

**VI Semester B.Pharm [Course and Examination Scheme with Credit Grade System]**

Subject Code	Subject	Teaching Scheme				Examination Scheme								
		Hours per week			No. of Credits	Theory					Practical			
		L	T	P		Duration of Paper (Hrs.)	Max. Mark	Max. Marks Sessional	Total	Min Passing Marks	Max Marks	Max. Marks Sessional	Total	Min Passing Marks
BP601	Pharmaceutical Engineering-II	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 602	Medicinal Chemistry-I	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 603	Pharmaceutical Analysis III	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 604	Pharmacology-IV	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 605	Pharmacognosy –IV	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 606	Quality Assurance	3	-	-	3	3	80	20	100	45	-	-	-	-
BP 607	Pharmaceutical Engineering-II	-	-	4	2	5	-	-	-	-	80	20	100	50
BP 608	Medicinal Chemistry-I	-	-	4	2	5	-	-	-	-	80	20	100	50
BP 609	Pharmaceutical Analysis-III	-	-	4	2	5	-	-	-	-	80	20	100	50
BP 6010	Pharmacology-IV	-	-	4	2	5	-	-	-	-	80	20	100	50
BP 6011	Pharmacognosy –IV	-	-	4	2	5	-	-	-	-	80	20	100	50
	<b>Total</b>	<b>18</b>	<b>0</b>	<b>20</b>	<b>28</b>				<b>600</b>				<b>500</b>	
<b>Semester total</b>						<b>1100</b>								

**B.Pharm-III (Semester- VI)**  
**PHARMACETICAL ENGINEERING-II (BP-601)**

SN	Topics	Hrs
01	<b>Heat Transfer</b> Mechanism- Conduction, Convection, Radiation, Fourier Law, Heat Exchanger- Heat Transfer In Parallel Flow & Counter Flow, Tubular Heat Exchanger, Application.	<b>10</b>
02	<b>Crystallization</b> Crystal form, theories of crystallization, Equipment-Swenson walker, vacuum, agitated batch, Krystal crystallizer, caking of crystal.	08
03	<b>Drying</b> Mechanism, theory, factor affecting, Dryer- tray dryer, fluidized bed dryer, spray dryer, freeze dryer, vacuum dryer, drum dryer.	06
04	<b>Corrosion</b> Mechanism, factor influencing corrosion process, prevention & control of corrosion.	<b>06</b>
05	<b>Evaporation</b> Theory, factor influencing evaporation, evaporator- pan, tubular (horizontal, vertical); climbing film, falling film, forced circulating, multiple effect evaporator- economy, and evaporator capacity.	<b>10</b>
06	<b>Environmental control</b> Air conditioning, refrigeration, Humidification and dehumidification, application to Pharmaceutical field.	<b>05</b>

## PHARMACETICAL ENGINEERING-II (BP-607)

### Semester VI

#### PRACTICALS:

1. To study of rate of drying of solid sample (amorphous & crystal)
2. To study of drying behavior of solid sample( amorphous & crystal)
3. To study crystallization of sodium chloride with seeding
4. To study crystallization of sodium chloride without seeding
5. To study effect of viscosity on rate of evaporation.
6. Determine critical solution temperature of phenol water solution.
7. Plotting boiling point diagram for given mixture.
8. To study effect of pressure on rate of evaporation.
9. To study crystallization of boric acid with seeding.
10. To study crystallization of boric acid without seeding.
11. To study of effect of cooling on crystal growth.
12. To determine rate of heat loss through different material.
13. To determine free moisture content & bound moisture content.
14. Engineering drawing sheet's Alphabets and numbering, and Geometric Constructions.

