Bachelor of Sciences (BSc)- Pharmaceutical Manufacturing and Quality 3 Yrs Degree Program (As per NEP 2020)

	Course Title	Nature	No of Credits	Univ. Exam Theory	Internal Exam Theory	Univ. Exam Practical	Internal Exam Practical	Total Marks
Semester I			**20**					
Technical Courses	Environmental Health and Safety in Pharmaceutical Manufacturing	Theory + Practical	4	60	40	30	20	150
	GMP Compliance for Pharmaceutical Manufacturing	Theory + Practical	4	60	40	30	20	150
Core Courses	General concept of Pharmacology	Theory	3	60	40	-	-	100
	Pharmaceutics	Theory	2	60	40	-	-	100
	Biochemistry	Theory	2	60	40	-	-	100
General Courses	English Language-I	Theory	3	60	40	-	-	100
	Environmental Science	Theory	2	60	40	-	-	100
Semester II			**20**					
Technical Courses	Sterile Manufacturing in Pharma	Theory + Practical	4	60	40	30	20	150
	Pharmaceutical Packaging	Theory+ Practical	4	60	40	30	20	150
Core Courses	Pharmaceutical engineering -I	Theory	3	60	40	-	-	100
	Industrial Microbiology	Theory	2	60	40	-	-	100
	Engineering for Non-engineer	Theory	2	60	40	-	-	100
General Courses	Communication skill	Theory	3	60	40	-	-	100
	Diversity and Inclusion: Sensitivity towards All Genders and People with Disabilities	Theory	2	60	40	-	-	100
Semester III			**20**					
Technical Courses	Production planning	Theory+ Practical	4	60	40	30	20	150
	Pharmaceutical regulatory affair	Theory + Practical	4	60	40	30	20	150
Core Courses	Bioprocess	Theory	2	60	40	-	-	100
	Pharmaceutical engineering -II	Theory	3	60	40	-	-	100
	Pharmaceutical Jurisprudence	Theory	2	60	40	-	-	100
General Courses	Biostatistics	Theory	3	60	40	-	-	100
	Computer Applications In Pharmacy	Theory	2	60	40	-	-	100
Semester IV			**20**					
Technical Courses	Documentation for Production Control and Quality	Theory + Practical	4	60	40	30	20	150
	Complaint Handling and Product Recall	Theory + Practical	4	60	40	30	20	150
	Process Equipment Design	Theory	3	60	40	-	-	100

Core Courses	Pharmaceutical Process Chemistry	Theory	2	60	40	-	-	100
	Water for Pharmaceutical use	Theory	2	60	40	-	-	100
General Courses	Design Thinking	Theory	3	60	40	-	-	100
	Vedic mathematics	Theory	2	60	40	-	-	100
Semester V			**20**					
Technical Courses	In process Quality Assurance Pharmaceutical Manufacturing	Theory + Practical	4	60	40	30	20	150
	Reporting, Review and CAPA management	Theory	4	60	40	-	-	100
Core Courses	Standards of Quality and Auditing	Theory	2	60	40	-	-	100
	Pharmaceutical Statistical	Theory	3	60	40	-	-	100
	Engineering controls for Pharma	Theory	2	60	40	-	-	100
General Courses	Organisational behaviour	Theory	2	60	40	-	-	100
	Indian Health Sciences	Theory	3	60	40	-	-	100
Semester VI			**20**					
	Apprenticeship		20			300	100	400
	Dissertation Viva					60	40	100
Total Marks								500

LFS101- Environmental Health and Safety in Pharmaceutical Manufacturing

Unit 1: Compliance and Hazard Identification
Understanding legislative requirements and company procedures for environment, health, and safety (EHS), including individual responsibilities.
Identification and reporting of workplace hazards in pharmaceutical manufacturing, with emphasis on timely reporting protocols.

Unit 2: Emergency Preparedness and Response
Comprehensive explanation of emergency procedures for various scenarios, such as fire, chemical spills, and medical emergencies.
Detailed evacuation procedures for employees, contract staff, and visitors to ensure swift and safe evacuation during emergencies.

Unit 3: Hygiene, Cleaning, and Sanitation Practices
Importance of maintaining high levels of hygiene standards in the production area and adherence to GMP and WHO guidelines.
Methods, materials, and checks required for cleaning various surfaces and equipment in pharmaceutical manufacturing, along with waste disposal guidelines.

Unit 4: Sterilization and Water Purification
Equipment Cleaning, Sterilization in Pharmaceutical Manufacturing, Microbial Control of Pharmaceuticals, Test of Sterility, Guidelines and Standard Organization for Microbial Control, Sterilization in Hygiene practice, Trace level impurity analysis, pyrogen and endotoxin level determination.

Purification of Water, Portability of Water, Removal of Course Disperse and Colloidal Impurity in Water, Sterilization and Disinfection of Water, Chemical Methods Of Sterilization of Water, Physical Methods of Sterilization of Water, Softening of Water.

Practical:

- Demonstrate how to perform hazard identification and reporting
- Demonstrate emergency procedures for fire, chemical spills, and medical emergencies.
- Demonstrate how to use different types of safety gears by following the procedures to use them.
- Demonstrate cleaning procedures for different surfaces and equipment in industries
- Perform trace level impurity analysis and sterility testing
- Demonstrate steps for water purification and softening methods

Reference Book:

- Industrial Hygiene & Chemical Safety", M. H. Fulekar, I.K. International Publishing House Pvt. Ltd, New Delhi.
- Prudent practices of handling of Hazardous chemicals in Laboratory, NRC, USA 7th Printing
- Chemical Process Safety, Roy E Sanders, 3rd Edition
- Industrial Safety And Health Management, C Ray Asfahl, 6th Edition
- Industrial Safety & environment, A K Gupta, 2nd Edition
- Industrial Safety Management, Shailander Umesh

LFS102- GMP Compliance for Pharmaceutical Manufacturing

Unit 1: Regulatory Guidelines and Operational Procedures

- Definition, Importance, General requirements of GM, GMP Categories, Key quality terms, Good Documentation Practice, GMP,GXP and validation for pharmaceuticals, Schedule M (M-1, M2, M3), Schedule T
- Understanding WHO regulations and Good Manufacturing Practices (GMP) pertaining to machine operations, machine maintenance, material handling and storage within pharmaceutical manufacturing facilities.
- Good documentation practices, WHO regulations and ICH-GMP guidelines for proper documentation practices, Importance of the ALCOA+ principle in maintaining data integrity and regulatory compliance.

Unit 2: Compliance Standards in Production Area Management

- Establishing and maintaining standard environmental conditions in compliance with regulatory standards.
- Developing and implementing Standard Operating Procedures (SOPs) for controlled entry and exit from GMP areas.
- Maintaining high levels of hygiene standards in the production area and enforcing compliance measures.
- Executing thorough cleaning protocols for various surfaces and equipment to meet regulatory requirements.
- Utilizing approved equipment, materials, and chemicals for cleaning and sanitation, as per regulatory guidelines.

Unit 3: Waste Management and Disposal Compliance

- Adhering to WHO regulations and GMP guidelines for the proper management of pharmaceutical waste.
- Implementing standard procedures for the segregation, handling, and disposal of waste materials.
- Ensuring compliance with waste disposal guidelines as stipulated by WHO, GLP/GMP, and organizational SOPs.
- Understanding the importance of cleaning validation in waste management practices and regulatory compliance.
- Integrating Good Manufacturing Practices and WHO guidelines into waste management processes for comprehensive compliance.

Unit 4: Regulatory Compliance in Machine Operations and Maintenance

- Following machine operations manuals and troubleshooting guidelines to ensure compliance.
- Adhering to WHO regulations and ICH-GMP guidelines for routine maintenance and calibration of machinery.
- Maintaining meticulous records and documentation in accordance with Good Documentation Practices and regulatory requirements.
- Recognizing the critical role of proper machine maintenance in upholding product quality and regulatory compliance.
- Implementing strategies to optimize machine operations while meeting regulatory standards and guidelines.

Practical:

- Demonstrate how to maintain accurate records following Good Documentation Practices (GDP) adhering to WHO and ICH-GMP guidelines.

- Demonstrate compliance with Schedule M (M-1, M-2, M-3) and Schedule T through practical applications and mock audits.
- Create and enforce Standard Operating Procedures (SOPs) for controlled entry and exit from GMP areas (stimulated College labs).
- Demonstrate standard procedures for the segregation, handling, and disposal of pharmaceutical waste in compliance with WHO regulations and GMP guidelines.
- Perform mock routine maintenance and calibration of machinery according to WHO regulations and ICH-GMP guidelines.
- Demonstrate how to maintain records and documentation of machine operations and maintenance activities as per GDP and regulatory requirements.

Recommended Book:

Pharmaceutical Manufacturing Handbook: Production and Processes, Shayne Cox Gad

LFS103-General Concepts of Pharmacology

UNIT 1: Pharmacokinetics

Absorption, Distribution, Metabolism and Excretion (ADME) of drugs, Biotransformation ,PK-PD correlations

UNIT 2: Pharmacodynamics

- Mechanism of drug action
- Receptors
- Transduction process
- Second messengers
- Dose response relationship

UNIT 3: Special Topics

- Adverse drug reactions (ADRs)
- Pharmacovigilance
- Drug interactions
- Therapeutic Drug Monitoring

UNIT 4: Autonomic Nervous System

- General concepts- neurohumoral transmission, neurotransmitters
- Cholinergic pharmacology
- Adrenergic pharmacology

Reference Book:

- The Pharmacological Basis of Therapeutics, Goodman and Gillman‘s
- Principles of Pharmacology. The Pathophysiologic basis of drug Therapyby David E Golan, Armen H, Tashjian Jr, EhrinJ, Armstrong, April W, Armstrong, Wolters, KluwerLippincott Williams & Wilkins Publishers
- Shargel and Leon. Applied Biopharmaceutics and pharmacokinetics. Latest edition. Publisher:Prentice Hall, London.

