RASHTRIYA UCHCHATAR SHIKSHA ABHIYAN (RUSA)

COURSES TO BE INTEGRATED IN AUTONOMOUS COLLEGE

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TABLE OF CONTENT

Recommendations of the RUSA Expert Committee to finalize choice based courses and course content in the vertical of Pharmacy.

Core Committee Members:

1. Dr. Anuradha Majumdar, Associate Professor of Pharmacology, Bombay College of Pharmacy, Mumbai, Chairperson
2. Dr. P. R. Vavia, Professor of Pharmaceutics and Dean, Academic Programmes, Institute of Chemical Technology, Mumbai
3. Dr. Sanish Davis, Country Head and Senior Medical Director, Covance
4. Dr. Mandar Kodgule, Ex VP, Global IP and Corporate strategy, Wockhardt Ltd, Chairman and CEO, IQGEN-X Pharma Pvt Ltd.
5. Dr. Stephen D'Silva, Professor of Marketing Management, Jamnalal Bajaj Institute of Management Studies

Taking into cognizance the suggestions of academicians and Industry key opinion leaders, the committee is recommending seven choice based Courses, namely:

1. Clinical Data Management
2. Industrial Pharmacy I
3. Industrial Pharmacy II
4. Industrial Pharmacy III
5. Pharmaceutical Marketing Management
6. Pharmaceutical Product Management
7. Pharmaceutical Business Innovation Management

- Each course is of 3 credit points, with total 45 hours of lectures/tutorials.
- All the seven courses can be introduced between sem. V to sem. VIII in the B Pharm Programme.
- Students can opt for the courses based on their interests and prospective career choices.
- The course of Clinical Data Management (CDM) can also be offered as elective to B.Sc (Any Biological Sciences), in TY B.Sc (Sem V or Sem VI).
- The courses of Pharmaceutical Marketing Management, Pharmaceutical Product Management, and Pharmaceutical Business Innovation Management can also be offered as electives to B.Sc. (Any Biological Sciences) in TY B.Sc (Sem V or Sem VI).

Course Introduction and Structure for B Pharm and BSc. Programmes

(Semester V to VIII)

Sr. no	Course Name	Total Credits	Time	Theory	Practical/ Tutorial	Course intends for Students	Suggestive Semesters for Courses to be Introduced	Assessment
1.	Clinical Data Management	3	3 hrs/week	45hrs	Practical is covered in theory classrooms using suitable software's	B.Pharma B.Sc (Any Biological Sciences)	V to VIII V to VI	The methodology of assessment consist of assignments /projects and written examination
2.	Industrial Pharmacy -I	3	3 hrs/week	30 hrs	15 hrs tutorial	B. Pharm	V to VIII	
3.	Industrial Pharmacy -II	3	3 hrs/week	30 hrs	15 hrs tutorial	B. Pharm	V to VIII	
4	Industrial Pharmacy -III	3	3 hrs/week	30 hrs	15 hrs tutorial	B. Pharm	V to VIII	
5	Pharmaceutical Marketing Management	3	3 hrs/week	45 hrs	Practical is covered in theory classrooms using suitable software's	B. .Pharm B.Sc (Any Biological Sciences)	V to VIII	
6.	Pharmaceutical Product Management	3	3 hrs/week	45 hrs			V to VI	
7.	Pharmaceutical Business Innovation Management	3	3 hrs/week	45 hrs				

- Syllabus for Elective/Core/Add on course in **Clinical Data Management**

- Electives intended for students in the following programmes:
    1. Undergraduate Programmes: B. Pharm, B.Sc (Any Biological Sciences) in TY B.Sc

- Semester in which the course is proposed to be introduced:
    - B. Pharm Sem. V to VIII
    - BSc.(Any Biological Sciences) Sem.V to VI

- Credit: 3

- Instruction Hours: 45 hrs (Time: 3 hrs/week)

- Course Prerequisites: Basic understanding of diseases (Pathology), Pharmacology and Clinical Research

Clinical Data Management (CDM)

(Semester V to VIII)

Program/Syllabus outline plan

Preamble

The Primary aim and scope of the CDM elective as part of the Pharmacy course is to make the candidates employable as entry level resource in the domain of Clinical Data management to be more employment ready in BPOs, Pharmaceutical companies, Contract Research Organizations (CROs) that are involved in this vertical of Clinical Research. The course will serve as a sound introduction to CDM domain for students pursuing education in Pharmacy and other relevant biological sciences even if they plan on not joining this domain in their careers. Clinical data management also has the scope of being extended to medical/health care data management. This course is expected to trigger initiatives in this domain as well.

