

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-I**  
**101APS MODERN ANALYTICAL TECHNIQUES**  
(COMPULSORY FOR ALL DISCIPLINES)

**Theory: (3 hrs/week; Credit 3)**

**Max. Marks : 100**

1. **Introduction to Chromatography** (3)
2. **UV – Visible spectroscopy:** (6)  
Brief review of electromagnetic spectrum, UV – Visible range, energy – wavelength – color relationships. Interaction of electro – magnetic radiation (UV-Vis) and matter and its effects, chromophores and their interaction with E.MR. Absorption spectra of organic compounds illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, shifts and their interpretation (including solvent effects).
3. **Infra-Red Spectroscopy:** (5)  
Nature of Infra-red radiation, interaction of I.R. radiation with organic molecules and effects on bonds, molecular or infra-red spectra, brief outline of classical I.R. instrumentation and interpretation of spectra including sample preparation for spectroscopy, qualitative interpretation of I.R. spectra, quantitative methods, recent advances in I.R. spectroscopy including FTIR, ATR, etc.
4. **Nuclear Magnetic Resonance Spectroscopy:** (08)
  - a. Fundamental principles of NMR (Magnetic properties of nuclei: applied field and precession: absorption and transition frequency), chemical shifts concept, factors affecting chemical shift, isotopic nuclei, reference standards; Proton magnetic spectra, their characteristics, presentation, terms used in describing spectra and their interpretation (signal no., position, intensity), brief outline of instrumental arrangements and some practical details, signal multiplicity phenomena in high resolution PMR; Spin spin coupling, application of signal splitting and coupling constant data to interpretation of spectra, proton exchange reactions, decoupling and shift reagent methods.
  - b. Brief outline of principles of FT-NMR with reference to <sup>13</sup>C NMR: Spin-spin and spin-lattice relaxation phenomena, free induction decay (FID), proton noise decoupling, signal averaging time domain and frequency domain signals, nuclear overhauser enhancement; <sup>13</sup>C NMR spectra; their presentation, characteristics, interpretation, examples and applications.
  - c. Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments, introduction to 2-D NMR techniques.
5. **Mass Spectrometry:** (5)  
Basic principles and brief outline of instrumentation, ion formation and types: molecular ions, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups, relative abundances of isotopes and their contribution to characteristic peaks, mass spectrum; its characteristics, presentation and interpretation, chemical ionization mass spectrometry, GC-MS including recent advances in MS, Fast atom bombardment mass spectroscopy.
6. **Chemiluminescence:** Principle, instrumentation and application. (2)
7. Flame Photometry (FES), AES, Atomic Absorption Spectroscopy (AAS) (8)
8. Fluorescence Spectroscopy (Fluorimetry) (4)
9. Radio and Enzyme immuno assay. Quality control of radio pharmaceuticals. (2)
10. Basic principle, introduction & applications of LASER (2)

**M .PHARM SEMESTER-I**  
**MODERN ANALYTICAL TECHNIQUES PRACTICAL**

**Practicals: (6 hrs/week; Credit 3)**

**Max. Marks : 100**

1. Experiments based on calibration and validation of analytical instruments.
2. Estimation of single drug (raw material / formulations) by colorimetry.
3. Determination of UV cut off wavelength for different solvents. U.V./Visible spectrum scanning of certain organic compounds, absorption and correlation of structures, comparison e.g. Chloramphenicol, Analgin, Paracetamol, Sulphadiazine, Ibuprofen etc. Effect of pH and solvent on UV Spectrum of certain drugs.
4. Estimation of single drug and combination (raw material & formulations) by UV Spectrophotometry.
5. Calibration of IR spectrophotometer, recording IR spectra for drugs and comparing with that of Pharmacopoeia.
6. Estimation of drugs by spectrofluorimetry.
7. Estimation of  $\text{Na}^+$ ,  $\text{K}^+$ ,  $\text{Ca}^{+2}$  by flame photometry.
8. Structural elucidation of at least 5 unknown compounds using IR, NMR and Mass spectra.

**Reference Books:**

1. Instrumental Methods of Analysis - Scoog and West.
2. Spectrometric Identification of Organic Compounds - Silverstein et., al.
3. Instrumental Method of Analysis - Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry — A.I. Vogel.
5. Pharmaceutical Chemistry Vol. I & Vol. II — Becket and Stanlake.
6. Pharmaceutical Chemistry Vol. I & Vol. II — L.G.Chatten.
7. Text Book of Pharmaceutical Analysis - K.A. Connors.
8. Pharmaceutical Analysis — Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis — Gearien, Graboski.
10. Text Book of BioPharmaceutic Analysis — Robert Smith and James Stewart.
11. Pharmaceutical Analysis — Modern methods — Part A and B — Munson James. W.
12. Quantitative Analysis of Drugs — Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations — P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds — Dyer.
16. Analytical Profiles of Drug Substances — Florey [Volume 13].
17. Spectroscopy of Organic Compound - P. 5. Kalsi, Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules — V. M. Parikh, Addison — Wesley Publishing Company, London.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-I**  
**1A02PFD PHARMACOKINETICS AND FORMULATION DESIGN**  
**(PHARMACEUTICS, INDUSTRIAL PHARMACY AND NDDS)**

