JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Industrial Pharmacy
(JNTUA-Affiliated Pharmacy Colleges 2017-18)

I YEAR - I Semester

S. No	Course Code	Subjects	L	T	P	C
1	17S01101	Modern Pharmaceutical Analytical Techniques	4	-	-	4
2	17S08101	Pharmaceutical Formulation Development	4	-	-	4
3	17S08102	Novel drug delivery systems	4	-	-	4
4	17S08103	Intellectual Property Rights	4	-	-	4
5	17S01105	Modern Pharmaceutical Analytical Techniques Practical	-	-	6	3
6	17S08104	Pharmaceutical Formulation Development Practical - I	-	-	6	3
7	17S08105	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

I YEAR II Semester

S. No	Course Code	Subject	L	T	P	C
1	17S08201	Advanced Biopharmaceutics and Pharmacokinetics	4	-	-	4
2	17S08202	Scale up and Technology Transfer	4	-	-	4
3	17S08203	Pharmaceutical Production Technology	4	-	-	4
4	17S08204	Entrepreneurship Management	4	-	-	4
5	17S08205	Industrial Pharmacy Practical II	-	-	6	3
6	17S08206	Industrial Pharmacy Practical III	-	-	6	3
7	17S08207	Seminar/Assignment	-	-	7	4
Total			16	-	19	26

III SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S01301	Research Methodology and Biostatistics	4	-	-	4
2.	17S08301	Journal Club	1	-	-	1
3.	17S08302	Teaching Assignment	10	-	-	2
4.	17S08303	Comprehensive viva voce	-	-	-	2
5.	17S08304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S08305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S08401	Journal Club	1	-	-	1
2.	17S08402	Research work	31	-	-	16
3.	17S08403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

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M. Pharm – I year I Sem. (Industrial Pharmacy)

L	T	P	C
4	0	0	4

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

This subject deals with various advanced analytical instrumental techniques for identification, characterization and quantification of drugs. Instruments dealt are NMR, Mass spectrometer, IR, HPLC, GC etc.

Objectives

After completion of course student is able to know,

- The analysis of various drugs in single and combination dosage forms
- Theoretical and practical skills of the instruments

THEORY **60 HOURS**

1. 11Hrs

UV-Visible spectroscopy: Introduction, Theory, Laws, Instrumentation associated with UV-Visible spectroscopy, Choice of solvents and solvent effect and Applications of UV-Visible spectroscopy.

IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling, Instrumentation of Dispersive and Fourier – Transform IR Spectrometer, Factors affecting vibrational frequencies and Applications of IR spectroscopy

Spectroflourimetry: Theory of Fluorescence, Factors affecting fluorescence, Quenchers, Instrumentation and Applications of fluorescence spectrophotometer.

Flame emission spectroscopy and Atomic absorption spectroscopy: Principle, Instrumentation, Interferences and Applications.

2 11Hrs

NMR spectroscopy: Quantum numbers and their role in NMR, Principle, Instrumentation, Solvent requirement in NMR,Relaxation process, NMR signals in various compounds, Chemical shift, Factors influencing chemical shift, Spin-Spin coupling, Coupling constant, Nuclear magnetic double resonance, Brief outline of principles of FT-NMR and 13C NMR. Applications of NMR spectroscopy.

3 11Hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of Mass Spectroscopy, Different types of ionization like electron impact, chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers of Quadrupole and Time of Flight, Mass fragmentation and its rules, Meta stable ions, Isotopic peaks and Applications of Mass spectroscopy

4 11Hrs

Chromatography: Principle, apparatus, instrumentation, chromatographic parameters, factors affecting resolution and applications of the following:
a) Paper chromatography b) Thin Layer chromatographyc) Ion exchange chromatography
d) Column chromatographye) Gas chromatography f) High Performance Liquid chromatography
g) Affinity chromatography

5 16Hrs

Electrophoresis: Principle, Instrumentation, Working conditions, factors affecting separation and applications of the following:

a) Paper electrophoresis b) Gel electrophoresis c) Capillary electrophoresis d) Zone electrophoresis e) Moving boundary electrophoresis f) I so electric focusing

X ray Crystallography: Production of X rays, Different X raymethods, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals and applications of X-ray diffraction.

b) Immunological Assays: Radioimmunology assay (RIA), ELISA(Theory & practical) and knowledge on Bioluminescence assays.

