JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR
Course Structure and Syllabi for M.Pharm-Pharmaceutical Technology
(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	17S10101	Pharmaceutical Product Development and technology Transfer	4	-	-	4
3	17S08102	Novel Drug Delivery System	4	-	-	4
4	17S08103	Intellectual Property Rights	4	-	-	4
5	**17S10102**	**Pharmaceutical Analysis Practical for Pharmaceutical Technology**	**-**	**-**	**6**	**3**
6	**17S10103**	**Pharmaceutical Technology Practical - I**	**-**	**-**	**6**	**3**
7	**17S10104**	**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	17S03204	Cosmetics and Cosmoceuticals	4	-	-	4
5	17S10202	Pharmaceutical Technology Practical II	-	-	6	3
6	17S10203	Pharmaceutical Technology Practical III	-	-	6	3
7	17S10204	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.	17S10301	Journal Club	1	-	-	1
3.	17S10302	Teaching Assignment	10	-	-	2
4.	17S10303	Comprehensive viva voce	-	-	-	2
5.	17S10304	Discussion / Presentation (Proposal presentation)	-	-	2	2
6.	17S10305	Research Work	-	-	28	14
Total			15	-	30	25

IV SEMESTER

S.No	Subject Code	Subject	L	T	P	C
1.	17S10401	Journal Club	1	-	-	1
2.	17S10402	Research work	31	-	-	16
3.	17S10403	Discussion/ Final Presentation	3	-	-	3
Total			35	-	-	20

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)	**L**	**T**	**P**	**C**
	4	**0**	**0**	**4**

(17S01101) MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Scope

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

Objectives

After completion of course student is able to know,

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

THEORY **60 HOURS**

1. 11 hrs

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

b. IR spectroscopy: Theory, Modes of Molecular vibrations, Sample handling,

Instrumentation of Dispersive and Fourier -Transform IR Spectrometer, Factors

affecting vibrationalfrequencies and Applications of IR spectroscopy

c. Spectroflourimetry: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers,

Instrumentation andApplications of fluorescence spectrophotometer.

d. Flame emission spectroscopy and Atomic absorptionspectroscopy: Principle,

Instrumentation, Interferences andApplications.

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-Spincoupling, Coupling constant, Nuclear magnetic double resonance,Brief outline of principles of FT-NMR and 13C NMR. Applicationsof NMR spectroscopy.

3. 11hrs

Mass Spectroscopy: Principle, Theory, Instrumentation of MassSpectroscopy, Different types of ionization like electron impact,chemical, field, FAB and MALDI, APCI, ESI, APPI Analyzers ofQuadrupole 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 Liquidchromatographyg) Affinity chromatography

5 11hrs

a. 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) Iso electric focusing

b. X ray Crystallography: Production of X rays, Different X raydiffraction methods, Bragg's law, Rotating crystal technique, Xray powder technique, Types of crystals and applications of Xray diffraction.

c. Immunological assays: RIA (Radio immuno assay), ELISA, Bioluminescence assays.5hrs

REFERENCES

1. Spectrometric Identification of Organic compounds - Robert M Silverstein,Sixth 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, 3rdEdition, CBS Publishers, New Delhi, 1997.
7. Pharmaceutical Analysis- Modern methods – Part B - J W Munson, Volume11, Marcel Dekker Series

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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	4	**0**	**0**	**4**

(17S10101) PHARMACEUTICAL PRODUCT DEVELOPMENT AND TECHNOLOGY TRANSFER

Scope

This deal with technology transfer covers the activities associated with DrugSubstance, Drug Product and analytical tests and methods, required followingcandidate drug selection to completion of technology transfer from R&D to thefirst receiving site and technology transfer related to post-marketing changes inmanufacturing places.

Objectives

Upon completion of this course the student should be able to

- To understand the new product development process
- To understand the necessary information to transfer technology fromR&D to actual manufacturing by sorting out various informationobtained during R&D
- To elucidate necessary information to transfer technology of existingproducts between various manufacturing places

THEORY 60 Hrs

1. 12Hrs

Principles of Drug discovery and development: Introduction,Clinical research process. Development and informational contentfor Investigational New Drugs Application (IND), New DrugApplication (NDA), Abbreviated New Drug Application (ANDA),Supplemental New Drug Application (SNDA), Scale Up PostApproval Changes (SUPAC) and Bulk active chemical Postapproval changes (BACPAC), Post marketing surveillance,Product registration guidelines – CDSCO, USFDA.

2 12Hrs

Pre-formulation studies: Introduction/concept, organolepticproperties, purity, impurity profiles, particle size, shape andsurface area. Solubility, Methods to improve solubility of Drugs:Surfactants & its importance, co-solvency. Techniques for thestudy of Crystal properties and polymorphism. Pre-formulationprotocol, Stability testing during product development.

