JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY HYDERABAD

IV Year B.Pharm - II Sem

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(R80032) NOVEL DRUG DELIVERY SYSTEMS & REGULATORY AFFAIRS

Objective: This course is designed to impart knowledge on controlled drug delivery systems including oral, transdermal, mocuadhesive, targeted (Liposomes and Nanoparticles). It also helps to know how regulatory agencies (Indian CDSCO, USFDA, Canadian HPFBI and Australian TGA) act on release of NDA & ANDA.

UNIT I

Oral Control Drug Delivery Systems: Fundamental study of different types of Oral Contolled drug delivery systems, sustained release concept, design of sustained release dosage form, Zero order release, first order release approximation, multiple dosing.

Dissolution Controlled, Diffusion Controlled, Ion Exchange Resins, Osmotic based systems, pH Independent Systems.

UNIT II

a. Transdermal Drug Delivery Systems: Fundamentals, types of TDDS, Materials Employed and Evaluation of TDDS.

b. Introduction to Good Manufacturing Practices: Salient features of Schedule – M (India).

UNIT III

a. Mucoadhesive Delivery Systems: Mechanism of bioadhesion, mucoadhesive materials, forumulation and development of mucoadhesive-based systems.

b. Targeted Drug Delivery Systems: Fundamentals and applications, formulation and evaluation of liposomes, resealed erythrocytes and nano particles.

UNIT IV

Governing Regulatory bodies across the globe

USFDA, CDSCO, Australian TGA, European FDA, NDA & ANDA Submissions of USFDA, Product filing.

UNIT V

Introduction to Validations: Process validation (prospective, retrospective & concurrent), analytical method validation (accuracy, precision, specificity, linearity, range, robustness etc.), cleaning validation (sampling procedure and acceptance criteria).

Outcome: Student shall be able to know the controlled, sustained drug delivery systems, their methods of preparation. They also know how regulatory agencies help filing and submissions of USFDA; Student shall be able to know the validation of the Analytical methods.

TEXT BOOKS

1. Novel drug delivery system by Prof. (Dr) A.K. Bandyopadhyay.
2. N.K. Jain, Control Drug Delivery Systems by
3. Y.Anjaneyulu & Maraiah, Quality Assurance & Quality Management in Pharmaceutical Industry.
4. L. Lachman, H.A, Lieberman and J.L. Kanig, Theory & Practice of industrial pharmacy by, Lea & Febieger, Philadelphia Latest Edn.

REFERENCES

1. Leon Shargel Isadore Kanfer, Generic Drug Product Development, Solid Oral Dosage Forms, Marcel Dekker.
2. Sagarian & MS Balsam, Cosmetics Sciences &Technology.Vol.1, 2 & 3.
3. Lippincott Williams and Wilkins, Remington Pharmaceutical Sciences.
4. E.A Rawlkins, Bentley's Text Book of Pharmaceutics, Elbs publ.
5. HC Ansel, Introduction to Pharmaceutical Dosage forms.
6. S.H. Willing, M.M Tucherman and W.S. Hitchings IV, Good Manufacturing Practices for Pharmaceuticals: A Plan for Total Quality Control, Marcel Dekker, Inc., New York.
7. Gilbert S. Banker and Christopher T Rhodes, Modern Pharmaceutics, Ivth ed, marcel dekker, usa, 2005.
8. Yiew Chien, novel drug delivery systems, 2nd ed, marcel dekker 2003.
9. Robert. A. Nash, Pharmaceutical Process Validation, 3rd Ed Marcel Dekker, 2003.
10. Good Manufacturing Practices – Schedule M Read with The Drugs And Cosmetic Rules 1945.
11. M.E. Aulton, Pharmaceuitcs- The science of Dosage form Design 2nd ed.
12. Aukunuru Jithan, Oral Drug Delivery Technology.
13. Quality Assurance of Pharmaceuticals WHO PMP.
14. Novel drug delivery system and regulatory affairs by S.Chand, Dr. Yajaman Sudhakar, Dr. K.N.Jayaveera.
15. Novel drug delivery system by, V.Sankar, S.Ramesh, V. Shanmugam.
16. Advances in Drug delivery systems by Y. Madhusudan Rao.