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,6th edition, John Wiley & Sons, 2004.
2. Principles of Instrumental Analysis - Doglas A Skoog, F. James Holler,Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.

3. Instrumental methods of analysis – Willards, 7th edition, CBS publishers.

4. Practical Pharmaceutical Chemistry – Beckett and Stenlake, Vol II, 4thedition, CBS Publishers, New Delhi, 1997.

5. Organic Spectroscopy - William Kemp, 3rd edition, ELBS, 1991.

6. Quantitative Analysis of Drugs in Pharmaceutical formulation - P D Sethi,3rd Edition, CBS Publishers, New Delhi, 1997.

7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume 11, Marcel Dekker Series.

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L	T	P	C
4	0	0	4

(17S08101) PHARMACEUTICAL FORMULATION DEVELOPMENT

Scope

This course is designed to impart knowledge and skills necessary to train the students on par with the routine of Industrial activities in R&D and F&D.

Objectives

On completion of this course it is expected that students will be able to understand-

- The scheduled activities in a Pharmaceutical firm.
- The pre formulation studies of pilot batches of pharmaceutical industry.
- The significance of dissolution and product stability

THEORY **60 Hrs**

1. 12Hrs

Preformulation Studies: Molecular optimization of APIs (drug substances), crystal morphology and variations, powder flow, structure modification, drug-excipient compatibility studies, methods of determination.

2 12Hrs

Formulation Additives: Study of different formulation additives, factors influencing their incorporation, role of formulation development and processing, new developments in excipient science. Design of experiments – factorial design for product and process development.

3 12Hrs

Solubility: Importance, experimental determination, phasesolubilityanalysis, pH-solubility profile, solubility techniques toimprove solubility and utilization of analytical methods –cosolvency, salt formation, complexation, solid dispersion, micellarsolubilization and hydrotropy.

4 12Hrs

Dissolution: Theories, mechanisms of dissolution, in-vitrodissolution testing models – sink and non-sink. Factorsinfluencing dissolution and intrinsic dissolution studies.Dissolution test apparatus – designs, dissolution testing forconventional and controlled release products. Data handling andcorrection factor. Biorelevent media, in-vitro and in-vivocorrelations, levels of correlations.

5 12Hrs

Product Stability: Degradation kinetics, mechanisms, stabilitytesting of drugs and pharmaceuticals, factors influencing-mediaeffects and pH effects, accelerated stability studies, interpretationof kinetic data (API & tablets). Solid state stability and shelf lifeassignment. Stability protocols, reports and ICH guidelines.

REFERENCES

1. Lachman L, Lieberman HA, Kanig JL. The Theory and Practice Of Industrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.

2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5thed., B.I. Publications Pvt. Ltd, Noida, 2006.

3. Lieberman HA, Lachman L, Schwartz JB. Pharmaceutical dosage forms: tablets Vol. I-III, 2nd ed., CBS Publishers & distributors, New Delhi, 2005.

4. Conners KA. A Text book of pharmaceutical analysi Wells JI.Pharmaceuticalpreformulation: The physicochemical properties of drugsubstances. Ellis Horwood Ltd., England, 1998.

5. Yalkowsky SH. Techniques of solubilization of drugs. Vol-12.Marcel Dekker Inc., New York, 1981

6. Dressman J, Kramer J. Pharmaceutical dissolution testing. Saurahprinterpvt. Ltd., New Delhi,2005.

7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rded., CBS publications, New Delhi, 2008.

8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rdCBS Publishers & distributors, New Delhi, 2005.

9. Yoshioka S, Stella VJ. Stability of drugs and dosage forms, Springer(India) Pvt. Ltd., New Delhi, 2006.

10. Banker GS, Rhodes CT. Modern Pharmaceutics, 4thInc, New York, 2005.

11. W. Grimm - Stability testing of drug products.ed., Marcel Dekker

12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd.,

Bangalore, 1999. 13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II., 4th2004.ed., CBS Publishers & distributors, New Delhi,

14. Indian Pharmacopoeia. Controller of Publication. Delhi, 1996.

15. British Pharmacopoeia. British Pharmacopoeia Commission Office,London, 2008.

16. United States Pharmacopoeia. United States PharmacopeialConvention,Inc, USA, 2003.

17. Encyclopaedia of Pharm. Technology, Vol I – III.

18. Wells J. I. Pharmaceutical Preformulation: The physicochemicalproperties of drug substances, Ellis Horwood Ltd. England, 1988.