LFS104-Pharmaceutics

Unit 1: History of the pharmaceutical industry

Basic structure, layout, sections, and activities of pharmaceutical manufacturing plants, and various professional associations. Pharmacopoeia: Introduction to IP, BP, USP, NF and Extra Pharmacopoeia. Salient features of Indian Pharmacopoeia

Unit 2 : Pharmaceutical Aids

Organoleptic (Colouring, flavouring, and sweetening) agents, Organoleptic Agents: Importance in enhancing palatability and patient compliance, Regulatory considerations and safety concerns, Preservatives: Definition and role in preventing microbial contamination, Types (e.g., antimicrobial, antioxidant) with examples and functions, Application in various dosage forms and regulatory guidelines

Unit 3 : Unit Operations in pharmaceutical manufacturing

Definition, objectives importance of :

- Size reduction: hammer mill and ball mill
- Size separation: Classification of powders according to IP, Cyclone separator, Sieves and standards of sieves,
- Mixing: Double cone blender, Turbine mixer, Triple roller mill and Silverson mixer homogenizer,
- Filtration: Theory of filtration, membrane filter and sintered glass filter,
- Drying: working of fluidized bed dryer and process of freeze drying,
- Extraction: Definition, Classification, method, and applications

Unit 4: Pharmaceutical Dosage Forms

Tablets – coated and uncoated, various modified tablets (sustained release, extended-release, fast dissolving, multilayered, etc.), Capsules - hard and soft gelatine capsules , Liquid oral preparations - solution, syrup, elixir, emulsion, suspension, dry powder for reconstitution, Topical preparations - ointments, creams, pastes, gels, liniments and lotions, suppositories, and pessaries, Nasal preparations, Ear preparations , Powders and granules - Insuflations, dusting powders, effervescent powders, and effervescent granules , Sterile formulations – Injectables, eye drops and eye ointments Immunological products: Sera, vaccines, toxoids, and their manufacturing methods.

Unit 5:

Packaging materials: Types- Glass, plastic, metal, and rubber packaging materials ,Properties, suitability, and applications in pharmaceutical packaging, selection criteria - Factors influencing the choice of packaging material, Compatibility with drug formulations and regulatory requirements, Cost-effectiveness and ease of handling, advantages and disadvantages of glass, plastic, metal, rubber as packaging materials

LFS105- Biochemistry

Unit 1:

Biomolecules: Introduction, classification, chemical nature and biological role of carbohydrate, lipids, nucleic acids, amino acids and proteins.

Bioenergetics: Concept of free energy, endergonic and exergonic reaction, Relationship between free energy, enthalpy and entropy; Redox potential. Energy rich compounds; classification; biological significances of ATP and cyclic AMP

Unit 2:

Carbohydrate metabolism : Glycolysis – Pathway, energetics and significance, Citric acid cycle- Pathway, energetics and significance, HMP shunt and its significance; Glucose-6-Phosphate dehydrogenase (G6PD) deficiency ,Glycogen metabolism Pathways and glycogen storage diseases (GSD), Gluconeogenesis- Pathway and its significance, Hormonal regulation of blood glucose level and Diabetes mellitus

Biological oxidation: Electron transport chain (ETC) and its mechanism, Oxidative phosphorylation & its mechanism and substrate phosphorylation, Inhibitors ETC and oxidative phosphorylation/Uncouplers

Unit 3:

Lipid metabolism: β-Oxidation of saturated fatty acid (Palmitic acid), Formation and utilization of ketone bodies; ketoacidosis , De novo synthesis of fatty acids (Palmitic acid) , Biological significance of cholesterol and conversion of cholesterol into bile acids, steroid hormone and vitamin D, Disorders of lipid metabolism: Hypercholesterolemia, atherosclerosis, fatty liver and obesity.

Amino acid metabolism: General reactions of amino acid metabolism: Transamination, deamination & decarboxylation, urea cycle and its disorders, Catabolism of phenylalanine and tyrosine and their metabolic disorders (Phenyketonuria, Albinism, alkeptonuria, tyrosinemia), Synthesis and significance of biological substances; 5-HT, melatonin, dopamine, noradrenaline, adrenaline, Catabolism of heme; hyperbilirubinemia and jaundice

Unit 4

Nucleic acid metabolism and genetic information transfer, Biosynthesis of purine and pyrimidine nucleotides, Catabolism of purine nucleotides and Hyperuricemia and Gout disease, Organization of mammalian genome, Structure of DNA and RNA and their functions , DNA replication (semi conservative model) Transcription or RNA synthesis ,Genetic code, Translation or Protein synthesis and inhibitors

Unit 5

Enzymes Introduction, properties, nomenclature and IUB classification of enzymes ,Enzyme kinetics (Michaelis plot, Line Weaver Burke plot), Enzyme inhibitors with examples ,Regulation of enzymes: enzyme induction and repression, allosteric enzymes regulation , Therapeutic and diagnostic applications of enzymes and isoenzymes, Coenzymes –Structure and biochemical functions

LFS106- English Language

UNIT 1 Vocabulary Enhancement

Synonyms, Antonyms, Prefixes and suffixes. Understanding the proper way of letter writing. Comprehension, Passage reading and question answer handling. Noun, Verb, Adjective. Construction of sentences and passages with proper grammar.

UNIT 2 Spelling and Punctuation/ Spelling Pitfalls, Grammar Revisited

Review of parts of speech. Proper pronunciation from language lab. Hearing fluent English and identifying and answering questions. Understanding the proper way to utilize punctuation and spelling Pitfalls.

UNIT 3 Functional English

Language functions: descriptive, expressive and social, Types of language functions: to inform, enquire, attract, influence, regulate and entertain. Understanding the importance of communication. Communication in an organization. Types of communication

UNIT 4 Reading Skills

Strategies for developing reading skills, Skimming and scanning, Predicting, Inferring, Reading critically. Reading passages , comprehension and letters. Reading with proper pronunciation. Book reading , Shakespearian Literature reading. Reading silently, sub-vocalization, Reading at speeds of at least 250 words per minute, Inferring meaning or content after reading the heading , Guessing meaning of unfamiliar words from context, Identifying the central idea as well as supporting ideas, Spelling pitfalls, Preparing notes in diagrammatic form after reading a text, showing the central idea and supporting ideas and the relationships between them.

Reference Book:

- Scot Ober, Contemporary business communication, fifth edition, biztantra.
- Lesiler &Flat lay, Basic Business communication. Tata McGraw Hill.

LFS107- Environmental Science

Unit 1: The Environment and Ecosystem

- Environment and Environmental studies: Definition, concept, components and importance.
- Ecosystem and Ecology: Structure and Function of ecosystem, Brief concept of Autecology and Synecology.
- Food chain, food web and ecological pyramids.
- Biogeochemical cycles in an ecosystems: (Carbon, Nitrogen and Phosphorous cycle)
- Ecological succession: Definition, types, concept and process (Hydrosere, Xerosere and Lithosere).

Unit 2 Environmental Pollution and Disaster Management

- Definition , causes, effects and control measures of : a. Air pollution b. Water pollution(thermal and marine pollution) c. Land pollution d. Radiation pollution and Nuclear hazard. e. Noise pollution
- Solid waste management: Causes , effects and control measures.
- Global warming and climate change Ozone depletion
- Acid rain: Causes , effects and control measures
- Types and management of Natural disasters (Earthquakes; Droughts; Floods; Landslides).

Unit 3: Environmental treaties, laws and Ethics

- Environmental Treaties : National and International(Brief account)
- Salient features of following Acts:
    a. Wildlife (Protection) Act, 1972.
    b. Water (Prevention and control of pollution) Act, 1974.
    c. Forest (Conservation) Act, 1980.
    d. Air (Prevention and control of pollution) Act, 1981.
    e. Environmental Protection Act, 1986.
- National Green Tribunal: Structure, composition and functions.
- Environmental Ethics
- Need for Sustainable Development. Field /Practical Work All the students are required to undertake the following field/practical work
    i. Visit to a local area to document environmental assets/ ecosystems River/ forest/ grassland/ mountain
    ii. Construction of Food chain/food web of the visited area
    iii. To identify the sources of air/water/soil/noise pollution of your area.

Unit- 4: Environment and Human health

- Human population growth and Family Welfare Programs.
- Common diseases: Air borne diseases (Chicken Pox, Tuberculosis, Influenza, Meningitis), Water and food borne diseases (Cholera, Diarrhoea, Hepatitis, Malaria, Salmonellosis).
- HIV/AIDS: Symptoms, causes, effect and control measures.
- Drug addiction: Causes, symptoms and prevention; Drug abuse in India.
- Role of IT in environment and human health

Reference Book:

- Basu, M. and Xavier, S.,Fundamentals of Environmental Studies, Cambridge University Press, 2016.
- Mitra, A. K and Chakraborty, R., Introduction to Environmental Studies, Book Syndicate, 2016.
- Enger, E. and Smith, B., Environmental Science: A Study of Interrelationships, Publisher: McGraw-Hill Higher Education; 12th edition, 2010.
- Basu, R.N, Environment, University of Calcutta, 2000.

