FACULTY OF PHARMACEUTICAL SCIENCE

PREAMBLE

The CVM University is committed to educational excellence. Education, especially higher education will have greater responsibility in future to keep pace with the advancements in the technology and industry needs. With the aims to contribute for education excellence and to serve the society with growth and sustainability. Pharmacy is one of the oldest professions in the human history. Medicines preparation and usage have been established successively so many years ago. Pharmacist are considered among the most respectable member of the society. Faculty of Pharmaceutical Science of the CVM University is offering Doctoral Programme in all the branches like Pharmaceutics, Pharmaceutical Chemistry & Analysis, Pharmacology, Pharmacognosy and Pharmacy Practice.

The constituent institutes of the CVM University offering in faculty of pharmaceutical science courses are endowed with well qualified and experienced faculty members to guide the prospective research scholar and lead him/her to Doctor of Philosophy (Ph. D.) Degree in his/her research of interest.

The booklet contains all relevant information about Ph.D. programme offered by theFaculty of Pharmaceutical Science of the CVM University, such as, the course structure, duration of the programme, academic requirements, and evaluation pattern. The booklet also contains detailed syllabus and pedagogical framework for the subjects to be studied during course work of the Ph. D. programme. Benefit of The Charutar Vidya Mandal University have wide faculties to explore collaborative research work, to create research expertise, training, allowing you to flourish good laboratory practice.

Wishing you a happy and fruitful learning.

Dr. (Mrs) Harshaben V. Patel
Dean - Faculty of Pharmaceutical Science
CVM University

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FACULTY OF PHARMACEUTICAL SCIENCE

Ph.D. Programme

Details of Ph.D. Programme Structure, Credit Requirements and other Aspects

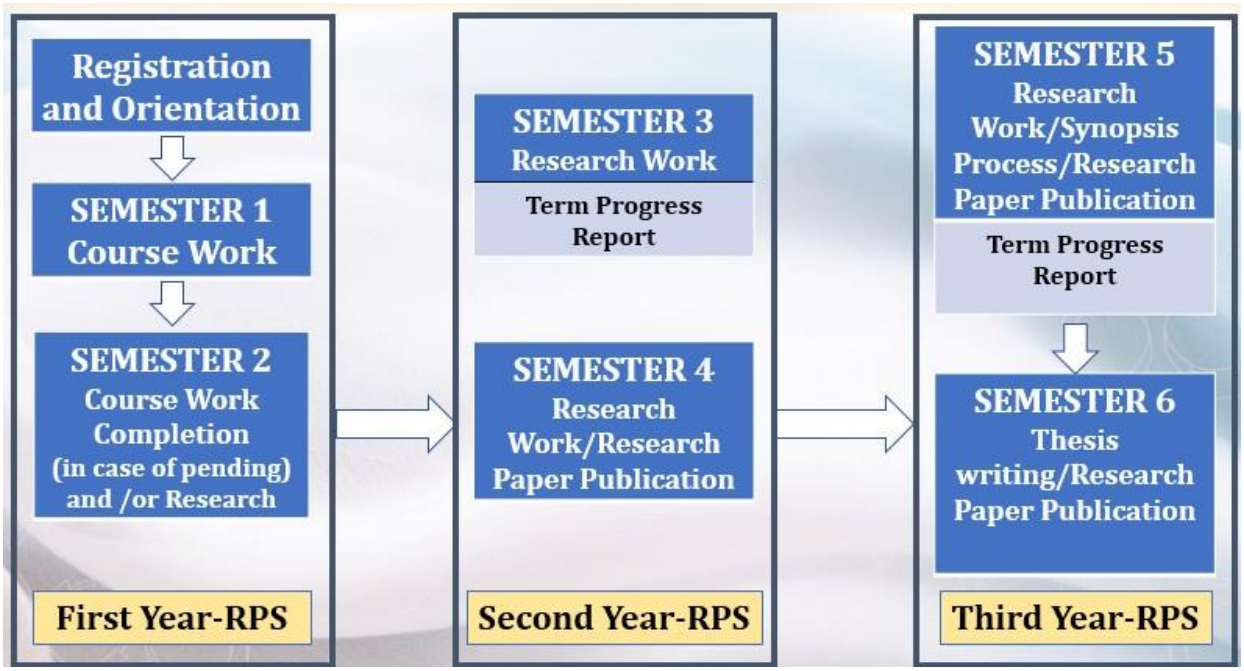

Figure 1: Ph.D. Programme - Structure

Note: Duration of the Ph.D. Programme shall be as per Ph.D. Guidelines framed by the University from time-to-time

A1. **Programme – Course Work Structure**

A1.1 The programme is structured into first Two Semesters out of minimum period / duration of Six Semesters for the Ph.D. Programme (shall be as per Ph.D. Guidelines) which shall be, consisting of classroom contact-based work (online / offline), field work, etc., if any.

