05.06.15 (M.Pharm-Reg)

Total No. of printed pages = 4

PY 134204

Roll No. of candidate

M.Pharm 2nd Semester End-Term Examination

ADV. IND. PHARM AND REG. AFFAIRS

(Theory)

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

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

1. Fill up the blanks : 2×10=20

   (a) Tartrazine produces ——— colour in pharmaceutical formulations.

   (b) The common name of FD and C blue No. 1 is ———.

   (c) The common name of FD and C green No.3 is ———.

   (d) Apricot kernel oil in cosmetics is used as ———.

[Turn over

(e) Mink oil in cosmetics (hair and skin) is used as ———.

(f) Anisyl formate gives ——— flavour in pharmaceutical formulations.

(g) Citral gives ——— flavour in pharmaceutical formulations.

(h) As per Drugs and Cosmetics Act (1940) and Rules (1945), the permitted synthetic organic colours and natural organic colours used in the cosmetics should not contain more than

(i) ——— parts per million of arsenic calculated as arsenic trioxide.

(ii) ——— parts per million of lead calculated as lead

(iii) ——— parts per million of heavy metals other than lead calculated as the total of the respective metals.

2. (a) Define the following :

(i) Drugs as per D & C Act (1940)

(ii) Cosmetics as per D & C Act (1940) 3×2=6

(b) Give an ideal label for ophthalmic preparation as per D & C Act (1940). 3

(c) Name three preservatives used in oral preparations with the permitted concentration limit. 3

(d) Define 'Geographical indicator'. 3

(e) What 'SPF' stands for ? For what purpose and in which type of formulation it is used ? 3

(f) Define 'patent' under the Patent Act 1970. 3

(g) What is 'Plagiarism' ? 3

(h) What does the number code specify in case of propellants ? 3

(i) What is 'Trademark' ? 3

3. Briefly discuss the materials used for packaging of pharmaceuticals. 5

4. Define flavour and outline the use of natural and synthetic flavours in pharmaceutical formulation. 5

5. Briefly discuss the procedure of applying for a patent. 5

6. Give an explanatory discussion on quality management in pharma industry. 5

7. What is validation ? Why validation is important ? Provide a typical validation report of any instrument used in pharmaceutical laboratory. 5

8. Justify the requirement of validation. What is the meaning of concurrent validation ? 5

9. What is layout design ? Discuss the economic importance of intellectual property right. What is the concept behind GATT ? 1+5+4=10

10. What is quality assurance ? Discuss in brief GLP. What are the responsibilities of quality improvement process in the quality system.

1+3+6=10