DAO-1612040701080400 Seat No. _____

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

April / May - 2022

Pharmaceutical Analysis - VI

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

Instructions : (1) Attempt three questions from each section.

(2) Questions 1 and 5 are compulsory

(3) Figure to the right indicates full marks for the respective question.

Section - I

1 Answer the following questions. (any seven) **14**

(1) Name the Indian Drug Regulatory Authority.

(2) Enlist ICH Quality Guideline.

(3) Explain term (1) TQM (2) ISO.

(4) What is Pharmaceutical Quality?

(5) What is difference between QA and QC?

(6) Define Impurities. Enlist types of Impurities according to ICH Q3 guideline.

(7) What is Intellectual Property Rights?

(8) Give full form of PCT, GATT, WIPO and TRIPS.

(9) Give Full name of (1) GMP (2) GPP

(10) Give Objective of WHO guideline.

2 Answer the following questions.

(1) Give Detail note on TQM. **7**

(2) Discuss Personal and Hygiene condition with a view to GMP in Pharma Industry. **6**

3 Answer the following questions.

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

(2) Briefly discuss about WIPO. **6**

4 Answer the following questions.

(1) Give a note on ICH Q-3 Guideline. **7**

(2) Discuss in detail role and responsibility of QA and QC in Pharma industry. **6**

Section - II

5 Write any two out of three: **14**

(1) Write a Note on QbD.

(2) Give note on GLP.

(3) Give Objective and Function of ICH guideline.

6 Answer the following questions.

(1) Write a note on Six Sigma. **7**

(2) Give importance of GPP and discuss role of Pharmacist in GPP. **6**

7 Answer the following questions:

(1) Write a note on USFDA regulatory requirements for cosmetics. **7**

(2) Give note on PAT. **6**

8 Answer the following questions:

(1) Give note on GMP. **7**

(2) What is ISO 9000 and 14000? Discuss with reference to Pharma industry. **6**