#### REFERENCE BOOKS:

1. W. McCabe, J.C. Smith, P. Harriot, "Unit operation of chemical Engineering". McGraw Hill, (1993).
2. E. Gonderton, "Pharmaceutical unit operation", Academic press.
3. Perry's , "Handbook of chemical engineering", McGraw Hill,(1984)
4. A.R. Paradkar, "Introduction to Pharmaceutical Engineering", Nirali prakashan, 10<sup>th</sup> Ed.2007
5. K. Sambamurthy-"Pharmaceutical Engineering", New Age international Pvt Ltd.
6. G.G Brown- "Unit operation", CBS publishers & Distributers, New Delhi.
7. W.I. Badger and J.T. Banchero, "Introduction to Chemical engineering"; McGraw Hill, Tata-McGraw Hill Publishing Company Ltd, New Delhi.(1988)
8. N.G.Padya., C.S.Shaha-"Elements of Heat Engines", Charotar Book Stall, Tulsi Sadan, Anand (W. Rly), India.
9. Donald P. Eckman -"Industrial Instrumentation", Seventh Wiley Eastern, Reprint, 1983, Wiley Eastern Ltd, 4835/24, Ansari Road, Daryaganj, New Delhi.
10. C.V.S Subramanyam- "Pharmaceutical Engineering principle & practices", Vallabh prakashan New Delhi.
11. Warren McCabe, Julian Smith and Peter Harriott, "Unit operations of chemical engineering", McGraw Hill Inc., Singapore.

**B.Pharm-III (Semester- VI)**  
**PHARMACEUTICAL MEDICINAL CHEMISTRY-I (BP-602)**

SN	Topics	Hrs
01	<b>Basic principles of medicinal chemistry:</b> Structure of biological membrane, physicochemical parameters affecting drug action, drug absorption, distribution and elimination. Stereochemical aspects of drug action, drug receptor interaction including transduction mechanism, blood brain barrier.	10
02	<b>Drug metabolism:</b> Phase I and phase II reactions, biological factors affecting drug metabolism, inducers and inhibitors of drug metabolism, significance of drug metabolism studies in drug development.	05
03	<b>Prodrug concept:</b> Principles of prodrug design and applications.	03
04	Following topics shall be treated covering nomenclature, synthetic procedure of official drugs, uses and SAR including physicochemical and steric aspects and mode of action. <b>Drugs Acting on CNS:</b> General and Local Anaesthetics, Sedative and hypnotics, Anticonvulsants, CNS Stimulants, Antidepressants. Drugs Used In Parkinsonism and Alzheimers Disease, Antipsychotics, Antianxiety, <b>Drugs Acting on GIT:</b> Antacids, Emetics, Antiemetics, Purgatives, Antidiarrhoeals.	24
05	Introduction and applications of Green Chemistry.	03

**Subject: Pharmaceutical Medicinal Chemistry-I (BP-608)**

**PRACTICAL:**

- To perform pharmacopoeial assay of following drugs containing dosage form  
Metoclopramide, Methadone, Chlorpromazine, Fluphenazine, Phenylbutazone, Thibendazon.
- Synthesis of following compound by green chemistry  
Acetanilide from aniline, Benzilic acid from benzil, Benzpinacol from Benzophenone, Benzpinacolone from Benzpinacol, 1,1-bis-2-naphthol from 2naphthol, Dihydropyrimidinone from benzaldehyde, Methyl ester from vegetable Oils.

**REFERENCES:**

1. Wilson and Gisvold's Text Book of Medicinal Chemistry, Lippincott Williams and Wilkins.
2. Indian Pharmacopoeia, Government of India, Ministry of Health and Family Welfare, Published by the Controller of Publications and Information Directorate ( CSIR), New Delhi
3. Ashutosh Kar, Advanced Practical Medicinal Chemistry, New Age International Publication.
4. J. N. Delagado and W. A. R. Remers, Eds, Wilson and Gisvold's Textbook of Organic, Medicinal and Pharmaceutical Chemistry, J. Lipponcott Co. Philadephia.
5. W. C. Foye, Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
6. H. E. Wolff, Ed. Burger's Medicinal Chemistry, John Wiley & Sons, New York Oxford University Press, Oxford.
7. Daniel Lednicer, Strategies for Organic Drug Synthesis & Design, John Wiley & sons, USA.
8. B. N. Ladu, H. G. Mandel & E. L. Way, Fundamental of Drug Metabolism & Disposition, William & Wilkins co., Baltimore.
9. I. L. Finar, Organic Chemistry, Vol. I & II, ELBS/ Longman, London.
10. Vogel's Text book of Practical Organic Chemistry, ELBS/ Longman, London
11. Mann & Saunder, Practical Organic Chemistry, Orient Longman, London.
12. Shriner, Hermann, Morrill, Curtin & Fuson, The Syntematic Identification of Organic Compounds, John Wiley & Sons. USA.
13. R. M. Silverstein, G. Claytron Bassel's, T. C. Movvill, Spectormetric identification of Organic compounds, John Wiley & Sons, USA
14. Kadam, Mahadik and Bothra "Advanced Practical Medicinal Chemistry"