LFS201- Sterile Manufacturing in Pharma

Unit 1: Control and Handling of Raw Materials, Containers, and Closures

- Overview of the role of machine operators in controlling and handling raw materials, containers, and closures.
- Techniques for inspecting and verifying the quality of raw materials, containers, and closures before use.
- Safe and efficient handling practices to prevent contamination and ensure product quality.

Unit 2: Sterile Intermediate Products: Handling and Monitoring

- Understanding the importance of maintaining sterility when handling intermediate products.
- Procedures for loading, unloading, and monitoring sterile intermediate products in manufacturing machines.
- Identifying and responding to potential contamination risks during machine operations.

Unit 3: Equipment Operation and Environmental Monitoring

- Operating pharmaceutical manufacturing equipment effectively and safely.
- Monitoring environmental conditions within manufacturing areas to ensure product integrity.
- Responding to environmental deviations and maintaining cleanliness standards during machine operation.

Unit 4: Maintenance and Troubleshooting of Manufacturing Equipment

- Performing routine maintenance tasks to ensure the smooth operation of manufacturing equipment.
- Troubleshooting common issues encountered during machine operation.
- Collaboration with maintenance teams and reporting equipment malfunctions promptly.
- Accurate documentation and compliance with regulatory requirements in sterile manufacturing operation

Practical :

- Demonstrate various techniques for inspecting and verifying the quality of raw materials, containers, and closures before use, using real or mock samples.
- Demonstrate the sanitization and gowning procedures as per clean room guidelines.
- Demonstrate the use of PPE during sterile formulation manufacturing operations.
- Identify and respond to potential contamination risks during machine operations through simulations and problem-solving exercises.
- Demonstrate how to operate reactor and utilities (Steam/ WPU/ Gases) in the correct pattern as per the batch record and SOP.
- Demonstrate how to perform accurate documentation and compliance with regulatory requirements in sterile manufacturing operations, practicing with mock documentation forms.

LFS202- Pharmaceutical Packaging

Unit 1 Introduction to Pharmaceutical Packaging

Pack function, hazards, users, compliance, environmental issues, overall requirements and definitions, Packaging Development - Material & pack testing, test method selection, properties vs. performance, specifications, product stability, shelf life, line trials, Types of packaging systems, Ideal requirements of pharmaceutical packaging materials

Unit 2 Selection of package types and packaging materials & closures

Criteria for selection of package types and packaging materials. Packaging and labeling controls, line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment.

Unit 3 Types of Packaging materials & closures

Package Types and Advantages of the packaging materials ie. Glass, Plastic, Metals, Paper and Board, Rubber, Cotton, Adhesives and Inks, Closure

Unit 4 Packaging evaluation, Dosage forms and package forms

Suitability testing and Quality Control, Dosage form condition, Route of delivery, Possible package form, Packaging of Medical / Surgical Device, Evaluation of Medical Device Packages

Unit 5 Regulatory aspects of Pharmaceutical packaging

Product recalls, Faulty packaging and labelling, Testing protocol for packaging for different pharmaceutical dosage forms, Quality specification of packaging by WHO.

Practical:

- Demonstrate how to identify and analyze the function and potential hazards associated with pharmaceutical packaging.
- Perform the visual inspection of the packaging material/ containers/ bottles for the desired quality, contamination/bloom and leakage/ tampering.
- Demonstrate the operating procedures for filling, packaging, printing and labeling machines as per SOP.
- Demonstrate the use of appropriate measuring instruments, equipment, tools for carrying out in-process checks.
- Demonstrate how to perform line clearance supporting activities before the next batch is processed for packaging

Reference Book:

- Pharmaceutical Packaging Technology, U K Jain (Author), D. C. Goupale (Author), S. Nayak (Author)
- Pharmaceutical Packaging Handbook, Edward Bauer
- Quality Control of Packaging Materials in the Pharmaceutical Industry, Kenneth Harburn
- Pharmaceutical Packaging Technology, D. A. Dean, E. R. Evans, I. H. Hall
- Packaging of Pharmaceuticals and Healthcare Products, H. Lockhart, Frank A. Paine

LFS203-Pharmaceutical Engineering-I

Unit 1 Size Reduction

Objectives, Mechanisms & Laws governing size reduction, factors affecting size reduction, principles, construction, working, uses, merits and demerits of Hammer mill, ball mill.

Unit 2 Size Separation

Objectives, applications & mechanism of size separation, official standards of powders, sieves, size separation Principles, construction, working, uses, merits and demerits of Sieve shaker, cyclone separator.

Unit 3 Evaporation

Objectives, applications and factors influencing evaporation, differences between evaporation and other heat process. principles, construction, working, uses, merits and demerits of Steam jacketed kettle, horizontal tube evaporator.

Unit 4 Distillation

Basic Principles and methodology of simple distillation, flash distillation, fractional distillation, distillation under reduced pressure, steam distillation & molecular distillation

Unit 5 Drying

Objectives, applications & mechanism of drying process, measurements & applications of Equilibrium Moisture content, rate of drying curve, principles, construction, working, uses, merits and demerits of Tray dryer, spray dryer, fluidized bed dryer.

Reference Book:

- Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
- Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
- Unit operation of chemical engineering – Mcabe Smith, Latest edition.
- Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
- Remington practice of pharmacy- Martin, Latest edition.
- Theory and practice of industrial pharmacy by Lachmann., Latest edition.
- Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
- Cooper and Gunn’s Tutorial pharmacy, S.J. Carter, Latest edition.

LFS204- Industrial Microbiology

Unit 1. Exploitation of microorganisms and their products, screening, strain development strategies, immobilization methods, fermentation media, raw material used in media production, antifoaming agents, buffers, downstream processing.

Unit 2. Fermentation equipment and its uses, fermentor design, Types of fermentors and fermentations- single, batch, continuous, multiple, surface, submerged and solid state.

Unit 3. Industrial products from microorganisms- antibiotics: production of penicillin, streptomycin. Interferons, vaccines, hormones, vitamins.

Unit 4. Enzymes from microbes: amylase, protease. Organic acids: citric acid, acetic acid, amino acids: glutamic acid, lysine.

Unit 5. Production of alcoholic beverages: bear and wine, biofuels: ethanol, methane, biogas.

Reference Book:

Patel, A.H.: Industrial Microbiology, McMillan India.
Pelczar, M.J., Chan, E.C.S. & Krieg, N.R.: Microbiology, Tata Mc Graw-Hill Publishing Company Limited, New Delhi.

LFS-205 Engineering for Non-engineer

Unit 1: Basics and Principles of Pharmaceutical Engineering

- Overview of pharmaceutical engineering and its significance in the pharmaceutical industry.
- Introduction to engineering principles and terminology relevant to pharmaceutical manufacturing.
- Understanding the role of engineering in ensuring compliance with Good Manufacturing Practices (GMP) and regulatory requirements.
- Basic concepts of Process and Instrumentation Diagrams (P&IDs) and their importance in pharmaceutical operations.

Unit 2: Clean Room Design and Qualification

- Principles of clean room design, including walls, ceiling, and floor materials.
- Comparison of different types of clean room wall systems and their suitability for pharmaceutical applications.
- GMP criteria for clean room walls and ceilings, and qualification tests for ensuring compliance.
- Examples and case studies illustrating successful clean room qualification processes in pharmaceutical facilities.

Unit 3: Engineering Impact on GMP Compliance

- Understanding the regulatory expectations for engineering in pharmaceutical manufacturing.
- Role of engineering in designing GMP facilities and equipment to meet regulatory standards.
- Fundamentals of engineering in HVAC (Heating, Ventilation, and Air Conditioning), water treatment, and utilities management.
- Importance of engineering in GMP maintenance, including instrument calibration, preventive maintenance, and change control.

Unit 4: GMP Audit Preparation and Compliance

- Points to consider during a GMP audit, including inspection by wandering around and examination of documents.
- Strategies for preparing for and successfully navigating a GMP audit in pharmaceutical facilities.
- Examples and categorization of audit findings, including minor, major, and critical observations.
- Importance of avoiding critical and major findings through proactive engineering and GMP compliance measures.

