Rajiv Gandhi Proudyogiki Vishwavidyalaya
M.Pharm. (Industrial Pharmacy)
III Semester Course Contents

MPY301-IP -INTELLECTUAL PROPERTY RIGHTS

Unit I

Intellectual property: Trade related intellectual property rights: Patent, Industrial Designs, Trade Mark, Copyright, Geographical Indication, Layout Designs of Integrated Circuit, Protection of Undisclosed Information/Trade Secrets. Types of patent applications.

Unit II

Patents Act (Indian Legislation): Inventions, Inventions not patentable, forms of application, Information and undertaking regarding foreign applications, Provisional and complete specifications, Contents of specifications, Priority dates of claims of a complete specification, Publication and examination of application, withdrawal of an application. Grant of patent: Grant and sealing of patent, Opposition to grant of patent, post grant opposition, Amendment of patent granted to deceased applicant, Important dates of patent, Rights of patentee, Rights of co-owners of patents, Term of patent, Patents of addition, Amendment of application and specification, restoration of lapsed patents, surrender and revocation of patents, Register of patents, use of inventions for purposes of government and acquisition of inventions by central government, Suits concerning infringement of patents. Offences and penalties. Forms and fees structure used in filing of patent.

Unit III

Patent Officials: Controller Generally; Power of controller, time frame, acceptance. Exclusive marketing rights: Application for grant of exclusive rights, Grant of exclusive rights, Compulsory licenses, Suits relating to infringements, Opposition to grant of patent, Refusal of patent without opposition, Anticipations, provisions for secrecy of certain inventions, Patent agents: Register of patent agents, Qualifications for registration as patent agents, Rights of patent agents, Subscription and verification of certain documents by patent agents, Restrictions on practice as patent agents, Removal from register of patent agents and restoration.

Unit IV

International Arrangements: Notification as to convention countries, Notification as to countries not providing for reciprocity, Patent Cooperation treaty, Overview of PCT process, Convention applications, Special provisions relating to convention applications, Multiple priorities, Supplementary provisions as to convention applications, Other provisions of Act to apply to convention applications

Unit V

Patent Drafting: Case study for proper drafting of complete specification relating to: title of invention, Field of invention, Background of invention with regard to the drawback associated with known art, Object of invention, Statement of invention, summary of invention, brief description of the accompanying drawing, detailed description of the invention with reference to drawing/examples, claim(s), Abstract.

Books and References Recommended:

1. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
2. J. L. Rogers, The complete patent book: Everything you need to know to obtain your patent. Sphinx Publishing.
3. www.uspto.gov.in 4. www.ep.espace.net

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MPY-302-IP INTERNATIONAL BUSINESS MANAGEMENT OF PHARMACEUTICAL PRODUCTS

Unit I

International business - meaning and modes of International business; Globalization – concepts, characteristics and drivers; International business environment – cultural, economic, political and legal environment;

Unit II

World Trade Organizations (WTO) – structure and overview of agreements; Regional economic groupings – meaning, levels and implications for International business; Foreign Direct Investments (FDI's) – concepts, types, motives, impact of FDI, Foreign Direct Investment in India

Unit III

Multinational Enterprises (MNEs) – features, types, factors affecting MNEs; Foreign market entry strategies and strategic alliances – basic entry decisions, entry modes selection, reasons and process of strategic alliance management.

Unit IV

Export-Import policy in India – salient features; International commercial terms (Incoterms); Import- Export documentation - Bill of Exchange, Marine Insurance policy, Invoices and other documents; Transport documents - Bill of lading, Airway Bill, Multimodal transport documents; Letter of Credit – meaning, types of letter of credit; Financing exports - preshipment credit, post-shipment finance; Financing imports; Export credit Insurance – standard and specific policies, guarantees.

Unit V

The Indian Contract Act, 1872 – meaning and essentials of contract ; Offer and Acceptance; Capacity of the parties; Consideration; Free consent; Legality of object; Performance; Discharge and remedies for breach of contract. Sale of Goods Act, 1930 – relevant provisions. Companies Act, 1956 – meaning, characteristics and types of companies; Formation of company; Meaning and contents of Memorandum of Association and Articles of Association; Company management and managerial remuneration; Company meetings and proceedings.

Books and References Recommended:

1. Sundram and Black: International business environment, Prentice Hall of India.
2. Charles WL Hill: International business, Tata Mc Graw Hill, New Delhi.
3. Arun Kumar Jain: Competing in the Global market place, Tata Mc Graw Hill New Delhi.
4. Francis Cherunilam; International business, Prentice Hall of India.
5. Sunil Gupta: International Marketing, Kalyani Publishers New Delhi.