**Theory: (3 hrs/week; Credit 3)**

**Max. Marks : 100**

1. Compartment Models: One Compartment, Two Compartment **(04)**  
Non compartment Analysis : based on statistical moment theory: statistical moments, Bioavailability, clearance, Half-life, Absorption kinetics, apparent volume of distribution etc., Steady state.
2. Nonlinear Pharmacokinetics: Michaelis-Menten Kinetics, Estimation of  $K_m$  and  $V_m$  **(04)**  
Clearance, half life and volume of distribution, steady state, Bioavailability etc., Urinary excretion process and other nonlinear elimination process, some problems in quantifying nonlinear pharmacokinetics.
3. Physiological Pharmacokinetic Models : Blood flow rate - limited models - blood clearance, lung clearance, apparent volume of distribution, nonlinear dispositions, Membrane limited models. **(03)**
4. Computer modeling of dissolution & Pharmacokinetic data. **(02)**
5. Preformulation studies - Perspective and concepts: Detailed study of parameters like solubility, partition coefficient, dissolution, crystal morphology, crystal optics, polymorphism and purity studies: drug excipients compatibility study. **(07)**
6. Stability studies: **(08)**  
- Basic concept and objectives of stability study, - Order of reaction and their applications in predicting shelf life and half-life of pharmaceutical formulations - Importance of accelerated stability study- Effect of various environmental / processing on stability of the formulation and techniques for stabilization of products against the same - Regulatory requirements related to stability testing with emphasis on matrixing/ bracketing techniques, climatic zone, impurities in stability study photo stability testing etc.- Application of microcalorimetry in stability study.
7. Polymers – Classification. General methods of synthesis, properties, characterization and evaluation : Biodegradable polymers – Classification - Mechanism of biodegradation in the body : Polymer processing with respect to novel formulation design : Applications of polymers in novel drug delivery systems, Medical prosthetics and packaging. **(07)**
8. Dissolution Study: **(10)**  
- Importance, objectives, equipments- Noyes-Whitney's dissolution rate-Biological classification system (BCS); its significance on dissolution study and application in dosage form development - Selection of dissolution medium and conditions- study of various approaches to improve dissolution of poorly soluble drugs-Comparison of dissolution profile by model independent (similarity and dissimilarity factor) and dependent method-In-vitro In-vivo Correlation (IVIVC), Methods of establishing IVIVC, Factors effecting IVIVC

**M .PHARM SEMESTER-I  
PHARMACOKINETICS AND FORMULATION DESIGN PRACTICAL  
(PHARMACEUTICS AND INDUSTRIAL PHARMACY)**

**Practicals: (6 hrs/week; Credit 3)**

**Max. Marks : 100**

The practical syllabus comprises of the exercises formulated bases on the topics mentioned in the Theory syllabus.

**Reference Books:**

1. Milo Gibaldi and Donald Perrier, "Pharmacokinetics", Drugs and Pharm. Sci. Series, VoL 15., Marcel Dekker Inc., N.Y.
2. J.C. Wagner, "Fundamentals of Clinical Pharmacokinetics", Drug Intelligence Publications, Hamilton, 1975.
3. Bert N. LaDu, "Fundamentals of Drug Metabolism & Disposition", Waverley .Press Inc., Baltimore, 1972.
4. T.Z.Laaky, "Intestinal Absorption & Malabsorption", Raven Press, N.Y., 1975.
5. J.T.Carstensen, "Theory of Pharm. Systems", Vols. 1-3, Academic Press, N.Y.
6. U.S. Beans, A.K.Beckett and J.E.Caraless, "Advances in Pharm.Sci.", Vol. 1 to 4.
7. J.T.Carstensen, "Drug Stability : Principles and Practices", Drugs and Pharm. Sci. Series, Vol. 43, Marcel Dekker Inc., N.Y.
8. Lisbeth Iliun & Stanley S. Davis : "Polymers in Controlled Drug Delivery", Wright, Bristol (1987).
9. Pharmaceutics "The Science of Dosage form design" by Aulton.
10. Encyclopedia of Pharmaceutical technology Volumes: 1 to 19.
11. Remingtons Pharmaceutical Sciences 19<sup>th</sup> edition.
12. Pharmaceutical dissolution testing by Banaker.
13. Pharmacokinetics by Welling and Tse.
14. Modern Pharmaceutics by G.S.Banker
15. Clinical Pharmacokinetics, Concepts and applications, by Rowland and Tozer.
16. Biopharmaceutics and Pharmacokinetics – An introduction by Notari.
17. Techniques of Solubilization of Drugs by Yalkowsky.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-I**  
**1A03APT ADVANCES IN PHARMACEUTICAL TECHNOLOGY**  
**(PHARMACEUTICS)**

**Theory: 3 hrs/week**

**Max. Marks : 100**

1. Production Management, Production Planning, Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines, and job balancing. **(07)**
2. Consideration for design of large scale manufacturing unit including design criteria for units to manufacture of sterile and nonsterile products with special reference to tablets, capsules and injections. As per Schedule M. **(07)**
3. Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non serial dosage forms. Stability & evaluation aspects of packaging, regulatory aspects of packaging. **(08)**
4. Process automation in Pharmaceutical manufacturing. **(07)**
5. Pilot plant, scale up technique, introduction to SUPAC guidelines. **(08)**
6. Advances in Pharmaceutical unit operation and utilities **(08)**

**Reference Books:**

1. H.A. Libermen & L. Lachman, Pharmaceutical Dosage Forms : Tablets, Vol. I to III, Marcel Dekker Inc., N.Y.
2. K.E.Avis, Pharmaceutical Dosage Forms : Parental Medication, Vol. I Marcel Dekker Inc., N.Y.
3. S. Turco and R.E. King, Sterile Dosage Forms, 2<sup>nd</sup> edition.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-I**  
**1B04ECS ENGLISH LANGUAGE & COMMUNICATION SKILLS**  
**(COMPULSORY FOR ALL DISCIPLINES)**

**Theory: (2 hrs/week; credit 2)**

**Max. Marks : 100**

**Objective of the Course**

1. To impart basic skills of communication in English through intensive practice to the second semester PG students of Pharmacy so as to enable them to function confidently and effectively in that language in the professional sphere of their life.
2. To improve the students' fluency in English, and enable them to listen to English spoken at normal conversational speed, respond appropriately in different socio-cultural and professional contexts.
3. To enable them know the communication in detail with four basic skills so that he/she may be effective communicator in his/her professional environment.