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(R80033) PHARMACEUTICAL BIOTECHNOLOGY

Objective: Pharmaceutical biotechnology is considered to be a logical extension of pharmaceutical microbiology, thus expected to show a dramatic change in the drug product scenario in future.

This course is designed to impart knowledge on isolation of industrially interesting microbes, various techniques employed in biotechnology Viz., r-DNA technology, Hybridoma technology, enzyme technology and the products derived using these techniques.

UNIT I

a. Fermentation Technology: Isolation, Selection and Screening of Industrially important microbes, Strain improvement. Types of fermentations, optimization of fermentation process.Types, design & operation of Bioreactor.

b. Specific Fermentations: Selection of organism, fermentation & purification of various antibiotics, vitamins, aminoacids, organic acids, solvents, biomass like penicillin, streptomycin, tertacycline, erythromycin, cyanocobalamin, glutamic acid, citric acid, alcohol, Lactobacillus sporogenes.

UNIT II

a. Recombinant DNA Technology: Introduction to r-DNA technology and genetic engineering, steps involved in isolation of enzymes, vectors, recombination and cloning of genes.

Production of r-DNA technology derived therapeutic proteins like humulin, humatrope, intron a, recombivax HB(hepatitis b).

b. Hybridoma Technology: Production and applications of Monoclonal Antibodies.

UNIT III

Immunology & Immunological Preparations: Principles of Immunity, Humoral immunity, cell mediated immunity, Antigen – Antibody reactions, Hypersensitivity reactions.

Active & passive immunizations preparation of vaccines, standardization & storage of BCG, cholera, smallpox, polio, typhus, tetanus toxoid, immuno serum & diagnostic agents.

UNIT IV

a. Enzyme Technology: Methods of immobilization of enzymes and cells and their applications, factors affecting immobilized enzyme kinetics, advantages of immobilized enzymes over isolated enzymes.Study of enzymes such as hyaluronidase, penicillinase, streptokinase & streptodornase, protease.

b. Blood Products: Collection processing, storage and control of official blood products, plasma substitutes (dextran) and sutures & ligatures.

UNIT V

a. Microbial Transformations: Types, Methods of bioconversions & Application in Pharma Industry, Steroidal transformations.

b. An introductory study on bioinformatics and its applications, Regulatory control of Biotechnological products.

Outcome: Upon completion of the course, the student shall be able to-

- Know screeing of industrially interesting microbes.
- Optimize fermentation process parameters
- Know about preparation, standardization, storage and labelling of biotechnologically derived products
- Know about bioinformatics and its applications in pharmacy.
- Know about the regulatory control of biotechnological products.

TEXT BOOKS

1. P. F. Stanbury & A. Whitaker, Principles of fermentation technology, Pergamon Press.
2. Sambamurthy. K, Text Book of Pharmaceutical Biotechnology.
3. S. S. Kori, Pharmaceutical biotechnology.

REFERENCES.

1. Wulf Crueger and Anneliese Crueger, Biotechnology, 2nd Ed, Publ-Panima publication co-peration, New Delhi.
2. U. Satyanarayana, Text book of Biotechnology
3. J. D. Watson, Recombinant DNA technology.
4. E.A. Rawlins, Bentley's, A text book of pharmaceutics, 8th Ed, 1982 Bailler Tindall & Co.
5. Alexander N. Glazer & Hiroshi Nikaido, Microbial biotechnology, W. H. Freeman Co.
6. Casida, Industrial microbiology.
7. Dr. P. K. Shiva kumar, Dr. M. M. Joe, Dr. K. Suresh An Introduction to industrial micro biology.
8. Pharmaceutical Bio technology by Dr. Chandrakanth Kokare.
9. S.P. Vyas and V.K. Dixit CBS Publisher, Delhi, Pharmaceutical Biotechnology.
10. I.D'Souza, Suresh G. Killedar - Biotechnology and fermentation process Indian Pharmacopoein, 1996.

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(R80034) PHARMACEUTICAL ANALYSIS - II

Objective: The principles involved in the determination of various bulk drugs and formulations are discussed. Modern methods and instrumental techniques are applied in the study and analysis of pharmaceutical substances.