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L	T	P	C
4	0	0	4

(17S08102) NOVEL DRUG DELIVERY SYSTEMS

Scope

This course is designed to impart knowledge and skills necessary to train thestudents in the area of novel drug delivery systems.

Objective

On completion of this course it is expected that students will be able tounderstand,

- The need, concept, design and evaluation of various customized,sustained and controlled release dosage forms.
- To formulate and evaluate various novel drug delivery systems

THEORY 60 Hrs

1. 12Hrs

Concept & Models for NDDS: Classification of rate controlled drug delivery systems (DDS), rate programmed release, activation modulated & feedback regulated DDS, effect of system parameters in controlled drug delivery, computation of desired release rate and dose for controlled release DDS, pharmacokinetic design for DDS – intermittent, zero order & first order release.

Carriers for Drug Delivery: Polymers / co-polymers introduction, classification, characterization, polymerization techniques, application in CDDS / NDDS, biodegradable & natural polymers.

2 12Hrs

a) Study of Various DDS: Concepts, design, formulation &evaluation of controlled release oral DDS, MucoadhesiveDDS(buccal, nasal, pulmonary) Pulsatile, colon specific, liquid sustained release systems, Ocular delivery systems

b) 08Hrs

Transdermal Drug Delivery Systems: Theory, design, formulation & evaluation including iontophoresis and other latest developments in skin delivery systems.

04Hrs

Sub MicronCosmeceuticals: Biology, formulation science and evaluation of various cosmetics for skin, hair, nail, eye etc and it's regulatory aspects.

3 08HrsTargeted

Drug Delivery Systems: Importance, concept,biological process and events involved in drug targeting, design,formulation& evaluation, methods in drug targeting –nanoparticles, liposomes, niosomes, pharmacosomes, resealederythrocytes, microspheres, magnetic microspheres. Specializedpharmaceutical emulsions – multiple emulsions, micro-emulsions.

4 04Hrs

Protein / Peptide Drug Delivery Systems: Concepts, delivery techniques, formulation, stability testing, causes of protein destabilization, stabilization methods.

06Hrs

Biotechnology in Drug Delivery Systems: Brief review of major areas-recombinant DNA technology, monoclonal antibodies, gene therapy.

5 06Hrs

New trends for Personalized Medicine: Introduction, Definition, Pharmacogenetics, Categories of Patients for Personalized Medicines: Customized drug delivery systems, Bioelectronic Medicines, 3D printing of pharmaceuticals, Telepharmacy.

REFERENCES

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.

2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.

3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, MarcelDekker, NY.

4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.

5. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.

6. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.

7. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.

8. Pharmaceutical Biotechnology, Vyas, CBS, Delhi.

9. Biotechnology of Industrial Antibiotics, E.J. Vandamme, Marcel Dekker,NY.

10. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.

11. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

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L	T	P	C
4	0	0	4

(17S08103) INTELLECTUAL PROPERTY RIGHTS

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on par with the routine of Industrial activities in drug regulatory affairs

Objectives

On completion of this course it is expected that students will be able to understand,

- Assist in Regulatory Audit process.
- Establish regulatory guidelines for drug and drug products
- The Regulatory requirements for contract research organization

THEORY 60 Hrs

1. 12 Hrs

Definition, Need for patenting, Types of Patents, Conditions to be satisfied by an invention to be patentable, Introduction to patent search. Parts of patents. Filling of patents. Theessential elements of patent; Guidelines for preparation of laboratory note book, Non-obviousness in Patent.

2 Role of GATT, TRIPS, and WIPO 12 Hrs

3 12 Hrs

Brief introduction to Trademark protection and WHO Patents. IPR's and its types, Major bodies regulating Indian Pharmaceutical sector.

4 12 Hrs

Brief introduction to CDSCO. WHO, USFDA, EMEA, TGA,MHRA, MCC, ANVISA

5 12 Hrs

Regulatory requirements for contract research organization. Regulations for Biosimilars.