**Course Contents:**

**Unit-I**

**6**

**Language Components:** Structures of English language: Tenses (active and passive structures both), Usage of Modal Auxiliaries and Perfect Modal auxiliaries patterns(A.V&P.V), Causal Verbs (A.V & P.V), Types of the sentences like Assertives, Interrogatives, Imperatives, Exclamations, Question Tags, Concord, Idioms and phrases, Proverbs and Sayings, Punctuation Marks.

**Unit-II**

**6**

**Introduction to Communication Skills:** Communication defined, Cycle of Communication, Flow of Communication, Basic Forms of Communication, Process of Communication, Principles of Effective Business Communication, 7 Cs. of Effective Business Communication, Media of Communication, Barriers of Communication.

**Unit-III**

**6**

**Basic Skills of communication:**

- **Listening skills:** Introduction, Definition, Process, Types, Barriers, Overcoming these barriers, How to do effective Listening.
- **Reading:** Introduction, Definition, Purpose, Process, Tactics, Strategies, Reading comprehension, How to improve Reading skill.
- **Writing:** Introduction, Definition, Purpose, Strategies, Writing style, How to improve Writing skill. Writing good report: Type of Report, Structure of report, collecting data, Tips of writing report. Writing proposal: Definition, Types, Characteristics, Style and Appearance, Evaluation.
- **Speaking:** Introduction, Definition, Components of Effective speaking, Tone of Voice, Body language, Public speaking strategies; time, content, delivery, knowing audience, selection of language etc.. How to improve Speaking skill

**Unit-IV**

**6**

**Presentation Skills :** How to Make Presentation, Presentation Tools along with Guidelines of Effective Presentation, Boredom Factors in Presentation and How to Overcome Them, Interactive Presentation & Presentation as a part of Selection Process, Art of Effective Listening.

## Unit-V

6

**Resume Writing and Interview Skills :** Guidelines for Writing an Impressive Resume, .Drafting of Job Application, How to face an Interview Board, Proper Body Posture, Importance of Gestures and Steps to Succeed in Interviews, Practice of Mock Interview in classrooms, Self introduction – highlighting positive and negative traits and Face to Face Communication

### **Text & Reference Books:**

1. Peechaatt J.S. *Essential English Grammar & Composition*. Holy Faith International Pvt. Ltd; New Delhi; 1984.
2. Raman, Meenakshi & Sharma Sangeeta. *Technical Communication Principles and Practice*. OUP, New Delhi; 2008.
3. Prasad D. *The Functional Aspects of Communication Skills*. S.K Kataria & Sons; New Delhi; 2003.
4. Doctor Aspi & Doctor Radha. *Principles and Practice of Business Communication*. Sheth Publishers Pvt Ltd; 2001.

### **M.PHARM SEMESTER-I**

#### **ENGLISH LANGUAGE AND COMMUNICATION SKILLS**

#### **Curriculum for Laboratory (Practical)**

**Practicals: (2 hrs/week; Credit 1)**

**Max. Marks : 100**

**Level: Advanced**

#### **Proficiency Development in Skills of Listening & Speaking**

### **COURSE DESCRIPTIONS:**

- Development of listening comprehension and oral proficiency of standard spoken English at the Advanced level.
- Listening focuses on note-taking and aural comprehension of standard spoken English in academic situations, media, and discussion.
- Speaking focuses on fluency of English speech, proficiency in clarifying and restating, and strategies for facilitating discussion.

### **STUDENT LEARNING OUTCOMES (SLO'S):**

By the completion of this course, students will be able to:

- A. Comprehend, recall, and record new information delivered orally in various contexts.
- B. Demonstrate clear pronunciation and adequate speed of speech appropriate to the high-intermediate level of English fluency.
- C. Demonstrate awareness of vocabulary unique to academic and professional realms by choosing language appropriate to context.
- D. Employ strategies such as clarification, explanation, and restatement of information to facilitate discussion in a group.

## **SPECIFIC INSTRUCTIONAL OBJECTIVES:**

### **A. Comprehend, recall, and record new information delivered orally in various contexts.**

- Employ strategies such as predicting, using context, analyzing, discussing, and problem solving to increase comprehension.
- Use note-taking, dictation, summary and methods of information recall.
- Use language and content from aural activities in extended discussions, projects, and practical applications.
- Recognize vocabulary and grammatical structures and be able to respond to and use them appropriately.
- Analyze context and cultural references to aid comprehension.

### **B. Demonstrate clear pronunciation and adequate speed of speech appropriate to the high-intermediate level of English fluency.**

- Demonstrate awareness of mouth, lip, and tongue positions in various segmental and suprasegmental (Morpheme & Phoneme) utterances with significant progress toward improvement of speech clarity
- Demonstrate awareness of stress, word endings, linking, and reductions with significant progress toward improvement of speech clarity.
- Be understood by most listeners with limited need for clarification.