UNIT I

a. UV & Visible Spectrophotometry: Introduction to Spectroscopy, Basic terminology – Chromophore, Auxochrome, Bathochromic shift, Hypsochromic shift, hyperchromic and hypochromic shift. UV & Visible Spectrophotometry: Principle, Theory, Beer-Lamberts Law & Deviations, Instrumentation – Single Beam and Double Beam Spectrophotometers, Applications, Woodward – Feiser rule.

b. Flourimetry: Principle, Theory, Quenching, Instrumentation and applications.

UNIT II

a. Infrared Spectrophotometry (IR): Introduction, principle, theory, types of vibrations, Instrumentation, Single and double beam spectrophotometer, sampling techniques, applications, basic principles in the interpretation of IR Spectra.

b. Atomic Absorption Spectroscopy: Principle, Theory, Instrumentation and applications.

UNIT III

Nuclear Magnetic Resonance Spectrophotometry (NMR) : Basic Principle, theory, instrumentation, chemical shift, shielding and deshielding, relaxation processes, spin-spin splitting, applications, basic principles in the interpretation of NMR spectra.

UNIT IV

Mass Spectrometry: Basic principle, theory, instrumentation and applications, basic principles in the interpretation of Mass Spectra.

UNIT V

An Elementary study of the following:

(a) GC: Columns, Carrier gas and detectors used

(b) HPLC & HPTLC: Basic Principles

(c) Electrophoresis: Various types of Electrohoresis

(d) ORD Curves, RIA & ELISA: Basic principles

Outcome: The students are exposed to the modern instrumental techniques for the study of pharmaceuticals to a high level which would be useful for their future in academia and industry.

TEXT BOOKS

1. R.M. Silvesterin and G.C. Bassler.Spectrometric Identification of Organic Compounds.
2. AH Beckett & Stenlake, Text book of Practical Pharmaceutical chemistry, Vol. I & II.
3. Al Vogel, Quantitative Chemical Analysis.
4. Hobart. H. Willard and others, Instrumental methods of analysis, CBS publ and Distributors New Delhi.

REFERENCES

1. Settle, Handbook of Instrumental Techniques for Analytical Chemistry.
2. Y.Anjaneyulu & Marajah, Quality Assurance & Quality Management in Pharmaceutical Industry.
3. P.D. Sethi, Quantitative analysis of Drugs and Pharmaceuticals.
4. K. A. Connors, A Textbook of pharmaceutical analysis, Wiley Interscienc, NY.
5. A.M. Knevel & F.E. Digengl, Jenkin's quantitative pharmaceutical chemistry, Mc Graw Hill Book Co., NY.
6. Pharmacopoeia (IP, BP, USP, PhI, Eu. PhI).
7. Robert D. Brown, Introduction to Instrumental Analysis.
8. Skoog, Principles of Instrumental Analysis.
9. B.K.Sharma, Instrumental and Chemical Analysis, Goel Publ House,
10. Organic spectroscopy by Y. R Sharma.

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(R80035) HUMAN VALUES AND PROFESSIONAL ETHICS

Objectives : This introductory course input is intended

- To help the students appreciate the essential complementarity between 'VALUES' and 'SKILLS' to ensure sustained happiness and prosperity which are the core aspirations of all human beings.
- To facilitate the development of a Holistic perspective among students towards life, profession and happiness, based on a correct understanding of the Human reality and the rest of Existence. Such a holistic perspective forms the basis of Value based living in a natural way.
- To highlight plausible implications of such a Holistic understanding in terms of ethical human conduct, trustful and mutually satisfying human behavior and mutually enriching interaction with Nature.

Unit I:

Course Introduction - Need, Basic Guidelines, Content and Process for Value Education: Understanding the need, basic guidelines, content and process for Value Education. Self Exploration–what is it? - its content and process; 'Natural Acceptance' and Experiential Validation- as the mechanism for self exploration. Continuous Happiness and Prosperity- A look at basic Human Aspirations. Right understanding, Relationship and Physical Facilities- the basic requirements for fulfillment of aspirations of every human being with their correct priority. Understanding Happiness and Prosperity correctly- A critical appraisal of the current scenario. Method to fulfill the above human aspirations: understanding and living in harmony at various levels.