The course will be structured as consisting of 45 contact hours. This unique combination of sound theoretical training along with exposure to the IT interfaces viz. clinical database management softwares will definitely ensure the employability of the candidate immediately on completion of their graduate Pharmacy Program. The course faculties can be drawn from the Contract Research Organizations, Research Laboratories & Institutes, Medical Colleges, Pharmaceutical companies, etc., and can be in the form of contact classes in specific institutions or webinars for wider reach.

Course Objective:

The course is designed to provide the learner in-depth theoretical knowledge about all aspects of Clinical Data Management. It aims to demonstrate to the leaner the use of suitable data management tools for the generation of high-quality, reliable, and statistically sound data from clinical trials.

Course Outcome: After completing the course, the students will understand the concepts of CDM and its importance, relevance and execution in the ambit of clinical development. This will make them employable in the clinical research associated sponsor, CRO and BPO companies for jobs associated with CDM.

Course Content:

Unit no.	Course content (topics and subtopics)	Allotted Hours of Lectures Per Unit
1	**Introduction to Clinical Data Management (CDM)**	4
1.1	Principles of CDM	
1.2	Data and databases	
1.3	Edit Checks	
1.4	Electro	
1.5	NIC data capture	
1.6	Data Entry	
1.7	Transcribing data	
1.8	Queries & Data Clarification	
	Softwares in CDM	
2	**Data Management Plan**	4
2.1	Designing study protocol	
2.2	Design eCRF/CRF	
2.3	Study report definition	
2.4	Data entry guidelines	
2.5	Data discrepancy management process	
2.6	Data Completion Guideline	
2.7	Coding Guideline	
2.8	Data Review & Validation Guideline	
2.9	Practical Hands on Training: Create eCRF, Database Build, Edit Check Programming, Coding	
3	**Clinical Data Management System** (demonstrated using suitable Electronic Database Management System)	4
3.1	Document management basics	
4	**Clinical data repositories**	2
4.1	Clinical data repositories in Healthcare	
4.2	Overview of Clinical Data Repositories- Traits, types and benefits of clinical data repositories	
	Metadata Repository & Data Late	
5	**Loading of external data into CDM system**	2
5.1	Introduction to External Data Handling	
6	**Query management**	2

Unit no.	Course content (topics and subtopics)	Allotted Hours of Lectures Per Unit
7	**Data clarification form**	2
8	**Remote data entry**	2
9 9.1	**Clinical data entry** Single, double, SAE reconciliation, coding of Adverse events	4
10 10.1 10.2 10.3 10.4	**Data cleaning and data validation** (using suitable software Kinds of Validation Validation methods Post Validation actions Quality criteria for data cleaning	4
11	**Analysis Data model** (ADaM) **and STDM** (Study Data Tabulation Model)	2
12	**Working with missing values, outliers, start and end dates**.	2
13 13.1	**Data base lock (DLP)** Scope and Importance	2
14 14.1 14.2	**System validation** Principles Process approaches	2
15 15.1 15.2	**eCRF designing & data tracking** Development of eCRF and user acceptance test Data tracking	2
16 16.1 16.2	**Clinical data archiving** Electronic archiving of Clinical trials. Challenges in clinical data archiving	2
17	**CDM Service Level Agreement (SLA)**	1
18 18.1 18.2	**Quality Assurance (QA) in CDM** Definitions of terminologies Study site audits	2
	Total	**45**

References:

Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.

1. Practical Guide to Clinical Data Management, Third Edition by Susanne Prokscha
2. Data Management for Researchers: Organize, maintain and share your data for research success (Research Skills) Paperback – September 1, 2015 by Kristin Briney
3. https://www.scdm.org/publications/gcdmp/ (several publications are available on SCDM website for free or for nominal fee if you join as a member)
4. Research Data Management: Practical Strategies for Information Professionals (Charleston Insights in Library, Information, and Archival Sciences) by Joyce M. Ray
5. Latest Regulatory Guidelines related to CDM and Clinical Data Reporting.

- Syllabus for Elective/Core/Add on courses in **Industrial Pharmacy-I**

- Electives intended for students in the following programmes:
    2. Undergraduate Programmes: B. Pharm

- Semester in which the course is proposed to be introduced: V to VIII

- Credit: 3 (3 hrs/ Week)

- Instruction Hours: 30 lecture hrs +15 tutorial hours

- Course Prerequisites: Knowledge of Pharmaceutics

Industrial Pharmacy-I

Program/Syllabus outline plan

Course objective:

- To give student an insight of different regulatory guidelines for manufacturing pharmaceutical dosage forms.
- To teach students how to implement Quality by Design (QBD) approach to the development of different pharmaceutical dosage forms.
- To give student an understanding of the documentation necessary during development, scale up and large-scale manufacturing of different pharmaceutical dosage forms.
- To familiarize students with the concept of continuous manufacturing using Process analytical tools in production of pharmaceutical dosage forms.