### **C. Demonstrate awareness of vocabulary unique to academic and professional realms by choosing language appropriate to context.**

- Analyze context and cultural references to aid comprehension.
- Recognize vocabulary and grammatical structures and be able to respond to and use them appropriately.

### **D. Employ strategies such as clarification, explanation, and restatement of information to facilitate discussion in a group.**

- Lead and participate in group discussions.
- Use clarifiers, explanation, and restatement accurately so that message is understood by listeners.
- Understand participant roles and work with others as part of a functioning discussion group.

## **COURSE CONTENT:**

The content of this course can include the following:

- Aural comprehension of unmodified standard American speech such as in recorded conversations, mini-lectures, and instructions
- Strategies for taking academic notes in real time
- Aural and contextual comprehension of authentic English speech such as in television, song, radio, or film
- Analysis of English culture, body language, and behavior as it relates to English communication
- Controlled and spontaneous conversation
- Register, formality vs. informality, and polite conventions



- Strategies for clarifying, sustaining, facilitating, and leading discussion
- Debates, mock trials, role-plays, or group presentations
- Out-of-class interview strategies and practice

### **REPRESENTATIVE METHODS OF INSTRUCTION:**

Language and utterance analysis is primary to this course, as it provides students with ample opportunity to critically examine the behaviors and nature of the English language. Contrastive analysis with students' own first language is useful and beneficial. Instruction methods may include:

- presentations of language in film or audio for deductive or inductive analysis
- pre-teaching of vocabulary to enhance listening activities and post-testing to ensure retention
- use of cloze exercises, dictations, dicto-comp exercises, read and look exercise and oral and written story reconstruction
- controlled and spontaneous discussion practice and fluency exercises
- regular interviews, discussions, and oral presentations demonstrating structures practiced in class
- ample extension of controlled conversation into spontaneous conversation, role-playing, and improvisation
- use of listening journals to practice comprehension of English TV, film, radio, and authentic language
- use of internet activities to deepen and broaden language exposure and acquisition

### **ASSIGNMENTS:**

Assignments can include:

- exercises from the CD /tape package of the textbook
- exercises from the internet or media stored at the media center
- mini-lectures, dictations, or dicto comps in simple language
- out-of-class interviews
- Films and television review
- analysis of songs or recorded speeches for presentation in class
- oral presentations, debates, role-plays, and discussions
- Language Games and activities

### **EVALUATION OF STUDENT PERFORMANCE:**

Typical methods of evaluation may include the following:

- Cloze activities to assess critical listening comprehension and accuracy
- Listening activities using authentic speech from media to measure applicability of listening skills
- Listening journals to monitor practice and effort in broadening listening skills
- Voice recordings to measure accuracy of pronunciation, appropriateness of vocabulary choice, and progress in speech development
- Dictations to measure accuracy of listening comprehension
- Role-plays and conversation measure proficiency in speaking and facilitating conversation
- Oral projects to measure synthesis of skills in speaking and vocabulary acquisition
- Group projects to assess synthesis of skills in listening and facilitating discussion
- Objective assessment (objective tests) of discrete skills to measure accuracy and proficiency

- Subjective assessment (oral or written projects) of soft skills such as cultural habits and language patterns to measure familiarity with U.S. culture

Students receive either a letter grade or credit/no credit based upon satisfactory completion at the level of 70% or better on all assignments and participatory activities.

### **RECOMMENDED or REQUIRED TEXT(S):**

1. Fragiadakis & Maurer (2000). Tapestry Listening & Speaking 4, 2<sup>nd</sup> ed. Heinle & Heinle: Boston. 0838400299
2. Delk, C. (2006). College Oral Communication 3. Heinle & Heinle: Boston. 0618230181
3. Dunkel & Pialorsi (2005) Listening & Notetaking Series 3: Advanced Listening Comprehension. Heinle & Heinle: Boston. 1413003966.
4. Handreddy & Whalley (2006) Mosaic 2 Listening & Speaking. McGraw-Hill: New York.
5. Numrich, C. (2001) Raise the Issues, 2<sup>nd</sup> ed. Pearson Education ESL: Boston. 0201621002
6. Schmidt & Solorzano (2003). Northstar Listening & Speaking, Advanced, 2<sup>nd</sup> ed. Pearson Education ESL: Boston. 0201755742

### **Proficiency Development in Skills of Reading & Writing**

#### **COURSE DESCRIPTION:**

- Development of reading and writing skills at the high-intermediate level of English acquisition.
- Reading strategies, fluency, vocabulary, comprehension, paragraph and essay writing

#### **STUDENT LEARNING OUTCOMES (SLO'S):**

**By the completion of this course, students will be able to:**

- A. Employ strategies such as predicting, previewing, skimming and scanning to unmodified texts written in standard American English.
- B. Demonstrate critical thinking in text comprehension and subsequent discussion and elaboration.
- C. Demonstrate ability to use new vocabulary in writing, reading, and discussion.
- D. Compose essays with unified theme, strong paragraphs, and effective sentence construction.

