

Total No. of printed pages = 4

PY134204

Roll No. of candidate

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2014

(Even Semester)

**ADVANCED INDUSTRIAL PHARMACY
AND REGULATORY AFFAIRS**

Full Marks-100 Pass Marks-35 Time-Three hours

The figures in the margin indicate full marks
for the questions.

1. Answer the following : $1 \times 10 = 10$

- (a) Quaternary ammonium compounds are used in pharmaceutical dosage forms as
- (b) is an example of a propellant.
- (c) is abbreviated as GATT.
- (d) is a film forming agent used in cosmetic preparations.
- (e) is a water soluble colorant used in shampoos and soaps.

[Turn over

- (f) Rose oil is used as in a lotion and oil is used as flavouring agent in dental products.
- (g) In a face foundation, titanium oxide is used as
- (h) is an advantage of process validation.
- (i) Class 100 is described as
- (j) Retrospective validation is required for

2. Answer any *ten* of the following : $4 \times 10 = 40$

- (a) Write short note on dental preparation.
- (b) Give a brief account on quality control test of herbal cosmetic products.
- (c) What do you mean by IPR ? What are the different mechanisms for protection of intellectual property ?
- (d) What do you mean by copyright and trade secrets ?
- (e) Differentiate between the manufacturing of cold cream and vanishing cream.

- (f) Write short notes on TRIPS and TRIMPS.
- (g) Is "software" patentable in India? Justify answer with respect to US patent regulations.
- (h) Define humectants and opacificier with examples.
- (i) What is the significance and advantage of validation?
- (j) Justify the effect of organoleptic properties on product appeal.
- (k) Explain in details the ISO series.
- (l) Write a brief note on pharmaceutical packaging material and testing.

3. Answer any *five* of the following : $10 \times 5 = 50$

- (a) What are pharmaceutical preservatives? Classify preservatives and write a brief note on them with examples.
- (b) (i) Explain the anatomy of skin with a neat diagram.
(ii) What are the different skin care products used? Describe the formulation and evaluation aspects of night massage creams.

- (c) What do you mean by aerosols ? Give a summary on propellants with example. How an aerosol packaged system is used for cosmetic industry ?
- (d) (i) What cannot be patented in India ?
- (ii) What do you mean by patent infringement ? What are the penalties for violation of rules in such cases ?
- (e) What like an invention should be to be patented ? Describe the process of filing and granting of a patent.
- (f) What is GMP and cGMP ? Explain the different aspects of GMP as per Schedule M.
- (g) What do you mean by validation of pharmaceutical process ? What are the different types of validation ? Explain in brief.