Course outcome:

- Student will be familiarized with the different regulatory guidelines for manufacturing pharmaceutical dosage forms.
- Students will learn to implement Quality by Design (QBD) approach to the development of different pharmaceutical dosage forms.
- Students will understand the documentation necessary during development, scale-up and large-scale manufacturing of different pharmaceutical dosage forms.
- Students will be familiarized with the concept of continuous manufacturing using Process analytical tools in production of pharmaceutical dosage forms.
- Students will be trained for personal hygiene and safety protocols.

Course Content

Unit No.	**Course Contents (Topics and subtopics)**	**Allotted Hours of Lectures Per Unit**
1 1.1	**GMP, C-GMP** FDA Regulations	

Unit No.	**Course Contents (Topics and subtopics)**	**Allotted Hours of Lectures Per Unit**
1.2 1.3 1.4 1.5	21 CFR Schedule M Sampling protocols ICH guidelines	5
2.	FDA and SUPAC Guidelines	5
3.	Quality by Design	5
4. 4.1 4.2 4.3	Audit and Documentations Filling documents BMR completion Other Documentation for Quality Assurance	5
5.	**Process Analytical Technology (PAT)**	5
6.	**Personnel Training**	5
6.1	Training on Personal protective equipment	
6.2	Training on facility design and material flow in facility	
6.3	Safety training	
6.4	Training of handling instruments	
7.	**Contaminations and Cross-contaminations**	5
7.1	Endogenous Impurity	
7.1.1	Raw Material	
7.1.2	Additives	
7.1.3	Decomposition of Formulation	
7.2	Exogenous Impurity	
7.2.1	Residual solvents	

Unit No.	**Course Contents (Topics and subtopics)**	**Allotted Hours of Lectures Per Unit**
7.2.2	Container	
7.2.3	Delivery system	
7.2.4	Particulate contaminant	
8.	**Validation**	5
8.1	Facility validation	
8.2	Manufacturing Process Validation	
8.3	Cleaning Validation	
9.	**Raw Material and finished goods Storage**	5
9.1	Raw Material Q.C	
9.2	Flow of raw materials in manufacturing Facility	
	Total	**45**

References: **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**	
1.	ICH Q7, Q8, Q9 and Q10 guidelines
2.	Pharmaceutical manufacturing handbook, Regulation and Quality by Shayne Cox Gad,
	PH.D., D.A.B.T., Wiley-Interscience
3.	Schedule M, D&C act 1940
4.	FDA and SUPAC guidelines
5.	DOE Simplified: Practical Tools for Effective Experimentation, Third Edition By Mark J. Anderson, Patrick J. Whitcomb
6.	RSM Simplified: Optimizing Processes Using Response Surface Methods for By Mark J. Anderson, Patrick J. Whitcomb

References: **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**	
7.	Pharmaceutical Quality by Design: A Practical Approach edited by Walkiria S. Schlindwein, Mark Gibson
8.	Juran on Quality by Design: The New Steps for Planning Quality Into Goods By J. M. Juran
9.	Continuous Manufacturing of Pharmaceuticals edited by Peter Kleinebudde, Johannes Khinast, Jukka Rantanen
10.	Process Analytical Technology: Spectroscopic Tools and Implementation edited by Katherine A. Bakeev
11.	Pharmaceutical Process Scale-Up edited by Michael Levin
12.	Encyclopaedia of Occupational Health and Safety, edited by Jeanne MagerStellman
13.	Validation of Pharmaceutical Processes, Third Edition edited by James P. Agalloco, Frederick J. Carleton
14.	Pharmaceutical Process Validation: An International, Robert A. Nash, Alfred H. Wachter
15.	Quality Assurance of Pharmaceuticals: A Compendium of Guidelines, Volume 2 By World Health Organization
16.	Handbook of Microbiological Quality Control in Pharmaceuticals and Medical edited by Rosamund M. Baird, Norman A. Hodges, Stephen P. Denyer
17.	Quality Systems and Controls for Pharmaceuticals By Dipak Kumar Sarker

- Syllabus for Elective/Core/Add on courses in **Industrial Pharmacy-II**

- Electives intended for students in the following programmes:
    3. Undergraduate Programmes: B. Pharm

- Semester in which the course is proposed to be introduced: V to VIII

- Credit: 3 (3 hrs/Week)

- Instruction Hours: 30 lecture hrs+15 tutorial hours

- Course Prerequisites: Knowledge of Pharmaceutics

Industrial Pharmacy-II

Program/Syllabus outline

Course Objective:

- To give student an insight of various aspects of manufacturing of solid oral dosage forms including large scale production.
- To give students an insight of various aspects of manufacturing of Liquid dosage forms including large scale production.
- To give students an insight of various aspects of manufacturing of semi solids dosage forms including large scale production.

