



**MAO-003-0047603** Seat No. \_\_\_\_\_

**B. Voc. (Sem. VI) (CBCS) Examination**

**March / April - 2018**

**BVPAQA - 603 : QC & QA**

*(Pharmaceutical Analysis & QA)*

**Faculty Code : 003**

**Subject Code : 0047603**

Time :  $2\frac{1}{2}$  Hours]

[Total Marks : 70

- Instructions :** (1) All questions are compulsory and carry equal marks.  
(2) Draw diagram and/or scheme wherever necessary.

**1 (A) Answer the following questions : 10**

- (1) Define Test Facility Manager.
- (2) What are the objectives of SOPs?
- (3) What is TQM?
- (4) What is the term of a copyright?
- (5) Who is responsible to pay fees for keeping Geographical Indication in force?
- (6) What are Intellectual Property Rights?
- (7) Who coordinates the activities of PCT?
- (8) IPR are defined as \_\_\_\_\_ rights.  
(positive, negative, neutral)
- (9) Differentiate tangible and intangible properties with example.
- (10) Elaborate NDA and ICH.

**(B) Answer the following questions : 20**

- (1) What is UPOV?
- (2) Explain Site Master File.
- (3) What can be protected by Trade Secret? Explain with application.

- (4) What is BMR? Explain briefly.
- (5) Explain the term Novelty with its classification.
- (6) Differentiate QA and QC.
- (7) Explain NDA in brief.
- (8) Enlist ICH guidelines for Quality.
- (9) Differentiate GMP and GLP.
- (10) Enlist various ICH guidelines.

**2** Answer any 4 out of the following 6 questions : **20**

- (1) Describe general structure of a granted Patent Document.
- (2) Write a detailed note on TQM.
- (3) Explain structure of a patent document. Differentiate between provisional specification and complete specification.
- (4) Explain requirements for registration of pharmaceuticals.
- (5) Write a detailed note on copyrights as an IPR tool.
- (6) Explain Geographical Indication with examples.

**3** Answer any 4 out of the following 6 questions : **20**

- (1) What are the legislations covering IPR in India?
- (2) Enlist conditions for Patentability. What are the types of inventions which are not patentable in India?
- (3) Explain Trademark, Well-known trademark, and service mark with examples.
- (4) Explain GMP with special reference to production area and personnel.
- (5) Enlist the advantages of Paris Convention. What does it mean by National Treatment?
- (6) Write a detailed note on SOP.