GANPAT UNIVERSITY
FACULTY OF PHARMACY
PH. D. Course work- Teaching and Examination Scheme

		TEACHING SCHEME	EXAMINATION SCHEME		
S.N	NAME OF SUBJECT	Credit	MARKS		
		Cr.	Int.	Ext.	Total
1	Research Methodology (Common)	4	60	40	100
2	Faculty Specific Topic (Elective)	4	60	40	100
3	Research Seminar (Elective)	2	60	40	100
		10	180	120	300

Note:

1. Ph.D Scholars shall require to opt one elective subject from the list decided by Faculty of Pharmacy for the Faculty specific topic. The selection of topic shall depend upon the specialization of the Ph.D scholar within the field of Pharmaceutical sciences.
2. Research Seminar shall be selected among the recent development of any subject area in consultation with guide allotted. Each scholar shall have to present research seminar on selected topic for the internal as well as external examination with documentary evidence for the efforts made on gathering required information in form of literature review.

GANPAT UNIVERSITY
FACULTY OF PHARMACY
PH. D. Course work
RESEARCH METHODOLOGY
(**COMPULSORY FOR ALL RESEARCH SCHOLARS**)
(Credit 4)

1. Research-Meaning, purpose, Types, (Educational, Clinical, Experimental, historical descriptive, Basic applied and Patent oriented Research) objective of research
2. Literature survey-Use of Library, books and journals-Medlines-Internet, Patent Search, and reprints of articles as a source for Literature survey.
3. Selecting a problem and preparing Research proposals
4. Methods and tools use in research –
    A. Qualities studies, quantitative studies B. Simple data organization descriptive data analysis,
    B. Limitation & sources of Error, D. Inquiries in form of Questionnaire, etc.
5. Documentation- "How" of documentation, Techniques of documentation, Importance of documentation, Use of computer packages in documentation.
6. The Research Report Paper writing/ thesis writing
7. **Presentation** (especially for oral presentation)
   Importance, types different skills, contained, format of model, introduction, Poster, Gestures, eye contact, facial, expressions, stage, fright, volume- pitch, speed, pause & language, Visual aids & seating, Questionnaire.
8. Cost analysis of the project – cost incurred on raw materials-Procedure, instrumentations and clinical trials.
9. Sources for procurement research grants – international agencies, Government and private bodies.
10. Industrial-institution interaction- Industrial projects, their, feasibility reports. Interaction with industries.

Recommended Reading:

- Research In Education- John V. Best, John V. Kahn 7th edition.
- Presentation skills - Michael Hallon- Indian Society for Institute education.
- Practical Introduction o copyright - Gavin Mcfarlane.
- Thesis projects in Science & Engineering – Richard M. Davis.
- Scientist in legal Systems- Ann labor science.
- Thesis & Assignment – Jonathan Anderson.
- Writing a technical paper- Donald Menzel.
- Effective Business Report Writing –Leland Brown.
- Protection of industrial Property rights- P. Das & Gokul Das.
- Spelling for the millions- Edna Furmess.
- Preparation for publication – King Edward Hospital Fund for London.

GANPAT UNIVERSITY
FACULTY OF PHARMACY
PH. D. Course work
FACULTY SPECIFIC TOPIC
(COMPULSORY FOR PHARMACEUTICAL CHEMISTRY / QUALITY ASSURANCE)
(Credit 4)
Pharmaceutical Quality by Design

1. Introduction: Definitions, regulatory requirements, goal, purpose, importance of quality by design in pharmaceutical development
2. Elements of pharmaceutical quality by design:
    - Quality target product profile (QTPP) and CQA
    - Product design
    - Process design
    - Control strategy
    - Process capability and continual improvement
3. Pharmaceutical quality by design tools
    - Risk assessment
    - DOE and data analysis
    - Process analytical technology
4. QbD Approach for Analytical Method Development
    - QbD Principle for Analytical Method Development
    - Characteristics of Successful QbD Program
    - Advantages of QbD
    - Quality by Testing (QbT) & Implementation of QbD
    - Applications of QbD in Various Analytical Methods
    - Opportunities & Barriers Against a QbD Approach to Analytical Methods

Recommended Reading:

- U. S. Food and Drug Administration. Guidance for Industry: Q8 (2) Pharmaceutical Development. 2009
- ICH Quality Implementation Working Group. Points to consider. ICH-endorsed guide for ICH Q8/Q9/Q10 implementation. 2011.
- U. S. Food and Drug Administration. Guidance for Industry: Q10 pharmaceutical quality system. 2009.
- Vogt F. G., Kord A. S.. Development of Quality by Design Analytical Methods. J. Pharm. Sci.. 2010; 100(3): 797-812.
- Embracing Quality by Design (QbD) in Pharmaceutical Industry. Pharma Mirror; 2013.

