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MCA-003-028202 Seat No. _____

P. G. D. S. A. I. T. P. I. (Sem. II) (CBCS) Examination

April / May - 2018

PGDI - 202 : IPR Patent Docu. Statutory & Regulatory Affairs

Faculty Code : 003

Subject Code : 028202

Time : $2\frac{1}{2}$ Hours] [Total Marks : **70**

Instructions : (1) All questions carry equal marks.

(2) All questions are compulsory.

1 Answer the followings : (Any **Seven**)

(1) Define the following terms :

(a) Drug Product

(b) Drug Self life

(2) Write a short note on quality assurance.

(3) Differentiate ruggedness and robustness.

(4) Explain trademark with suitable example.

(5) What is IPR? List the different types of IPRs.

(6) Explore the term Calibration with its importance.

(7) Explain the terms repeatability and reproducibility.

(8) Differentiate working standard and certified reference material.

(9) Discuss different zones according to their climatic condition with reference to Q1 guideline.

(10) Write an importance of labeling in pharmaceutical.

2 Answer the followings : (Any **Three**)

(1) What is residual solvent? Classify residual solvent with examples.

(2) What is stability study? Describe main objective and factor affecting to stability study.

(3) Write about different types of LOD measurement methods in detail.

(4) Define the following terms :

(a) Specification

(b) Placebo

(c) Out of Trend

(d) Active Pharmaceutical Ingredients

3 Answer the followings :

(1) What is qualification documents? Discuss about IQ, OQ, PQ, DQ documents.

OR

(1) Give brief account of ICH guidelines.

(2) Describe in detail cleaning validation.

OR

(2) Write short note on : Indian Pharmacopeia

4 Answer the followings : (Any **Two**)

(1) What is analytical method validation? Write a detail procedure for precision study.

(2) Discuss in detail ICH guideline Q1B.

(3) Write short note on Q 6 guideline.

5 Answer the followings : (Any **Two**)

(1) Write a note on Patentability criteria.

(2) Discuss in detail Schedule-M.

(3) What is impurity? Classify impurities as per guideline with examples.

(4) What is SoP? Discuss the format to prepare SoP.