Course Outcome:

- Students will get insight of various aspects of manufacturing of solid oral dosage forms including large scale production.
- Students will get insight of various aspects of manufacturing of Liquid dosage forms including large scale production.
- Students will get insight of various aspects of manufacturing of semi-solid dosage forms dosage forms including large scale production.

Unit no.	**Course Contents (Topics and subtopics)**	**Allotted Hours of Lectures Per Unit**

Unit no.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1. 1.1 1.2 1.3 1.4 1.5 1.6 1.7	**Solid Orals** (Tablets, Capsules, Lozenges, powders and granules, pellets, mini tablets) Facility Layout Equipments Processes IPQC tests Packaging Stability	15
2. 2.1 2.2 2.3 2.4 2.5 2.6	**Semisolids** (Gels, Ointments, Creams) Facility Layout Equipments Process IPQC tests Packaging Stability	15
3. 3.1 3.2 3.3 3.4 3.5 3.6	**Liquids** (Suspension, emulsion, solution, Lotions, Tinctures, Syrups) Facility Layout Equipment's Process IPQC tests Packaging Stability	15
	Total	**45**

References: **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**	
1.	Lachman/Lieberman's the Theory and Practice of Industrial Pharmacy
2.	Herbert A. Lieberman, Martin A. Rieger, G.S. Banker , Pharmaceutical Dosage Form: Dispersed Systems (Vol.1 &2), 2 nd edition, Marcel Dekker Inc, 1993
3.	Gilbert S.Banker, C.T. Rhodes, Modern Pharmaceutics, ,4th Edition, Marcel Dekker Inc, 2002
4.	Howard C. Ansel, Nicholas G. Popovich, Lord V. Alien, Pharmaceutical Dosage Form And Drug Delivery Systems, 10th edition, 1995, B.I.WaverlyPvt.Ltd., New

	Delhi, 2013
5.	Allen, Loyd V., Jr, Remington-The Science And Practice of Pharmacy (Vol.1& 2), 22nd edition, Lippincott Williams &Wilkins, 2012
6.	J.W. Cooper, Colin Gunn,Tutorial Pharmacy, 4th edition, Sir Isaac Pitman & Sons Ltd.,London, 1950
7.	Michael E. Aulton, Pharmaceutics: The Science Of Dosage FormDesign, Churchill-Livingstone, 1988
8.	Graham C.Cole, Pharmaceutical Production Facilities:Design& Applications, 2st Edition , Ellis Horwood, 1998
9.	Pharmacopoeias: Indian Pharmacopoeia, British Pharmacopoeia, United States Pharmacopoeia, all editions
10.	ICH Guidelines

- Syllabus for Elective/Core/Add on courses in **Industrial Pharmacy-III**

- Electives intended for students in the following programmes:
    - Undergraduate Programmes: B. Pharm

- Semester in which the course is proposed to be introduced: V to VIII

- Credit: 3

- Instruction Hours: 30 lecture hrs+15 tutorial hours (3hrs/Week)

- Course Prerequisites: Knowledge of Pharmaceutics

Industrial Pharmacy-III

Program/Syllabus outline

Course Objective:

- To give student an insight of various aspects of manufacturing of parenteral dosage forms including large scale production.
- To give student an insight of various aspects of manufacturing of transdermal forms including large scale production.
- To give student an insight of various aspects of manufacturing of novel dosage forms including large scale production.

Course outcome:

- Students will get insight of various aspects of manufacturing of parenteral dosage forms including large scale production.
- Students will get insight of various aspects of manufacturing of transdermal forms including large scale production.
- Students will get insight of various aspects of manufacturing of novel dosage forms including large scale production.

Course Content

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1.	**Parenteral** (Small volume parenteral, LVPS)	15
1.1	Facility Layout (clean rooms)	
1.2	Equipments	
1.3	Process	
1.4	IPQC tests	
1.5	Packaging	
1.6	Stability	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
2. 2.1 2.2 2.3 2.4 2.5 2.6	**Transdermal Patches** Facility Layout Equipment Process IPC test Packaging Stability	15
3. 3.1 3.2 3.3 3.4 3.5 3.6 3.7 3.8 3.9	**Novel Dosage Form** Microsphere Nanotechnology Based Products Facility Layout Equipments Process IPQC tests Packaging Stability	15
	Total	**45**

Sr. no.	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
1	Encyclopedia of Pharmaceutical Technology, J. Swarbrick, New York, Marcel Dekker, 1993
2	Modern Pharmaceutics, G. S. Banker, New York, Marcel Dekker 1990
3	Novel Drug Delivery Systems, Second Edition, YieChien
4	Advances Controlled & Novel Drug Delivery, N. K. Jain
5	Mechanisms of Transdermal Drug Delivery edited by Russel O. Potts
6	Transdermal Drug Delivery Systems: Revised and Expanded edited by Jonathan Hadgraft