A1.2 Each semester will be of maximum 60 contact hours for classroom work, covering classroom contact sessions, laboratory/tutorial/library/group work, case discussions and presentation, field-based as well as library/internet search-based assignments and projects, classroom exercises, short quizzes, and class tests.

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A2. Credits

A2.1 Research Scholar of Ph.D. Programme who earns 12 credits by pursuing the prescribed course workand passing all tests, examinations, assignments, laboratory work, projects, and all other evaluationcomponents as per the passing standards of the University will be eligible for the Course Completion Certificate / Grade Card as per the Ph.D. Programme Guidelines decided by the University.

A2.2 The current distribution of credits over the six months to one-year period for classroom contact sessions and laboratory/ tutorial/ library/ group work sessions will be as follows:

Table 1: Semester-wise Distribution of Credits

Sr. No.	Semester	Number of Credits
1	Semester – 1	12
OR		
2	Semester – 2	Applicable for Pending Credits / Courses, if any – As per Ph.D. Guidelines
Total		12

A2.3 A course will be of two / four or more credits as shown in the detailed list of courses (refer Table 2) for the programme.

A2.4 All courses shown in the list of courses are compulsory for all Ph.D. Programme – course work.

A2.5 Some courses will have only classroom contact sessions and some others will have tutorial/ laboratory/ library/ group work sessions, as shown in the list of courses (refer Table 3).

A2.6 The University has provision which provides scope for Research Scholars being allowed to take/ study courses being offered by all the Faculties/ Institutes/ Departments across University as approved by host faculty / discipline especially for Interdisciplinary Research Studies.

A3. Courses, Curricular and Revision

A3.1 The University shall in consonance with the UGC Guidelines on Ph.D. Programme shall update the Curricula keeping the contemporary issues / trends in focus and make it relevant to the needs of different organs of society.

A3.2 The review of the programme, its structure, the course curricula, pedagogy, and evaluation shall be undertaken at regular intervals by the concerned Faculty / Boards of Studies and other appropriateacademic / other bodies.

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Table 2: Teaching & Examination Scheme for Ph.D. Course Work

CourseCode	Course Title	Total Number of Credits	Contact Hours	Course Evaluation Type	Remarks
Semester – 1 or/to 2					
208610001	Research Methodology [RM]	04	04	Theory	
208610002	Research & Publication Ethics [RPE]	02	02	Theory	
208610003	Academic Writing, Review of Literature & Presentation [AWRoLP]	02	04	Practical	
	Discipline Specific Course(s) [DSC]	04	04	Theory	Course(s) / Credit(s) to be offered in part or full by offering one or more courses (E.g.: one or more courses / modules. etc.) from Internal / External (online coursesfrom SWAYAM. MOOCs, NPTEL, Other National and International Certificate Courses,) etc. sources
	ne Specific Course(s) [DSC] to be offered by Concerned Faculties / Department(s) / Area/Topic-wise etc. approved by RPC/RAC or FRAC or URC				

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Table 3: Ph.D. Programme – Course Work Teaching / Assessment / Evaluation Scheme Semester 1-2

Sr. No.	Course Group Name	Board of Study / Faculty Ownership	Course Paper Code	Course Name	Th.HR / Week	Prac.HR / Week	Tutor. HR / Week	Credit	Theory Exam Hrs	Practical Exam Hrs	INT(T) TOTAL / PASSIN G	EXT(T) TOTAL / PASSING	INT(P) TOTAL / PASSING	EXT(P) TOTAL / PASSING
1	CORE	Pharmaceutical Science	208610003	ACADEMIC WRITING, REVIEW OF LITERATURE &PRESENTATION	0.00	4.00	0.00	2.00	0.00	2.00	0.00/0.00	0.00/0.00	50.00/25.00	50.00/25.00
2	CORE	Pharmaceutical Science	208610002	RESEARCH AND PUBLICATION ETHICS	2.00	0.00	0.00	2.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00
3	CORE	Pharmaceutical Science	208610001	RESEARCH METHODOLOGY	4.00	0.00	0.00	4.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00
4	DISCIPLINE SPECIFIC COURSE	Pharmaceutical Science	208610011	QUALITY ASSURANCE	4.00	0.00	0.00	4.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00
5	DISCIPLINE SPECIFIC COURSE	Pharmaceutical Science	208610012	PHARMACY PRACTICE	4.00	0.00	0.00	4.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00
6	DISCIPLINE SPECIFIC COURSE	Pharmaceutical Science	208610013	PHARMACEUTICS AND PHARMACEUTICAL TECHNOLOGY	4.00	4.00	0.00	4.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00
7	DISCIPLINE SPECIFIC COURSE	Pharmaceutical Science	208610014	PHARMACOGNOSY	4.00	8.00	0.00	4.00	2.00	0.00	50.00/25.00	50.00/25.00	0.00/0.00	0.00/0.00

