M. Pharm. (Quality Assurance)

Semester- I

S. N	Course code	Course Title	Teaching Scheme (Hrs/Week)					
			Theory	Credit	Weighted Credit Point(10*C)	Practical	Credit	Weighted Credit Point
1	1A01MAT	MODERN ANALYTICAL TECHNIQUES	3	3	30	6	3	30
2	1A02PQA	PHARMACEUTICAL QUALITY ASSURANCE	3	3	30	6	3	30
3	1A03QMR	QUALITY MANAGEMENT & REGULATORY AFFAIRS	3	3	30	-	-	-
4	1B04ECS	ENGLISH LANGUAGE & COMMUNICATION SKILLS	2	2	20	2	1	10
		Total	11	11	110	14	7	70
Total credit = 11 + 7 = 18 and Total weighted credit point 110 + 70 = 180								

Semester- II

Sr. No	Course code	Course Title	Teaching Scheme (Hrs/Week)					
			Theory	Credit	Weighted Credit Point(10*C)	Practical	Credit	Weighted Credit Point
	2A01APS	ADVANCES IN PHARMACEUTICAL SCIENCES	3	3	30	-	-	-
	2A02ASM	STANDARDIZATION AND STABILIZATION METHODS	3	3	30	6	3	30
	2A03STD	SPECIAL TECHNIQUES IN DRUG ANALYSIS	3	3	30	6	3	30
	2B04CSS	COMMUNICATION AND SOFT SKILLS	3	3	30	-	-	-
		Total	12	12	120	12	6	60
Total credit = 12 + 6 = 18 and Total weighted credit point 120 + 60 = 180								

Semester- III

Sr. No	Course code	Course Title	Teaching Scheme (Hrs/Week)					
			Theory	Credit	Weighted Credit Point (10*C)	Practical	Credit	Weighted Credit Point
	3A01RMD	RESEARCH METHODOLOGY	3	3	30	-	-	-
	3A02APS	SEMINAR ON ADVANCES IN PHARMACEUTICAL SCIENCE	5	5	50	-	-	-
	3A03ITD	INTRODUCTION TO DISSERTATION	8	8	80	-	-	-
		Total	16	16	160	-	-	-
Total credit = 16 and Total weighted credit point = 160								

Semester- IV

Sr. No	Course code	Course Title	Teaching Scheme (Hrs/Week)					
			Theory	Credit	Weighted Credit Point (10*C)	Practical	Credit	Weighted Credit Point
	4A01DST	DISSERTATION	16	16	160	-	-	-
		Total	16	16	160	-	-	-
Total credit = 16 and Total weighted credit point = 160								

Total Progressive Credits offered = 68 and Total Progressive Credit points offered = 680

GANPAT UNIVERSITY

M .PHARM SEMESTER-I

1A01MAT 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 – Visble 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, berief 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:** **(8)**
   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 ^{13}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; ^{13}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. **Chemilumeniscence:** 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 spectroflourimetry.
7. Estimation of Na^{+}, K^{+}, 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, Addision — Wesley Publishing Company, London.

GANPAT UNIVERSITY
M .PHARM SEMESTER-I
1A02PQA PHARMACEUTICAL QUALITY ASSURANCE
(QUALITY ASSURANCE)

Theory: (3 hrs/week; Credit 3) **Max. Marks: 100**

1. A critical review of Pharmacopoeial methods used for qualitative and quantitative estimation of drugs and their formulations. **(7)**
2. An approach to the development and validation of bio-analytical methods for drugs in bulk and in their formulations, recovery studies, stability indicating analytical methods. **(7)**
3. Pharmacopoeial and other methods of analysis of common excipients/ additives in bulk and formulations. Determination of active constituents in presence of these excipients. Techniques of checking and eliminating interference by excipients in analysis of API. **(8)**
4. Analysis of drugs/metabolites in biological fluids like urine, blood and tissues, enzymatic analysis. **(8)**
5. Biochemical analysis of drugs, estimation of enzymes and other endogenous materials. **(8)**
6. Microbiological assay of antibiotics and vitamins. Sterility testing and Bacterial Endotoxin Test. **(7)**

PHARMACEUTICAL QUALITY ASSURANCE PRACTICAL
(PHARMACEUTICAL QUALITY ASSURANCE)

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. IP, BP & USP
2. Enzymes – Biochemistry, Biotechnology, Clinical Chemistry
3. Michael E. Swartz, Analytical method development & validation.
4. S.Suzanne Nielsen, “Introduction to the Chemical analysis of foods”.
5. D.C.Garratt “The quantitative analysis of drugs” 2nd edition.