LFS206- Communication Skills

Unit - 1

Communication Skills: Introduction, Definition, The Importance of Communication, The Communication Process – Source, Message, Encoding, Channel, Decoding, Receiver, Feedback, Context

Barriers to communication: Physiological Barriers, Physical Barriers, Cultural Barriers, Language Barriers, Gender Barriers, Interpersonal Barriers, Psychological Barriers, Emotional barriers Perspectives in Communication: Introduction, Visual Perception, Language, Other factors affecting our perspective - Past Experiences, Prejudices, Feelings, Environment

Unit– 2

Elements of Communication: Introduction, Face to Face Communication - Tone of Voice, Body Language (Non-verbal communication), Verbal Communication, Physical Communication

Communication Styles: Introduction, The Communication Styles Matrix with example for each -Direct Communication Style, Spirited Communication Style, Systematic Communication Style, Considerate Communication Style

Unit – 3

Basic Listening Skills: Introduction, Self-Awareness, Active Listening, Becoming anActive Listener, Listening in Difficult Situations

Effective Written Communication: Introduction, When and When Not to Use Written Communication - Complexity of the Topic, Amount of Discussion' Required, Shades of Meaning, Formal Communication

Writing Effectively: Subject Lines, Put the Main Point First, Know Your Audience, Organization of the

Message

Unit – 4

Interview Skills: Purpose of an interview, Do's and Dont's of an interview

Giving Presentations: Dealing with Fears, Planning your Presentation, Structuring Your Presentation, Delivering Your Presentation, Techniques of Delivery

Unit- 5:

Group Discussion: Introduction, Communication skills in group discussion, Do's andDont's of group discussion

Reference Book:

- Basic communication skills for Technology, Andreja. J. Ruther Ford, 2nd Edition, Pearson Education, 2011
- Communication skills, Sanjay Kumar, Pushpalata, 1st Edition, Oxford Press, 2011
- Organizational Behaviour, Stephen .P. Robbins, 1st Edition, Pearson, 2013
- Brilliant- Communication skills, Gill Hasson, 1st Edition, Pearson Life, 2011
- The Ace of Soft Skills: Attitude, Communication and Etiquette for success, Gopala Swamy Ramesh, 5th Edition, Pearson, 2013
- Developing your influencing skills, Deborah Dalley, Lois Burton, Margaret, Green hall, 1st Edition Universe of Learning LTD, 2010
- Communication skills for professionals, Konar nira, 2nd Edition, New arrivals – PHI, 2011

- Personality development and soft skills, Barun K Mitra, 1st Edition, Oxford Press, 2011
- Soft skill for everyone, Butter Field, 1st Edition, Cengage Learning india pvt.ltd, 2011
- Soft skills and professional communication, Francis Peters SJ, 1st Edition, Mc Graw Hill Education, 2011
- Effective communication, John Adair, 4th Edition, Pan Mac Millan,2009
- Bringing out the best in people, Aubrey Daniels, 2nd Edition, Mc Graw Hill, 1999

LFS207 - Diversity and Inclusion: Sensitivity towards All Genders and People with Disabilities

Unit 1: Understanding Gender Sensitivity in the Workplace

- Overview of the Sexual Harassment of Women at Workplace (Prevention, Prohibition, and Redressal) Act
- Penalties for Violating the Act: Legal Consequences of Sexual Harassment
- Importance of Gender-Sensitive Behavior: Creating Safe and Inclusive WorkEnvironments

Unit 2: Promoting Equal Opportunity Work Culture

- Procedure to Report Inappropriate Behavior: Steps for Reporting Sexual Harassment and Seeking Redressal
- Significance of an Equal Opportunity Work Culture: Fostering Fairness, Respect, and Diversity
- Respecting Others' Cultures, Religions, and Castes: Embracing Diversity in theWorkplace

Unit 3: Sensitivity towards People with Disabilities

- Understanding the Importance of Sensitivity towards People with Disabilities
- Communication and Collaboration with People with Disabilities: Legal Framework and Best Practices
- Identifying and Challenging Stereotypes and Prejudices: Promoting Inclusion and Empowerment

Unit 4: Promoting Inclusive Practices for People with Disabilities

- Importance of Accessible Communication and Collaboration: Ensuring Inclusivity for All
- Breaking Down Barriers: Creating Supportive Environments for People with Disabilities
- Consequences of Stereotypes and Prejudices: Understanding the Harm and Promoting Change

Reference Book:

- Handbook of Research on Workforce Diversity in a Global Society, edited by Scott, Chaunda L.
- Diversity in the Workforce: Current Issues and Emerging Trendsedited by Marilyn Y. Byrd, Chaunda L. Scott

LFS301- Production planning

Unit 1: Introduction to Sterile Pharmaceutical Production Planning

- Overview of sterile pharmaceutical production planning and its importance in ensuring product quality and safety.
- Understanding the regulatory requirements and industry standards governing sterile manufacturing processes.
- Role of production planning in optimizing resource utilization, minimizing production costs, and meeting market demands.
- Introduction to key concepts such as batch sizing, production scheduling, and capacity planning in sterile pharmaceutical manufacturing.

Unit 2: Facility Design and Layout for Sterile Manufacturing

- Principles of facility design and layout specific to sterile pharmaceutical manufacturing.
- Considerations for cleanroom design, including HVAC systems, air filtration, and environmental monitoring.
- Layout planning for equipment, utilities, and personnel flow to maintain sterility and optimize workflow efficiency.
- Importance of ergonomic design and space utilization in sterile manufacturing facilities.

Unit 3: Material Management and Inventory Control

- Strategies for effective material management and inventory control in sterile pharmaceutical production.
- Techniques for managing raw materials, packaging materials, and consumables to ensure continuous production flow.
- Implementation of inventory control systems, including just-in-time (JIT) inventory management and vendor-managed inventory (VMI).
- Role of automation and technology in streamlining material handling processes and minimizing inventory waste.

Unit 4: Production Scheduling and Batch Release

- Principles of production scheduling in sterile pharmaceutical manufacturing.
- Techniques for creating production schedules based on demand forecasting, capacity constraints, and lead times.
- Importance of batch release procedures in ensuring product quality and compliance with regulatory requirements.
- Implementation of batch release protocols, including in-process testing, quality assurance checks, and documentation review.

Practical:

- Demonstrate through role-playing activities to simulate production planning scenarios, focusing on optimizing resource utilization and minimizing production costs.
- Design a cleanroom layout considering HVAC systems, air filtration, and environmental monitoring.
- Develop strategies for effective material management and inventory control specific to sterile pharmaceutical production.
- Create detailed production schedules based on demand forecasting, capacity constraints, and lead times.

- Develop and implement batch release protocols, including in-process testing, quality assurance checks, and documentation review.

LFS 302 Pharmaceutical regulatory affair

Unit 1: Essential Documentation in Pharmaceutical Production

- Overview of crucial documentation in pharmaceutical production, focusing on Master Formula Records (MFRs), Drug Master Files (DMFs), and distribution records.
- Understanding the pivotal role of each type of documentation in ensuring product quality, safety, and adherence to regulatory standards.
- Best practices for maintaining accurate and up-to-date documentation throughout the production process to support regulatory submissions, inspections, and post-marketing surveillance.
- Importance of documentation in facilitating effective communication and collaboration among production teams, regulatory authorities, and other stakeholders.

Unit 2: Regulatory Pathways for Generic Drug Development

- Introduction to generic drug product development and the regulatory landscape governing generic drugs, particularly in the United States.
- Overview of the Hatch-Waxman Act and its amendments, including provisions for Abbreviated New Drug Applications (ANDAs) and the role of bioequivalence (BE) studies.
- Understanding the relevant sections of the Code of Federal Regulations (CFR) governing generic drug development and regulatory approval processes.
- Regulatory requirements and procedures for ANDA approval, emphasizing the importance of comprehensive documentation and adherence to regulatory standards.

Unit 3: Regulatory Pathways for Product Approval

- Overview of regulatory pathways for various pharmaceutical products, including Active Pharmaceutical Ingredients (APIs), biologics, and novel therapies.
- Understanding the processes and requirements for obtaining New Drug Applications (NDAs) for novel drugs and ANDAs for generic drugs.
- Regulatory considerations for scale-up processes, approval changes, and post-marketing surveillance activities to ensure ongoing compliance and product safety.
- Outsourcing bioavailability (BA) and bioequivalence (BE) studies to Contract Research Organizations (CROs) and the regulatory implications associated with such partnerships.

Unit 4: International Regulatory Frameworks and Compliance

- Overview of global regulatory requirements and submission formats, with a focus on the Common Technical Document (CTD) and Electronic Common Technical Document (eCTD).
- Understanding the importance of industry and FDA liaison processes for effective communication and collaboration on regulatory matters.
- Introduction to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, including Quality (Q), Safety (S), and Efficacy (E) guidelines.

- Exploring regulatory requirements in other regions, including the European Union (EU), Medicines and Healthcare products Regulatory Agency (MHRA), Therapeutic Goods Administration (TGA), and rest of the world (ROW) countries, to ensure global compliance and market access.

Practical :

- Simulate scenarios demonstrating the role of documentation in ensuring product quality, safety, and regulatory compliance.
- Analyze case studies on the regulatory landscape for generic drugs, focusing on the Hatch-Waxman Act and Abbreviated New Drug Applications (ANDAs).
- Develop regulatory strategies for obtaining New Drug Applications (NDAs) and ANDAs for various pharmaceutical products.
- Develop submission formats for the Common Technical Document (CTD) and Electronic Common Technical Document (eCTD).
- Perform practical exercises on regulatory considerations for scale-up processes and approval changes.

LFS303- Bioprocess

Unit 1 : Introduction to fermentation technology

Basic principles of fermentation, Study of the design and operation of bioreactor, Ancillary parts and function, impeller design and agitation, power requirements on measurements and control of dissolved oxygen, carbon dioxide, temperature, pH and foam. Types of bioreactor CSTR, tower, airlift, bubble column, packed glass bead, hollow fiber, configuration and application Computer control of fermentation process System configuration and application

Unit 2: Mass transfer

Mass transfer Theory, diffusional resistance to oxygen requirements of microorganisms, measurements of mass transfer co- efficient and factor affecting them, effects of aeration and agitation on mass transfer, supply of air, air compressing, cleaning and sterilization of air and plenum ventilation, air sampling and testing standards for air purity.

Rheology Rheological properties of fermentation system and their importance in bioprocessing.

Unit 3 Scale up of fermentation process

Principles, theoretical considerations, techniques used, media for fermentation, HTST sterilization, advantage and disadvantage, liquid sterilization. Cultivation and immobilized culture system, Cultivation system - batch culture, continuous culture, synchronous cultures, fed batch culture. Graphical plot representing the above systems. Introduction to immobilization Techniques, immobilization of whole cell, immobilized culture system to prepare fine chemicals. Immobilization of enzymes and their applications in the industry. Reactors for immobilized systems and perspective of enzyme engineering.