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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610001**

Course Title: **Research Methodology**

Course Objectives:

1. To inculcate skills in the literature review for conduction of research, the acquired knowledge and understanding.
2. To provide skills for identification, definition of research problems/hypotheses, based on literature survey, secondary data, and observations.
3. To help students in preparation of a research proposal, designing the research instruments and collection, coding and tabulating of data for analysis.
4. To enable develop understanding of the common statistical procedures used to analyze data from survey and experimental studies, and to use the statistical software packages like SPSS, SYSTAT, R to carry out these procedures and report the results of such statistical analyses in a manner appropriate for research and decision-making.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	50/25	50/25	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Foundation of Research/scientific research** Definition: Research, Scientific Research, Need of research/Philosophy, Objectives of Research/Importance of researchmethodology in scientific research, Characteristic of research, Identification of problem and status of problem, Conceptual and theoretical Models, Preparation of research design/Phases ofresearch.	08
2	**Types and Methods of Research** Classification of Research, Pure and Applied Research, Descriptive Research, Qualitative and Quantitative research, Exploring or Formulative Research, formulating objective and problem, Diagnostic Research/Study, Evaluation research/Studies, Experimental Research including Optimization techniques, Analytical Study of Statistical Method, Surveys, Case Study, Field Studies.	15
3	**Review of Literature** Purpose of literature survey/ Need for Reviewing Literature, Sourcesof Literature: internet, library, books, journals, patents, reprints of article and thesis, Current research literature, finding resources, Literature Search Procedure, Planning of Review work, Note Taking, Abstraction of research paper, Presentation & documentation of literature review	06
4	**Planning of Research** The planning process, Selection of a Problem for Research,Formulation of the Selected Problems, Hypothesis formation Measurement, Research Design	04
5	**Outcome of research** Relevance, Interest, Available data, Analysis of data, Generation andinterpretation of analysis, Preparation of report, Testing validity	03

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6	**Sampling & Field Work** Sampling Techniques or Methods, Choice of sampling Techniques, Sample size, Sampling and Non-Sampling errors, Estimation of Population Proportion and Population Mean, Estimation of StandardError and Confidence Interval. The Nature of Field Work, Selection and Training of Investigators.	**03**
7	**Statistical Data Analysis** Statistical Analysis, Measures of Central Tendency, Hyper geometric and uniform distribution, Confidence Interval, Nullhypothesis, Modelling of hypothesis testing, Test of Significance,Probability distribution: Binomial, Poisson's, Normal Distribution. Exponential Statistic and probability theories, Chi square test, T test,Z test, paired t test, ANOVA, Association of attributes, Standarddeviation, Coefficient of variation, Correlation and regressionanalysis, Characterization of experiments (Accuracy, Reliability, Reproducibility, sensitivity, Precision), Non-parametric Methods.	**15**
8	**Tools for data collection** Types of Data, Construction of Schedules and Questionnaires, Measurement of Scales and Indices, Pilot Studies, and Pre-tests	**02**
9	**Documentation and Report writing** Types of Reports: Research paper, thesis, Research project report, graphs, pictures. Planning of Report Writing, Research Report Format, Principles of Writing, Structure and component of research report, Citation style, writing review, Bibliography, Briefing. Research grants: Source for getting research grants- international agencies, Government and Private bodies. Steps to apply for Grants.	**04**

Reference Books:

1	Research Methodology: Methods and Techniques by C. R. Kothari, New Age International Publishers, ISBN:81-224-1522-9
2	Statistical Methods for Research Workers by Fisher R. A., Cosmo Publications, New Delhi ISBN:81-307-0128-6
3	Design and Analysis of Experiments by Montogomery D.C. (2001), John Wiley, ISBN: 0471260088
4	MINITAB online manual
5	Dawson, Catherine, 2002, Practical Research Methods, New Delhi, UBS, Publishers'Distributors.
6	Kothari, C.R.,1985, Research Methodology-Methods and Techniques, New Delhi, WileyEastern Limited.
7	Kumar, Ranjit, 2005, Research Methodology-A Step-by-Step Guide for Beginners, (2nd.ed), Singapore, Pearson Education.
8	Computer Applications in Pharmaceutical Research and Development, SeanEkins, 2006, John Wiley & Sons.
9	Geoffrey R. Norman, David L. Streiner, Biostatistics: The Bare Essentials, PMPH USA
10	Beth Dawson, Robert G. Trapp, Basic & Clinical Biostatistics, McGraw-Hill
11	Marcello Pagano, Kimberlee Gauvreau, Principles of Biostatistics, CRC Press
12	Antonella Bacchieri, Giovanni Della Cioppa, Fundamentals of Clinical Research, Springer

Pedagogy:

1. LCD projector, Laptop
2. Traditional Method (Black Board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
30	25	10	10	10	15	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Learning Outcomes (LO):

Sr. No.	Learning Outcome Statements
LO-1	Demonstrate the ability to choose methods appropriate to research aims and objectives
LO-2	Develop skills in qualitative and quantitative data analysis and presentation with the help of statistical tools.
LO-3	Be aware about the different sampling techniques, estimation of error and sources for getting research grants
LO-4	Develop advanced critical thinking skills and enhance writing skills

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2021
Last Reviewed on (Month-Year):	June 2021
Next Review on (Month-Year):	June 2025

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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610002**

Course Title: **Research And Publication Ethics**

Course Objectives:

1. To learn basics of philosophy of science and ethics
2. To practice research integrity, publication ethics through practical sessions designed
3. To identify research misconduct and predatory publications.
4. To develop comprehensive understanding on Indexing and citation databases, open access publications, research matrices (citation, h-index, Impact factor etc.) and plagiarism tools

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		
Lecture	Tutorial	Practical		Internal	External	Internal	External	Total
2	-	-	2	50/25	50/25	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Philosophy and Ethics** Introduction to Philosophy: Definition, Nature and Scope, Concept, Branches Ethics: Definition, Moral Philosophy, Nature of Moral Judgments and Reactions	02
2	**Scientific Conduct** Ethics with respect to Science and Research Intellectual Honesty and Research Integrity Scientific Misconducts: Falsification, Fabrication and Plagiarism (FFP) Redundant Publications: Duplicate and Overlapping publications. Selective Reporting and Misrepresentation of Data	06
3	**Publication Ethics** Publication Ethics: Definition, Introduction and Importance Best Practices / Standards Setting Initiatives and Guidelines: COPE, WAME Conflicts of Interest Publication Misconduct: Definition, Concept, Problem that led to Unethical Behavior and Vice-versa Types. Violation of Publication Ethics, Authorship and Contributor-ship Identification of Publication Misconduct, Complaints and Appeals Predatory Publishers and Journals	04
4	**Open Access Publishing** Open Access Publications and Initiatives SHERPA/RoMEO online resources to check publishers copyright & self-archiving policies, Software Tool to Identify Predatory Publications developed by SPPU. Journal Finder/Journal suggestion tools viz. JANE, Elsevier Journal Finder, Springer Journal Suggested etc.	04
5	**Publication Misconduct Group Discussion** Subject Specific Ethical Issues, FFP, Authorship Conflicts of Interest Complaints and Appeals Examples and Fraud from India and Aboard **Software Tools**: Use of Plagiarism software like Turnitin, Urkund and other Open-Source Software tools.	06
6	**Database and Research Metrices** Databases **Indexing Databases** Citation Databases: Web of Science, Scopus etc. **Research Metrices** Impact Factor of Journal as per Journal Citation Report, SNIP, SJR, IPP Cite Score Metrices: h-index, g index, i10 index, allometries	08

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Reference Books:

1	Bird, A. (2006) Philosophy of Science Rout ledge
2	Mac Intyre, Alasdair (1967) A short History of Ethics. London
3	P. Chaddah (2018) Ethics in competitive research: Do not get scooped; do not get plagiarized, ISBN:978-9387480865
4	National Academy of Sciences, National Academy of Engineering, and Institute of Medicine (2009) On Being a Scientist: A Guide to Responsible Conducting Research: Third Edition National Academic Press
5	Resnik, D. B. (2011) What is ethics in Research & why it is important, National Institute of Environmental Health Sciences, 1-10 Retrieved from https://www.niehs.nih.gov/research/resources/bioethics/whatis/index.cfm
6	Beall, J. (2012) Predatory publishers are corrupting open access, Nature, 489(7415), 179-179. https://doi.org/10.1038/489179
7	Indian National Science Academy (INSA), Ethics in Science Education, Research and Governance (2019) ISBN:978-81-939482-1-7. http://www.insaindia.res.in/pdf/ethicsBook