3 12Hrs

Pilot plant scale up: Concept, Significance, design, layout ofpilot plant scale up study, operations, large scale manufacturingtechniques (formula, equipment, process, stability and

qualitycontrol) of solids, liquids, semisolid and parenteral dosage forms.New era of drug products: opportunities and challenges.

4 12Hrs

Pharmaceutical packaging: Pharmaceutical dosage form andtheir packaging requirments, Pharmaceutical packaging materials,Medical device packaging, Enteral Packaging, Aseptic packagingsystems, Container closure systems, Issues facing modern drugpackaging, Selection and evaluation of Pharmaceutical packagingmaterials.

Quality control test: Containers, closures and secondarypacking materials.

5 12Hrs

Technology transfer: Development of technology by R & D,Technology transfer from R & D to production, Optimization andProduction, Qualitative and quantitative technology models.

Documentation in technology transfer: Development report,technology transfer plan and Exhibit.

REFERENCES

1. The process of new drug discovery and development. I and II Edition(2006) by Charles G. Smith, James T and O. Donnell. CRC Press, Groupof Taylor and Francis.

2. Leon Lac Lachman, Herbert A. Liberman, Theory and Practice of IndustrialPharmacy. Marcel Dekker Inc. New York.

3. Sidney H Willing, Murray M, Tuckerman. Williams Hitchings IV, Goodmanufacturing of pharmaceuticals (A Plan for total quality control) 3rdEdition. Bhalani publishing house Mumbai.

4. Tablets Vol. I, II, III by Leon Lachman, Herbert A. Liberman, Joseph B.Schwartz, 2nd Edn. (1989) Marcel Dekker Inc. New York.

5. Text book of Bio- Pharmaceutics and clinical Pharmacokinetics by MiloGibaldi, 3rd Edn, Lea & Febriger, Philadelphia.

6. Pharmaceutical product development. Vandana V. Patrevale. John I.Disouza. Maharukh T.Rustomji. CRC Press, Group of Taylor and Francis.

7. Dissolution, Bioavailability and Bio-Equivalence by Abdou H.M, MackPublishing company, Eastern Pennsylvania.

8. Remingtons Pharmaceutical Sciences, by Alfonso & Gennaro, 19thEdn.(1995)OO2C Lippincott; Williams and Wilkins A Wolters KluwerCompany, Philadelphia.

9. The Pharmaceutical Sciences; the Pharma Path way ‘Pure and appliedPharmacy’ by D. A Sawant, Pragathi Books Pvt. Ltd.

10. Pharmaceutical Packaging technology by D.A. Dean. E.R. Evans, I.H. Hall.1st Edition(Reprint 2006). Taylor and Francis. London and New York.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)	**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 controlleddrug delivery systems (DDS), rate programmed release,activation modulated & feedback regulated DDS, effect of systemparameters in controlled drug delivery, computation of desiredrelease rate and dose for controlled release DDS,pharmacokinetic design for DDS – intermittent, zero order & firstorder release.

Carriers for Drug Delivery: Polymers / co-polymersintroduction,classification, characterization, polymerizationtechniques, application in CDDS / NDDS, biodegradable & naturalpolymers.

2 12Hrs

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

08Hrs

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

04Hrs

c. Sub-Micron Cosmeceuticals: Biology, formulation science andevaluation of various cosmetics for skin, hair, nail, eye etc. and it’sregulatory aspects.

3 08Hrs

Targeted 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, deliverytechniques, formulation, stability testing, causes of proteindestabilization, stabilization methods.

06Hrs

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

5 06Hrs

New trends for Personalized Medicine: Introduction, Definition,Pharmacogenetics, Categories of Patients for PersonalizedMedicines: Customized drug delivery systems, BioelectronicMedicines, 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)	**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 thestudents to be on par with the routine of Industrial activities in drug regulatoryaffairs

Objectives

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

- 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 tobe satisfied by an invention to be patentable, Introduction topatent search. Parts of patents. Filling of patents. Theessential elements of patent; Guidelines for preparation oflaboratory 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 IndianPharmaceutical 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 andWilliams

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

4. ISO 9000-Norms and explanations

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year I Sem. (Pharmaceutical Technology)	**L**	**T**	**P**	**C**
	0	**0**	**6**	**3**

(17S10102) PHARMACEUTICAL ANALYSIS PRACTICAL FOR PHARMACEUTICAL TECHNOLOGY

1. Analysis of pharmacopoeial compounds and their formulations by UV Vis spectrophotometer
2. Simultaneous estimation of multi component containing formulations by UV spectrophotometry
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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S10103) PHARMACEUTICAL TECHNOLOGY PRACTICAL-I

1. To perform In-vitro dissolution profile of CR/ SR marketed formulation

2. Formulation and evaluation of sustained release matrix tablets

3. Formulation and evaluation osmotically controlled DDS

4. Preparation and evaluation of Floating DDS- hydro dynamically balanced DDS

5. Formulation and evaluation of Muco adhesive tablets.

6. Formulation and evaluation of trans dermal patches.

7. To carry out preformulation studies of tablets.

8. To study the effect of compressional force on tablets disintegration time.

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.