GANPAT UNIVERSITY
M .PHARM SEMESTER-I
1A03QMR QUALITY MANAGEMENT & REGULATORY AFFAIRS (QUALITY ASSURANCE)

Theory: (3 hrs/week; Credit 3) **Max. Marks : 100**

1. Basic concepts of quality assurance, ISO 9000, Practice of Schedule M, cGMP, WHO GMP,GLP,GCP, etc. **(8)**
2. Quality audit and self inspections, SOPs, Documentation, Master formula records, Batch Manufacturing records Contract Licenses, Complaints Recalls etc. **(5)**
3. In process quality control tests for various dosage forms including packaging and labeling operations. **(3)**
4. Validation : Basic concepts, types of process validation, benefits, protocol. Process validation of nonsterile & sterile processes. **(10)**
5. Validation of Personnel, Equipments, Water supply system, cleaning methods, electronic data. **(4)**
6. Regulatory aspects of Pharmaceutical & bulk drug manufacture and biotechnology derived product. **(3)**
7. Brief introduction to general requirements of health regulatory agencies such as US FDA, MCA, TGA, WHO, ANVISA etc. Preparation of documents for Investigational New drug (IND), new drug application (NDA) (Phase I-IV): content and format, Abbreviated new drug application (ANDA) & Drug Master File (DMF). **(9)**
8. Precision, accuracy and biases, sampling and operating characteristic curves, sampling plans, statistical inference in estimation of hypo thesis testing, statistical procedure in assay development. **(3)**

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.
5. P.P.Sharma “How to practice GMPs”, 3rd edition Vandana Publi.
6. P.P.Sharma “How to practice GLP” GLP. Vandana Publi.

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 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 ed. Pearson Education ESL: Boston. 0201621002
6. Schmidt & Solorzano (2003). Northstar Listening & Speaking, Advanced, 2nd 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 4th 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 2nd. Pearson Ed/Longman: Boston. 0-13-061199-9.
4. Miller & Cohen. (2003). NorthStar Reading & Writing Advanced. 2nd ed. Pearson Ed./Longman: Boston. 0201755750.
5. Oshima & Hogue (2007) Writing Academic English 3rd 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 4th ed. McGraw-Hill: New York. 0-07-232964-5.
9. Wholey, M. (2007). Reading Matters 4. 2nd ed. Thomson/Heinle:

GANPAT UNIVERSITY
M. PHARM SEMESTER-II

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

Theory: (3 hrs/week; Credit 3) **Max. Marks : 100**

1. **Applicatioon 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:** **(2)**
   Approach to develop different analytical procedures. Validation of analytical procedures according to different guidelines.

3. **Product Registration:** **(4)**
   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)**
   Defination, 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" 3rd 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, 11th edition

GANPAT UNIVERSITY
M. PHARM SEMESTER-II
2A02ASM STANDARDIZATION AND STABILIZATION METHODS
(QUALITY ASSURANCE)

Theory: (3 hrs/week; Credit 3) **Max. Marks : 100**

1. WHO, ISCOP, DBA, BHC and other regulatory guide lines for quality control of Herbal raw materials and finished products. Physicochemical, morphological, and microscopical characterization in whole form and powder. Methods of determination of physical and chemical constants such as extractive values, moisture content, alcohol content, volatile oil content, ash values, swelling index, bitterness values, foreign matters, and physical constants applicable to the lipid containing drugs. **(08)**
2. Standardization of Ayurvedic formulations as per Ayurvedic Pharmacopoeia. Determination of heavy metal and pesticide residue and acceptance criteria as per different guidelines. **(4)**
3. Microbial counts, bioburden and Pharmacopoeial microbial assays. **(4)**
4. Standardization of nutraceuticals and food products (specialty food, supplementary dietary materials and minerals & vitamins). Standards for different types of food additives (colors, flavors, sweeteners) and methods of detection of adulteration in food products. **(9)**
5. Standardization of cosmetic formulation. Information on ingredients used in various cosmetics such as creams, powders, lotions, hair products, nail polishes, lipsticks, depilatories, toiletries etc. and their analysis. **(10)**
6. Factors affecting stability of a formulation. Stabilizers and Methods of stabilization. ICH guidelines for stability testing. **(6)**
7. Standards and controls for different packaging materials **(4)**

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M. PHARM SEMESTER-II
STANDARDIZATION AND STABILIZATION METHODS PRACTICAL (QUALITY ASSURANCE)

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. Food additive- R. J. Taylor
2. Antimicrobial in food- Alfred larry branen. P Michael division publishing corporation
3. Method of protein analysis by Istran Kerese.
4. Cosmetic analysis- selective methods and techniques by P. Borc
5. Henry's cosmeticology- Martin M. Rieger.
6. Cosmaceuticals Drug vs Cosmetics
7. Herbal cosmetics. Beauty through Herbs- Dr. Urjita Jain.
8. Morris B. Jacobs. The chemical analysis of foods and food products.
9. S. Suzanne Neilson. " Introduction to chemical analysis of foods.'
10. Jems T Carstenson. Drug stability- Principles and Practices. 2nd edition, Marcel Deccer.
11. Applied Microbiology. Vinita kale & Kishor Bhusari.
12. Michael J. Pelezar / Chan/ Krig. " Microbiology", 5th edition,
13. Tortora, Funke, "Case Microbiology- An introduction", 8th edition.
14. P. P. Sharma.- Cosmetics Formulation, Manufacturing and Quality control.
15. WHO Guide line for the quality control of herbal plant material.
16. The practical evaluation of Phytopharmaceutical by Brain & Turner
17. Indian Herbal Pharmacopoeia- Vol-I & II

