

10-06-13 (Reg)

S/E

Total No. of printed pages = 3

48(M.Ph) 2:3 PRA



**ADVANCED INDUSTRIAL PHARMACY AND  
REGULATORY AFFAIRS**

Accession No. ....  
Date .....

Paper: 2:3

Full Marks - 80

Time Three hours

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

Answer any *six* questions taking *three* from each Section.

Question Nos. 1 and 5 are compulsory.

**SECTION - A**

1. (a) Write a note on preservation of oral liquids from microbial degradation.
- (b) How different parenteral preparations are labelled ?
- (c) Describe the pharmacopoeial test which are performed on glass container as packaging material. 4+3+7=14

[Turn over

2. (a) Describe the type of colourants used to prepare oral liquid and tablet dosage form. What are problems encountered to impart colour to the pharmaceutical product ?

4+3=7

- (b) What are the types of tablet packaging ? Write in brief about Alu-Alu and Blister packaging.

3+3=6

3. What do you mean by quality control and quality assurance ? Write in detail about quality planning process.

6+7=13

4. (a) Describe different methods of sampling.

- (b) Describe method development of analytical process for pharmaceutical raw materials.

4+9=13

### SECTION - B

5. (a) Describe method of preparation and evaluation of a shaving cream with a suitable formula. Also explain the use of each ingredient in the formula.

5+3=8

- (b) Write a note on herbal cosmetics.

6

6. What is process validation ? Write a note on retrospective validation. Explain design qualification and installation qualification of equipments.  $3+4+6=13$

7. (a) Write in brief about the role of IPP and IPR on Indian economy.

(b) Write note on WTO and TRIPS.

(c) What do you mean by copyright ?

$5+5+3=13$

8. (a) Write the use of following materials in different cosmetic products :

(i) Diethyl phthalate

(ii) Sorbitol

(iii) Cetyl alcohol

(iv) Bees wax

(v) Stearic acid

(vi) Butylated hydroxy anisole

(vii) Propylene glycol monolaurate

(b) Write a note on evaluation of shampoos.

$8+5=13$