#### **SPECIFIC INSTRUCTIONAL OBJECTIVES:**

- A. Employ strategies such as predicting, previewing, skimming and scanning to unmodified texts written in standard American English.**
  - Use discussion, pictures, and schematic knowledge to predict content in readings.
  - Use jigsaw readings, timed readings, cloze readings, and other exercises to develop reading fluency.
  - Demonstrate comprehension of text in exercises, discussions, quizzes, and tests.
- B. Demonstrate critical thinking in text comprehension and subsequent discussion and elaboration**

- Use prediction, skimming and scanning, and active reading strategies to increase comprehension of abstract and unfamiliar texts.
- Demonstrate comprehension of text in exercises, discussions, quizzes, and tests.

**C. Demonstrate ability to use new vocabulary in writing, reading, and discussion.**

- Use vocabulary logs, journals, word lists, or other methods of dedicating focus to the learning of vocabulary.
- Use response writing to practice language learned through reading.
- Expand upon readings with group discussion, debate, or projects.
- Attend to common writing conventions such as punctuation, indentation, paragraphing and margins, titles, sufficient support, detail, reasoning, and logical order.
- Explore and use language particular to various academic and professional communication purposes.

**COURSE CONTENT:**

The content of this course comprises a little review and focuses intensely on the mastery of intermediate grammar structures including the following:

- Strategies for vocabulary acquisition, retention, and use
- Guessing vocabulary from context
- Topic sentences, supporting details, concluding and transitional sentences
- Identification of main idea, support, inference, fact versus opinion, analysis, and tone
- Reading of news and commentary items, opinion pieces, novels and stories
- Supportive research using the internet and other sources to broaden and deepen reading comprehension and writing
- Elements of the paragraph and its relationship to the sentence and to the essay
- Various simple rhetorical modes that can include narrative, process, expository, description, and analysis

**REPRESENTATIVE METHODS OF INSTRUCTION:**

Vocabulary, comprehension, and paragraph construction are primary to this course. Activities that increase self-confidence in reading are highly recommended. Contrastive analysis of English vocabulary, prose styles, and writing conventions with that of students' own first language is useful and beneficial. Instruction methods may include:

- accompanying pre-reading discussions or expansion activities with other media (film, song, art, etc.)
- use of scaffolding, graphic organizers, and templates to aid the understanding of texts and writing conventions
- writing activities that include academic and professional expression
- use of language logs to record writing errors and to inform correction of them
- use of vocabulary journals to record and analyze vocabulary and aid in its retention
- searches of internet texts to broaden understanding and increase exposure to the language

## **ASSIGNMENTS:**

Each grammar structure taught in the course should be demonstrated effectively by the student in speaking and in writing. Assignments can include:

- Paragraph editing and peer review of essays
- Professional writing like reports, research, and surveys.
- Academic essays
- authentic readings
- writing journals
- internet research
- library visits and reading leveled library books
- vocabulary analysis

## **EVALUATION OF STUDENT PERFORMANCE:**

### **Typical methods of evaluation may include the following:**

- Reading comprehension activities to gauge accuracy of reading comprehension
- Vocabulary quizzes to measure attainment of vocabulary
- Written responses to text to measure progress in text-based writing
- Editing exercises to demonstrate knowledge of grammar and writing conventions
- Group projects to demonstrate depth of understanding of texts and ability to discuss text in an academic setting
- Paragraph assignments to review ability to compose effective academic paragraphs

Students receive either a letter grade or credit/no credit based upon satisfactory completion at the level of 70% or better on all assignments and participatory activities.

## **RECOMMENDED or REQUIRED TEXT(S):**

One reading and writing text, or two texts that together address reading and writing are necessary for this course. Some suggestions are the following (see combination suggestions as well):

1. Blass & Pike-Baky (2002). Mosaic 2 Writing 4<sup>th</sup> ed. McGraw-Hill: New York. 0-07-246911-0.
2. Folse, et al. (2003). Blueprints 2: Composition Skills for Academic Writing. Thomson/Heinle: Boston. 0-618-14410-2.
3. Mikulecky & Jeffries (2005). More Reading Power 2<sup>nd</sup>. Pearson Ed/Longman: Boston. 0-13-061199-9.
4. Miller & Cohen. (2003). NorthStar Reading & Writing Advanced. 2<sup>nd</sup> ed. Pearson Ed./Longman: Boston. 0201755750.
5. Oshima & Hogue (2007) Writing Academic English 3<sup>rd</sup> ed. Pearson Ed./Longman: Boston. 0131523597
6. Sokolik, M. (2000). Tapestry Reading 4. Thomson/Heinle: Boston. 0838400604.
7. Sokolik, M. (2000). Tapestry Writing 4. Thomson/Heinle: Boston. 0838400450.
8. Wegmann & Knezevic (2002). Mosaic 2 Reading 4<sup>th</sup> ed. McGraw-Hill: New York. 0-07-232964-5.
9. Wholey, M. (2007). Reading Matters 4. 2<sup>nd</sup> ed. Thomson/Heinle:

## M. PHARM SEMESTER-II

### 2A01APS ADVANCES IN PHARMACEUTICAL SCIENCES (COMPULSORY FOR ALL DISCIPLINES)

Theory: (3 hrs/week; Credit 3)

