BBF-161204070108040 0 Seat No. _____

M. P. M. (Sem. VIII) (W.E.F.-2016) Examination

July – 2021

Pharmaceutical Analysis – VI

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

Instructions : (1) Write and tie up both sections separately.
(2) Question no 1 and 5 are Compulsory.
(3) Answer any 3 questions from each section.
(4) Make suitable assumptions wherever necessary.
(5) Figures to the right indicate full marks.

SECTION - I

1 Answer the following questions : (Any 7 out of 10) **7×2=14**

(1) Explain in brief about ONADE.
(2) Define PCT along with its functions.
(3) Explain trademark and its importance.
(4) Enumerate different activities of WIPO.
(5) Briefly explain different types of patents.
(6) Explain the advantages and disadvantages of TQM.
(7) Differentiate between service mark and trademark.
(8) Define and explain the functions of CBER and CDER.
(9) Define and enumerate different types of IP with examples.
(10) Explain the application and registration process for geographical indications.

2 Answer the following questions : **13**

(1) Explain inter-relation between QA, QC and GMP ? Define cGMP. Explain general components of cGMP. **7**
(2) Write a note on the activities and functions of TQM in pharmacy. **6**

3 Answer the following questions : **13**

(1) Enumerate different offices and program centers of the FDA. Write a note on CFSAN. **7**
(2) Classify ICH guidelines and explain Q1 and Q5 guidelines in brief. **6**

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4 Answer the following questions : **13**

(1) Explain functions and scope of QA and QC in the Pharmaceutical industry. **7**

(2) Briefly explain objectives and scope of GLP. **6**

SECTION - II

5 Answer the following questions : (Any 2 out of 3) **14**

(1) Why QbD is required ? Explain in detail.

(2) Define and explain the different methodology of six sigma.

(3) Differentiate between QA and QC. Explain the concept of URS, DQ, IQ, OQ and PQ in brief.

6 Answer the following questions : **13**

(1) Define and classify different types of medication errors. Explain the role of pharmacists in patient counselling. **7**

(2) Briefly explain the scope and importance of intellectual property rights. **6**

7 Answer the followings : **13**

(1) Define process analytical technology. Write about current approaches and limitations of PAT. **7**

(2) Write a note on USFDA regulatory requirement for cosmetics. **6**

8 Answer the following questions : **13**

(1) What are the advantages of provisional patent filling ? Explain the procedure involved in granting a patent. **7**

(2) Enlist different WHO guidelines. Write a detailed note on WHO stability guidelines. **6**
