(MPY-201 DRA) - ADVANCE DRA – I
(Indian Legislation)

UNIT I

The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for ayurvedic siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics.

UNIT II

Requirements for registration of pharmaceutical products into India. Preparation of dossier for product registration as per Indian legislative requirements**.**

UNIT III

Documentation: Master formula record (MFR), Master formula card (MFC), Batch processing record (BPR), Packaging records, Standard operating procedure (SOP), Site master file, specifications, Certificate of analysis (COA), Material safety data sheet (MSDS), Method of Analysis (MOA), Annual product review, validation protocols, Stability protocol, T- License, forms, maintenance of records in Pharmaceutical industry.

UNIT IV

Regulatory requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials (schedule Y).

UNIT V

Regulatory requirements for packaging material– Pharmacopoeial requirements, D & C act & rules, Weight & Measure acts, DCGI / DPCO guidelines, FDA guidelines and various other foreign regulatory guidelines.

Books and References Recommended:

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.

(MPY202 DRA)- ADVANCE DRA – II
(USFDA & European legislation)

UNIT I

Requirements of cGMP with specific reference of USFDA (21 CFR part 210 and 211), European Medicines Agency (EMEA) guidelines.

UNIT II

Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act.

UNIT III

Guidance for Industry: IR/ MR Solid Oral Dosage Forms Scale - Up and Postapproval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Dissolution Testing, and In Vivo Bioequivalence Documentation

Guidance for Industry: Sterile/Non Sterile Semisolid Dosage Forms Scale - Up and Postapproval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Release Testing, and In Vivo Bioequivalence Documentation

UNIT IV

Registration of product in European market: New drug product and generic product.
Preparation of dossier of Drug product and Drug master file.
Regulatory requirements good laboratory practice in US (USFDA 21 CFR part 58)

UNIT V

Guidance for Industry : Dissolution testing of immediate release solid oral dosage forms.

Guidance for Industry : Extended release oral dosage forms: Development, evaluation and application of In Vitro/In Vivo Correlations.

Guidance for Industry : Waiver of In Vivo Bioavailability and Bioequivalence Studies for Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

Books and References Recommended:

www.emea.europa.eu
www.fda.gov

(MPY203 DRA) - ADVANCE DRA – III
(Regulations of other important countries)

UNIT I

Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA brazil guidelines, Chinese and Japanese regulation.

UNIT II

International organization for standardization (ISO): Fundamentals of quality management system

UNIT III

ICH Guidelines with specific reference to stability, analytical validation, impurities, pharmacopeias, specification, quality risk management and pharmaceutical development.

UNIT IV

Preparation of Common technical document (CTD) as per ICH guidelines, electronic documentation and e-filing (e-CTD).

UNIT V

Guidelines for reporting adverse drug reaction in various countries

Practicals

1. Analytical method validation as per ICH Guidelines
2. Preparation stability protocol and stability report.
3. Accelerated stability studies of marketed products as per ICH Guidelines.
4. Dossier preparation as various countries guidelines.

Books and References Recommended:

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals
2. Common Technical documents (ICH guidelines).
3. ISO Guidelines
4. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
5. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
6. WHO GMP guidelines
7. www.ich.org
8. www.anvisa.gov.
9. www.picscheme.org
10. www.mhra.gov.uk
11. www.tga.gov.au
13. www.mccza.com
14. www.who.int
15. www.ep.espace.net

(MPY204 DRA) - ADVANCE DRA - IV

UNIT I

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

UNIT II

Drugs *(*Prices Control*)* Order 1995, Factory Act, Labour Act, Medicinal and Toilet preparation (Excise duties) Act and Rules,

UNIT III

Narcotic Drugs and Psychotropic Substances Act and Rules,1985 and latest amendments. The drug and Magic remedies (Objectionable advertisements) act and rules, 1954.

UNIT IV

Inspection and quality audit: Self inspection, Internal and External audits. Procedure for inspection of pharmaceutical manufacturing plants. Audits for vendor approvals, Contract manufacturing.

Biostatistics tools techniques, data analysis and presentation.

UNIT V

Sewage disposal and pollution control from pharmaceutical Industry: Categorization of pharmaceutical industry as per EPA, Solid waste management of the expiry and rejected materials. Biomedical waste (Management and Handling) Rules, 1998

Books and References Recommended:

1. www.patentoffice.nic.in
2. www.ep.espace.net
3. www.uspto.gov
4. www.epa.gov
5. Vijay Malik, Law relating to Drugs & Cosmetics.
6. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
7. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
8. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals
9. www.picscheme.org

Practicals

Practicals related to ADVANCE DRA – I

1. Preparation of SOP's for operation of manufacturing and analytical equipments.
2. Preparation of MFR, BPR and packaging record for manufacturing of various dosage forms.
3. Validation of mfg. process, equipment, analytical method, disinfectant, and cleaning process.
4. Process validation for various dosage forms.

Practicals related to ADVANCE DRA – II

1. Comparison of dissolution profiles and calculation of F1 and F2 values of tablets of innovator/standard and generic manufaturers.
2. Comparison of In-vitro release and calculation of F1 and F2 values of semisolid preparations of innovator/standard and generic manufaturers.
3. Preparation dossier of a pharmaceutical product.
4. Experiments to find out the BCS class of pharmaceuticals.

Practicals related to ADVANCE DRA – III

1. Analytical method validation as per ICH Guidelines
2. Preparation stability protocol and stability report.
3. Accelerated stability studies of marketed products as per ICH Guidelines.
4. Dossier preparation as various countries guidelines.

Practicals related to ADVANCE DRA – IV

1. Drafting a non infringing patent as per US patent office requirements and Indian patent office requirements.
2. Preparation audit protocol to inspect manufacturing pharmaceutical plants.
3. Practical for finding BOD of laboratory sewage.
4. Practical for finding COD of laboratory sewage.