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BBL-003-028202 Seat No. _____

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

July – 2021

PGDI - 202 : IPR, Patent, Documentation, Statutory And Regulatory Affair.

(New Course)

Faculty Code : 003

Subject Code : 028202

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

Instruction:1. Attempt any five questions

2. All question carry equal marks.

1: Answer the followings **14**

a. Enlist the laboratory calibrated by NABL
b. Who are responsible for administration of IPR in India?
c. Enlist the advantage of accreditation.
d. What is the scope of ICH-CTD?
e. Define the term, Patent and what is the life time of Patent?
f. Differentiate tangible and intangible properties.
g. Enlist Various tools of IPR.

2: Answer the followings **14**

a. Mention the function of accreditation body.
b. What is regulatory affair?
c. Define the term, SOP.
d. Write the full form of the followings;
e. EU (ii) ICH (iii) FDA (iv) ASMF
f. What types of laboratories can accreditation?
g. What is ISO? Where it is located and what is the purpose of ISO?
h. Which guide lines are accept by NABL for the accreditation of chemical Lab.?

3: Answer the followings: **14**

a. Discuss the quality guideline in details.
b. Discuss the advantage of e-CTD over CTD in dossier preparation.

4: Answer the followings: **14**

a. Enlist condition for patentability. What are the types of invention which are not patentable in India?
b. Enlist the process of NABL accreditation

5: Answer the followings: **14**

a. Write a note on "Patent as an IPR Tool".

b. Discuss technical requirement for NABL accreditation in details.

6: Answer the followings: **14**

a. Write down all components of GLP and explain them in short.

a. Discuss the safety guideline in details.

7: Answer the followings: **14**

a. Write the advantages of SOP.

b. Write the functions of QM & TM.

8: Answer the followings: **14**

a. What work is done in Regulatory Affairs department?

b. Draw the schematic diagram of organization chart-A for NABL accreditation in testing chemical lab.

9: Answer the followings: **14**

a. Draw the Fishbone diagram for resolve the quality problem.

b. Write the SOP of IR instrument operation.

10: Answer the followings: **14**

a. Enlist the USFDA guideline for GLP

b. Enlist the information required for test report.