Unit 4 Scale down of fermentation process

Theory, equipment design and operation, methods of filtration, solvent extraction, chromatographic separation, crystallization turbidity analysis and cell yield determination, metabolic response assay, enzymatic assay, bioautographic techniques and disruption of cells for product recovery. Isolation and screening Primary and secondary, maintenance of stock culture, strain improvement for increased yield. 12 Hrs

Unit 5 Bioprocessing of the industrially important microbial metabolites

a) Organic solvents – Alcohol and Glycerol
b) Organic acids - Citric acids, Lactic acids,
c) Amino acids - Glutamic acids, Lysine, Cyclic AMP and GMP
d) Antibiotics - Penicillin, Streptomycin, Griseofulvin,
e) Vitamins - B12, Riboflavin and Vitamin C

Biosynthetic pathways for some secondary metabolites, microbial transformation of steroids and alkaloids Regulation governing the manufacturing of biological products

Reference Book:

- Principles of Fermentation technology - Peter Stanbury, Allan Whitaker & Stephen Hall. Elsevier.
- Industrial Microbiology - L.E. Casida. John Wiley & Sons.
- Current protocols in Molecular Biology - F.M. Asubel. Vol 1 & 2. John Wiley Publishers.
- Bioreactor Design and Product Yield - Biotol Board. Butterworth and Helhemann Publishers.
- Industrial Microbiology - H. Patel. Macmillan India Limited.
- Atkinson, B. (2002), Reactores Bioquímicos, Reverté (Barcelona).
- Doran, P.M. (2010), Bioprocess Engineering Principles, Academic Press (Londres).
- Shuler, M.L. y Kargi, F. (2002), Bioprocess Engineering, Prentice Hall, Upper Saddle River, NJ, EE.UU.

LFS304- Pharmaceutical engineering -II

Unit 1 Mixing

Objectives, applications & factors affecting mixing, Difference between solid and liquid mixing, mechanism of solid mixing, liquids mixing and semisolids mixing. Principles, Construction, Working, uses, Merits and Demerits of Double cone blender, ribbon blender

Unit 2 Filtration

Objectives, applications, Theories & Factors influencing filtration, filter aids, filter medias. Principle, Construction, Working, Uses, Merits and demerits of plate & frame filter, rotary drum filter.

Unit 3 Centrifugation

Objectives, principle & applications of Centrifugation, principles, construction, working, uses, merits and demerits of Perforated basket centrifuge, Non-perforated basket centrifuge.

Unit 4 Materials of pharmaceutical plant construction, Corrosion and its prevention:

Factors affecting materials during selection for Pharmaceutical plant construction, Theories of corrosion, types of corrosion and there prevention. Ferrous and nonferrous metals, inorganic and organic non-metals, basic of material handling systems.

Unit 5 Pharmaceutical equipment's

List of equipment's used in manufacturing of various dosage forms, Functions and Mechanisms of the equipment

Reference Book:

- Introduction to chemical engineering – Walter L Badger & Julius Banchero, Latest edition.
- Solid phase extraction, Principles, techniques and applications by Nigel J.K. Simpson- Latest edition.
- Unit operation of chemical engineering – Mcabe Smith, Latest edition.
- Pharmaceutical engineering principles and practices – C.V.S Subrahmanyam et al., Latest edition.
- Remington practice of pharmacy- Martin, Latest edition.
- Theory and practice of industrial pharmacy by Lachmann., Latest edition.
- Physical pharmaceutics- C.V.S Subrahmanyam et al., Latest edition.
- Cooper and Gunn's Tutorial pharmacy, S.J. Carter, Latest edition.

LFS305- Pharmaceutical Jurisprudence

Unit 1 Drugs and Cosmetics Act, 1940 and its rules 1945

Drugs and Cosmetics Act, 1940 and its rules 1945: Objectives, Definitions, Legal definitions of schedules to the Act and Rules Import of drugs – Classes of drugs and cosmetics prohibited from import, Import under license or permit. Offences and penalties. Manufacture of drugs – Prohibition of manufacture and sale of certain drugs, Conditions for grant of license and conditions of license for manufacture of drugs, Manufacture of drugs for test, examination and analysis, manufacture of new drug, loan license and repacking license.

UNIT-2 Various regulation

Drugs and Cosmetics Act, 1940 and its rules 1945. Detailed study of Schedule G, H, M, N, P,T,U, V, X, Y, Part XII B, Sch F & DMR (OA) Sale of Drugs – Wholesale, Retail sale and Restricted license. Offences and penalties Labeling & Packing of drugs- General labeling requirements and specimen labels for drugs and cosmetics, List of permitted colors. Offences and penalties. Administration of the Act and Rules – Drugs Technical Advisory Board, Central drugs Laboratory, Drugs Consultative Committee, Government drug analysts, Licensing authorities, controlling authorities, Drugs Inspectors

UNIT-3 Various Act related to Pharma

- Pharmacy Act –1948: Objectives, Definitions, Pharmacy Council of India; its constitution and functions, Education Regulations, State and Joint state pharmacy councils; constitution and functions, Registration of Pharmacists, Offences and 122 Penalties
- Medicinal and Toilet Preparation Act –1955: Objectives, Definitions, Licensing, Manufacture In bond and Outside bond, Export of alcoholic preparations, Manufacture of Ayurvedic, Homeopathic, Patent & Proprietary Preparations. Offences and Penalties.
- Narcotic Drugs and Psychotropic substances Act-1985 and Rules: Objectives, Definitions, Authorities and Officers, Constitution and Functions of narcotic &Psychotropic Consultative Committee, National Fund for Controlling the Drug Abuse, Prohibition, Control and Regulation, opium poppy cultivation and production of poppy straw, manufacture, sale and export of opium, Offences and Penalties

UNIT- 4 salient features of Pharma act

- Study of Salient Features of Drugs and Magic Remedies Act and its rules: Objectives, Definitions, Prohibition of certain advertisements, Classes of Exempted advertisements, Offences and Penalties
- Prevention of Cruelty to animals Act-1960: Objectives, Definitions, Institutional Animal Ethics Committee, CPCSEA guidelines for Breeding and Stocking of Animals, Performance of Experiments, Transfer and acquisition of animals for experiment, Records, Power to suspend or revoke registration, Offences and Penalties
- National Pharmaceutical Pricing Authority: Drugs Price Control Order (DPCO)- 2013. Objectives, Definitions, Sale prices of bulk drugs, Retail price of formulations, Retail price and ceiling price of scheduled formulations, National List of Essential Medicines (NLEM)

UNIT-5 Legislation

- Pharmaceutical Legislations – A brief review, Introduction, Study of drugs enquiry committee, Health survey and development committee, Hathi committee and Mudaliar committee

- Code of Pharmaceutical ethics Definition, Pharmacist in relation to his job, trade, medical profession and his profession, Pharmacist's oath
- Medical Termination of Pregnancy Act
- Right to Information Act
- Introduction to Intellectual Property Rights (IPR)

LFS306-Biostatistics

Unit 1: Bio statistics

Keywords and terms used in biostatistics. Concept of frequency distribution (frequency distribution table, simple and group frequency distribution, data presentation), mean, median, mode, standard deviation; Simple problems on mean, median, mode and standard deviation. Unit

2: Correlation and Regression analysis

Relation between two variables, scatter diagram, definition of correlations, curve fitting, principles of least squares, Two regression lines, Pearson's coefficient of correlation, Rank correlation, Tied ranks.

Unit 3: Probability theory:

Random variable (discrete and continuous), Probability density function (discrete and continuous), Distribution function for discrete random variable. Distribution function for continuous random variable, Joint probability distribution, Conditional and marginal distribution. The expected value of a random variable.

Unit 4 : Standard distributions:

Uniform distribution. Binomial distribution, Poisson distribution, Normal and standard normal distributions.

Reference Book:

- Le CT (2003) Introductory biostatistics. 1st edition, John Wiley, USA
- Glaser AN (2001) High YieldTM Biostatistics. Lippincott Williams and Wilkins, USA
- Edmondson A and Druce D (1996) Advanced Biology Statistics, Oxford University Press.
- Danial W (2004) Biostatistics : A foundation for Analysis in Health Sciences, John Wiley and Sons Inc.