**B.Pharm-III (Semester- VI)**  
**PHARMACEUTICAL ANALYSIS III (BP-603)**

SN	Topics	Hrs
01	<b>UV-Visible Spectroscopy:</b> Brief review of Electromagnetic Spectrum & its properties. Absorption Law & Limitations. Theory of Electronic Spectroscopy. The Chromophore concept, Choice of Solvent and Solvent Effects. Modern Instrumentation (Single Beam, Double Beam) Design, Working & Principle, with significant emphasis on Source, Filters, Monochromators including Gratings, Sample Holder (Cuvette) and Detectors. Application of UV-Visible Spectroscopy (Qualitative & Quantitative analysis) including Difference & Derivative Spectroscopy.	<b>10</b>
02	<b>IR Spectroscopy:</b> IR regions, Requirements for IR absorption. Basic Principle. Vibrational Frequency & Factors influencing vibrational frequency. Fundamental Modes of Vibrations in diatomic molecule Instrumentation with significant emphasis on Sampling Techniques and Heat Detectors. Applications in identification of functional groups.	10
03	<b>Nephelometry and turbidimetry:</b> Theory, Instrumentation and Application.	05
04	<b>Polarography:</b> Theory, Mass Transport Process, Current Processes, Current Potential Relationship, Polarization, Choice of Electrodes, Effect of Oxygen, Calculation of Concentration, Applications, Normal and Differential Polarography.	<b>04</b>
05	<b>Amperometric titrations</b> and its applications	<b>04</b>
06	<b>Coulometry:</b> Introduction, coulometry at controlled potential, coulometry at constant current, instrumentation and application.	<b>04</b>
07	<b>Fluorescence spectroscopy:</b> Fluorescence And Phosphorescence, Excitation and Emission Spectra, Factors Affecting Fluorescence Intensity, Instrumentation, Application, Determination of Quinine Sulphate, Thiamine Hydrochloric Acid.	<b>05</b>
08	<b>Flame photometry:</b> Theory, Instrumentation and Applications.	<b>03</b>

**Subject: Pharmaceutical Analysis III (BP-609)**

**PRACTICAL:**

1. Calibration of UV-Visible Spectrophotometer.
2. Determination of Wavelength of maximum absorbance using UV spectrophotometer & validity of Lambert Beer's law.
3. To study the effect of solvent & pH on UV spectrophotometer of a given compound.

4. Assay of Paracetamol Tablets using UV Spectrophotometer.
5. Assay of Metformin Tablets using UV Spectrophotometer.
6. Assay of Metoprolol Tablets using UV Spectrophotometer.
7. Assay of Propranolol Tablets using UV Spectrophotometer.
8. Assay of Furosemide Tablets using UV Spectrophotometer.
9. Assay of Hydrochlorothiazide Tablets using UV Spectrophotometer.
10. Demonstration of IR spectrophotometer.
11. To study IR spectra of given compound(s)
12. Identification of functional group by IR.
13. Determination of sodium concentration by flame photometry
14. Determination of potassium concentration by flame photometry
15. Nitrogen estimation by Kjeldahl's method.