Max. Marks : 100

1. **Application of Biostatistics in Pharmaceutical research** (11)  
Mean, Median and Mode, Standard Deviation and Coefficient of variation, Students t-test, F-test, ANOVA, Chi-square test, Probability, Frequency distribution, Regression analysis, Cross-over study, Wilcoxon signed rank test, control charts.
2. **Analytical Method Development and Validation:** (4)  
Approach to develop different analytical procedures. Validation of analytical procedures according to different guidelines.
3. **Product Registration:** (2)  
Preparation of documents for Investigational New Drug (IND), New Drug Application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA).
4. **Cheminformatics,** (1)
5. **Prodrugs:** basic concepts and types, (2)
6. Basic concepts in Drug discovery includes direct and indirect drug design (2)
7. **Experimental Designs** (6)  
Introduction to Full and Fractional Factorial Designs, central composite designs, Evolution of full and reduced mathematical models in experimental designs, Applications of the experimental designs for the subjects mentioned under Pharmainformatics. Introduction to contour plots.
8. **Patent** (5)  
Definitions, Procedures for applying, Indian scenario GATT TRIPS and TRIMS Legal aspects. Trademark and copyright. Geographical indication.
9. **Bioinformatics** (4)  
Definition, concepts, importance, biological databases, primary sequence database, protein sequence database, DNA sequence database, multiple sequence alignment and its importance for drug design.
10. **Screening** (8)  
Introduction to CPCSEA guidelines, CPCSEA guidelines for animal house and conducting animal experiments, Basic models for studying biological activity on tissues, organ systems and animals.  
Phytochemical screening techniques, Concept of reverse pharmacognosy and new drug discovery from natural sources, HTS assays for screening of herbal drugs.

### **Reference Books:**

1. Web Resources in Pharmacy, In Pharma Publication, Bangalore
2. Basic Statistics and Pharmaceutical Statistical Applica. by James E.De Muth, Marcel Dekker Inc.
3. Method in Biostatistics by B.K.Mahajan, JayPee Brothers, New Delhi.
4. Statistical Methods in Biological & Health Sciences by J.Susan Milton, Tata Mc GrawHill Int. Ed.
5. Pharmaceutical Statistics by Standards Bolton, Marcel Dekker Inc.
6. Pharmaceutical Experimental Design by G.A.Lewis, D.Mathiea, Roger Phan-Tan-Luu, Marcel
7. Dekker Inc.
8. Pharmaceutical Experimental Design and Interpretation by N.A.Armstrong L.K.C. James, Taylor
9. & Francis.
10. Current Patent Acts of Various countries.
11. Sanford Bolton, "Pharmaceutical Statistics" 3<sup>rd</sup> edition, Drug & Pharmaceutical Sciences series
12. Vol:80, Marcel Dekker Inc.
13. James E. Demath "Basic Statistics and Pharmaceutical Statistical Application Marcel Dekker Inc.
14. Mueen Ahmed K.K. "Web Resources in Pharmacy"
15. Gareth A. Lewis, Didier Mathieu, Roger Phan – Tan-Luu, "Pharmaceutical Experimental Design", Vol-92, Marcel Dekker Inc.
16. Introduction to bioinformatics by Parry and Attwood-Smith.
17. Wilson and Gisvold's textbook of Organic Medicinal and Pharmaceutical Chemistry, 11<sup>th</sup> edition

**GANPAT UNIVERSITY**  
**M. PHARM SEMESTER-II**

**2A02PVG PROCESS VALIDATION AND CGMP**  
**(PHARMACEUTICS, INDUSTRIAL PHARMACY AND NDDS)**

**Theory: (3 hrs/week; Credit 3)**

**Max. Marks : 100**

1. Basic concepts of quality assurance, Requirements of CGMP/GLP, ISO 9000 series, OHSAS 14000, Quality audits etc. **08**
2. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypothesis testing, statistical procedure in assay development. **04**
3. In-process quality control tests for various dosage forms including packaging and labeling operations. **06**
4. Brief introduction to general requirements of health regulatory agencies such as US FDA, MHRA, TGA, WHO, ANVISA, EMEA etc. **06**
5. Preparation of documents for new drug application and export registration. Clinical study and basic concepts of Good clinical practice. **03**
6. Concepts in validation, validation of manufacturing and analytical equipments. Process validation in production of pharmaceuticals. Electronic records (21CFR11) **10**
7. Introduction to orange book, freedom of information (FOI), inactive ingredient guide (IIG), Drug master file (DMF), open part of DMF, codes of therapeutic equivalency, CDER, CBER. **08**

**M. PHARM SEMESTER-II**

**PROCESS VALIDATION AND CGMP**  
**(PHARMACEUTICS AND INDUSTRIAL PHARMACY)**

**Practicals: (6 hrs/week; Credit 3)**

**Max. Marks : 100**

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

**Reference Books:**

1. S. H. Willig, M.M.Tuckeman and W.S.Hitchings, "Good Manufacturing Practices for Pharmaceuticals", Drugs and Pharm. Sci. Series, Vol. 16, Marcel Dekker Inc., N.Y.
2. B.T.Loftus & R.A.Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 23, Maarcel Dekker Inc., N.Y.
3. S. Bolton, "Pharmaceutical Statistics : Practical & Clinical Applications", Drugs and Pharm. Sci. Series, Vol. 25, Marcel Dekker Inc., N.Y.
4. G.S, Banker & C.T.Rhodes, "Modern Pharmaceutics", Drugs and Pharm. Sci. Series, Vol. 7, Maracel Dekker Inc., N.Y.