7	Dekker Encyclopedia of Nanoscience and Nanotechnology, Volume 5 edited by James A. Schwarz, Cristian I. Contescu, Karol Putyera
8	Microparticulate Systems for the Delivery of Proteins and Vaccines edited by Smadar Cohen, Howard Bernstein

- Syllabus for Elective/Core/Add on courses in **Pharmaceutical Marketing Management**

- Electives intended for students in the following programmes:
    - Undergraduate Programmes:
        - B. Pharm
        - B.Sc. (Any Biological Sciences) in TY B.Sc
- Semester in which the course is proposed to be introduced:
    - B. Pharm Sem. V to VIII
    - BSc Sem. V to VI

- Credit: 3

- Instruction Hours: 45 hrs (3 hrs/week)

- Course Prerequisites: Knowledge of Basics of Pharmacy

Pharmaceutical Marketing Management

Program/Syllabus outline plan

Course Objective:

- To impart knowledge on the basic concepts in marketing and learn to cater to the needs of the industry.
- To increase understanding of the important issues in planning and evaluating brand strategies.
- To provide the appropriate theories, models, and other tools to make better branding decisions.
- To provide information on the basic fundamentals of drugs, their storage and transportation.

Course Outcome:

Students who successfully complete this course will be able to:

1) Identify wants and environmental factors that shape marketing activities for certain target markets.
2) Identify the organizational processes involved in the planning, implementation and control of marketing activities.
3) Understand the concepts of brand equity, brand performance and key principles of strategic brand management.
4) Determine the best organizational structure for its sales force.
5) Design a plan to motivate, monitor, and control the sales force.
6) Estimate the market potential for each product, determine sales territories, quotas and forecast sales performance.
7) Differentiate areas of the supply chain and their interrelationships.
8) Classify the products according to their significance for logistics management.
9) Identify storage, maintenance and handling systems required in different logistic situations.

Course Content:

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1	**Principles of Marketing**	12
1.1	**Introduction to Marketing**	
1.1.1	Definition, Concepts Significance & functions of Marketing,	
	Approaches to the study of Marketing, Relevance of Marketing in a developing economy.	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1.1.2	Role & functions of Marketing Manager.	
1.1.3	Types of Marketing: Tele Marketing, E-Marketing-Service etc.	
1.1.4	Rural Marketing feature & importance suggestions for	
	improvement of Rural Marketing.	
1.1.5	Marketing Planning and Strategies	
2	**Marketing Mix**	11
2.1	Using PubMed and Standard Treatment Algorithms to build brand communication strategies	
2.1.2	IFPMA Code of Ethics – Guidelines for Pharmaceutical Promotion; Developing content and designing of Scientific Promotional Literatures, Visual Aids and Journal. Advertisements Preparing the Promotional Budget as a part of the Marketing Budget.	
2.2	**International Marketing in Pharmaceutical Industry**	
2.2.1	India and Global Scenario: Essential differences between	
	domestic Marketing in India and International Marketing;	
2.2.2	Generic products dominated market vis-à-vis patented products	
2.2.3	Dominated markets	
2.2.4	Role of pharmacies in dispensing products	
2.2.5	Role of mass media in product advertisements and social campaigns for market expansion.	
2.2.6	Factors governing International business environment.	
2.2.7	Demand estimation of pharmaceuticals in International markets.	
2.2.8	Market-entry strategies.	
3	**Sales Management**	**11**
3.1	**Need and scope of Pharmaceutical selling**.	
3.1.1	Direct selling – concepts & types. Role and responsibilities of Medical Representatives.	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
3.1.2	New product adoption process; impact of sales calls;	
3.1.3	Analysis of prescription behaviour of doctors using Prescription Audit Data.	
3.2	**Importance of Physician's Prescription**:	
3.2.1	Key influencers of doctors' prescription behavior.	
3.2.2	Distribution channel and network in pharmaceutical industry.	
3.2.2	Trade channel relationship	
3.3	**Managing sales force**.	
3.3.1 3.3.2	Sales forecasting of pharmaceutical products. Forecasting methods for different therapeutic categories.	
3.3.4	Strategic decision making using IMS-Health and C-MARC data for sales and market trend analysis;	
3.3.5	Using Medical Databases	
3.3.6	Monitoring & Controlling long-term projects, field-force activities and promotional expense budget.	
3.4	**Pricing of pharmaceutical products.** Pricing types and strategies relevant in the pharmaceutical market.	
4	**Logistics & Distribution Management**	**11**
	Total	**45**

Sr. No	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
1	Marketing Management, Philip Kotler
2	Marketing – A Managerial Introduction, Gandhi
3	Marketing Information System, Davis & Olsan
4	Consumer Behavior, Schiffman & Kanuk
5	Principles and practice of Marketing, John Frain
6	Pharmaceutical Marketing, Ross Mullner