REFERENCES:

1. Pharmaceutical Process Validation: By Fra R. Berry and Robert A. Nash, Vol57, 2nd Edition

2. Applied Production and Operation Management By Evans, Anderson and Williams

3. GMP for pharmaceuticals Material Management by K.K. Ahuja Published by CBS publishers

4. ISO 9000-Norms and explanations

5. GMP for pharmaceuticals- Willing S.H. Marcel and Dekker.

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	0	**0**	**6**	**3**

(17S01105) MODEREN PHARMACEUTICAL ANALYSIS PRACTICAL

1. Analysis of pharmacopoeial compounds and their formulations by UV Visspectrophotometer
2. Simultaneous estimation of multi component containing formulations by UVspectrophotometry
3. Experiments based on HPLC / GC
4. Estimation of riboflavin/quinine sulphate by fluorimetry
5. Estimation of sodium/potassium by flame photometry
6. Effect of surfactants on the solubility of drugs.

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	0	**0**	**6**	**3**

(17S08104) PHARMACEUTICAL FORMULATION DEVELOPMENT PRACTICAL - I

1. Effect of pH on the solubility of drugs.
2. Stability testing of solution and solid dosage forms for photo degradation.
3. Stability studies of drugs in dosage forms at 25°C, 60% RH and 40°C, 75% RH.
4. Compatibility evaluation of drugs and excipients (DSC & FTIR).
5. Preparation and evaluation of different polymeric membranes.
6. Formulation and evaluation of sustained release oral matrix tablet/ oralreservoir system.
7. Formulation and evaluation of microspheres / microcapsules.
8. Formulation and evaluation of transdermal drug delivery systems.
9. Design and evaluation of face wash, body- wash, creams, lotions, shampoo, toothpaste, lipstick.
10. Electrophoresis of protein solution.
11. Preparation and evaluation of Liposome delivery system.

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L	T	P	C
4	0	0	4

(17S08201) ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

Scope

This course is designed to impart knowledge and skills necessary for dosecalculations, dose adjustments and to apply Biopharmaceutics theories inpractical problem solving.

Objectives

On completion of this course it is expected that students will be able to understand,

- The basic concepts in Biopharmaceutics and pharmacokinetics.
- The use of raw data and derive the pharmacokinetic models and parameters the best describe the process of drug absorption, distribution, metabolism and elimination.
- To critically evaluate Biopharmaceutics studies involving drug productequivalency.
- To design and evaluate dosage regimens of the drugs usingpharmacokinetic and biopharmaceutic parameters.

THEORY 60 Hrs

1. 12Hrs

Drug Absorption From The Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting, pH–partition theory, Formulation and physicochemicalfactors: Dissolution rate, Dissolution process, Noyes–Whitneyequation and drug dissolution, Factors affecting the dissolutionrate. Gastrointestinal absorption: role of the dosage form: Solution(elixir, syrup and solution) as a dosage form ,Suspension as adosage form, Capsule as a dosage form, Tablet as a dosage form, Dissolution methods ,Formulation and processing factors, Correlation of in vivo data with in vitro dissolution data. Transportmodel: Permeability-Solubility-Charge State and the pH Partition Hypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-Junction Complex. Solubility: Experimental methods. Permeability: In-vitro, in-situ and In-vivo methods.

2 12Hrs

Biopharmaceutic Considerations in Drug Product Designand In Vitro Drug Product Performance: Introduction, Biopharmaceutic Factors Affecting Drug Bioavailability, Rate-Limiting Steps in Drug Absorption, Physicochemical Nature of the Drug Formulation Factors Affecting Drug Product Performance, In Vitro: Dissolution and Drug Release Testing, CompendialMethods of Dissolution, Alternative Methods of DissolutionTesting, Meeting Dissolution Requirements, Problems of VariableControl in Dissolution Testing Performance of Drug Products: InVitro–In Vivo Correlation, Dissolution Profile Comparisons, DrugProduct Stability, Considerations in the Design of a Drug Product.

3 12Hrs

Pharmacokinetics: Basic considerations, Pharmacokineticmodels, Compartment modeling: One compartment model- IVbolus, IV infusion, Extra-vascular; Multi Compartment model: Twocompartment - model in brief, Non-Linear Pharmacokinetics:Cause of non-linearity, Michaelis – Menten equation, EstimationKmax and Vmax. Drug interactions: Introduction, The effect ofprotein-binding interactions, The effect of tissue-bindinginteractions, Cytochrome P450-based drug interactions, Druginteractions linked to transporters.