**GANPAT UNIVERSITY**  
**M. PHARM SEMESTER-II**

**2A03DDN: DESIGN & DEVELOPMENT OF NOVEL DELIVERY SYSTEMS**  
**(PHARMACEUTICS)**

**Theory: (3 hrs/week; Credit 3)**

**Max. Marks : 100**

1. Theory of controlled release drug delivery systems : kinetics & mechanism (04)  
General methods of design and evaluations of controlled release products.
2. Microencapsulation – Methods of encapsulation, kinetics of drug release from (04)  
microcapsules, technology and applications.
3. Transdermal drug delivery systems – Theory, formulation, production and evaluation. (04)
4. Implants and Inserts – Types of implants, Osmotic pumps, design and evaluation (05)  
methods. Types if Inserts, design and evaluation methods.
5. Targeted drug delivery systems – concept of drug targeting, importance in therapeutics; (04)  
Principals of molecular biology – Cell recognition and signaling – signal transduction – cell  
surface receptors – Methods in Drug Targetting.
6. Liposomes – Structure and stability, composition of liposomes, methods of preparation, (04)  
application in drug delivery and drug targeting. Commercial concepts in liposomes.  
Neosomes and pharmacosomes – Long circulating liposomes.
7. Advanced concepts in the design, development and production of sustained release (04)  
products.
8. Recent innovations in conventional dosage form like tablets, capsules, sterile dosage (04)  
form, pellets and etc.
9. Introduction of formulation of protein and peptides, supercritical fluid technique, (04)  
PEGylation, Biotechnology based pharmaceuticals, taste masking, particle coating.
10. Mucoadhesive drug delivery systems- Buccal, stomach and vaginal drug delivery (04)  
systems concepts, advantages and disadvantages. Nasal and pulmonary drug delivery  
systems and its applications.
11. Nanoparticulate based drug delivery systems: Classification of formulations, composition (04)  
& methods of preparation, Characterization, application in drug delivery,



**M. PHARM SEMESTER-II**  
**DESIGN & DEVELOPMENT OF NOVEL DELIVERY SYSTEMS PRACTICAL**  
**(PHARMACEUTICS)**

**Practicals: (6 hrs/week; Credit 3)**

**Max. Marks : 100**

Laboratory examination including oral and practical examination in general course illustrative of theory section in the syllabus.

**Reference Books:**

1. Joseph R. Robinson, "Sustained and Controlled Release Drug Delivery Systems", Drugs & Pharm. Sci. Series, Vol. 6 Marcel Inc., N.Y.
2. Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc. N.Y.
3. J.N.Nixon, Microencapsulation, Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc., N.Y.,
4. G. Jolles and R.H. Wooldridge, Drug Design – Faact of Fantasy? Academic Press, 1984
5. J.R.Robinson and Vincent H.L. Lee, Controlled Drug Delivery, Drugs and Pharm. Sci. Series, Vol. 29, Marcel Dekker Inc. N.y.
6. J.R.Juliano, Drug Delivery Systems Oxford University Press, Oxford, 1980.
7. M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
8. E.B.Roche, Design of Biopharmaceutical properities through prodrug and analogs, Am. Pharm. Assoc. Academy of Pharm. Sci. 1977.
9. Lisbeth, Ilum & Stanley S. Davis. Polymers in controlled drug delivery wright Bristol (1987)

## M. PHARM. SEMESTER – II

### 2B04CSS COMMUNICATION AND SOFT SKILLS

#### Objective of the Course

1. To impart basic knowledge of soft skills in communication through intensive class room practice and inter action among the P.G students of Pharmacy so as to enable them to function confidently and effectively in different socio-cultural and professional contexts.
2. To orient them with the office communication and office correspondence to help them know the importance, effectiveness and implementation in their real professional life.

#### **Course Contents:**

##### **Unit-I**

9

**Self Development and Communication:** Introduction, Meaning, Objectives, Improve personal communication skills, How communication leads to self development, How to develop Oneself; Change perception, Best use of brain, Responsible Pro-active approach, Never stop learning, Cultivation of professional values.

##### **Unit-II**

9

**Professional skills and Communication:** Skill of Leadership; Meaning; Types, How to be an effective leader, Skill of Decision Making; Importance, Types, Process, Affecting factors, How to be the best decision maker, Stress Management Skills, Motivation and Counseling, Self –esteem.

##### **Unit-III**

9

**Social skills and communication:** Social Etiquettes; Socially expected behaviour as a pharmacy professionals, Dressing sense, Dealing with people, Skills of healthy social inter action, Individual and Group behaviour, Social telephonic-talk; code of conduct, Individual image building and Image retaining, Values of values in life.

##### **Unit-IV**

9

**Skills of Office Communication:** Office behaviour, Office Telephonic code of conduct, E-mail etiquettes, manners of upward, down word, lateral and cross-wise office communication, settling issues, co-ordination with office staff.

##### **Unit-V**

9

**Skills of Office Correspondence:** Holding a Meeting; types, expected behaviour in meeting, drafting notice with agenda, writing minutes of the meeting. Technical Proposal; Definition, Purposes, Types, Characteristics, Elements of Structure, Style and Appearance. Individual and Committee Reports; Introduction, Objectives, Characteristics, Importance, Structure, Revising, Editing, Proof-reading, Samples.

