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PAK-014-003806 Seat No. _____

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

August - 2020

Pharmaceutical Analysis - VI

(Theory)

Faculty Code : 014

Subject Code : 003806

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 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 terms with suitable example : **14**
(Any **Seven**)

(a) How quality of pharma products maintained in industry?
(b) Explain qualification with reference to validation.
(c) Give the full name of QMS and TQM.
(d) Comment : Six sigma concept first time introduced for pharma company.
(e) How PAT and QbD are different?
(f) What is the objective of GPP and PAT?
(g) Enlist the things which cannot be patented? Why?
(h) What is 21 CFR? Where it is implemented?
(i) What is the role of WHO in pharma?
(j) Give the full name of ISO and ICH.

2 Answer the following questions :

(a) How QA and QC are two sides of one coin? Discuss their role and responsibilities. **7**

(b) Why at each stage of production quality must be evaluated? Discuss with suitable example. **6**

3 Answer the following questions :

(a) How overall quality is improved with the concept of TQM? Discuss with example. **7**

(b) Enlist and discuss the activities of TQM. **6**

4 Answer the following questions :

(a) What is GLP? How OECD is associated with it? Discuss the functions of GLP. **7**

(b) How regulatory authorities like WHO and US FDA work for better lifestyle of human being? Discuss with example. **6**

SECTION - II

5 Answer the following questions : (Any **Two**) **14**

(a) What is QbD all about? Discuss with two examples.

(b) What are advantages of PAT over a conventional technique? Discuss.

(c) Write an informative note : WIPO

6 Answer the following questions :

(a) What do you mean by IPR? Enlist and discuss their types. **7**

(b) What is the difference between GMP and cGMP? Discuss the role of GMP. **6**

7 Answer the following questions :

(a) Enlist the objectives of ICH and discuss its functions. **7**

(b) Write a note: GCP **6**

8 Answer the following questions :

(a) What is the concept of Six sigma? Discuss its types and importance. **7**

(b) Discuss ISO 9000 and ISO 14000 in detail. **6**