Pedagogy:
LCD projector, Laptop
Traditional Method (Black Board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
30	25	20	15	10	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Learning Outcomes (LO):

Sr. No.	Learning Outcome Statements
LO-1	Be aware about the publication ethics and publication misconducts
LO-2	Develop hands -on skills to identify research misconduct and predatory publications
LO-3	Differentiate indexing and citation databases, open access publication and research metrics
LO-4	Use plagiarism tools

Curriculum Revision:	
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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610011**

Course Title: **Quality Assurance**

Course Objectives: Upon completion of the course, student will be able to learn

1. Chromatographic techniques and its applications
2. Analytical method development, validation, and Calibration of equipment
3. Methods to perform stability study
4. Extraction and standardization methods for plant extract
5. Basics of Quality by design approach

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		
Lecture	Tutorial	Practical		Internal	External	Internal	External	Total
4	-	-	4	50/25	50/25	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Chromatography:** Principle, factors affecting resolution, theories of Chromatography. Instrumentation and Applications of: High performance Thin Layer chromatography, High Performance Liquid Chromatography Hyphenated techniques: LC-MS, HPTLC-MS, GC-MS etc.	15
2	**Analytical Method Development and Validation** Steps involved in Analytical method development. Analytical method validation: General principles, Validation of analytical method as per ICH guidelines and USP **Calibration and validation of Following Instruments/Equipments** Electronic balance pH Meter UV-Visible spectrophotometer HPLC HPTLC Dissolution	15
3	**Extraction and standardization of Plant extract** Modern methods of extraction of plant, application of latest techniques like Spectroscopy and chromatography in the isolation, purification, and identification of crude drugs. Herbal Drug Standardization: WHO and Pharmacopoeia guidelines; Phytopharmaceuticals as per CDSCO	15
4	**ICH Quality Guidelines on** **Drug Stability:** ICH guidelines for stability testing of drug substances and drug products. Stability testing of natural products **Impurities:** Impurities in new drug substance, new drug product, Residual solvent, and elemental impurities **Quality by design Approach:** Study of ICH Q8, Quality by Design and Process development	15

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Reference Books:

1	Principles of Instrumental Analysis - Douglas A Skoog, F. James Holler, Timothy A. Nieman, 5th edition, Eastern press, Bangalore, 1998.
2	Instrumental methods of analysis – Willards, 7th edition, CBS publishers
3	Pharmaceutical Equipment Validation: The Ultimate Qualification Handbook, Phillip -A. Cloud, Inter-pharm Press
4	Analytical Method validation and Instrument Performance Verification by Churg Chan, Heiman Lam, Y. C. Lee, Yue. Zhang, Wiley Inter science
5	B. T. Loftus & R. A. Nash, "Pharmaceutical Process Validation", Drugs and Pharm Sci. Series, Vol. 129,3rdEd., Marcel Dekker Inc. N.Y.
6	Herbal drug industry by R.D. Choudhary (1996), 1st Ed, Eastern Publisher, New Delhi.
7	Mohammad Ali. Pharmacognosy and Phytochemistry, CBS Publishers & Distribution, New Delhi.
8	ICH Guidelines
9	AYUSH guideline on herbal drug standardization

Pedagogy:
LCD projector, Laptop
Smart Interactive panel

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
15	30	30	10	10	5	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Learning Outcomes (LO):

Sr. No.	Learning Outcome Statements
LO-1	Learn sophisticated Instrumentation technique
LO-2	Describe regulatory guideline on stability, impurities, and quality by design approach
LO-3	Study analytical method development, validation, and qualification of Instrument
LO-4	Learn techniques related to isolation and standardization of plant materials

Curriculum Revision:	
Version:	1
Drafted on (Month-Year):	June 2021
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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610012**

Course Title: **Pharmacy Practice**

Course Objectives: Upon completion of this course, it is expected that students shall be able

1. To Understand the regulatory and ethical requirements clinical trials activities & regulatory aspects of quality use of medicines.
2. To learn community pharmacy management.
3. To Understand the elements of pharmaceutical care and provide comprehensive patient care services.
4. To understand the various epidemiological methods and their applications.
5. To conduct Pharmacovigilance Program of India (PvPI) requirement for ADR reporting in India.
6. To learn and apply ICH guidelines for ICSR, PSUR, expedited reporting, pharmacovigilance planning.