LFS307- Computer Applications In Pharmacy

Unit – 1

Number system: Binary number system, Decimal number system, Octal number system, Hexadecimal number systems, conversion decimal to binary, binary to decimal, octal to binary etc, binary addition, binary subtraction – One's complement ,Two's complement method, binary multiplication, binary division Concept of Information Systems and Software : Information gathering, requirement and feasibility analysis, data flow diagrams, process specifications, input/output design, process life cycle, planning and managing the project

Unit –2

Web technologies: Introduction to HTML, XML,CSS and Programming languages, introduction to web servers and Server Products Introduction to databases, MYSQL, MS ACCESS, Pharmacy Drug database

Unit – 3

Application of computers in Pharmacy – Drug information storage and retrieval, Pharmacokinetics, Mathematical model in Drug design, Hospital and Clinical Pharmacy, Electronic Prescribing and discharge (EP) systems, barcode medicine identification and automated dispensing of drugs, mobile technology and adherence monitoring Diagnostic System, Lab-diagnostic System, Patient Monitoring System, Pharma Information System

Unit – 4

Bioinformatics: Introduction, Objective of Bioinformatics, Bioinformatics Databases, Concept of Bioinformatics, Impact of Bioinformatics in Vaccine Discovery

Unit-5

Computers as data analysis in Preclinical development: Chromatographic dada analysis(CDS), Laboratory Information management System (LIMS) and Text Information Management System(TIMS)

Reference Book:

1. Computer Application in Pharmaceutical Research and Development –Sean Ekins – Wiley-Interscience, A John Willey and Sons, INC., Publication, USA
2. Bioinformatics (Concept, Skills and Applications) – S.C.Rastogi-CBS Publishers and Distributors, 4596/1- A, 11 Darya Gani, New Delhi – 110 002(INDIA)
3. Microsoft office Access - 2003, Application Development Using VBA, SQL Server, DAP and Infopath – Cary N.Prague – Wiley Dreamtech India (P) Ltd., 4435/7, Ansari Road, Daryagani, New Delhi - 110002

LFS401- Documentation for Production Control and Quality

Unit 1: Understanding Essential Production Documents

- Overview of critical production documents including Batch Manufacturing Records (BMR) and Batch Packaging Records (BPR).
- Detailed examination of BMR and BPR contents, emphasizing batch-specific instructions, formulations, and manufacturing procedures.
- Importance of accurate documentation for ensuring product consistency, traceability, and regulatory compliance.
- Role of production supervisors in reviewing, verifying, and approving BMR and BPR to maintain quality standards and facilitate smooth production processes.

Unit 2: Establishing Robust Document Control Procedures

- Developing and implementing document control procedures tailored for BMR, BPR, and Standard Operating Procedures (SOPs).
- Ensuring version control, change management, and distribution protocols to maintain document accuracy, integrity, and accessibility.
- Training production personnel on document control procedures and reinforcing adherence to document management policies.
- Collaboration with cross-functional teams, including quality assurance and regulatory affairs, to align with organizational standards and regulatory requirements.

Unit 3: Comprehensive Documentation in Pharmaceutical Production

- Introduction to various production documents essential for pharmaceutical manufacturing, including Exploratory Product Development Brief (EPDB), Product Development Plan (PDP), and Product Development Report (PDR).
- Detailed exploration of Master Formula Record (MFR), Batch Reconciliation, and Print Pack Specifications.
- Understanding the purpose, content, and calculations involved in BMR and BPR.
- Practical exercises on preparing and reviewing production documents to ensure accuracy and compliance.

Unit 4: Integration and Application of Production Documentation

- Integration of production documents into the overall quality management system.
- Importance of effective communication and collaboration among production, quality assurance, and regulatory affairs departments.
- Application of production documentation in process optimization, troubleshooting, and continuous improvement initiatives.

Practical:

- Demonstrate how to Create and analyze Batch Manufacturing Records (BMR) and Batch Packaging Records (BPR) and then prepare.
- Demonstrate the activities that highlight the importance of accurate documentation for product consistency, traceability, and regulatory compliance.
- Demonstrate how to ensure version control, change management, and distribution protocols to maintain document accuracy and integrity.
- Demonstrate how to perform necessary calculations and ensure document accuracy.

- Apply production documentation in process optimization, troubleshooting, and continuous improvement initiatives through case studies and practical exercises.

LFS402- Complaint Handling and Product Recall

Unit 1: Understanding Pharmaceutical Complaint Handling in Production

- Introduction to the role of production in pharmaceutical complaint handling.
- Overview of regulatory requirements and guidelines for complaint handling applicable to production departments.
- Procedures for receiving, documenting, and escalating complaints within the production environment.
- Training production personnel on their roles and responsibilities in the complaint handling process.

Unit 2: Investigating Complaints in Production Processes

- Techniques for conducting investigations into complaints related to production processes.
- Utilizing root cause analysis methods to identify underlying issues within production operations.
- Collaboration between production, quality assurance, and other departments to investigate complaints thoroughly.
- Documentation and reporting requirements for complaint investigations conducted within production departments.

Unit 3: Managing Product Recalls in Production Facilities

- Overview of product recall procedures tailored for production environments.
- Identifying triggers for initiating a product recall within production, such as deviations from standard operating procedures or equipment failures.
- Developing and executing a recall strategy specific to production processes, including line clearance, quarantine procedures, and batch disposition.
- Coordinating communication and actions with relevant stakeholders within and outside the production department during a recall event.

Unit 4: Post-Recall Evaluation and Process Improvement in Production

- Evaluating the effectiveness of recall actions taken within production processes.
- Conducting post-recall reviews to identify opportunities for process improvement and preventive measures.
- Implementing changes to production procedures, equipment, or training based on lessons learned from complaint handling and recall management.
- Integration of feedback from complaint handling and recall management processes into continuous improvement efforts within production operations.

Practical :

- Demonstrate various activities to understand regulatory requirements and guidelines for complaint handling specific to production.
- Demonstrate the process of receiving, documenting, and escalating complaints within the production environment through role-playing scenarios.
- Demonstrate various root cause analysis methods to identify and document underlying issues within production operations.
- Demonstrate development and execution of recall strategies specific to production, including line clearance, quarantine procedures, and batch disposition.

LFS403- Process Equipment Design

Unit 1: Fundamentals of Process Equipment Design

- Introduction to process equipment design principles.
- Importance of equipment design in pharmaceutical manufacturing.
- Regulatory considerations with respect to process design: FDA guidelines, cGMP requirements.
- Case studies illustrating the impact of equipment design on product quality and regulatory compliance.

Unit 2: Material Selection for Pharmaceutical Equipment

- Properties of materials commonly used in pharmaceutical equipment.
- Material compatibility with pharmaceutical products and cleaning agents.
- Corrosion resistance, durability, and hygienic considerations in material selection.
- Real-world examples of material selection challenges and solutions in pharmaceutical equipment design.

Unit 3: Pressure Vessels, Reactors, and Safety Considerations

- Design considerations for pressure vessels in pharmaceutical processes.
- Selection of reactor types and considerations for safe operation.
- Safety considerations and regulatory requirements in vessel and reactor design.
- Case studies highlighting the importance of safety in pressure vessel and reactor design.

Unit 4: Heat Transfer, Cooling Systems, and Energy Efficiency

- Types of heat exchangers and their applications in pharmaceutical manufacturing.
- Design principles for efficient heat transfer and temperature control.
- Cooling system design considerations and energy efficiency measures.
- Case studies demonstrating innovative approaches to heat transfer and cooling system design in pharmaceutical processes.

LFS 404- Pharmaceutical Process Chemistry

Unit 1 : Process chemistry Introduction, Synthetic strategy Stages of scale up process: Bench, pilot and large scale process. In-process control and validation of large scale process. Case studies of some scale up process of APIs. Impurities in API, types and their sources including genotoxic impurities

Unit 2 : Unit Operations a) Extraction: Liquid equilibria, extraction with reflux, extraction with agitation, counter current extraction. b) Filtration: Theory of filtration, pressure and vacuum filtration, centrifugal filtration, c) Distillation: azeotropic and steam distillation d) Evaporation: Types of evaporators, factors affecting evaporation. e) Crystallization: Crystallization from aqueous, nonaqueous solutions factors affecting crystallization, nucleation. Principle and general methods of Preparation of polymorphs, hydrates, solvates and amorphous APIs.

Unit 3 : Unit Processes - I a) Nitration: Nitrating agents, Aromatic nitration, kinetics and mechanism of aromatic nitration, process equipment for technical nitration, mixed acid for nitration, b) Halogenation: Kinetics of halogenations, types of halogenations, catalytic halogenations. Case study on industrial halogenation process.
c) Oxidation: Introduction, types of oxidative reactions, Liquid phase oxidation with oxidizing agents. Nonmetallic Oxidizing agents such as H2O2, sodium hypochlorite, Oxygen gas, ozonolysis.

Unit 4: Unit Processes - II a) Reduction: Catalytic hydrogenation, Heterogeneous and homogeneous catalyst; Hydrogen transfer reactions, Metal hydrides. Case study on industrial reduction process. b) Fermentation: Aerobic and anaerobic fermentation. Production of i. Antibiotics; Penicillin and Streptomycin, ii. Vitamins: B2 and B12 iii. Statins: Lovastatin, Simvastatin c) Reaction progress kinetic analysis i. Streamlining reaction steps, route selection, ii. Characteristics of expedient routes, characteristics of cost-effective routes, reagent selection, families of reagents useful for scale-up.