Sr. No	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
7	Pharmaceutical Marketing, Subba Chaganti Rao
8	Pharmaceutical Marketing in India: Concepts Strategies Cases, Subba Rao Changanti
9	The Rx Factor: Strategic Creativity in Pharmaceutical Marketing, Pavan Choudary
11	Managing Brand Equity, David Aaker
12	Product Management in India, Ramanuj Majumdar
13	Successful Branding, Pran K. Chaudhary
14	Pharmaceutical Marketing, Mickey C. Smith
15	Sales Management, Still and Cundiff
16	Sales Force Management -M. Johnston
17	Sales & Distribution Management, Krishna Havaldar
18	Sales and Distribution Management, Tapan K. Panda
19	Sales Promotions Management, Bir Singh
20	Sales Management: Decision Strategy and Cases, Richard R. Still
21	Essentials of Supply Chain Management, Michael H. Hugos
22	Logistics and Supply Chain Management, Martin Christopher
23	Supply Chain Management: Strategy, Planning, and Operation, Sunil Chopra and Peter Meindl
24	Integral Logistics Management: Operations and Supply Chain Management Within and Across Companies, Paul Schönsleben
25	Supply Chain Logistics Management, Donald Bowersox
26	The Handbook of Logistics and Distribution Management, Alan Rushton

- Syllabus for Elective/Core/Add on courses in **Pharmaceutical Product Management**

- Electives intended for students in the following programmes:
    - Undergraduate Programmes:
        - B. Pharm
        - B.Sc. (Any Biological Sciences) in TY B.Sc

- Semester in which the course is proposed to be introduced:
    - B. Pharm Sem. V to VIII
    - BSc Sem. V to VI

- Credit: 3

- Instruction Hours: 45 hrs (3 hrs/week)

- Course Prerequisites: Knowledge of Basics of Pharmacy

Pharmaceutical Product Management

Program/Syllabus outline plan

Course Objective:

- To enhance the students understanding of the marketing research industry.
- To develop skills to understand different applications of Marketing Research.
- To demonstrate different approaches of marketing research.
- To impart knowledge on Marketing Research data for management decision-making.
- To elicit interest in learner to help them investigate ideas, inspire change and improve performance in product management practices.

Course Outcome:

After completing the course the student will be able to:

- Understand the process of marketing research and its different processes
- Analyze how product management can be applied to products and services that are both external and internal to an organization
- Analyze and interpret both qualitative and quantitative data of marketing research.

Course Content:

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1	**Pharmaceutical Marketing Research**	**22**
1.1 1.1.1 1.1.2 1.1.3 1.1.4 1.1.5 1.1.6	**Introduction to Marketing Research Management** Value of Information Meaning & Objectives of Marketing Research Types of Marketing Research Marketing Research Approaches Marketing Research Processes Problems encountered by Researchers in India.	
1.2 1.2.1	**Research Problem** Defining & selecting the Problem	
1.2.2	Technique involved in defining the Research problem.	
1.3	**Research Design**	
1.3.1	Concept of Research Design	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1.3.2	Need & features of a Research Design	
1.3.3	Some important Concepts related to Research Design	
1.3.4	Types of Research Design	
1.4	**Sampling Design**	
1.4.1	Census & Sample Survey	
1.4.2	Steps in Sampling	
1.4.3	Characteristics of a good Sample Design	
1.4.4	Types of Sample Design	
1.4.5	Random Sampling	
1.4.6	Measurement & Scaling Techniques	
1.4.7	Methods of Data collection	
1.4.8	Processing & Analysis of Data	
1.4.9	Testing of Hypothesis	
1.4.10	Chi-square Test	
1.4.11	Variance & Co-variance.	
1.5	**Sales Analysis & Forecasting**	
1.5.1	New Product Development & Test Marketing.	
1.5.2	Advertising Research, Interpretation & Report Writing	
2	**Product Management**	**23**
2.1	Introduction and History of Product Management.	
2.1.1	How Pharmaceutical product Management is different from General	
2.1.2	Product Management.	
2.1.3	The 4 'Ps' in a regulated Pharma market, the Strategic Triangle	
2.1.4	Market Segmentation in the pharmaceutical context, conceptual	
2.1.5	difference with consumer products market segmentation.	
2.1.6	Relation of Product Management Teams vis-à-vis Sales Force in	
	Pharmaceutical companies.	
2.2	**Product Life Cycle Management**.	
2.2.1	Product-mix Optimization & Promotional-mix Optimization	
2.2.2	Portfolio Analysis by factoring key determinants, BCG Matrix, brand	
	building decisions	
2.2.3	Leveraging the Promotional-mix for Brand Building.	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
2.3	**Designing Marketing Programs for New Product launch and**	
	Total	**45**