### **Text & Reference Books:**

1. Bhatia R.C *Business Communication* Ane Books India; New Delhi; 2006
2. Raman, Meenakshi & Sharma Sangeeta. *Technical Communication Principles and Practice*. OUP, New Delhi; 2008.
3. Prasad D. *The Functional Aspects of Communication Skills*. S.K Kataria& Sons; New Delhi; 2003.
4. Doctor Aspi & Doctor Radha. *Principles and Practice of Business Communication*. Sheth Publishers Pvt Ltd; 2001.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-III**  
**3A01RMD: RESEARCH METHODOLOGY**  
 (COMPULSORY FOR ALL DISCIPLINES)

*Theory: (3 hrs/week; Credit 3)*

**Max. Marks: 100**

- |    |   |   |
|----|---|---|
| 1. | Research - meaning, purpose, types (educational, clinical, experimental, historical descriptive, basic, applied and patent oriented research), & objective of research  | 4 |
| 2. | Literature survey-use of library, books and journals – MEDLINE - internet, patent search, and reprints of articles as a source for literature survey.   | 4 |
| 3. | Selecting a problem and preparing research proposals  | 4 |
| 4. | Methods and tools use in research –   | 4 |
|    | A. Qualitative & quantitative studies   |   |
|    | B. Simple data organization & descriptive data analysis   |   |
|    | C. Limitation & sources of error  |   |
|    | D. Inquiries in form of questionnaire, etc  |   |
| 5. | Documentation-  | 3 |
|    | “How” of documentation  |   |
|    | Techniques of documentation   |   |
|    | Importance of documentation   |   |
|    | Use of computer packages in documentation.  |   |
| 6. | The Research Report Paper writing/ thesis writing   | 8 |
|    | 1. Title –title of project with authors name  |   |
|    | 2. Abstract- statement of the problem, background list in brief, purpose & scope.   |   |
|    | 3. Key Words.   |   |
|    | 4. Methodology - subject, apparatus, instrumentation & procedure.   |   |
|    | 5. Results- tables, graphs, figures & statistical presentation  |   |
|    | 6. Discussion support or non support of hypothesis, practical & theoretical implications  |   |
|    | 7. Conclusion   |   |
|    | 8. Acknowledgements   |   |
|    | 9. References   |   |
|    | 10. Errata  |   |
|    | 11. Importance of Spell check for entire project  |   |
|    | 12. Uses of footnotes   |   |
| 7. | <b>Presentation</b> (especially for oral presentation)  | 5 |
|    | Introduction and importance, types of different skills, contained, format of model, poster, gestures, eye contact, facial expressions, stage fright, volume- pitch, speed, pause & language, visual aids & seating, questionnaire, etc. |   |
| 8. | Cost analysis of the project – cost incurred on raw materials, procedure, instrumentations and human resources.   | 5 |
| 9. | Sources for procurement research grants – international and national agencies, government and private bodies.   | 4 |
| 10 | Industrial - institution interaction- industrial projects, their feasibility reports, interaction with industries.  | 4 |

**References Books:**

1. Research In Education- John V. Best, John V. Kahn 10<sup>th</sup> edition, Allyn & Bacon Publisher, 2005.
2. Practical Introduction of copyright.by Gavin Mcfarlane, McGraw-Hill Inc.,US, 1982
3. Thesis projects in Science & Engineering – Richard M. Davis, St. Martin's Press, 1979
4. Assignment And Thesis Writing, Jonathan Anderson, Millicent Poole, Juta Academic Publisher, 4<sup>th</sup> ed, 2008
5. Writing a technical paper- Donald H. Menzel, Mcgraw Hill Higher Education, 1961
6. Effective Business Report Writing –Leland Brown, Prentice Hall College Div, 4<sup>th</sup> ed., 1961
7. Manual for evaluation of industrial projects, by United Nations Industrial Development Organization.; Vienna: United Nations Industrial Development Organization, United Nations, 1986.
8. Manual for the preparation of industrial feasibility studies, United Nations; Rev Exp Su edition, 1991
9. Biomedical Research by G. Jagadeesh, Sreekant Murthy, Y.K. Gupta and Amitabh Prakash, 1<sup>st</sup>ed., Ideation to Publication, 2010.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-III**

**3A02APS: SEMINAR ON ADVANCES IN PHARMACEUTICAL SCIENCE**

(COMPULSORY FOR ALL DISCIPLINES)

**Credit: 5**

**Max. Marks: 100**

**Instructions:**

1. Student will be allotted a recent topic of pharmaceutical science by the concern teacher. Student has to complete literature search and compiles the collection of the literature search. The hard copies of the same have to submitted dully signed by Research Guide, Head of the Department and Principal of Institute to University on completion of Semester – III.
2. Utmost care should be taken in selection of the topic so that repetition of the work is avoided.
4. Candidates work will be evaluated by the examiners appointed by University through Presentation and viva-voce

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-III**

**3A03ITD: INTRODUCTION TO DISSERTATION**

(COMPULSORY FOR ALL DISCIPLINES)

**Credit: 8**

**Max. Marks: 100**

**Instructions:**

1. Student must complete literature search and preliminary experimental work of his/her research project and submit the report, dully signed by Research Guide, Head of the department and Principal of Institute to University on completion of Semester – III.
2. Utmost care should be taken in selection of research topic so that repetition of research work is avoided.
3. For change in research topic, written permission of institute level committee should be taken.
4. Candidates work will be evaluated by the examiners appointed by University through presentation and viva-voce.

**GANPAT UNIVERSITY**  
**M .PHARM SEMESTER-IV**

**4A01DST: DISSERTATION**

(COMPULSORY FOR ALL DISCIPLINES)

**Credit: 16**

**Max. Marks: 200**

**Instructions:**

1. The research project allotted during the M. Pharm Semester-III have been continued and the experimental work of his/her research project to be completed.  
The Thesis containing literature review on the project, experimental work, result of the experimental work with discussion and future scope of the project, dully signed by Research Guide, Head of the Department and Principal of Institute submitted to the University on completion of Semester – IV.
2. The thesis will be evaluated by the examiners appointed by University through presentation followed by viva-voce.