Unit 5: Industrial Safety a) MSDS (Material Safety Data Sheet), hazard labels of chemicals and Personal Protection Equipment (PPE) b) Fire hazards, types of fire & fire extinguishers c) Occupational Health & Safety Assessment Series 1800 (OHSAS-1800) and ISO-14001(Environmental Management System), Efluents and its management

Reference Book:

- Process Chemistry in the Pharmaceutical Industry: Challenges in an Ever- Changing Climate-An Overview; K. Gadamasetti, CRC Press.
- Pharmaceutical Manufacturing Encyclopedia, 3rd edition, Volume 2.
- Medicinal Chemistry by Burger, 6th edition, Volume 1-8.
- W.L. McCabe, J.C Smith, Peter Harriott. Unit operations of chemical engineering, 7th edition, McGraw Hill
- Polymorphism in Pharmaceutical Solids .Dekker Series Volume 95 Ed: H G Brittain (1999)
- Regina M. Murphy: Introduction to Chemical Processes: Principles, Analysis, Synthesis
- Peter J. Harrington: Pharmaceutical Process Chemistry for Synthesis: Rethinking the Routes to Scale-Up
- P.H.Groggins: Unit processes in organic synthesis (MGH)
- F.A.Henglein: Chemical Technology (Pergamon)
- M.Gopal: Dryden's Outlines of Chemical Technology, WEP East-West Press
- Clausen,Mattson: Principle of Industrial Chemistry, Wiley Publishing Co.,
- Lowenheim & M.K. Moran: Industrial Chemicals
- S.D. Shukla & G.N. Pandey: A text book of Chemical Technology Vol. II, Vikas Publishing House
- J.K. Stille: Industrial Organic Chemistry (PH)

LFS405- Water for Pharmaceutical Use

Unit 1: Types of Water for Pharmaceutical Use

- Overview of different types of water used in pharmaceutical manufacturing.
- Examination of Purified Water (PW), Water for Injection (WFI), Highly Purified Water (HPW), and their specific applications.
- Understanding the importance of water quality and compliance with pharmacopeial standards.
- Validation And Qualification Of Water Purification, Storage, and Distribution Systems
- Introduction to Water BET (Bacterial Endotoxin Test) and its significance in pharmaceutical water testing.

Unit 2: Purified Water (PW) Systems

- In-depth exploration of Purified Water (PW) systems, including design, operation, and maintenance.
- Overview of purification technologies employed in PW systems, such as reverse osmosis, filtration, and UV irradiation.
- Validation and qualification requirements for PW systems to ensure compliance with regulatory standards.
- Practical considerations for routine monitoring, testing, and maintenance of PW systems.

Unit 3: Water for Injection (WFI) Systems

- Understanding the critical role of Water for Injection (WFI) in pharmaceutical manufacturing.
- Detailed examination of WFI production methods, including distillation and reverse osmosis.
- Regulatory requirements and validation strategies for WFI systems.
- Procedures for monitoring and controlling microbial contamination in WFI systems.

Unit 4: Highly Purified Water (HPW) and Water BET Testing

- Overview of Highly Purified Water (HPW) and its applications in specific pharmaceutical processes.
- Principles and methods of Water BET (Bacterial Endotoxin Test) for assessing water quality.
- Importance of Water BET testing in ensuring the absence of bacterial endotoxins in pharmaceutical water.
- Regulatory requirements and best practices for conducting Water BET testing in pharmaceutical manufacturing.

Reference Book:

- "Pharmaceutical Water Systems" by William V. Collentro
- "Water and Wastewater Systems for Pharmaceutical and Biotechnology Industries" by Basant Puri
- "Guide to Microbiological Control in Pharmaceuticals and Medical Devices" by Stephen P. Denyer and Rosamund M. Baird
- "Microbial Contamination Control in Parenteral Manufacturing" by Kevin Williams and S. F. Bloomfield

LFS406- Design Thinking

Unit 1

What is Different About Design thinking? Design Thinking Skills Principles of Design Thinking, The Basis for Design Thinking, The Design Thinking Team, Design Thinking Workshops and Meetings – Exercises and case based discussions

Unit 2

Listening and Empathizing Techniques – observation – structured open ended approach - , Design Thinking Frameworks, Ideation tools – brainstorming, innovation heuristics, behaviour models, overcoming cognitive fixedness – Exercises and case based discussions

Unit 3

Use of Diagrams and Maps in Design Thinking – Empathy map. Affinity diagram, mind map, journey map, combining ideas into complex innovation concepts. Story telling – improvisation, scenario planning, development of scenarios, evaluation tools, frog design and prototyping - – Exercises and case-based discussions Assess developer and user perspectives for bias – apply frameworks to strengthen communication – sustain a culture of innovation.

Unit 4

Sustainable product design, Ergonomics, Semantics, Entrepreneurship/business ideas, Product Data Specification, Establishing target specifications, Setting the final specifications. Design projects for teams.

Reference Book

- Roger Martin, "The Design of Business: Why Design Thinking is the Next Competitive Advantage",Harvard Business Press , 2009.
- Hasso Plattner, Christoph Meinel and Larry Leifer (eds), "Design Thinking: Understand – Improve– Apply", Springer, 2011
- Idris Mootee, "Design Thinking for Strategic Innovation: What They Can't Teach You at Business or Design School", John Wiley & Sons 2013
- Jeanne Liedtka , Andrew King, Kevin Bennett , “Book - Solving Problems with Design Thinking - Ten Stories of What Works” (Columbia Business School Publishing), 2013
- Maurício Vianna, Ysmar Vianna, Isabel K. Adler, Brenda Lucena, Beatriz Russo, “Design thinking: Business Innovation” MJV Press, 2011

LFS407- Vedic Mathematics

Unit- 1 Vedic Maths- High Speed Addition and Subtraction Sessions/Lectures

- Vedic Maths: History of Vedic Maths and its Features
- Vedic Maths formulae: Sutras and Upsutras • Addition in Vedic Maths: Without carrying, Dot Method
- Subtraction in Vedic Maths: Nikhilam Navatashcaramam Dashatah (All from 9 last from 10)
- Fraction -Addition and Subtraction

Unit- 2 Vedic Maths- Miracle Multiplication and Excellent Division

- Multiplication in Vedic Maths: Base Method (any two numbers upto three digits)
- Multiplication by Urdhva Tiryak Sutra
- Miracle multiplication: Any three-digit number by series of l's and 9's
- Division by Urdhva Tiryak Sutra (Vinculum

method) Unit- 3 Vedic Maths-Lightening Squares and

Rapid Cubes

- Squares of any two-digit numbers: Base method
- Square of numbers ending in 5: Ekadhikena Purvena Sutra
- Easy square roots: Dwandwa Yoga (duplex) Sutra
- Square root of 2: Baudhayana Shulbasutra
- Cubing: YavadunamSutra

Unit- 4

- Vedic Maths-Enlighten Algebra and Geometry
- Factoring Quadratic equation: Anurupyena, Adyamadyenantyamanty Sutra
- Concept of Baudhayana (Pythagoras) Theorem
- Circling a square: Baudhayana Shulbasutra
- Concept of pi: Baudhayana Shulbasutra
- Concept angle (8) 0o, 300, 450, 600 and 900: Baudhayana number

Reference Book:

- S. B. Tirthaji, Vedic Mathematics, Motilal Banarsidass Private Limited, Revised Edition, 1992 (Scope as in Chapters 2, 3, 4, 5, 10, 26, 27, 28, 31, 32, 33, 34, 35, 36)
- K. R. Williams, Vedic Mathematics Teacher's Manual, Inspiration Books, Revised Edition, 2009 (Scope as in Chapters 1, 2, 3, 5, 7, 9, 10, 11)

M. Tyra, Magical Book On Quicker Maths, ESC Publications, 5th Edition, 2018 (Scope as in Chapters 2-10, 18, 20, 22, 23, 24, 25)

LFS501- In process Quality Assurance Pharmaceutical Manufacturing

Unit 1: In-Process Quality Checks and Parameters

- Various in-process checks performed during pharmaceutical manufacturing and packing operations.
- Understanding critical quality attributes (CQA), critical process parameters (CPP), and their significance in ensuring product quality.
- Standard procedures for end process sampling plans and control measures.
- Blending of batches of intermediate and final products.

Unit 2: Equipment Qualification and Validation

- Procedures for equipment qualification and validation to meet regulatory requirements.
- Handling incidents, deviations, Out of Specification (OOS), and Out of Trend (OOT) measures related to equipment performance.
- Instrument management and calibration procedures to ensure accurate measurements.

Unit 3: Quality by Design (QbD) and Process Analytical Technology (PAT)

- Introduction to Quality by Design (QbD) principles and their role in pharmaceutical manufacturing.
- Advantages and limitations of QbD and PAT approaches.
- Elements of QbD, including Quality Target Product Profile (QTPP) and Critical Material Attributes (CMA).
- FDA initiatives and regulatory requirements for implementing PAT in pharmaceutical manufacturing.

Unit 4: various other Aspects of In-Process Quality Assurance

- Contamination prevention measures during manufacturing.
- Compliance requirements and issues related to labeling.
- Testing of intermediate products and analytical validation procedures.
- Review of Certificate of Analysis (COA), stability monitoring, expiry dating, and sample retention.
- Handling change management/control and processes for rejection, release, resourcing, reworking, and recovery of materials and solvents

Practical :

- Perform various in-process checks during manufacturing and packing operations.
- Demonstrate how to develop and implement standard procedures for end process sampling plans and control measures.
- Demonstrate how to perform equipment qualification and validation procedures to meet regulatory requirements.
- Apply Quality by Design (QbD) principles in pharmaceutical manufacturing through practical exercises.
- Demonstrate how to ensure compliance with labeling requirements and address related issues.

LFS502- Reporting, Review and CAPA management

Unit 1: Quality Review and Reporting

- Understanding the importance of quality review and reporting in maintaining product quality and regulatory compliance.
- Overview of quality review processes, including data analysis, trend identification, and performance metrics.
- Techniques for effective quality reporting, including report generation, dissemination, and presentation to stakeholders.
- Regulatory requirements and industry standards governing quality review and reporting in pharmaceutical manufacturing.

Unit 2: CAPA Management: Introduction and Regulations

- Overview of Corrective and Preventive Action (CAPA) management and its significance in quality assurance.
- Understanding regulatory requirements and guidelines for CAPA implementation, including FDA's 21 CFR Part 820 and ISO 13485 standards.
- Importance of establishing robust CAPA systems to identify, investigate, and address quality issues effectively.