12. To plot Heckal plot, Higuchi and peppas plot and determine similarity factors

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)	**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. Basic theoretical discussions of the principles ofbiopharmaceutics and pharmacokinetics are provided to help the students' toclarify the concepts.

Objectives

Upon completion of this course it is expected that students will be ableunderstand,

- The basic concepts in biopharmaceutics and pharmacokinetics.
- The use raw data and derive the pharmacokinetic models andparameters the best describe the process of drug absorption,distribution, metabolism and elimination.
- The critical evaluation of biopharmaceutic studies involving drugproduct equivalency.
- The design and evaluation of dosage regimens of the drugs usingpharmacokinetic and biopharmaceutic parameters.
- The potential clinical pharmacokinetic problems and application ofbasics of pharmacokinetic

THEORY **60 Hrs**

1. 12 hrs

Drug Absorption from the Gastrointestinal Tract:Gastrointestinal tract, Mechanism of drug absorption, Factorsaffecting drug absorption, pH–partition theory of drug absorption.Formuulation and physicochemical factors: Dissolution rate,Dissolution process, Noyes–Whitney equation and drugdissolution, Factors affecting the dissolution rate. Gastrointestinalabsorption: role of the dosage form: Solution (elixir, syrup andsolution) as a dosage form ,Suspension as a dosage form,Capsule as a dosage form, Tablet as a dosage form ,Dissolutionmethods ,Formulation and processing factors, Correlation of invivo data with in vitro dissolution data.Transport model:Permeability-Solubility-Charge State and the pH PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), pHMicroclimate Intracellular pH Environment, Tight-JunctionComplex.

2 12hrs

Biopharmaceutic considerations in drug product designand In Vitro Drug Product Performance: Introduction,biopharmaceutic factors affecting drug bioavailability, rate-limitingsteps in drug absorption, physicochemical nature of the drugformulation factors affecting drug product

performance, in vitro:dissolution and drug release testing, compendial methods ofdissolution, alternative methods of dissolution testing,meetingdissolution requirements,problems of variable control in dissolutionTestingperformance of drug products. In vitro–in vivo correlation,dissolution profile comparisons, drug productstability,considerations in the design of a drug product.

3 12 hrs

Pharmacokinetics: Basic considerations, pharmacokineticmodels, compartment modeling: one compartment model- IVbolus, IV infusion, extra-vascular. Multi compartment model:twocompartment - model in brief, non-linear pharmacokinetics: causeof non-linearity, Michaelis – Menten equation, estimation of kmaxand vmax. Drug interactions: introduction, the effect of proteinbindinginteractions,the effect of tissue-bindinginteractions,cytochrome p450-based drug interactions,druginteractions linked to transporters.

4 12 hrs

Drug Product Performance, In Vivo: Bioavailability andBioequivalence: drug product performance, purpose ofbioavailability studies, relative and absolute availability. Methodsfor assessing bioavailability, bioequivalence studies, design andevaluation of bioequivalence studies, study designs, crossoverstudy designs, evaluation of the data, bioequivalence example,study submission and drug review process. Biopharmaceutics classification system, methods. Permeability: In-vitro, in-situ andIn-vivo methods.generic biologics (biosimilar drugproducts),clinical significance of bioequivalence studies, special concerns in bioavailability and bioequivalence studies, genericsubstitution.

5 12 hrs

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Introduction to Pharmacokinetics andpharmacodynamic, drug interactions. Pharmacokinetics andpharmacodynamics of biotechnology drugs. Introduction, Proteinsand peptides, Monoclonal antibodies,

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. Jaiswal., VallabPrakashan, Pitampura, Delhi

3. Applied Biopharmaceutics and Pharmacokinetics by Shargel. LandYuABC, 2ndedition, 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, MarcelDekker Inc.,New York, 1982

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

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

8. Dissolution, Bioavailability and Bioequivalence, Abdou. H.M, Mack PublishingCompany, 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 JambhekarandPhilip JBreen,pharmaceutical press, RPS Publishing,2009.

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

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – I year II Sem. (Pharmaceutical Technology)	**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 thestudents 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 tounderstand,

- 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,Vallabh Prakashan,Dehli.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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	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, and 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.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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	4	**0**	**0**	**4**

(17S03204) COSMETICS AND COSMECEUTICALS

Scope

This course is designed to impart knowledge and skills necessary For the fundamental need for cosmetic and cosmeceutical products.