4 12Hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: Drug Product Performance, Purpose ofBioavailability Studies, Relative and Absolute Availability,Methods for Assessing Bioavailability, Bioequivalence Studies,Design and Evaluation of Bioequivalence Studies, Study Designs,Crossover Study Designs, Evaluation of the Data, BioequivalenceExample, Study Submission and Drug Review Process, TheBiopharmaceutics Classification System, Generic Biologics(Biosimilar Drug Products),Clinical Significance of BioequivalenceStudies, Special Concerns in Bioavailability and BioequivalenceStudies, Generic Substitution.

5 12Hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Relationship between Pharmacokinetics includingPharmacodynamics: Generation of a pharmacokinetic–pharmacodynamic (PKPD) equation, Pharmacokinetic andpharmacodynamic, interactions. Pharmacokinetics andpharmacodynamics of biotechnology drugs: Introduction, Proteinsand peptides, Monoclonal antibodies, Oligonucleotides, Vaccines(immunotherapy),Gene therapies.

REFERENCES

1. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4thedition,Philadelphia, Lea and Febiger, 1991

2. Biopharmaceutics and Pharmacokinetics, A. Treatise, D .M. Brahmankarand Sunil B.J aiswal.,VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2nd edition, Connecticut Appleton Century Crofts, 1985

4. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R.Hiremath,Prism Book

5. Pharmacokinetics by Milo Gibaldi and D. Perrier, 2nd edition, MarcelDekkerInc.,New York, 1982

6. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics,Swarbrick. J, Lea and Febiger, Philadelphia, 1970

7. Clinical Pharmacokinetics, Concepts and Applications 3rd edition byMalcolm Rowland and Thom~ N. Tozer, Lea and Febiger, Philadelphia,1995

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, MackPublishing Company, Pennsylvania 1989

9. Biopharmaceutics and Clinical Pharmacokinetics, An Introduction, 4thedition, revised and expande by Robert. E. Notari, Marcel Dekker Inc, NewYork and Basel,1987.

10. Biopharmaceutics and Relevant Pharmacokinetics by John. G Wagner andM.Pemarowski, 1st edition, Drug Intelligence Publications, Hamilton,Illinois, 1971.

11. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick,James. G.Boylan, Marcel Dekker Inc, New York, 1996.

12. Basic Pharmacokinetics,1 st edition, Sunil S Jambhekar and Philip JBreen,pharmaceutical press, RPS Publishing,2009.

13. Absorption and Drug Development- Solubility, Permeability, and ChargeState, Alex Avdeef, John Wiley & Sons, Inc,2003.

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L	T	P	C
4	0	0	4

(17S08202) SCALE UP AND TECHNOLOGY TRANSFER

Scope

This course is designed to impart knowledge and skills necessary to train the students to be on scale up, technology transfer process and industrial safetyissues.

Objectives:

On completion of this course it is expected that students will be able to understand,

- Manage the scale up process in pharmaceutical industry.
- Assist in technology transfer.
- To establish safety guidelines, which prevent industrial hazards.

THEORY 60 Hrs

1. 12Hrs

Pilot plant design: Basic requirements for design, facility, equipment selection, for tablets, capsules, liquid orals, parentraland semisolid preparations.

Scale up: Importance, Technology transfer from R & D to pilotplant to plant scale, process scale up for tablets, capsules, liquidorals, semisolids, parentral, NDDS products – stress on formula, equipments, product uniformity, stability, raw materials, physicallayout, input, in-process and finished product specifications, problems encountered during transfer of technology

2 12Hrs

Validation: General concepts, types, procedures & protocols, documentation, VMF. Analytical method validation, cleaningvalidation and vender qualification.

3 12Hrs

Equipment Qualification: Importance, IQ, OQ, PQ forequipments – autoclave, DHS, membrane filter, rapid mixergranulator, cone blender, FBD, tablet compression machine,liquid filling and sealing machine. Aseptic room validation.

4 12Hrs

Process validation: Importance, validation of mixing,granulation, drying, compression, tablet coating, liquid filling andsealing, sterilization, water process systems, environmentalcontrol.