Unit II:

Understanding Harmony in the Human Being - Harmony in Myself! : Understanding human being as a co-existence of the sentient 'I' and the material 'Body'. Understanding the needs of Self ('I') and 'Body' - Sukh and Suvidha. Understanding the Body as an instrument of 'I' (I being the doer, seer and enjoyer). Understanding the characteristics and activities of 'I' and harmony in 'I'. Understanding the harmony of I with the Body: Sanyam and Swasthya; correct appraisal of Physical needs, meaning of Prosperity in detail. Programs to ensure Sanyam and Swasthya.

Unit III:

Understanding Harmony in the Family and Society- Harmony in Human - Human Relationship : Understanding harmony in the Family- the basic unit

of human interaction. Understanding values in human-human relationship; meaning of Nyaya and program for its fulfillment to ensure Ubhay-tripti; **Trust (Vishwas) and Respect (Samman) as the foundational values of relationship.** Understanding the meaning of Vishwas; Difference between intention and competence. Understanding the meaning of Samman, Difference between respect and differentiation; the other salient values in relationship. Understanding the harmony in the society (society being an extension of family): Samadhan, Samridhi, Abhay, Sah-astitva as comprehensive Human Goals. Visualizing a universal harmonious order in society- Undivided Society (Akhand Samaj), Universal Order (Sarvabhaum Vyawastha)- from family to world family!

Unit IV:

Understanding Harmony in the Nature and Existence – Whole existence as Co-existence : Understanding the harmony in the Nature. Interconnectedness and mutual fulfillment among the four orders of nature- recyclability and self-regulation in nature. Understanding Existence as Co-existence (Sah-astitva) of mutually interacting units in all-pervasive space. Holistic perception of harmony at all levels of existence.

Unit V:

Implications of the above Holistic Understanding of Harmony on Professional Ethics : Natural acceptance of human values. Definitiveness of Ethical Human Conduct. Basis for Humanistic Education, Humanistic Constitution and Humanistic Universal Order. Competence in professional ethics:

a) Ability to utilize the professional competence for augmenting universal human order,

b) Ability to identify the scope and characteristics of people-friendly and eco-friendly production systems,

c) Ability to identify and develop appropriate technologies and management patterns for above production systems.

Case studies of typical holistic technologies, management models and production systems. Strategy for transition from the present state to Universal Human Order:

a) At the level of individual: as socially and ecologically responsible engineers, technologists and managers.

b) At the level of society: as mutually enriching institutions and organizations.

TEXT BOOKS

1. R R Gaur, R Sangal, G P Bagaria, 2009, A Foundation Course in Human Values and Professional Ethics.

2. Prof. KV Subba Raju, 2013, Success Secrets for Engineering Students, Smart Student Publications,3rd Edition.

EFERENCE BOOKS

1. Ivan Illich, 1974, Energy & Equity, The Trinity Press, Worcester, and HarperCollins, USA.
2. E.F. Schumacher, 1973, Small is Beautiful: a study of economics as if people mattered, Blond & Briggs, Britain.
3. A Nagraj, 1998, Jeevan Vidya ek Parichay, Divya Path Sansthan, Amarkantak.
4. Sussan George, 1976, How the Other Half Dies, Penguin Press. Reprinted 1986, 1991.
5. PL Dhar, RR Gaur, 1990, Science and Humanism, Commonwealth Purblishers.
6. A.N. Tripathy, 2003, Human Values, New Age International Publishers.
7. Subhas Palekar, 2000, How to practice Natural Farming, Pracheen(Vaidik) Krishi Tantra Shodh, Amravati.
8. Donella H. Meadows, Dennis L. Meadows, Jorgen Randers, William W. Behrens-III, 1972, Limits to Growth – Club of Rome's report, Universe Books.
9. E G Seebauer & Robert L. Berry, 2000, Fundamentals of Ethics for Scientists & Engineers, Oxford University Press.
10. M Govindrajran, S Natrajan & V.S. Senthil Kumar, Engineering Ethichs (including Human Values), Eastern Economy Edition, Prentice Hall of India Ltd.