Sr. no	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
1	Marketing Research: An Applied Approach, Naresh K. Malhotra
2	Marketing Research: Measurement and Method, Donald S.
3	Qualitative Inquiry and Research Design, John W. Creswell
4	Qualitative Data Analysis, Matthew B. Miles
5	Research Design: Qualitative, Quantitative, and Mixed Methods, John W. Creswell
6	Doing Qualitative Research: A Practical Handbook, David Silverman
7	Market Research: A Guide to Methods and Sources, Tom Mcnulty
8	A Concise Guide to Market Research: The Process, Data, and Methods, Marko Sarstedt
9	Product Management, Lehman & Winer
10	Pharmaceutical Product Development, N. K. Jain
11	How Top Product Managers Launch Awesome Products, Richard Banfield
12	Marketing Strategy for Pharmaceutical Products, S. Anil Kumar
13	Pharmaceutical Marketing Management, Uday Raj Sharma

Sr. no	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
14	The Product Manager's Survival Guide, Steven Haines
15	Product Management in Practice Paperback, Matt Lemay

- Syllabus for Elective/Core/Add on courses in **Pharmaceutical Business Innovation Management**

- Electives intended for students in the following programmes:
    - Undergraduate Programmes:
        - B. Pharm
        - B.Sc. (Any Biological Sciences) in TY B.Sc
- Semester in which the course is proposed to be introduced:
    - B. Pharm Sem. V to VIII
    - BSc Sem. V to VI

- Credit: 3

- Instruction Hours: 45 hrs (3 hrs/week)

- Course Prerequisites: Knowledge of Basics of Pharmacy

Pharmaceutical Business Innovation Management

Program/Syllabus outline plan

Course Objective:

- To teach what Innovation Management is and how it relates to business strategy.
- To create awareness on how innovation drives economic competitiveness.
- To familiarize on how macroeconomic indicators play a role in shaping policy.
- To impart knowledge on the role of organizational structures and strategies in innovation.
- To understand the enablers and inhibitors of bringing out innovation and creativity of people.
- To provide comprehension about the fundamentals of change managements and its relevance to innovation.
- To teach the fundamentals of intellectual property and its management.
- To provide overview of innovation in product development and in operations management.

Course Outcome:

Students who successfully complete this course will be able to:

- Demonstrate understanding of the concepts of innovation, growth and value creation.
- Apply different analytical frameworks to assess the potential of organizational and technological inventions.
- Understand managerial challenges in growing an organization and managing innovations.
- Demonstrate both creative and reflective thinking on how firms can be created.
- Capture value through organizational and technological innovations

Course Content:

Unit No.	**Course Contents (Topics and subtopics)**	**Allotted Hours of Lectures Per Unit**
1 1.1	**Introduction to Innovation Management: Basic Concepts** What is innovation?	5
1.2	Innovation Myths and Mantras	
1.3	Innovation Vocabulary	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
1.4	Models of Innovation	
1.5	Centers of Innovation	
2	**The Social and Economic Dimensions of Innovation**	5
2.1	International Innovation Indices	
2.2	Innovation, Productivity and Economic Competitiveness	
2.3	Productivity vs. Competitiveness	
3	**Innovation in Business Models**	5
3.1	"Traditional" vs. Emerging Business Models	
3.2	Examples for Innovative Business Models	
3.3	Implementing Business Models	
4	**The Essentials of Product Innovation**	5
4.1	Scale of Product Innovation	
4.2	Product vs. Process Innovation	
4.3	Examples of Disruptive Innovations	
4.4	New Product Development Framework	

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
5	**The Essentials of Process Innovation**	5
5.1	The Drivers of Process Innovation	
5.2	Business Process Management	
5.3	Business Process Mapping	
5.4	Management of Change	
6	**The Innovative Organization: Structures and Systems**	5
6.1	What Makes an Organization Innovative	
6.2	Balanced Scorecard	
6.3	People Leadership	
6.4	Team dynamics / structures	
6.5	Communication strategies	
6.6	Intellectual Property Management	
7	**Leadership in Innovation**	**5**
7.1	Common Myths About Leadership	
7.2	Characteristics of a Leader	
7.3	Motivation, Performance, Reward Systems	
7.4	Voice of the Customer	
8	**Managing Change**	**5**

Unit No.	Course Contents (Topics and subtopics)	Allotted Hours of Lectures Per Unit
8.1	Innovation and Change	
8.2	Why Change? What is Change Management?	
8.3	Factors in Change – CAP Model	
8.4	Creating the Need for Change	
8.5	Implementing Change	
9	**Service Innovation**	**5**
9.1	What is Service Innovation	
9.2	Examples of Service Innovations	
9.3	Closed vs. Open Innovation	
9.4	Product or Service?	
	Total	**45**