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M. PHARM SEMESTER-II

2A03STD SPECIAL TECHNIQUES IN DRUG ANALYSIS

(QUALITY ASSURANCE AND PHARMACEUTICAL ANALYSIS)

Theory: (3 hrs/week; Credit 3) **Max. Marks : 100**

1. **Chromatographic techniques:**

   Methods in preparative and quantitative TLC, instrumentation of HPTLC, programmed, multiple development and other advances in TLC techniques. **(4)**

   Liquid chromatography: Instrumentation in HPLC, analytical, preparative and micro bore columns, packing materials, column selection, mobile phase selection, efficiency parameters and resolution, detectors in HPLC. Reverse phase, amino acid analysis, tryptic mapping and hydrophobic interaction chromatography. **(5)**

   Ion-exchange, ion pair, size exclusion and affinity chromatography. **(3)**

   Supercritical fluid chromatography (SFC). **(2)**

   Gas chromatography: Instrumentation, packed and open tubular column, column efficiency parameters, the Van Deemter equation, resolution, stationary phases, derivatization methods of GC including acylation, perfluoroacylation, alkylation and esterification, Detectors: FID, ECD, TCD, NPD. **(5)**
2. **Electrophoresis:** Moving boundary electrophoresis, zone electrophoresis, isotachophoresis, isoelectric focusing, continuous electrophoresis (Preparative); **(4)**
3. **X-ray diffraction methods:** Introduction, Generation of X-ray, Elementary crystallography, Milier indices, Brags' law, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data. **(4)**
4. Flow Injection Analysis (FIA) **(4)**
5. **Thermal methods of analysis:** Introduction to TGA, DTA and DSC theory, instrumentation and applications. **(6)**
6. **Electron spins resonance:** Principle, instrumentation, interpretation and applications. **(4)**
7. **Reference standards:** Source, preparation, characterization, usage, storage and records. **(2)**
8. **Photoacoustic spectroscopy** – principle, instrumentation & application. **(2)**

M. PHARM SEMESTER-II

SPECIAL TECHNIQUES IN DRUG ANALYSIS PRACTICAL (QUALITY ASSURANCE)

Practicals: (6 hrs/week; Credit 3) **Max. Marks : 100**

1. Gradient elution techniques in column chromatography.
2. Two dimensional paper chromatography and TLC.
3. Separation by electrophoresis.
4. Experiments using HPLC, GC, HPTLC: Determination of chromatographic parameters — capacity factor, selectivity, resolution, efficiency of column, HETP, asymmetric factor. Effect of polarity of mobile phase on retention of samples in normal / reversed phase mode in HPLC, Estimation of single component or multicomponent drugs in formulations — using different methods of quantitative analysis (Direct comparison method, calibration curve method, internal standard method).
5. Experiments based on application of the following reagents in pharmaceutical analysis: 2, 6 — dichloroquinone chlorimide, 1, 2 — napthaquione -4- sulfate, 2,3,5-triphenyltetrazolium salt, 3 — Methyl - 1,2- benzothiazoline hydrazone hydrochloride (MBTH), Folium ciocalteu reagent, p-dimethylamino benzaldehyde / cinnamaldehyde (PDAB), (PDMAC), Ninhydrin reagent.
6. Qualitative and quantitative determination in biological fluids (blood, urine) —barbiturates, sulpha drugs, adrenaline, amphetamine, hydantoins, morphine, pethidine, diazepam.
7. Case studies on Q. C. lab planning and analytical reporting of raw materials, inprocess and finished goods.

Reference Books:

1. Trace and Ultra Trace Analysis by HPLC — Ahuja.
2. HPLC in Pharmaceutical Analysis - Szepesi [2 Volumes]
3. HPLC Analysis of Biological Compounds, Lab. Guide Chromatography Series -Hancock and Spparrow Vol. 26.
4. Chromatography of Pharmaceuticals: Natural Synthetic & Recombinant Products -Ahuja.
5. HPLC — Pharma Analysis — Modern Methods Part — B, Vol. — 2, Editor — James W.Munson.
6. X-Ray methods — Clive Whiston — John Wiley & Sons.
7. Jenkins Quantitative Pharmaceutical Chemistry — A. M. Khevel, F. E. Diagangi.
8. Pharmaceutical Analysis — H. Takeru.
9. Advances in Automated Analysis / Clinical Analysis.

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.

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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 – A. Qualitative & quantitative studies B. Simple data organization & descriptive data analysis C. Limitation & sources of error D. Inquiries in form of questionnaire, etc	**4**
5.	Documentation- "How" of documentation Techniques of documentation Importance of documentation Use of computer packages in documentation.	**3**
6.	The Research Report Paper writing/ thesis writing 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	**8**
7.	**Presentation** (especially for oral presentation) 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.	**5**
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 10th 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, 4th 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, 4th 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, 1sted., Ideation to Publication, 2010.

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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

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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.

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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.