Relevant CDs, Movies, Documentaries & Other Literature:

1. Value Education website, http://www.uptu.ac.in
2. Story of Stuff, http://www.storyofstuff.com
3. Al Gore, An Inconvenient Truth, Paramount Classics, USA
4. Charlie Chaplin, Modern Times, United Artists, USA
5. IIT Delhi, Modern Technology – the Untold Story

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(R80036) CLINICAL PHARMACY PRACTICE

Objective: To impart quality use of medicines & their therapeutics of various diseases management.Monitor adverse drug reaction,interpret selected laboratory results of specific disease states,retrieve, analyse, interpret and formulate drug or medicine information.

UNIT I

Basic concepts of Pharmacotherapy

a. Introduction to Clinical Pharmacy

b. Clinical Pharmacokinetics and individualization of Drug Therapy.

c. Special precautions in drugs usage during infancy and in the elderly (Pediatrics & Geriatrics).

d. Special precautions in drugs usage during pregnancy & lactation

e. Adverse Drug Reactions and Pharmacovigilance

f. The Basics of Drug Interactions

g. Interpretation of Clinical laboratory Tests.

UNIT II

Important Disorders of Organ Systems and their Management:

a. **Cardiovascular Disorders**: Hypertension, congestive heart failure, angina, acute myocardial infarction, cardiac arrhythmias.

b. **CNS Disorders**: Epilepsy, parkinsonism, schizophrenia depression.

UNIT III

Important Disorders of Organ Systems and their Management

a. **Respiratory Disease:** Asthma, COPD.

b. **Gastrointestinal Disorders:** Peptic Ulcer Disease, Ulcerative Colitis, Hepatitis, and Cirrhosis.

c. **Infectious Diseases**: Enteric Infections, sexually transmitted diseases, AIDS, Conjunctivits.

UNIT IV

Important Disorders of Organ Systems and their Management

a. **Endocrine Disorders:** Diabetes mellitus and Thyroid Disorders.

b. **Neoplastic Diseases**: Leukaemias, Hodgkin's disease,Lymphomas

UNIT V

a. Therapeutic Drug Monitoring, Concept of Essential Drugs, Drug and

Poison information, Drug induced diseases.

b. Commmunity Pharmacy practice, patient counselling, medication review ward round participation, drug utilization review.

Outcome: Know the pathophysiology of selected disease states and the rationale for drug therapy, their therapeutic approach in management of diseases. Understand the needs to identify the patient-specific parameters relevant in initiating drug therapy and its monitoring.

TEXT BOOKS

1. Roger, Walker, Clinical Pharmacy and Therapeutics.
2. G. Parthasarathi / Karin Nyfort-Hansu A text book of Clinical Pharmacy practice – Universities Press.
3. Dr. D.R Krishna, V. Klotz, Clinical pharmaco kinetics, Publ Springer Verlab.

REFERENCES

1. Laurence, DR and Bennet PN. Clinical Pharmacology, Scientific book agency.
2. Lippincott Williams and Wilkins: Remington Pharmaceutical Sciences, 20th edn.
3. Hamsten, Drug interaction, Kven Stockley.
4. J.K. Mehra, Drug interaction, Basic Bussiness Publ, Bombay.
5. Grahame smith and Aronson, Clinical pharmacology and drug therapy.
6. Richard A Helms, Text Book of Therapeutics Drug and Disease Management Hardbound.
4. Herfindal E T and Hirschman JL, Williams and Wilkins, Clinical Pharmacy and therapeutics.
5. Applied Therapeutics, The clinical uses of Drugs applied therapeutics INC.
6. Dr. A.R. Paradker, Hospital and Clinical Pharmacy, Nirali Prakashan.
7. D. Sudheer Kumar. Fundamentals of Clinical Pharmacy Practice-Pharm Med Press.
8. Katzung, B.G.Basic and Clinical Pharmacology, Prentice hall, International.
9. M Rowland and T N Tozer, "Clinical Pharmacokinetics" 2nd ed Lea & Febiger, NY.