GANPAT UNIVERSITY
FACULTY OF PHARMACY
PH. D. Course work
FACULTY SPECIFIC TOPIC
(COMPULSORY FOR PHARMACEUTICAL TECHNOLOY)
(Credit 4)
Novel Drug Delivery System

1. Theory of controlled release drug delivery systems: kinetics & mechanism General methods of design and evaluations of controlled release products.
2. Advanced concepts and Recent innovations in the design, development and production of sustained release products like Multiple compressed tablets including compression coated tablet, layered tablet, inlay tablet, Modified Release tablet/ Delayed action tablet/ Targeted tablet like Floating tablet, and Colon targeting tablet, Dispersible tablet/ Mouth Dissolve Tablets/Oro Dispersible Tablets/ Chewable/Chewable cum Dispersible tablet, etc.
3. Mucoadhesive drug delivery systems- Buccal, stomach and vaginal drug delivery systems concepts, advantages and disadvantages. Nasal and pulmonary drug delivery systems and its applications.
4. Transdermal drug delivery systems – Theory, formulation, production and evaluation.
5. Microencapsulation – Methods of encapsulation, kinetics of drug release from microcapsules, technology and applications.
6. Vesicular formulations: liposomes, noisome, pharmacosomes, ethosomes etc. Structure and stability, compositions, methods of preparation, application in drug delivery and drug targeting, commercial concepts, etc.
7. Nanoparticulate based drug delivery systems: Classification of formulations, composition & methods of preparation, Characterization, application in drug delivery.

Recommended Reading:

- Joseph R. Robinson, “Sustained and Controlled Release Drug Delivery Systems”, Drugs &Pharm. Sci. Series, Vol. 6 Marcel Inc.,N.Y.
- Yie W. Chien, Novel Drug Delivery Systems, Drugs and Pharm. Sci. Series, Vol.14, Marcel Dekker Inc.N.Y.
- J.N.Nixon, Microencapsulation, Drugs and Pharm. Sci. Series, Vol.3, Marcel Dekker Inc.,N.Y.
- G. Jolles and R.H. Wooldridge, Drug Design – Faact of Fantasy? Academic Press, 1984.
- J.R.Robinson and Vincent H.L. Lee, Controlled Drug Delivery, Drugs and Pharm. Sci. Series,Vol. 29, Marcel Dekker Inc. N.Y.
- J.R.Juliano, Drug Delivery Systems Oxford University Press, Oxford, 1980.
- M.I.Gutcho, Microcapsules and Microencapsulation Techniques, Noyes Data Corporation, 1976.
- E.B.Roche, Design of Biopharmaceutical properities through prodrug and analogs, Am. Pharm. Assoc. Academy of Pharm. Sci. 1977.

GANPAT UNIVERSITY
FACULTY OF PHARMACY
PH. D. Course work
FACULTY SPECIFIC TOPIC
(COMPULSORY FOR PHARMACOLOGY AND PHARMACOGNOSY)
(Credit 4)
Drug discovery and Screening

1. General principle of Screening, Correlation between Various animal models and human situations and *In-vitro* and *In-vivo* screens.
2. Detailed study of guidelines for maintenance, breeding techniques and experimentation using laboratory animals: a) CPCSEA b) OECD c) ICH d) GLP e) ICMR f) Guidelines according to official compendia.
3. Organization of screening: Pharmacological activity of new substances and safety assessment tests. Toxicity studies: acute, subacute (Repeated dose), subchronic and chronic toxicity.
4. Alternatives to animal experimentation: a) Animal cell lines and their uses b) Radioligand binding assay c) Patch clamp and ELISA d) Stem cell research etc.
5. Natural product drug discovery from different sources (Marine, Microbial, Mineral etc): Introduction, recent development, methods of extraction and isolation, applications etc.
6. General methods of extraction of herbal drugs for alkaloids, saponins, cardiac sterols, tannins, flavonoids, volatile oils and other important glycosides.
7. Preliminary phytochemical screening, bioactivity guided fractionation, lead molecule, biological targets and HTS assays for important biological activities.

Recommended Reading:

- Drug Discovery & Evaluation by H. Gerhard Vogel.
- Drug screening methods by S. K. Gupta.
- Screening methods in pharmacology by Robert A. Turner.
- Shot protocols in pharmacology & drug discovery by S. J. Enna and Michael Williams.
- Genetics by Strickberger, Monroe W.
- Molecular Biology of Genes by Watson et al.
- Quality Control of Herbal Drugs by Mukherji P. K.
- High Throughput Screening: The Discovery of Bioactive Substances by John P. Devlin.
- The Practical Evaluation of Phytopharmaceuticals by Brain K. R. & Turner T. D.
- Herbal drug technology by S. S. Agrawal and M. Paridhavi.