#### **REFERENCES:**

1. William Kemp. Organic Spectroscopy, Palgrave, New York.
2. United States Pharmacopoeia & National Formulary, The United States Pharmacopoeial Convention, Washington DC.
3. Skoogh, Principles of Instrumental Analysis, Saunders College Publishing, USA.
4. K.A. Connors, Text Book of Pharmaceutical Analysis- Wiley Intersciences, New York.
5. Indian Pharmacopoeia, Government of India, Ministry of Health and Family Welfare, Published by the Controller of Publications and Information Directorate ( CSIR), New Delhi
6. H.H., Willard, L.L. Merrit & John A. Dean, Instrumental Method of Analysis, CBS Publishers & Distributors, New Delhi.
7. D.C. Garatt, Quantitative Analysis of Drug, CBS Publishers and Distributors, New Delhi.
8. D.A., Skoog, F.J. Holler, S.R. Crouch, Principles of Instrumental Analysis. Baba Barkha Nath Printers, Haryana. Ed. Fenniri Hicham, Combinatorial Chemistry, Oxford University.
9. British Pharmacopoeia, MHRA, London
10. Bentley and Driver, Textbook of Pharmaceutical Chemistry, Oxford University Press, Walton Street, Oxford
11. A.H. Beckett, J.B. Stenlake, Practical Pharmaceutical Chemistry, Part I and Part II, CBS Publishers and Distributors, New Delhi.
12. B.K. Sharma. Instrumental Methods of Chemical Analysis, Goel Publishing House, Meerut.
13. G. R. Chatwal And Shyam K. Anand "instrumental methods of chemical analysis"
14. A. V. Kasture, K. R. Mahadik, S. G. Wadodkar, H. N. More, A Textbook of Pharmaceutical Analysis, Vol. I, 6th edition, 2002, Nirali Prakashan, New Delhi.

**B.Pharm-III (Semester- VI)  
Pharmacology-IV (BP-604)**

<b>SN</b>	<b>Topics</b>	<b>Hrs</b>
01	Study of Pharmacological action of following classes of drug with respect to classification including recently available drugs, mechanism of action, receptors, adverse effects, Drug interaction, contraindication and therapeutic uses:	<b>10</b>
02	<b>Pharmacology of drug acting on endocrine systems</b> A. Pituitary hormone and regulation of secretion B. Thyroid hormone, Anti-Thyroid agents C. Parathyroid hormone, calcitonin, vitamin D. D. Insulin, Oral Hypoglycemic agents. E. Adreno-corticoids, Anabolic Steroids and Fertility Agents	10
03	<b>Chemotherapy of microbial infection</b> A. Introduction B. Penicillin and cephalosporin's C. Macrolides and Amino Glycosides and Polypeptides D. Quinolones and Fluoroquinolones E. Chemotherapy of Fungal Infections F. Chemotherapy of Viral Infections G. Chemotherapy of Malaria H. Chemotherapy of Tuberculosis and Leprosy I. Pharmacology of Anthelmintics J. Anti-Neoplastic agents	<b>24</b>
04	<b>Drugs acting on Immune system:</b> A. Immunostimulants B. Immunosuppressant	<b>03</b>
05	<b>Clinical trial:</b> A. Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls. B. Management of Clinical trials: Role and responsibilities of Stakeholders of clinical trials such as FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient. C. Guidelines for clinical research: ICH-GCP.	<b>08</b>



## **Pharmacology-IV (BP-6010)**

### **PRACTICAL:**

1. To determine pA<sub>2</sub> value of antagonist using different tissues isolated from rats.
2. To study antipsychotic activity by using conditioned avoidance response.
3. To study antiparkinson activity using catalepsy test.
4. Demonstration of ED<sub>50</sub> determination of some drugs in rats or mice.
5. To study learning memory enhancing activity using radial arm maze.
6. To study learning memory enhancing activity using water maze.
7. To study learning memory enhancing activity using elevated plus maze.
8. To study addiction and abuse liability of some drugs.
9. To study analgesic activity using acetic acid induced writhing.
10. To demonstrate BP of rats by non invasive method
11. To demonstrate ECG and EEG of rats by non invasive method.