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MPY-303-IP: PHARMACEUTICAL DOCUMENTATION & REGULATORY AFFAIRS

Unit I

Pharmaceutical manufacturing documentation (PMD) – Guidelines for designing and implementation of PMD programme. Advantages and applications of pharmaceutical documentation, Regulatory requirement of pharmaceutical documentation: Standard practices in preparation, issue, use and archival of documents, records, reports and disposal of documents.

Unit II

Pharmaceutical documents for production operations: Standard formats, contents, designing and preparation of- Batch Processing Record/Batch Manufacturing Record (BPR/BMR), Batch Packaging records, Batch testing records, Site Master File, Standard Operating Procedure (SOP), Certificate of Analysis (COA), quality specification, Material Safety Data Sheet (MSDS).

Unit III

Pharmaceutical documents for R&D and quality operations: Standard formats, contents, designing and preparation of- Master Formula Record (MFR), Product Development Record (PDR), Drug Master File (DMF), Method of Analysis/Standard Testing Procedure (MOA/STP), Validation master plan, Validation protocols, validation reports, inspection & audit reports.

Unit IV

Standard formats, contents and preparation of SOP and validation documents of various Non-sterile processes, i.e., Mixing, granulation, drying, compression, coating, blending, homogenization; Sterile processes, i.e., sterilization, depyrogenation, Cleaning/washing, filling, lyophilization, filtration processes. SOP and validation documents of packaging operations.

Unit V

ICH guidelines for pharmaceutical quality aspects: Common Technical Documents (CTD),Quality of Biotechnological Products Q5A - Q5E, Specifications Q6A- Q6B, Impurities Q3A Q3D , Stability Q1A - Q1F , Pharmacopoeias Q4 - Q4B , Quality Risk Management Q9, Pharmaceutical Quality System Q10 , Electronic documentation and electronic filing .

Recommended Books

1. The Pharmaceutical Regulatory Process, 2nd ed. – Ira R. Berry, Robert P. Martin
2. Medical Product Regulatory Affairs: Pharmaceutical , Diagnostics, Medical Devices –John J. Tobin and Gary Walsh
3. FDA Regulatory Affairs: A Guide for Prescription Drugs, Medical Devices and Biologics, 2nd ed. – Douglas J. Pisano and David S. Mantus
4. Good Drug Regulatory Practices: a Regulatory Affairs Quality Manual (Good Drug Development Series) – Helene I. Dumitriu
5. ICH guidelines- www.ich.org

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MPY 304 IP: NOVEL DRUG DELIVERY SYSTEMS

Unit I

Controlled Drug Delivery Systems- Concepts and Rationale, Classification of controlled release systems , Carriers for CDDS , Design and evaluation , Release Kinetics

Unit II

General Considerations, Methods of Preparation, Characterization and Applications of following drug Delivery Systems: Microspheres, Liposomes, Niosomes, Resealed Erythrocytes, Nanoparticles, Solid Lipid Nanoparticles, Dendrimers , Multiple emulsions Submicron emulsion.

Unit III

Transdermal Drug Delivery System (TDDS) : General considerations , Basic Components, Different approaches, Methods of enhancements of percutaneous absorption , Evaluations and applications of TDDS

Unit IV

Implants and Inserts : General considerations, Mechanism of drug release, Various approaches and Devices , Applications

Unit V

Osmotically Regulated Systems i General considerations , Classifications and development of Osmotic Pumps , Applications

Unit VI

Colon – Specific drug delivery, General considerations, Various approaches and applications

Unit VII

An overview of oral controlled drug delivery

Book and References Recommended

1. Jain, N. K., “Controlled & Novel drug delivery”, CBS Publishers & distributors, New Delhi. 2. Jain, N. K., “Advances in Controlled & Novel drug delivery”, CBS Publishers & distributors, New Delhi
3. Vyas , S. P. and Khar, R. K. “Controlled drug delivery – Concepts & Advances”, Vallabh Prakashn, Delhi
4. Vyas, S. P. and Khar, R. K, “Targeted & Controlled drug delivery Novel Carrier Systems”, CBS Publishers, New Delhi.
5. Mathiowitz, E., “Encyclopedia of Controlled drug delivery” Vol - 1 & II, John Wiley & Sons, Canada
6. Swarbick , J. and Boyln, J ., “Encyclopedia of pharmaceutical technology” Vol. 1- III, Marcel Dekker , Inc ., New York. 7. Jones, D. A., “Transdeermal & related drug delivery system”, Marcel Dekker , Inc ., NY.
8. Robinson, J. R. and Lee,. H., “Controlled drug delivery fundamentals & applications” Marcel Dekker , Inc., New York.
9. Chein , Y. W. , “Transdermal controlled systemic medications” Marcel Dekker, Inc., New York .
10. Hillery , A . and Llyod, A. W., “Drug delivery & Targetting”, Taylor & Francis, London
11. Deasy, P. B., “Microencapsulations & related drug processes” Marcel Dekker, Inc., New York.