



Seat No. _____

HO-003-028202
P.G.D.S.A.I.T. (Sem. II) Examination
April – 2023
IPR, Patent, Documentation, Statutory and
Regulatory Affair : PGDI-202
(New Course)

Faculty Code : 003
Subject Code : 028202

Time : $2\frac{1}{2}$ Hours / Total Marks : 70

Instructions :

- (1) All questions are compulsory.
- (2) All questions carry equal marks..

- 1** Answer the following : (any **seven**) **14**
- (a) What is regulatory affair ?
 - (b) Enlist the criteria used for analytical method validation.
 - (c) Where GI registration office located in India and what is the validation period for GI ?
 - (d) Define the term SOP and why it is important ?
 - (e) Which ICH guideline deals with impurity profile ?
 - (f) Who can apply for copyright and also mention its validation period.
 - (g) Write the source of SOP.
 - (h) Define the term patent and write types of patents.
 - (i) Enlist the criteria for pentability.
 - (j) Write the full form of NABL and its function.

2 Answer the following : (any **two**) **14**

- (a) Mention the components of GLP and discuss it in detail.
- (b) Explain structure of ICH in detail.
- (c) Discuss the quality guideline in detail.

3 Answer the following : **14**

- (a) Write the SOP for spectro photometer operation.
- (b) Write a note on IPR in detail.

OR

- (a) Give a brief account on patent as an IPR tool.
- (b) What is calibration ? Discuss the importance of its and explain characteristics of reagent, chemicals used for it.

4 Answer the following : **14**

- (a) What is the basic requirement in QC ?
- (b) Discuss any four types of degradation study in method validation.

5 Answer the following : (any **two**) **14**

- (a) Write the SOP of GS-MS operation.
- (b) Write note on NABL accreditation and its advantages.
- (c) Explain all parameters of equipment validation.
- (d) Define the term trade mark and write at least eight example of it.