### **References:**

1. Aviado, Doningo M Krantz and Carrs Pharmacologic Principles of Medical Practice. The Williams and Wilkins Co., Baltimore, U.S.A.
2. Braunwald E., Harrisons Principles of Internal Medicine. McGraw-Hill Medical.
3. Brunton L. L. and Others Goodman and Gilman"s The Pharmacological Basis of Therapeutics. Mc Graw Hill Medical Pub. Div. New York.
4. Christopher H., Davidsons Principles and Practice of Medicine. Churchill Livingstone.
5. Girdwood R.H. Clinical Pharmacology. Varghese Publishing House, Bombay
6. James Crossland, Lewis Pharmacology. Churchil Livingston.
7. Maickel, Pradhan, Pharmacology in Medicines – Principles and Practice. SP Press International INC.
8. Rang, H.R. Dale, M. Pharmacology E.L.B.S., London
9. Rosenteld, G.C., Loose Mitchell and Jones J. B. Lippincott Williams and Wilkins U.S.A. Board Review Pharmacology.
10. Lawarence, D.R. and Bacharach, A.L.: Evaluation of Drugs Activities : Pharmacometrics. Academic press, London
11. Parrthsarhi G, Hansen Kavin Nytor & Nahata Milap C. A Textbook of Clinical Practice: Essential Concepts & skills, Orient Longman
12. Perry, W. L. M. Pharmacological Experiments on isolated preparations. E and S Livingstone, London. Pubications.
13. Remington"s Pharmaceutical Science and practice pharmacy. Lippincott Williams and Wilkins, New Delhi
14. Wilma M and Hayek R.N. Essential Drug Dosage Calculations. Prentice Hall.
15. Vogel H.G. Drug Discovery and Evaluation, Pharmacological Basis. Springer-Verlog Berlin, Heidelberg.
16. Turner R.A. Screening methods in Pharmacology. Academic Press, London.

**B.Pharm-III (Semester- VI)  
Pharmacognosy IV (BP-605)**

<b>SN</b>	<b>Topics</b>	<b>Hrs</b>
01	<p><b>Glycosides</b></p> <p>a. Introduction, definition, occurrence, properties, classification, uses, general biosynthetic pathways. General extraction and isolation method.</p> <p>b. Pharmacognostic study of following drugs</p> <p>Anthraquinones: Senna, Aloe, Rhubarb</p> <p>Cardioactive: Digitalis, Squill, Strophanthus</p> <p>Saponins: Liquorice, Dioscorea, Shatavari</p> <p>Bitter: Quassia, Kalmegh</p> <p>Cynogenetic: Bitter almond</p> <p>Isothiocyanate: Black mustard</p> <p>Flavonoid: Orange peels</p>	12
02	<p><b>Resins:</b></p> <p>A) Introduction, Classification, Physical &amp; Chemical properties, occurrence/distribution, General extraction methodology and analysis of resins.</p> <p>Biological source, collection, preparation, chemical constituents, Identification tests, uses, adulterants and substituents of following:</p> <p>Asafoetida, Guggul, Podophyllum, Capsicum, Turmeric, Cannabis and Ginger.</p> <p>B) Biological source &amp; Uses of following Balsam of Tolu, Balsam of Peru, Benzoin ,Myrrh, Storax, Colophonys &amp; Jalap.</p>	10
03	<p><b>Tannins</b></p> <p>a. Introduction, definition, classification, properties, uses, chemical tests and general method of extraction.</p> <p>b. Pharmacognostic study of following drugs</p> <p>Pale catechu, Black catechu, Ashoka, Arjuna, Bahera, Amala, Myrobalon, Galls</p>	08
04	<p><b>A study of structural elucidation of following phytoconstituents –</b></p> <p>Camphor, eugenol,</p>	06
05	<p><b>Isolation, purification &amp; chromatographic profiles of following –</b>Eugenol, cineole, camphor, menthol, citral</p>	06
06	<p><b>Marine Drugs-</b></p> <p>Introduction, classification and studies of categories of marine drugs</p> <p>Anticancer, Cardiovascular agents and marine toxins.</p>	03

## Pharmacognosy IV (BP-6011)

### PRACTICAL:

1. Demonstration of percolation and continuous extraction technology (Soxhlet extractor)
2. Determination of total content of tannins from Black catechu.
3. Extraction of total sennosides from Senna leaves.
4. Study of morphological and microscopical characters of –  
a) Senna b) Digitalis c) Liquorice d) Shatavari e) Quassia f) Kalmegh
5. Chemical test of resinous crude drugs. ex: Asafoetida, Guggul, Turmeric, Tolu and Peru balsam, Myrrh.
6. Determination of balsamic acids in Tolu or Peru balsam
7. Extraction of ginger OR capsicum oleo resin
8. To determine vein-islet number, vein-termination number, stomatal index of given sample.

