ACADEMIC REGULATIONS, COURSE STRUCTURE AND DETAILED SYLLABUS

M – PHARMACY (INDUSTRIAL PHARMACY)

FOR
M.PHARMACY TWO YEAR PG COURSE
(Applicable for the batches admitted from 2022-2023)

SCHOOL OF PHARMACY
ANURAG UNIVERSITY
Venkatapur, Ghatkesar, Hyderabad – 500088

Academic Regulations - for M. Pharm (Regular)

(Effective for the students admitted into I year from the Academic Year **2022-2023** onwards)

ANURAG UNIVERSITY

M. PHARM. (INDUSTRIAL PHARMACY)

(R20) COURSE STRUCTURE ANDSYLLABUS

I YEAR ISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
A41001	Theory	Modern Pharmaceutical Analytical Techniques	4	4
A41011	Theory	Pharmaceutical Formulation Development	4	4
A41012	Theory	Novel Drug Delivery Systems	4	4
A41013	Theory	Intellectual Property Rights	4	4
A41207	Lab	Industrial Pharmacy Practical I	12	6
A41208	-	Seminar/Assignment	7	4
		TotalCredits	**35**	**26**

I YEAR IISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
A42005	Theory	Research Methodology and Biostatistics	4	4
A42007	Theory	Advanced Biopharmaceutics& Pharmacokinetics	4	4
A42014	Theory	Scale Up and Technology Transfer	4	4
A42015	Theory	Pharmaceutical Production Technology	4	4
A42016	Theory	Entrepreneurship Management	4	4
A42207	Lab	Industrial Pharmacy Practical II	12	6
A42208	-	Seminar/Assignment	7	4
		TotalCredits	**39**	**30**

II YEAR - ISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
		Comprehensive Viva-Voce	-	4
-	-	Project work Review I	24	12
		TotalCredits	**24**	**16**

II YEAR - IISEMESTER

Code	Group	Subject	Hrs/Wk	Credits
-	-	Project work Review II	8	6
-	-	Project Evaluation (Viva-Voce)	16	12
		TotalCredits	**24**	**16**

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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41001)MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

60 Hours

SCOPE

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

OBJECTIVES

After completion of course student is able to know,

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

UNIT-I **11 Hours**

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

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, Data interpretation.

c)**Spectroflourimetry**: Theory of Fluorescence, Factorsaffecting fluorescence, Quenchers, Instrumentation andApplications of fluorescence spectrophotometer.

d)**Flame emission spectroscopy and Atomic absorptionspectroscopy**: Principle, Instrumentation, Interferences andApplications.

UNIT-II **11 Hours**

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.

UNIT-III **11 Hours**

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 Massspectroscopy.

UNIT-IV **11 Hours**

Chromatography: Principle, apparatus, instrumentation,chromatographic parameters, factors affecting resolution, isolation of drugs from excipients, data interpretation andapplications of the following:

a) Paper chromatography

b) Thin Layer chromatography

c) High PerformanceThin Layer chromatography

d) Ion exchange chromatography
e) Column chromatography
f) Gas chromatography
g) High Performance Liquidchromatography
h) Ultra High Performance Liquidchromatography
g) Affinity chromatography
h) Gel Chromatography

UNIT-V **16 Hours**

a)**Electrophoresis**: Principle, Instrumentation, Workingconditions, factors affecting separation and applications of thefollowing:
i) Paper electrophoresis
ii) Gel electrophoresis
iii) Capillaryelectrophoresis
iv) Zone electrophoresis
v) Moving boundaryelectrophoresis
vi) 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 Xraydiffraction.
c)**Immunological assays**: RIA (Radio immuno assay), ELISA,Bioluminescence assays.

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.
8. Spectroscopy of Organic Compounds, 2nd edn., P.S/Kalsi, Wiley esternLtd., Delhi.
9. Textbook of Pharmaceutical Analysis, KA.Connors, 3rd Edition, John Wiley& Sons, 1982.

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4/- 4

(A41011)PHARMACEUTICAL FORMULATION DEVELOPMENT

60 Hours

SCOPE

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

OBJECTIVES

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

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

UNIT-I **12Hrs**

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

UNIT-II **12Hrs**

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

UNIT-III 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.

UNIT-IV 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.

UNIT-V 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 ofIndustrial Pharmacy, 3rd ed., Varghese Publishers, Mumbai 1991.
2. Sinko PJ. Martin's physical pharmacy and pharmaceutical sciences, 5th ed., 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.Pharmaceutical preformulation: 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. Saurah printerpvt. Ltd., New Delhi,2005.
7. Sethi PD. Quantitative analysis of drugs in pharmaceutical formulations, 3rd ed., CBS publications, New Delhi, 2008.
8. Carstensen JT, Rhodes CT. Drug stability principles and practices, 3rd ed., CBS 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, 4th ed., Marcel DekkerInc, New York, 2005.
11. W. Grimm - Stability testing of drug products.
12. Mazzo DJ. International stability testing. Eastern Press Pvt. Ltd.,Bangalore, 1999.
13. Beckett AH, Stenlake JB. Practical pharmaceutical chemistry, Part I &II., 4thed., CBS Publishers & distributors, New Delhi,2004.
14. Indian Pharmacopoeia. Controller of Publication.Delhi, 1996.
15. British Pharmacopoeia. British Pharmacopoeia Commission Office,London, 2008.
16. United States Pharmacopoeia. United States Pharmacopeial Convention,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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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41012) NOVEL DRUG DELIVERY SYSTEMS

60 Hours

SCOPE

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

OBJECTIVES

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

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

UNIT-I **12Hrs**

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

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

UNIT-II **20Hrs**

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

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

UNIT-III **12Hrs**

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.

