PHARMACEUTICS QP No.-10

Topic cover

1. Bio-pharmaceutics

a) Fate of drug after drug absorption, various mechanisms for drug absorption, drug concentration in blood, biological factors in drug absorption, physicochemical factors, dosage form consideration for gastrointestinal absorption.

b) Drug Absorption:

- Gastrointestinal absorption-biological considerations.
- Gastrointestinal absorption - physicochemical considerations.
- Gastrointestinal absorption-role of the dosage form.
- Pharmacokinetics. Compartmental and non-compartmental pharmacokinetics. Biotransformation, drug disposition - distribution, drug disposition - elimination. Variability-Body weight, age, sex and genetic factors. Pharmacokinetic variability-diseases. Pharmacokinetic variability-drug interactions. Individualization and optimization of drug dosing regimens.

2. Bio-availability & Bio-equivalence Quality parameters of dosage forms. Assay methods & its validation. Physico - chemical properties of drugs & added substances and its effect on preparations and biological availability of dosage forms. Pharmaceutical properties of dosage forms, disintegration, dissolution rate. Biological, pharmacological effects of dosage forms. Factors affecting Bioavailability, Determination of bioavailability.Significance of bio-equivalence studies. Statistical analysis of bioequivalence studies. Development, scale up & post approval changes [SUPAC] & in vitro [dissolution] in vivo [plasma concentration profile] correlation or IV/IV correlation (IVIVC). Multi stage - Bioequivalence studies. Therapeutic equivalence. Titration design for clinical rationales. New Drug Application [NDA].

3. Bio- pharmaceutical statistics Post Marketing Surveillance. Process Validation.

2. PHARMACEUTICAL JURISPRUDENCE

- Historical background Drug legislation in India, Code of Ethics for Pharmacists.
- The Pharmacy Act 1948 (inclusive of recent amendments).
- Drugs and Cosmetics Act 1940, Rules 1945, including New Drug applications.
- Narcotic Drugs and Psychotropic Substances Act, and Rules there under.
- Drugs and Magic Remedies (Objectionable Advertisements) Act 1954.

- Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976.
- Medical Termination of Pregnancy Act 1970 and Rules 1975.
- Prevention of Cruelty to Animals Act 1960.
- Drug (Price Control) Order.
- Shops and Establishment Act.
- Factory Act.
- Consumer Protection Act.
- Indian Pharmaceutical Industry- An Overview.
- Industrial Development and Regulation act 1951.
- Introduction to Intellectual Property Rights and Indian Patent Act 1970.
- An Introduction to Standard Institutions and Regulatory Authorities such as BIS, ASTM, ISO, TGA, USFDA, MHRA, ICH, WHO.
- Minimum Wages Act 1948.
- Prevention of Food Adulteration Act 1954 and Rules 1955.