### Reference Books

1. Ashutosh Kar. Pharmacognosy and Pharmacobiotechnology, New Age International Publishers, New Delhi.
2. C.K. Atal and B.M. Kapoor: Cultivation and Utilization of Medicinal & Aromatic Plants, RRL, Jammu.
3. Pharmacognosy and Phytochemistry- Part I and Part II – V. D. Rangari, Career Publication, Nashik.
4. C.K. Kokate. 1994. Practical Pharmacognosy, 4 th Ed., Vallabh Prakashan, Delhi.
5. C.S. Shah, J.S. Quadri. Textbook of Pharmacognosy, 7th edition, B.S. Shah Prakashan, Ahmedabad.
7. G.E. Trease, W.C. Evans, 2008. Pharmacognosy, 15 th Ed., WB Saunders, Balliere, Tindall, London.
8. H.S. Puri. Rasayana - Traditional Herbal Medicines for modern times, Vol. I- II, Taylor & Francis, London
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10. Indian Pharmacopoeia. Government of India, Ministry of Health and Family Welfare, New Delhi.
11. M.Z. Abdin, Y.P. Abrol. Traditional Systems of Medicine. Narosa Publishing House, New Delhi.
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15. Quality Standards of Indian Medicinal Plants, Vol. I-X, Indian Council of Medical Research, New Delhi.
16. Quality Control Methods for Medicinal Plant Material, WHO, Geneva, 1998.
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19. T. Swain, J.B. Pridham, 1965. Biosynthetic pathway in higher plants, Academic Press, New York.
20. T.E. Wallis, 1960. Text Book of Pharmacognosy, CBS Publishers, New Delhi.

21. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
22. V. Rajpal and D. P. S. Kohli. 2009. Herbal Drug Industry, 2nd Edition, Business Horizons Publication, New Delhi.
23. V.E. Tyler, L.R. Brady, J.E. Robbers, 1988. Pharmacognosy, 9th Edn., Lea and Febiger, Philadelphia.

<b>B.Pharm-III (Semester- VI) Quality Assurance (BP-606)</b>		
<b>SN</b>	<b>Topics</b>	<b>Hrs</b>
01	Basic concept of Quality Control & Quality Assurance, Total Quality Management, Philosophy of GMP, GLP, ISO and introduction to ICH guidelines.	<b>05</b>
02	Quality Control Laboratory: Responsibilities, routine controls, instruments, protocols, standard test procedure sampling plans etc. Quality control documentation and audits of QC facilities.	<b>05</b>
03	Quality Control in Pharmaceutical Industries - Introduction to validation – Equipment, Method, Personnel and Process validations, Validation of water and air handling systems.	<b>05</b>
04	In process quality control on various dosage forms. Standard Operating Procedures for operations like cleaning, filling, drying, compression, coating, sterilization etc.	<b>05</b>
05	Concept and historical development of pharmaceutical product registration. Effect of GATT and WTO with regard to pharmaceuticals.	<b>05</b>
06	Regulations, requirements, procedures and application of new drug approval process: Preclinical studies, Brochure preparation for IND and ANDA. Clinical research protocols.	<b>05</b>
07	Regulatory requirements – European community, United State, Japan, India and other territories. New Developments in regulatory affairs across the world with regard to WHO and ICH guidelines.	<b>07</b>
08	Introduction to Intellectual Property Right. Introduction Understanding Intellectual property rights (IPR) and review of IPR regime: - Copyrights, Trademarks, Geographical indications,	<b>08</b>

	Appellations of origin, Industrial designs, and Intellectual property laws in India. Patent procedure, filing, search and licensing.	
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**References Books:**

1. Quality Control by Dale H. Bester field, Prentice Hall International Inc., New Jersey, 5th edn., (1998).
2. Good Laboratory Practice by Sandy Weinberg, Merce Dekker, New York, 2nd edn. Vol. 69 (1995).
3. New Drug Approval Process by Richard A Guarino, Merce Dekker, New York, 2<sup>nd</sup> edn., Vol. – 56 (1993).
4. Validation of Pharmaceutical Process by Carleton F.J. and Agalloco, Merce Dekker, Inc. New York.
5. How to Practice GMP, by P P Sharma, 2nd edn., Vandana Publishing, New Delhi