5 12Hrs

Industrial safety: Hazards – fire, mechanical, electrical,chemical and pharmaceutical, Monitoring & prevention systems,industrial effluent testing & treatment. Control of environmentalpollution.

REFERENCES

1. Pharmaceutical process validation, JR Berry, Nash, Vol 57, Marcel Dekker,NY.

2. Pharmaceutical Production facilities, design and applications, by GC Cole,Taylor and Francis.

3. Pharmaceutical project management, T.Kennedy, Vol 86, Marcel Dekker,NY.

4. The theory & Practice of Industrial Pharmacy, L.Lachman, H.A.Lieberman,Varghese Publ. Bombay.

5. Tablet machine instruments in pharmaceuticals, PR Watt, John Wiloy.

6. Pharmaceutical dosage forms, Tablets, Vol 1, 2, 3 by Lachman,Lieberman, Marcel Dekker, NY.

7. Pharmaceutical dosage forms, Parentral medications, Vol 1, 2 by K.E.Avis, Marcel Dekker, NY.

8. Dispersed system Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker,NY.

9. Subrahmanyam, CVS, Pharmaceutical production and Management, 2007,VallabhPrakashan,Dehli.

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L	T	P	C
4	0	0	4

(17S08203) PHARMACEUTICAL PRODUCTION TECHNOLOGY

Scope

This course is designed to impart knowledge and skills necessary to train thestudents to be on par with the routine of Industrial activities in Production

Objectives

On completion of this course it is expected that students will be able tounderstand,

- Handle the scheduled activities in a Pharmaceutical firm.
- Manage the production of large batches of pharmaceuticalformulations.

THEORY 60 Hrs

Improved Tablet Production: Tablet production process, unit

1. 12Hrs

operation improvements, granulation and pelletizationequipments, continuous and batch mixing, rapid mixinggranulators, rota granulators, spheronizers and marumerisers,and other specialized granulation and drying equipments.Problems encountered.

Coating Technology: Process, equipments, particle coating,fluidized bed coating, application techniques. Problemsencountered.

2 12Hrs

Parenteral Production: Area planning & environmental control,wall and floor treatment, fixtures and machineries, change rooms,personnel flow, utilities & utilities equipment location, engineeringand maintenance.

3 12Hrs

Lyophilization& Spray drying Technology: Principles,process, freeze-drying and spray drying equipments.

4 12Hrs

Capsule Production: Production process, improved capsulemanufacturing and filling machines for hard and soft gelatincapsules. Layout and problems encountered.Disperse Systems Production: Production processes,applications of mixers, mills, disperse equipments including finesolids dispersion, problems encountered.Packaging Technology: Types of packaging materials,machinery, labeling, package printing for different dosage forms.

5 12Hrs

Air Handling Systems: Study of AHUs, humidity &temperaturecontrol, air filtration systems, dust collectors. Water TreatmentProcess: Techniques and maintenance – RO, DM, ultra –filtration, WFI.

REFERENCES

1. The Theory & Practice of Industrial Pharmacy, L. Lachman, VarghesePubl, Bombay.

2. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.

3. Pharmaceutical Dosage Forms, Vol 1, 2, 3 by Lachman, Lieberman,Marcel Dekker, NY.

4. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E.Avis, Marcel Dekker, NY.

5. Pharmaceutical Production Facilities, design and applications, by G.C.Cole, Taylor and Francis.

6. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.7. Product design and testing of polymeric materials by N.P. Chezerisionoff.

8. Pharmaceutical Project Management, T.Kennedy, Vol 86, Marcel Dekker,NY.

9. Packaging Pharmaceutical and Health Care, H.Lockhard.

10. Quality Control of Packaging Materials in Pharmaceutical Industy,.Kharburn, Marcel Dekker, NY.

11. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L.Ray, Vol 96, Marcel Dekker, NY.

12. Tablet Machine Instrumentation In Pharmaceuticals, PR Watt, EllisHorwoods, UK.

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L	T	P	C
4	0	0	4

(17S08204) ENTREPRENEURSHIP MANAGEMENT

Scope

This course is designed to impart knowledge and skills necessary to train thestudents on entrepreneurship management.