Sr. No	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
1	H. S. Fogler and S.E. LeBlanc, Strategies for Creative Problem Solving, Prentice Hall, 1995.
2	E. Sickafus, Unified Structured Inventive Thinking, Ntelleck, 1997
3	E. Lumsdaine and M. Lumsdaine, Creative Problem Solving, McGraw Hill, 1995.
4	Kaplan, Introduction to TRIZ, Ideation International, Inc., 1995.
5	G. Altschuller, Creativity as an Exact Science, 1983

Sr. No	**References:** **Latest editions/versions/revisions of the books and regulatory schedules and guidelines to be referred.**
6	G. Altshuller and H. Altov, And Suddenly the Inventor Appeared: Triz, the Theory of Inventive Problem Solving, 1996
7	G. Altshuller and S. Rhodman, Principles, Keys to Technical Innovation, Technical Innovation Center, 1997
8	E. de Bono, The Use of Lateral Thinking, Penguin Books, 1990
9	E.de Bono, De Bono's Thinking Course, Facts on File, 1981
10	Serious Creativity, Harper Collins, 1992
11	E. de Bono, Six Thinking Hats, Little, Brown & Co., 1985
12	CoRT Thinking, Advanced Practical Thinking Training, Inc., 1995
13	Tony Buzon, Use Both Sides of Your Brain, Dutton, 1983
14	Scott G. Isaksen, Brian Dorval, and Donald Treffinger, Creative Approaches to Problem Solving, Kendall Hunt, 1994
15	F. Osborn, Applied Imagination: Principles and Procedures of Creative Problem Solving, Charles Scribner's Sons, 1979
16	D. Tanner, Total Creativity in Business and Industry, Advanced Practical Thinking Training, 1997
17	D. Pressman, Patent It Yourself, NOLO Press, 2006
18	T. Kelley, The Art of Innovation. Doubleday, 2001
19	T. Kelley, The Ten Faces of Innovation. Doubleday, 2005
20	J. Goldenberg and D. Mazursky, Creativity in product innovation, Cambridge University Press, 2002

Training Calendar

Faculty Development Programme

Institute of Chemical Technology-CEPSTM
PROPOSED PROGRAM FOR 2018-19

Sr. No.	Activity		Dates *	Programs/ Workshop/ Symposium Topic
1	10 programs, each of 10 days duration.	1	17th December, 2018 to 27th December 2018	Clinical Data Management
		2	6th January ,2019 to 15thJanuary,2019	Pharmaceutical Management
		3	16th January,2019 to 25th January,2019	Clinical Data Management
		4	8th February,2019 to 17th February,2019	Industrial Pharmacy
		5	18th February, 2019 to 27th March, 2019	Pharmaceutical Management
				Pharmaceutical Management
2	**Induction Programs**	1	16th January,2019 to 15th February,2019	
		2	4th March, 2018 to 3rd April, 2018	
3	**Symposium/ conferences**	1	8th & 9th September, 2018	Extraction and Isolation of Phytoconstituents
		2	8th & 9th December, 2018	
		3	January, 2019	
		4	1st March, 2019 to 2nd March , 2019	Industrial Medicinal Chemistry
4	**Seminars and Workshops**	1	15th May, 2018 to 30th June, 2018	Extraction and Isolation of Phytoconstituents
				Industrial Medicinal Chemistry

*Dates are tentative and may be modified as per convince of experts and participants.

Registration Details for Faculty:

- **Eligibility**: Teachers of AICTE Approved Colleges of Pharmacy.
- **Participants**: Restricted to 30 in number, first come-first served for each batch
- **Accommodation**: Will be on a sharing basis at concessional rates for out of the city participants on or near the campus.
- **Resource Personnel**: Highly experienced & trained clinical pharmacy industry experts.
- **No Registration Fee**
- **Address for Correspondence**: Pharma Office, Dept. of Pharmaceutical Sciences and Technology, Institute of Chemical Technology, N.P. Marg, Matunga (E), Mumbai-19, Maharashtra, phone no: 022 3361 2218
- **Note: Registered participants are expected to conduct elective courses/ certificate course for students in their institute within 1 year of participation**.
- **Recommendation Letter from the Head of the Institution / Department**
  - Click/Copy the link below to download / print recommendation letter. This letter has to be mailed at the above given email address. The same has to be submitted on the first day of the workshop as a hard copy.
  - https://drive.google.com/open?id=1oOnVZj9BTJPMc2Wser-fSAJa6Xv4woQE
- **Registration**
  - Fill this Google form to register. https://goo.gl/forms/NGnCIXONZwvtkNC

- **Apply on / before: 7th November, 23:59 hours for 1st Program**

- Contact Person: Dr. Mariam S. Degani, Professor in Pharmaceutical Chemistry, Head, Dept. of Pharma Sci. & Tech. Institute of Chemical Technology(formerly UDCT), N. P. Marg, Matunga, Mumbai- 400 019 Phone: +9122-233612201/13