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	50/25	50/25	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Introduction to Clinical Pharmacy**: Definition, evolution and scope of clinical pharmacy, International and national scenario of clinical Pharmacy practice Understand, pharmaceutical care. **Clinical Pharmacy Services**: Patient medication history interview, Basic concept of pharmacovigilance, Hemovigilance, Materio vigilance and AEFI, Patient medication counseling, Drug utilization evaluation, Basic concept of medicine and poison information services, Documentation of clinical pharmacy services	**12**
2	**Introduction to Pharmacovigilance:** WHO International drug monitoring Programme, Pharmacovigilance program of India (**PvPI),** ICH Guidelines for Pharmacovigilance**.** **Introduction to Pharmacoepidemiology:** Definition, Scope, Need, Aims & application, Qualitative models: Drug Utilization Review; Quantitative models: case reports, case series, Cross-sectional studies, Drug effects study in populations: Spontaneous reporting, Prescription event monitoring, post-marketing surveillance, Record linkage systems.	**12**
3	**Ethics in Biomedical Research:** Ethical Issues in Biomedical Research – Principles of ethics in biomedical research, ICH GCP guidelines and ICMR guidelines in the conduct of Clinical trials, Drug Safety Reporting. **Types and Designs used in Clinical Research:** Planning and execution of clinical trials, Randomization techniques (Simple randomization, restricted randomization, blocking method, and stratification), Types of research designs based on Controlling Methods (Experimental, Quasi-experimental, and Observational methods) Time Sequences (Prospective and Retrospective), Sampling methods (Cohort study, case Control study and cross-sectional study), Health outcome measures (Clinical & Physiological, Humanistic and economic)	**12**

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4	**Clinical Trial Study team:** Roles and responsibilities of Investigator, Study Coordinator, Sponsor, Monitor, Contract Research Organization. **Clinical trial Documents:** Guidelines to the preparation of the following documents: Protocols, Investigator's Brochure, Informed Consent Form, Case report forms, Contracts, and agreements, Dairy Cards **Clinical Trial Data Management:** Standard Operating Procedures, Data management plan, CRF & Database design considerations, Study set-up, Data entry, CRF tracking and corrections, Data cleaning, Managing laboratory and ADR data, Data transfer and database lock, Quality Control and Quality Assurance in CDM, Data mining and warehousing.	**12**
5	**Introduction to Quality use of medicines (QUM):** Definition and Principles of QUM, Key partners, and responsibilities of the partners, building blocks in QMC, Evaluation process in QMC, Communication in QUM, Cost-effective prescribing. **QUM in various settings**: Hospital settings, Ambulatory care/Residential care, Role of health care professionals in promoting the QUM, Strategies to promote the QUM, Impact of QUM on E-health, integrative medicine, and multidisciplinary care **Health related quality of life (HRQOL):** Definition, Need for measurement of HRQOL, Common HRQOL measures. **Pharmacoeconomic evaluations**: Definition, Steps involved, Cost Minimization Analysis (CMA), Cost Benefit Analysis (CBA), Cost Effective Analysis (CEA).	**12**

Reference Books:

1	A Textbook of Clinical Pharmacy Practice – Essential concepts and skills –Parthasarathi G, Karin Nyfort-Hansen, and Milap Nahata
2	Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers
3	Community Pharmacy Practice – Ramesh Adepu, BSP Publishers, Hyderabad
4	Ethical Guidelines for Biomedical Research on Human Subjects. Indian Council of Medical Research, New Delhi.
5	Textbook of Clinical Trials edited by David Machin, Simon Day and Sylvan Green, John Wiley and Sons
6	Clinical Data Management edited by R K Rondels, S A Varley, C F Webbs. Second Edition, Jan 2000, Wiley Publications.
7	Online: http://medicinesaustralia.com.au/files/2012/05/MA_QUM_External_Red uced.pdf http://curriculum.racgp.org.au/statements/quality-use-of-medicines/ http://www.rug.nl/research/portal/files/14051541/Chapter_2.pdf
8	Andrew Briggs, Karl Claxton, Mark Sculpher. Decision Modelling for Health Economic Evaluation, Oxford University Press, London.
9	Michael Drummond, Mark Sculpher, George Torrence, Bernie O'Brien, and Greg Stoddart. Methods for the Economic Evaluation of Health Care Programmes Oxford University Press, London.

