

Total No. of Questions :6]

SEAT No. :

[Total No. of Pages :2

P2015

[5145] - 806

Fourth Year B. Pharmacy

**4.8.6: NATURAL PRODUCTS: COMMERCE, INDUSTRY &
REGULATIONS**

(2013 Pattern) (Semester - VIII)

Time : 3 Hours]

[Max. Marks :70

Instructions to the candidates:

- 1) *All questions are compulsory.*
- 2) *Answer 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]

Add an exhaustive note on the Global market size with respect to sale of Herbal natural products.

OR

Add an exhaustive note on the Global market size with respect to sale of Nutraceuticals.

Q2) Solve any Five:

[15]

- a) Write the significance of biofuels in national economy.
- b) Give the significance of pharmacovigilance.
- c) Add a note on herbal cosmetic products.
- d) Give the procedure for registration of traditional medicinal products in India.
- e) Add a brief note on potential spices exported from India.
- f) List the documents need to be submitted for company registration.
- g) Explain the advantages of using herbal medicines.

P.T.O.

Q3) Write notes on any Two: [10]

- a) Comment on major herbs and herbal extracts exported from India.
- b) Explain the meaning, need, and significance of pharmacovigilance of Herbal medicines.
- c) Note on Traditional Medicinal Products and Domestic market.
- d) Add a note on Leading Manufacturers of Herbal drugs in India.

SECTION -II

Q4) Solve any One: [10]

Comment on Quality Assurance of herbal medicinal products.

OR

Give the general procedure for drug export registration to various countries and give the objective of regulation of herbal medicine along with its classification.

Q5) Solve any Five: [15]

- a) What is ICH and who are the members of ICH.
- b) Write a toxicity and drug interaction of –Liquorice.
- c) Define allergy and give examples of plants causing allergenic reactions.
- d) Give the structure of ICH steering committee and its sub groups.
- e) Explain different category of herbal medicines.
- f) Define herbal drug interaction and give the possible causes for the herb drug interaction.
- g) What is CITES and give its objectives.

Q6) Write notes on any Two: [10]

- a) Explain the challenges encountered in regulation of Herbal medicines.
- b) Add a brief note on concepts on Quality by Design (QbD).
- c) Give the methods of preparation of allergenic extracts.
- d) Note on adverse drug reaction (ADR) report.

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