UNIT-IV **6Hrs**

a) Protein / Peptide Drug Delivery Systems: Concepts, deliverytechniques, formulation, stability testing, causes of proteindestabilization, stabilization methods.

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

UNIT-V1 **0Hrs**

a) **Sub Micron Cosmeceuticals**: Biology, formulation science andevaluation of various cosmetics for skin, hair, nail, eye etc and it'sregulatory aspects.

b) **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.

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M.Pharmacy I year I Sem. **T/P C**

4/- 4

(A41013)INTELLECTUAL PROPERTY RIGHTS

60 Hours

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,

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

UNIT-I **12Hrs**

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.

UNIT-II **12Hrs**

Role of GATT, TRIPS, and WIPO.

UNIT-III **12Hrs**

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

UNIT-IV **12Hrs**

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

UNIT-V **12Hrs**

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.

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M.Pharmacy I year I Sem. **T/P C**

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(A41207)PHARMACEUTICS PRACTICAL I

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 flourimetry.
5. Estimation of sodium/potassium by flame photometry.
6. Effect of surfactants on the solubility of drugs.
7. Effect of pH on the solubility of drugs.
8. Stability testing of solution and solid dosage forms for photo degradation.
9. Stability studies of drugs in dosage forms at 25^{o}C, 60% RH and 40^{o}C, 75% RH.
10. Compatibility evaluation of drugs and excipients (DSC & FTIR).
11. Preparation and evaluation of different polymeric membranes.
12. Formulation and evaluation of sustained release oral matrix tablet/ oralreservoir system.
13. Formulation and evaluation of microspheres / microcapsules.
14. Formulation and evaluation of transdermal drug delivery systems.
15. Design and evaluation of face wash, body- wash, creams, lotions, shampoo,toothpaste, lipstick.
16. Electrophoresis of protein solution.
17. Preparation and evaluation of Liposome delivery system.

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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42007)ADVANCED BIOPHARMACEUTICS & PHARMACOKINETICS

60 Hours

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 tounderstand,

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

UNIT-I **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 PartitionHypothesis, Properties of the Gastrointestinal Tract (GIT), PhMicroclimate Intracellular pH Environment, Tight-JunctionComplex. Solubility: Experimental methods. Permeability: In-vitro,in-situ and In-vivo methods.

UNIT-II **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 theDrug Formulation Factors Affecting Drug Product Performance, InVitro: 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.

UNIT-III **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, and Druginteractions linked to transporters.

UNIT-IV **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, Bioequivalence Example, Study Submission and Drug Review Process, theBiopharmaceutics Classification System, Generic Biologics(Biosimilar Drug Products),Clinical Significance of Bioequivalence Studies, Special Concerns in Bioavailability and BioequivalenceStudies, Generic Substitution.

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UNIT-V **12Hrs**

Application of Pharmacokinetics: Modified-Release DrugProducts, Targeted Drug Delivery Systems and BiotechnologicalProducts. Relationship between Pharmacokinetics including Pharmacodynamics: 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, MarcelDekker Inc.,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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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42014)SCALE UP ANDTECHNOLOGY TRANSFER

60 Hours

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,

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

UNIT-I **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.

UNIT-II **12Hrs**

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

UNIT-III **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.

UNIT-IV **12Hrs**

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

UNIT- V **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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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42015)PHARMACEUTICAL PRODUCTION TECHNOLOGY

60 Hours

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,

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

UNIT-I **12Hrs**

Improved Tablet Production: Tablet production process, unitoperation 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, applicationtechniques. Problemsencountered.

UNIT-II **12Hrs**

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

UNIT-III **12Hrs**

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

UNIT-IV **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.

UNIT-V **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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M.Pharmacy I year II Sem. **T/P C**

4/- 4

(A42016)ENTERPRENEURSHIP MANAGEMENT

60 Hours

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,

1. The Role of enterprise in national and global economy
2. Dynamics of motivation and concepts of entrepreneurship
3. Demands and challenges of Growth Strategies and Networking

UNIT-I **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.

UNIT-II **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.

UNIT-III **12Hrs**

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

UNIT-IV **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.

UNIT-V **12Hrs**

Preparing Project Proposal To Start On New Enterprise Project 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.Pharmacy II year I Sem.	L	T/P	C
	4	-/-	4

(A42005) RESEARCH METHODOLOGY AND BIOSTATICS

UNIT – I **12Hrs**

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 **12Hrs**

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

UNIT – III **12Hrs**

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 **12Hrs**

CPCSEA guidelines for laboratory animal facility: Goals, veterinary care,quarantine, surveillance, diagnosis, treatment and control of disease, personal hygiene, 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 **12Hrs**

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

ANURAG UNIVERSITY

M.Pharmacy I year II Sem.	L	T/P	C
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(A42207)INDUSTRIAL PHARMACY PRACTICAL II

1. Improvement of dissolution characteristics of slightly soluble drug by Soliddispersion 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.
7. Formulation and evaluation of tablets.
8. Formulation and evaluation of capsules.
9. Formulation and evaluation of injections.
10. Formulation and evaluation of emulsion.
11. Formulation and evaluation of suspension.
12. Formulation and evaluation of enteric coating tablets.
13. Preparation and evaluation of a freeze dried formulation.
14. Preparation and evaluation of a spray dried formulation.