Pedagogy:
LCD projector, Laptop
Traditional Method (Black Board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
30	25	10	10	10	15	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

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Learning Outcomes (LO):	
Sr. No.	**Learning Outcome Statements**
LO-1	Describe the development and scope of clinical pharmacy and documentation requirements for clinical trials.
LO-2	Describe national and international pharmacovigilance programs and recognize the role of ICH and GCP guidelines.
LO-3	Understands the principles, regulatory aspects and promote quality use of medicines.
LO-4	Identify the application and methods to measure outcomes of pharmacoepidemiology and Pharmacoeconomics in clinical settings.
LO-5	Understand the elements of pharmaceutical care and provide comprehensive patient care service.

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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610013**

Course Title: **Pharmaceutics and Pharmaceutical Technology**

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

1. The various approaches for development of novel drug delivery systems.
2. The criteria for selection of drugs and polymers for the development of delivering system
3. The formulation and evaluation of Novel drug delivery systems

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		
Lecture	Tutorial	Practical		Internal	External	Internal	External	Total
4	-	-	4	50/25	50/25	-	-	100/50

* **J**: Jury; **V**: Viva; **P**: Practical

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Controlled release drug delivery systems:** Theory and fundamentals. Different mechanisms of drug release. Factor influencing design and development of CRDDS. Various approaches in development and evaluation of rate controlled drug delivery systems for oral, parenteral, transdermal, and ocular drug delivery. Innovation and advance technologies in modified drug delivery systems. Regulatory requirement for Modified Drug delivery systems.	20
2	**Polymers:** Polymer classification, physiochemical properties and polymer solutions, biodegradable and non-biodegradable polymers, application of polymers in controlled release of drugs.	05
3	**Vesicular formulations:** liposomes, niosome, pharmacosomes, ethosomes etc. Structure and stability, compositions, methods of preparation, application in drug delivery and drug targeting, commercial concepts etc.	10
4	**Micro and Nanoparticulate based drug delivery systems:** Classification of formulations, composition & methods of preparation, characterization, applications in drug delivery.	10
5	**Nasal and pulmonary drug delivery systems:** Recent advances, innovation and approaches in design and development of Inhalers (dry powder and metered dose), nasal sprays, nebulizers, nanoemulsion and micro emulsion etc.	10
6	**Mucoadhesive drug delivery systems:** Buccal, Stomach and Vaginal drug delivery systems; concepts, advantages and disadvantages, formulation approaches and evaluation.	05

Reference Books:

1	Y. W. Chien, Novel Drug Delivery Systems, 2nd edition, revised and expanded, Marcel Dekker, Inc., New York, 1992.
2	S. P. Vyas and R. K. Khar, Controlled Drug Delivery - concepts and advances, Vallabh Prakashan, New Delhi, First edition 2002.
3	N. K. Jain, Controlled and Novel Drug Delivery, CBS Publishers & Distributors, New Delhi, First edition 1997 (reprint in 2001).
4	Robinson, J. R., Lee V. H. L, Controlled Drug Delivery Systems, Marcel Dekker Inc., New York, 1992.

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5	Encyclopedia of controlled delivery, Editor- Edith Mathiowitz, Published by Wiley Interscience Publication, John Wiley and Sons, Inc, New York! Chichester/Weinheim.
6	Transdermal Controlled Systemic Medications, Marcel Dekker, N.Y. 3. N.K. Jain, Controlled and novel drug delivery, CBs, New Delhi.
7	J. R. Juliano, Drug Delivery Systems Oxford University Press, Oxford, 1980.
8	M. I. Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
9	J. N. Nixon, Microencapsulation, Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc., New York.
10	FDA regulatory affairs: a guide for prescription drugs, medical devices, and biologics/edited By Douglas J. Pisano, David Mantus.

Pedagogy:
LCD projector, Laptop
Traditional Method (Black Board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
20	30	10	20	20	0	

Note: This specification table shall be treated as a general guideline for students and teachers. The actual distribution of marks in the question paper may vary slightly from above table.

Learning Outcomes (LO):

Sr. No.	**Learning Outcome Statements**
LO-1	Knowledge of the need, concept, and design of various sustained and controlled release dosage forms.
LO-2	Formulation aspects and evaluation of various novel drug delivery systems
LO-3	Updation about recent advances in drug delivery

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FACULTY OF PHARMACEUTICAL SCIENCE

Effective from Academic Batch: 2021-22

Programme: **Ph D in Pharmaceutical Science**

Semester: **Ph D Course Work**

Course Code: **208610014**

Course Title: **Pharmacognosy**

Course Objectives: Upon completion of the course, student will be able to

1. Learn extraction and isolation of phytoconstituents
2. Conduct standardization of herbal drugs
3. Comprehend screening of biological methods (In vitro and In vivo models)
4. Formulate Novel herbal formulations
5. Acquire knowledge of Natural product drug discovery
6. Understand Regulatory aspects of nutraceuticals