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(R80079) PROJECT WORK & COMPREHENSIVE VIVA

1. Industrial Pharmacy / Technology
2. Clinical Pharmacy / Pharmacology
3. Pharmacognosy / Medical Chemistry
4. Pharmaceutical Analysis / Quality Assurance
5. Pharmaceutical Marketing
6. Herbal Drugs
7. Pharmainformatics
8. Computer aided drug design
9. Neutraceuticals
10. Nano Technology
11. Bio Technology
12. Pharmaco economics

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IV Year B.Pharm - II Sem

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(R80080) NOVEL DRUG DELIVERY SYSTEMS AND REGULATORY AFFAIRS LAB

1. Preparation and Evaluation of Matrix Tablets
2. Formualtion and Evaluation of Film Coated Tablets.
3. Formualtion and Evaluation of Enteric Coated Tablets.
4. Prepartion and Evaluation of Transdermal Drug Delivery Systems.
5. Formulation and Evaluation of Mucoadhesive Delivery Systems.
6. Evaluation of Market SR Formualtions.
7. Preparation and evalution of Nano particles (Minimum two drugs)
8. Preparation and evaluation of Liposomes
9. Preparation and Evaluation of Alginate Beads.
10. Analytical Method Validation.
11. Assignment on Product development and filing to various regulatory agencies , FDA,MCC, EMEA,TGA.Etc (Ref.: www.fda.gov)

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(R80081) PHARMACEUTICAL BIOTECHNOLOGY LAB

*** 3 hours on same day and 1 hour in the next day morning**

1. Isolation of antibiotic producing microorganisms from soil.
2. Immobilization of Enzymes / Cells using different methods and comparision of their efficacy.
3. Determination of minimum inhibitory concentration of the given antibiotic.
4. Standardization of Cultures.
5. Microbiological assay of Antibiotics by cup plate method.
6. Microbiological assay of Antibiotics by Turbidimetry method.
7. Production of alcohol by fermentation technique.
8. Sterility testing of Pharmaceutical products.
9. Isolation of mutants by gradient plate technique.
10. Preparation of bacterial vaccine and standardization.
11. Extraction of DNA.
12. Separation techniques: Various types of Gel electrophoresis, Centrifugation.

TEXT BOOKS

1. Dr. R.S. Gaud, G. D. Gupta - Pratical Biotechnology
2. Indian Pharmacoepia – 1997
3. F.C. Garg, Experimental microbiology

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IV Year B.Pharm - II Sem

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(R80082) PHARMACEUTICAL ANALYSIS – II LAB

Experiments

1. Interpretation of IR Spectra of any two compounds.
2. Determination of λ_{max} of few bulk drugs.
3. Assay of any two bulk drugs and their formulations by UV-spectro photometry.
4. Assay of any two bulk drugs and their formulations by Colorimetric method.
5. Assay of Quinine Sulphate by Flourimetry
6. Ascending paper chromatography.
7. Radial paper chromatography.
8. Two dimensional paper chromatography
9. Thin layer chromatography.
10. Column chromatography
11. Determination of amino acids by Paper electrophoresis.
12. Gel electrophoresis (**Demonstration Only**).
13. HPLC (**Demonstration Only**).

BOOKS RECOMMENDED FOR REFERENCE:

PHARMACEUTICS

1. Cooper and Gunns "Tutorial Pharmacy" ed. S.J Carter, 6th edition, CBS Publisher, Delhi,
2. A N Martin, Arthur Cammarata, James Swarbrick, "Physical Pharmacy", 3rd edition, K M Varghese & Co., Bombay,
3. E Shotton and K Ridgway, "Physical Pharmaceutics" Oxford University Press, London,
4. "Remington's Pharmaceutical Sciences", ed. A R Gennaro, 18th ed, Mack Publishing Co.. P.A..
5. Leon Lachmen, H A Lieberman and J L Kanig, "The Theory and Practice of Industrial Pharmacy, 3rd ed. Lea & Febiger Philadelphia.
6. H C Ansel "Introduction to Pharmaceutical Dosage Forms", 3rd (Indian ed) K M Varghese & Co. Bombay .
7. Cooper and Gunn's "Dispensing for Pharmaceutical Students" ed S J Carter, 12th ed., CBS Publishers, Delhi.