Objectives

Upon completion of the course, the students shall be able to understand

- Key ingredients used in cosmetics and cosmeceuticals.
- Key building blocks for various formulations.
- Current technologies in the market
- Various key ingredients and basic science to develop cosmetics andcosmeceuticals
- Scientific knowledge to develop cosmetics and cosmeceuticals withdesired Safety, stability, and efficacy.

THEORY **60 Hrs**

1. 12 hrs

Cosmetics – Regulatory : Definition of cosmetic products as perIndian regulation. Indian regulatory requirements for labeling ofcosmetics Regulatory provisions relating to import of cosmetics.,Misbranded and spurious cosmetics. Regulatory provisionsrelating to manufacture of cosmetics – Conditions for obtaininglicense, prohibition of manufacture and sale of certain cosmetics,loan license, offences and penalties.

2 12 hrs

Cosmetics - Biological aspects : Structure of skin relating toproblems like dry skin, acne, pigmentation, prickly heat, wrinklesand body odor. Structure of hair and hair growth cycle. Commonproblems associated with oral cavity. Cleansing and care needsfor face, eye lids, lips, hands, feet, nail, scalp, neck, body andunder-arm.

3 12 hrs

Formulation Building blocks: Building blocks for differentproduct formulations of cosmetics/cosmeceuticals. Surfactants –Classification and application. Emollients, rheological additives:classification and application. Antimicrobial used as preservatives,their merits and demerits. Factors affecting microbial preservativeefficacy. Building blocks for formulation of a moisturizing cream,vanishing cream, cold cream, shampoo and toothpaste. Soapsand syndetbars.

Perfumes; Classification of perfumes. Perfume ingredients listedas allergens in EU regulation. Controversial ingredients: Parabens, formaldehyde liberators, dioxane.

4 12 hrs

Design of cosmeceutical products: Sun protection, sunscreens classification and regulatory aspects. Addressing dry skin, acne,sun-protection, pigmentation, prickly heat, wrinkles, body odor. ,dandruff, dental cavities, bleeding gums, mouth odor and sensitive teeth through cosmeceutical formulations.

5 12 hrs

Herbal Cosmetics : Herbal ingredients used in Hair care, skincare and oral care. Review of guidelines for herbal cosmetics by private bodies like cosmos with respect to preservatives, emollients, foaming agents, emulsifiers and rheology modifiers. Challenges in formulating herbal cosmetics.

REFERENCES

1. Harry's Cosmeticology. 8th edition.

2. Poucher'sperfumecosmeticsandSoaps, 10th edition.

3. Cosmetics - Formulation, Manufacture and quality control, PP.Sharma, 4thedition

4. Handbook of cosmetic science and Technology A.O.Barel, M.Paye andH.I. Maibach. 3 rd edition

5. Cosmetic and Toiletries recent suppliers' catalogue.

6. CTFA directory.

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S10202) PHARMACEUTICAL TECHNOLOGY PRACTICAL-II

1. To study the effect of temperature change , non solvent addition, incompatible polymer addition in microcapsules preparation
2. Preparation and evaluation of Alginate beads
3. Formulation and evaluation of gelatin /albumin microspheres
4. Formulation and evaluation of liposomes/niosomes
5. Formulation and evaluation of spherules
6. Improvement of dissolution characteristics of slightly soluble drug by Solid dispersion technique.
7. Comparison of dissolution of two different marketed products /brands
8. Protein binding studies of a highly protein bound drug & poorly protein bound drug
9. Bioavailability studies of Paracetamol in animals.
10. Pharmacokinetic and IVIVC data analysis by WinnolineR software
11. In vitro cell studies for permeability and metabolism

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

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

(17S10203) PHARMACEUTICAL TECHNOLOGY PRACTICAL-III

1. DoE Using Design Expert® Software
2. Formulation data analysis Using Design Expert® Software
3. Quality-by-Design in Pharmaceutical Development
4. Computer Simulations in Pharmacokinetics and Pharmacodynamics
5. Computational Modeling of Drug Disposition
6. To develop Clinical Data Collection manual
7. To carry out Sensitivity Analysis, and Population Modeling.
8. Development and evaluation of Creams
9. Development and evaluation of Shampoo and Toothpaste base
10. To incorporate herbal and chemical actives to develop products
11. To address Dry skin, acne, blemish, Wrinkles, bleeding gums and dandruff

JAWAHARLAL NEHRU TECHNOLOGICAL UNIVERSITY ANANTAPUR

M. Pharm – III Sem. (Pharmaceutical Technology)	**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, Correlationcoefficient, 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 andbeneficence/non-maleficence, euthanasia, informed consent, confidentiality,criticisms of orthodox medical ethics, importance of communication, controlresolution, 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.