



NCC-003-028202 Seat No. _____

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

April / May - 2017

**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**) **14**
- (A) Define the following terms.
 - (a) Out of Specification
 - (b) Active Pharmaceutical Ingredient
 - (B) Classify residual solvent as per ICH guideline with example.
 - (C) What are the vital responsibilities of "Quality Assurance Program?"
 - (D) Describe accuracy and recovery study in detail.
 - (E) Explain Robustness with example.
 - (F) What is Calibration? Give its importance as per GMP.
 - (G) What is ICH? Explain Q6 guideline.
 - (H) What is Photo stability study?
 - (I) Explain IPR with their different types.
 - (J) What are qualifications? Define OQ and PQ.
- 2** Answer the followings : (Any **Three**) **14**
- (A) Define the following terms.
 - (a) Self-life
 - (b) Quality unit
 - (c) Specification
 - (d) Content uniformity

- (B) Differentiate LOD and LOQ with their measurement procedure.
- (C) Explain bracketing protocol for stability study.
- (D) Write a calibration procedure for polarimeter and pH meter.

3 Answer the followings : **14**

- (A) Discuss GMP with its key components.
- (B) List out all ICH guidelines with brief explanation.

OR

- (A) Discuss repeatability and reproducibility with example.
- (B) Discuss patent with their benefits.

4 Answer the followings : (Any Two) **14**

- (A) Explain Process validation.
- (B) Describe in detail GMP.
- (C) Write a short note on Ruggedness study.

5 Answer the followings : (Any Two) **14**

- (A) What is Impurity? Give the classification and importance of impurity.
- (B) What is Validation? Explain cleaning validation with suitable example.
- (C) Define the following terms.
 - (a) Out of Trend
 - (b) Out of Statistical Control
 - (c) Drug Self life
 - (d) Polymorph
- (D) What is force degradation study? Write stress condition with example.
