P.G. Diploma in Pharmaceutical Regulatory Affairs
Annual Examinations – 2006

Paper PGPRAD – 103
Drug Regulatory Affairs in India

Time allowed: Three hours Maximum Marks: 100

SECTION – I Marks

Q1. Attempt all the objective questions given below . 1X20=20

i) If a drug is imported under a name which belongs to another drug, then it is called as

A) Adulterated Drug B) Spurious Drug
C) Misbranded Drug D) None of these

ii) To qualify as R and D intensive company in India, the Pharmaceutical Research and Development committee has suggested –

a) Investment of at least 5% of its turnover per annum in R & D
b) Investment of at least 20% of its turnover per annum in R & D
c) Employment of at least 1000 research scientists in India
d) None of these

iii) The meaning of MAPE is

a) Medicine and Pharmaceutical Expenses
b) Maximum Allowable Post Manufacturing Expenses
c) Maximum Applicable Pharmaceutical Expenses
d) None of these.

iv) The schduele 'M' to the Drugs and Cosmetic Rules 1945 is actually for

a) Drugs sold under the prescription of a physician
b) GMPs
c) Large Volume Parenterals
d) Narcotic Drugs.

v) A National Pharmacovigilance Advisory Committee (NPAC) was constituted in OCT, 2004 under the chairmanship of

a) Director General of WHO b) Director General of CSIR
c) Director General of Health Services d) Director General of CDRI

vi) The drugs and magic Remedies Act was formed in

a) 1940 b) 1954 c) 1985 d) 1998

vii) Drugs that can be sold from licensed dealers without professional supervision and without prescription

a) Spurious Drugs
b) Misbranded Drugs
c) Over-the-counter drugs
d) Narcotic Drugs

viii) The form of the completed pharmaceutical preparation e.g. tablet, capsule, elixir is called

a) Dosage form
b) Finished Product
c) Bulk Product
d) Controlled Product

ix) The Ayurvedic and Unani Drugs Technical Advisory Board consist of

a) The Director General of Health Services
b) One Pharmacognocist, nominated by Central Government
c) Both A & B
d) None of these A & B

x) A dealer or his agent or a stockist appointed by a manufacturer or an importer for the sale of his drugs to a retailer.

a) Wholesaler
b) Salesman
c) Medical Representative
d) None of these

xi) The full form of DPCO is _____.

xii) _____ means a person carrying on the business of purchase or sale of drugs, whether as a wholesaler or retailer and whether or not in conjuction with any other business and includes his agents.

xiii) _____ means a dealer carrying on the retail business of sale of drugs to customer.

xiv) cGMP means _____.

xv) The full form of SOPs is _____.

xvi) Ganja is the flowering or fruiting tops of the _____ plant.

xvii) A _____ is a holder of a degree or diploma in Pharmacy from a recognised higher institution of learning and is registered or licensed to practice pharmacy.

xviii) A process for withdrawing or removing a pharmaceutical product from the pharmaceutical distribution chain because of defects in the product or complaints of serious adverse reactions to the product is called _____.

xix) The full form of SPCs is _____.

xx) _____ include any shop, stall or place where any article of food is sold or manufactured or stored for sale.

SECTION – II

Q2. Attempt any six questions in about 150 words each 5X6=30

i) Give the main objectives of the Drug Policy 1994 in India in brief.
ii) Write a short note on National Drug Authority.
iii) What are the functions of National Pharmaceutical pricing Authority (NPPA) in India?
iv) Give the main objectives of the Center for Veterinary products.
v) Give the definitions of 'Addict', 'Coca leaf', 'illicit traffic' and 'narcotic drugs', 'Under Narcotic and Psychotropic Substances Act 1985'.
vi) Discuss the Penalties for unlawful importation of a poison under the Poisons Act 1919.
vii) Write in brief the drug categories which are nearly 85% of the domestic formulation market in Indian Pharmaceutical Sector
viii) What are the rifampicin and Penicillin G policies?

SECTION – III

Attempt any four questions in about 500 words each. (12.5X4=50)

Q3. Discuss the objectives and key issues of Drugs Price Control Order (DPCO). Give its significance.

Q4. Elaborate the role of GMP in quality control and rational use of drugs.

Q5. Discuss the space, equipment and supplies required for blood bank for licensing purpose.

Q6. Give the mission and objective of FDA, Maharashtra, India

Q7. Discuss the powers of Inspectors under Drugs and Cosmetic Act 1940.

Q8. Discuss the future aspects of Pharmaceuticals R & D of pharmaceutical sectors in India.

Q9. What are the functions of state drug control authorities? Give its organizational setup.