Total No. of Questions : 6]

SEAT No. :

P3187

[Total No. of Pages : 3

[5245]- 806

Final Year B. Pharmacy (Semester - VIII)

NATURAL PRODUCTS : COMMERCE, INDUSTRY & REGULATIONS

(2013 Pattern)

Time : 3 Hours] *[Max. Marks :70*

Instructions to the candidates:

1) *All question are compulsory.*
2) *Answers to the two sections should be written in separate answer books.*
3) *Neat diagrams must be drawn wherever necessary.*
4) *Figures to the right indicate full marks.*

SECTION - I

Q1) Solve any One : **[10]**

Explain the initiatives taken up by the Government of India to promote Export of herbal drugs and products. And a note on Major herbs and herbal extracts exported from India.

OR

List the Ayurvedic medicine suppliers of India and explain their products and market share.

Q2) Solve any Five: **[15]**

1. Add an exhaustive note on "National Medicinal Plant Board."
2. Give the significance of pharmacovigilance.
3. Give the procedure for registration of traditional medicinal products in India.
4. Leading manufacturers of herbal drugs.

P.T.O

5. List the documents need to be submitted for company registration.

6. Explain the advantages of using herbal medicines.

7. Add a brief note on potential spices exported from India.

Q3) Write notes on any Two : **[10]**

1. Note on Traditional medicinal products and domestic market.

2. Add a note on Biofuels its demand and supply in future market.

3. Give the general procedure for drug export registration to various countries.

4. Note on herbal cosmetics products.

SECTION - II

Q4) Solve any One : **[10]**

Explain the minimum regulatory requirement as per WHO Guide lines in context to safety and efficacy parameters for the registration of herbal drugs.

OR

Give reasons for toxicity in herbal medicine. And add a note on pharmacokinetics and pharmacodynamics in herbal drug toxicity.

Q5) Solve any Five : **[15]**

1. Define allergy and give examples of plants causing allergic reactions.

2. Define the terms Common Technical Document (CTD) and Electronic Common Technical Document (ECTD)

3. Give the structure of ICH steering committee and its sub groups.

4. Discuss few examples of herb drug interaction.

5. Discuss the different categories of TSM products as per WHO guidelines

6. Toxicity and drug interaction of Garlic.

7. Add a brief note on concepts on Quality by Design (QbD)

Q6) Write Notes on (any two) : **[10]**

1. Note on Quality Control (safety parameters) of herbal drugs.
2. Add a note on Good Laboratory Practices (GLP).
3. Define herbal drug interaction and explain toxicity and interaction of St. Johns Wart.
4. Explain how you will achieve quality, safety and efficacy of herbal medicine.