Unit 3: Issue Identification and Problem Investigation

- Techniques for identifying quality issues and deviations within manufacturing processes.
- Introduction to Problem Investigation methodologies, including Root Cause Analysis (RCA) and Failure Mode and Effects Analysis (FMEA).
- Practical application of RCA techniques to identify underlying causes of quality issues and deviations.

Unit 4: Developing Effective CAPA Processes

- Components of an effective CAPA process, including issue identification, root cause analysis, corrective actions, preventive actions, and effectiveness checks.
- Utilizing RCA tools and methodologies to drive continuous improvement in CAPA processes.
- Documenting CAPA activities, including CAPA plans, investigations, actions, and outcomes.
- Integration of CAPA with other quality management systems and processes for continuous improvement.

Unit 5: Continuous Improvement through CAPA

- Importance of integrating CAPA with continuous improvement initiatives in pharmaceutical manufacturing.
- Strategies for developing a culture of quality and accountability within the organization.
- Leveraging CAPA data and insights to drive process optimization, risk reduction, and product quality enhancement.
- Regulatory considerations for implementing CAPA-driven continuous improvement programs

LFS503- Standards of Quality and Auditing

Unit 1: Introduction to Quality Standards

- Overview of quality assurance principles and their significance in organizational performance.
- Understanding international quality standards and regulatory frameworks governing various industries.
- Introduction to quality management systems (QMS) and their role in ensuring product/service quality and regulatory compliance.
- Importance of adhering to quality standards in different organizational settings.
- Introduction to Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) as part of equipment qualification processes in pharmaceutical manufacturing

Unit 2: Quality Management Systems (QMS)

- Components and principles of quality management systems (QMS) in different industries.
- Implementation of QMS standards such as ISO 9001, ISO 14001, and ISO 45001.
- Importance of quality policy, objectives, processes, and performance monitoring in maintaining organizational excellence.
- Successful QMS implementation and its impact on organizational performance.

Unit 3: Auditing Practices and Methodologies

- Introduction to auditing principles, objectives, and types of audits across various industries.
- Planning, preparation, and execution of internal and external audits, including audit scope, criteria, and checklist development.
- Techniques for gathering evidence, conducting interviews, and evaluating compliance during audits.
- Various audit scenarios to enhance auditing skills.

Unit 4: Audit Follow-Up and Continuous Improvement

- Importance of audit follow-up procedures, including findings documentation, corrective action implementation, and effectiveness verification.
- Strategies for driving continuous improvement based on audit findings and organizational performance metrics.
- Regulatory considerations and industry best practices for maintaining compliance with quality standards.
- The role of audits in identifying opportunities for process optimization and organizational excellence.

LFS504-Pharmaceutical Statistics

Unit 1: Fundamentals of Pharmaceutical Statistics (4 hours)

- Introduction to statistical applications within the pharmaceutical industry and their pivotal role in decision-making and quality assurance processes.
- Basic statistical concepts and terminologies essential for comprehending pharmaceutical data analysis.
- Exploration of statistics' significance in drug development, clinical trials, quality control, and adherence to regulatory requirements.
- Introduction to commonly utilized statistical software platforms in pharmaceutical data analysis.

Unit 2: Statistical Methods in Clinical Trials (8 hours)

- Comprehensive understanding of statistical design and analysis principles applicable to clinical trials, encompassing randomized controlled trials and observational studies.
- Examination of hypothesis testing, confidence intervals, and p-values within the context of clinical trial data analysis.
- Overview of survival analysis, non-parametric methods, and adaptive trial designs, illustrating their practical application through case studies.
- Utilization of statistical methods across different phases of clinical trials, demonstrated through practical examples and real-world scenarios.

Unit 3: Statistical Quality Control in Pharmaceutical Manufacturing (8 hours)

- In-depth exploration of statistical process control (SPC) methodologies employed for monitoring and regulating pharmaceutical manufacturing processes.
- Detailed examination of control charts, process capability analysis, and acceptance sampling plans within the realm of quality control.
- Application of statistical techniques in validation studies, stability testing, and method validation processes.
- Practical implementation of statistical methodologies for investigating deviations, out-of-specification results, and process optimization in pharmaceutical manufacturing settings.

Unit 4: Regulatory Requirements and Compliance in Pharmaceutical Statistics (4 hours)

- Comprehensive overview of regulatory mandates governing statistical analysis in pharmaceutical research, development, and manufacturing, including guidelines from regulatory bodies such as the FDA, EMA, and ICH.
- Emphasis on the importance of documentation, data integrity, and reproducibility in statistical analyses for regulatory submissions.
- Strategies for ensuring compliance with regulatory standards and best practices in pharmaceutical statistics, with a focus on maintaining data integrity and adherence to regulatory guidelines.

Reference Book:

Pharmaceutical Statistics Practical and Clinical Applications by Stanford Bolton, CharlesBon; Marcel Dekker Inc

LFS505- Engineering Controls for Pharma

Unit 1: Introduction to Engineering Controls and Regulatory Compliance

- Overview of engineering controls and their pivotal role in maintaining product quality and safety in pharmaceutical manufacturing.
- Regulatory requirements and guidelines governing engineering controls, including those outlined by regulatory authorities such as the FDA and EMA.
- Introduction to cleanroom classifications and design principles aimed at minimizing contamination risks and ensuring product integrity.
- Understanding the critical role of engineering controls in contamination control and assurance of product quality throughout the manufacturing process.

Unit 2: Cleanroom Design, HVAC Systems, and Qualification

- Principles of cleanroom design and layout to meet specific cleanliness requirements in pharmaceutical manufacturing facilities.
- Examination of HVAC systems and their crucial role in maintaining optimal air quality, temperature, and humidity levels within cleanrooms.
- Overview of filtration technologies and airflow patterns utilized in cleanrooms to control particulate matter and microbial contamination.
- Considerations for HVAC system validation to ensure compliance with regulatory requirements and ongoing maintenance practices.

Unit 3: Containment Technologies, Facility Layout Optimization, and Validation

- Introduction to containment technologies designed for handling hazardous materials and potent compounds safely within pharmaceutical manufacturing environments.
- Design considerations for containment systems, including isolators and gloveboxes, to prevent cross-contamination and ensure operator safety.
- Facility layout optimization strategies to enhance workflow efficiency, minimize contamination risks, and facilitate cleaning and maintenance activities.
- Implementation of validation protocols for containment systems and facility layout to verify their effectiveness in controlling contamination and ensuring product quality.

Unit 4: Environmental Monitoring, Regulatory Compliance, and Validation

- Importance of environmental monitoring in pharmaceutical manufacturing facilities for assessing air quality, surface cleanliness, and microbial contamination levels.
- Monitoring protocols for air quality, surface cleanliness, and microbial contamination, in alignment with regulatory requirements and data integrity standards.
- Regulatory requirements for environmental monitoring and best practices for implementing effective monitoring programs to maintain compliance.
- Execution of validation protocols for environmental monitoring systems to ensure their accuracy, reliability, and compliance with regulatory standards.

LFS506- Organizational Behavior

Unit 1 Organisational Behaviour

Organisational Behaviour – What is O.B., Nature and Structure and Structure of O.S. approaches to O.B. behaviorists frame work, social learning frame work. Basic understanding of Individual behaviors:- personality – meaning, development, Freudian stage, Neo Freudian stage.

Unit 2 Perception

Perception-nature, Importance, meaning, learning & perception. Attitudes & satisfaction:- nature, dimensions of attitudes, meaning of job satisfaction. Sources & consequences of job satisfaction. Job stress – meaning, causes & effects. Group dynamics:- Nature of Groups, types- committee organization, its nature & functions. Informal Organization structure, Informal communication system.

Unit 3 Conflicts

Conflicts – Organizational conflicts, types of conflict, Strategies of interpersonal conflicts. Group decision making & control:- Nature and meaning of decision making, phases of decision making process, Meaning of Control, elements of control process.

Reference Book:

- Business Organization and Management by Bhushan Y.K.
- Business Organization by Gupta C.B
- Organizational Behaviour by L.M. Prasad

LFS507-Indian Health Sciences

Unit 1: Vedic Foundations of Ayurveda

Understanding the roots of Ayurveda in Vedic literature, Exploration of Ayurveda's philosophical foundations, Tracing the ancient practices and beliefs that laid the groundwork for Ayurvedic principles.

Unit 2: Basic Concepts of Ayurveda

Delving into fundamental concepts such as the Three Gunas and Three Doshas, Exploring the role of Pancha-mahabhuta and Sapta-dhatu in Ayurvedic physiology, Understanding the significance of Agni (digestive fire) in maintaining health and treating diseases.

Unit 3: Ayurvedic Health Regimens

Studying Dinacharya (daily regimen) for maintaining good health, Exploring Ritucharya (seasonal regimen) and its importance in adapting to environmental changes.

Unit 4: Texts and Practices in Ayurveda

Selected extracts from Astāngahrdaya (selections from Sūtrasthāna) and Suśruta-Samhitā (sections on plastic surgery, cataract surgery and anal fistula), Understanding the Ayurvedic pharmacopeia and its role in traditional medicine, Charaka and Sushruta on the qualities of a Vaidya.

Unit 5: Evolution and Revival of Ayurveda

Investigating the historical development of Ayurveda until the 18th and 19th centuries, Exploring the continuity of surgical practices and the introduction of inoculation, Understanding the contemporary revival of Ayurveda and its integration with modern healthcare systems, including the resurgence of interest in Yoga.