Objectives:

On completion of this course it is expected that students will be able tounderstand,

- The Role of enterprise in national and global economy
- Dynamics of motivation and concepts of entrepreneurship
- Demands and challenges of Growth Strategies And Networking

THEORY 60 Hrs

1. 12Hrs

Conceptual Frame Work: Concept need and process inentrepreneurship development. Role of enterprise in national andglobal economy. Types of enterprise – Merits and Demerits.Government policies and schemes for enterprise development.Institutional support in enterprise development and management.

2 12Hrs

Entrepreneur: Entrepreneurial motivation – dynamics ofmotivation. Entrepreneurial competency – Concepts. DevelopingEntrepreneurial competencies - requirements and understandingthe process of entrepreneurship development, self-awareness,interpersonal skills, creativity, assertiveness, achievement, factorsaffecting entrepreneur role.

3 12Hrs

Launching AndOrganising An Enterprise: Environmentscanning – Information, sources, schemes of assistance,problems. Enterprise selection, market assessment, enterprisefeasibility study, SWOT Analysis. Resource mobilisation -finance, technology, raw material, site and manpower. Costingand marketing management and quality control. Feedback,monitoring and evaluation.

4 12Hrs

Growth Strategies And Networking: Performance appraisal andassessment. Profitability and control measures, demands andchallenges. Need for diversification. Future Growth – Techniquesof expansion and diversification, vision strategies. Concept anddynamics. Methods, Joint venture, co-ordination and feasibilitystudy.

5 12Hrs

Preparing Project Proposal To Start On New EnterpriseProject work – Feasibility report; Planning, resource mobilization and implementation.

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD,New Delhi.

2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health& Co., Toranto.

3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting,Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.

4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.

5. Patel, V.C. (1987): Women Entrepreneurship – Developing NewEntrepreneurs, Ahmedabad EDII.

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M. Pharm – I year II Sem. (Industrial Pharmacy)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S08205) INDUSTRIAL PHARMACY PRACTICAL - II

1. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
2. Comparison of dissolution of two different marketed products /brands
3. Protein binding studies of a highly protein bound drug & poorly protein bounddrug
4. Bioavailability studies of Paracetamol (Animal).
5. Pharmacokinetic and IVIVC data analysis by WinnolineR software
6. In vitro cell studies for permeability and metabolism

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M. Pharm – I year II Sem. (Industrial Pharmacy)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S08206) INDUSTRIAL PHARMACY PRACTICAL - III

1. Formulation and evaluation of tablets
2. Formulation and evaluation of capsules
3. Formulation and evaluation of injections
4. Formulation and evaluation of emulsion
5. Formulation and evaluation of suspension.
6. Formulation and evaluation of enteric coating tablets.
7. Preparation and evaluation of a freeze dried formulation.
8. Preparation and evaluation of a spray dried formulation.

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M. Pharm – III Sem. (Industrial Pharmacy)

L	T	P	C
4	0	0	4

(17S01301) RESEARCH METHODOLOGY & BIOSTATISTICS

UNIT – I

General Research Methodology: Research, objective, requirements, practical difficulties, review of literature, study design, types of studies, strategies to eliminate errors/bias, controls, randomization, crossover design, placebo, blinding techniques.

UNIT – II

Biostatistics: Definition, application, sample size, importance of sample size, factors influencing sample size, dropouts, statistical tests of significance, type of significance tests, parametric tests(students "t" test, ANOVA, Correlation coefficient, regression), non-parametric tests (wilcoxan rank tests, analysis of variance, correlation, chi square test), null hypothesis, P values, degree of freedom, interpretation of P values.

UNIT – III

Medical Research: History, values in medical ethics, autonomy, beneficence, non-maleficence, double effect, conflicts between autonomy and beneficence/non-maleficence, euthanasia, informed consent, confidentiality, criticisms of orthodox medical ethics, importance of communication, control resolution, guidelines, ethics committees, cultural concerns, truth telling, online business practices, conflicts of interest, referral, vendor relationships, treatment of family members, sexual relationships, fatality.

UNIT – IV

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care, quarantine, surveillance, diagnosis, treatment and control of disease, personalhygiene, location of animal facilities to laboratories, anesthesia, euthanasia, physical facilities, environment, animal husbandry, record keeping, SOPs, personnel and training, transport of lab animals.

UNIT – V

Declaration of Helsinki: History, introduction, basic principles for all medical research, and additional principles for medical research combined with medical care.