry. **7**
(b) What is the role of total quality control and management ? Enlist activities of TQM. **6**

3 Answer the following questions :

(a) What is the difference between GMP and cGMP ? Discuss inter relationship of QA, QC and GMP. **7**

(b) Discuss personnel and hygiene conditions with a view to GMP for pharma industry. **6**

4 Answer the following questions :

(a) What is the role and objective of GCP? Discuss ICH GCP in detail. **7**

(b) Briefly Discuss about WIPO. **6**

SECTION – II

5 Answer the following questions : (any **two**) **14**

(a) What is the motive to grant a patent to any one ? What is the difference between product patent and process patent ? Discuss.

(b) What is PAT ? How it is different from routine testing procedure ?

(c) Write an informative note on QbD.

6 Answer the following questions :

(a) Why GPP is required? Discuss the role of pharmacist in GPP. **7**

(b) Define GLP and discuss the benefits of GLP with example. **6**

7 Answer the following questions :

(a) What is ISO 9000 and 14000? Discuss with reference to pharma industry. **7**

(b) How TRIPS and Paris Convention is associated with IPR ? Discuss. **6**

8 Answer the following questions :

(a) What is the objectives and functionality of ICH ? Discuss. **7**

(b) What is six sigma? Discuss its role in pharmaceutical manufacturing. **6**
