DBX-003-028202 Seat No. _____

PGDSAIT (Sem. II) Examination

July - 2022

P:202 : IPR, Patent, Documentation, Statutory and Regulatory Affair

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 followings : (Any **seven**) **14**

(a) Define the term: Reference material & Impurity.

(b) Enlist the advantages of accreditation.

(c) Define the term patent and what is the life time of patent?

(d) Which ICH guidelines deals with impurities?

(e) Who are the responsible for administration of IPR in India?

(f) Define the term: Dosage form and Shelf life.

(g) Write the full form of the followings :

(i) ISO (ii) EU (iii) IEC (iv) IAF

(h) Define the term, SOP.

(i) Write the full form of ICH, FDA, MSDS and API.

(j) What is regulatory affair?

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

(a) Discuss the advantages of SOP.

(b) Write the SOP for pH meter operation.

(c) What is GMP? Explain sanitation, personnel and safety as per GMP point of view.

3 Answer the followings : **14**

(a) Discuss the quality guidelines in details.

(b) Enlist the process of NABL accreditation.

OR

3 Answer the followings : **14**

(a) Write a note on patent as an IPR tool.

(b) Discuss safety guideline in details.

4 Answer the followings : **14**

(a) Explain all parameters of equipment validation.

(b) What is calibration? Discuss the importance of calibration and explain characteristics of reagents, chemicals used for calibration.

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

(a) Write down the components of GLP and explain it.

(b) Discuss any four types of degradation study.

(c) How do you explain the term novelty?

(d) What are the basic requirement of QC ?