Teaching & Examination Scheme:

Contact hours per week			Course Credits	Examination Marks (Maximum / Passing)				
				Theory		J/V/P*		Total
Lecture	Tutorial	Practical		Internal	External	Internal	External	
4	-	-	4	50/25	50/25	-	-	100/50

*** J: Jury; V: Viva; P: Practical**

Detailed Syllabus:

Sr. No.	Contents	Hours
1	**Techniques for extraction and isolation of natural compounds.** Recent advances in extractions with emphasis on selection of method and choice of solvent for extraction, successive and exhaustive extraction and other methods of extraction commonly used like microwave assisted extraction, Methods of fractionation. Separation of phytoconstituents by latest SCFE techniques including preparative HPLC and Flash column chromatography.	15
2	**Herbal Drug Standardization** CDSCO guidelines for phytopharmaceuticals, WHO Guidelines for Assessment of Crude Drugs, AYUSH guidelines, Phytochemical reference standards (PRS), Phytochemical finger printing: HPTLC and LCMS/GCMS applications in the characterization of herbal extracts.	15
3	**Biological screening of herbal drugs:** Introduction and need for Phyto-Pharmacological Screening, New Strategies for evaluating Natural Products, In vitro evaluation techniques for Antioxidants, Antimicrobial and Anticancer drugs. In vivo evaluation techniques for Anti-inflammatory, Antiulcer, Anticancer, Wound healing, Antidiabetic and Diuretics, Toxicity studies as per OECD guidelines	18
4	**Overview of Novel herbal formulations**: Phytosomes, Liposomes, Microspheres, novel vesicular herbal formulations etc	06
5	**Natural product drug discovery from different sources (Marine, Microbial, Mineral etc)**: Introduction, recent development, and its applications. **Nutraceuticals:** Regulatory aspects, FSSAI guidelines.	06

Reference Books:

1	Evans, W. C., & Trease, G. E. (2002). *Pharmacognosy*. London: Saunders.
2	Brady, T. V., & Pharmacognosy, L. R. J. (1985). 9th Ed, Lea & Febiger publication.
3	Haynes, L. J., Peach, K. I., & Tracey, M. V. (1955). Modern Methods in Plant Analysis. Vol. I and II, edited by Peach, K. and Tracey, MV Springer-Verlag, Berlin.
4	Wallis, T. E. (1946). Textbook of pharmacognosy.

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5	Marine Natural Products-Vol. I to IV.
6	Ikan, R. (1991). *Natural products: a laboratory guide*. Academic Press.
7	Clarke, G. C. (1975). *Isolation and identification of drugs*. London: Pharmaceutical press.
8	Gupta, M., Chauhan, D. N., Sharma, V., & Chauhan, N. S. (Eds.). (2019). *Novel drug delivery systems for phytoconstituents*. CRC Press.
9	Mukherjee, P. K., & Houghton, P. J. (Eds.). (2009). *Evaluation of Herbal Medicinal Products: perspectives on quality, safety, and efficacy* (pp. 399-401). London: Pharmaceutical press.
10	Mukherjee, P. K. (2019). *Quality control and evaluation of herbal drugs: Evaluating natural products and traditional medicine*. Elsevier.
11	Standardization of Botanicals. Testing and extraction methods of medicinal herbs by V. Rajpal (2004), Vol. I, Eastern Publishers, New Delhi.
12	WHO guidelines for assessing quality of herbal medicines with reference to contaminants and residues
13	General guidelines for Safety/Toxicity Evaluation of Ayurvedic Formulations

Pedagogy:
LCD Projector, Laptop
Traditional Method (Black Board)

Suggested Specification table with Marks (Theory) (Revised Bloom's Taxonomy):

Distribution of Theory Marks in %						**R**: Remembering; **U**: Understanding; **A**: Applying; **N**: Analyzing; **E**: Evaluating; **C**: Creating
R	**U**	**A**	**N**	**E**	**C**	
10	10	30	20	20	10	

Note: This specification table shall be treated as a general guideline for students and teachers.
The actual distribution of marks in the question paper may vary slightly from above table.

Learning Outcomes (LO):

Sr. No.	Learning Outcome Statements
LO-1	Apply basic knowledge of modern methods of extraction and separation of phytoconstituents by suitable chromatography methods.
LO-2	Explain guidelines, regulatory aspects, and biological screening methods for assessment of herbal drugs and natural products.
LO-3	Describe overview of novel herbal formulations.

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