



MODEL CURRICULUM

GOOD MANUFACTURING PRACTICES
COURSE CODE: PKC006

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Name of Syllabus: Good manufacturing Practices

Course Code: PKC006

Sector: Life science Industry

CURRICULUM/SYLLABUS

The program is aimed at training candidates for the job of a “Good Manufacturing Practice-Life Sciences “, in the “Life sciences” Sector/Industry and aims at building the following key competencies amongst the learner

Program Name	Good Manufacturing Practice-Life Sciences
Version No.	00
Version Update date	ddmmyy
Pre- requisites to Training	B.Pharm / M.Pharm / B.Tech /M.Tech, B.Sc/M.Sc – Pharmacy & Life Science (any specialization)
Training Outcomes	<p>After Completing this programme, participants will be able to:</p> <ul style="list-style-type: none"> • Gain Knowledge about Life sciences Industry, and Regulations (cGMP) to enable him/herself for establishing the Industry Standards in his/her performance. • Gain Scientific Knowledge about Basic of API & Formulation. • Gain knowledge about Equipment, Production Process for API & Formulations, Equipment and Machinery and how to use them, • Gain knowledge about QMS for Production, EHS requirement and industrial Practices, Detailed norms of cGMP, Quality Risk Management and required documentation to enable him/her to deal with potential risks and challenges for quality and data integrity. • Gain knowledge to maintain a healthy, safe, and secure environment.

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Program Name	Good Manufacturing Practice-Life Sciences
	<ul style="list-style-type: none"> • Gain knowledge to maintain shop floor and area around that at pharmaceutical industry. He/she become capable of managing emergency • Learn how to supervise production process activities and how to manage staff and inventory to achieve the organizational Goals • Learn how to coordinate with team, cross functional teams and within the team for effective supervision and development and grooming of team. • Learn how to ensure all time audit readiness and participate in shop floor audits and /or one-o-one discussion with auditors as a production team member and generate the responses for audit queries. • Learn Professional skills like decision Making, planning & organizing, Customer Centricity, Problem Solving, Objection Handling, Analytical Thinking and Critical Thinking.

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Module No.: 1

Orientation Module

Theory Duration: 04:00

Practical Duration: 01:00

Category	Division	Key Learning Outcomes	Equipment Required
A.	Theory	<ul style="list-style-type: none"> • Know about Pharma companies and its sub-sectors • History of Pharmaceutical Industry • Know about Standards for Manufacturing in Life Sciences like GMP. • History of GMP <ul style="list-style-type: none"> • Thalidomide Tragedy • Basic Principles of GMP • Difference between GMP and cGMP • Flow Process in Pharma Company Six components <ul style="list-style-type: none"> • Quality • Production • Laboratory • Materials • Facilities & Equipment • Packaging & Labeling • Brief about Guidelines & Pharmacopeias • Glossary/Terminology Used in pharma 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
B.	Hands on Practical	<ul style="list-style-type: none"> Flowcharts of pharma companies and its process flows Videos of GMP in pharmaceuticals Pharmacopeias Useful websites/URL links of pharmacopeias and regulatory guidelines 	Computer system, Internet, mobile
C.	Self-Learning	<ul style="list-style-type: none"> Read the various Medicines regulatory bodies guidelines (e.g, ISO, MHRA, TGA, ICH, CDSCO, WHO etc) Understand & review the pharmacopeias (e.g, USP, JP, BP, EU, IP etc) 	Computer system, Internet, mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the Orientation Module 	Computer system, Internet, mobile

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Module No.: 2

Various GMP Requirements on: Premises

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Important aspects to be kept in mind to ensure the suitability of the operations to be carried out for different dosage forms and product range: • Location • Design • Construction • Adaptation • Maintenance • Design Principles: Material Flow, People flow & Process Flow • Specific areas of Premises: Ancillary areas, Storage areas, weighing areas, production areas & Quality Control areas 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> • Examples of Materials, People Flow & Process Flow • Layouts of Premises • Pictures & videos of different areas of premises 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
C.	Self-Learning	<ul style="list-style-type: none"> • Draw the design of premises • Draw the layout plan of API & Injectable plants • Draw specific areas of premises 	Computer system, Internet, mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> • Mock test of all topics covered in the various GMP requirements on: Premises 	Computer system, Internet, mobile

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Module No.: 3

Various GMP Requirements on: Facilities

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> It includes the manufacturing space, the storage warehouse for raw and finished product, and support lab areas. GMP requirements for the cleanrooms and for the HVAC systems are, depending on the type of manufacture. Definition of Cleanroom Entry & Exit procedure in Cleanroom Types of contaminations Control of contamination Personal Hygiene Gowning procedure Chemical Handling in cleanroom Classification of Cleanroom as per ISO , USP & EU guidelines Examples of operations to be carried out in the various grades Tests performed in cleanroom Instruments used for tests Role of AHU system in cleanroom 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> Terminology used in cleanroom 	
B.	Hands on Practical	<ul style="list-style-type: none"> Examples of Cleanroom classification Layouts of classified area Pictures and videos of facility Guidelines related to facility 	Computer system, Internet, mobile
C.	Self-Learning	<ul style="list-style-type: none"> Draw the layout of facility (e.g, OSD, Tablet manufacturing, Microbiology Lab, Sterility area etc) Draw the layout plan of API & Injectable plants Draw specific areas of Chemical Lab, Production plant, Microbiology Lab etc 	Computer system, Internet, mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Facilities 	Computer system, Internet, mobile

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Module No.: 4

Various GMP Requirements on: Utility

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • It includes Purified Water System, WFI System, Pure Steam Generation & Distribution, Compressed Air, Nitrogen Generation & Distribution, HVAC • Overview of water system • Overview of Compressed gases • Overview of Steam • Overview of Pure steam generation • Overview of HVAC • Qualification of Utilities • V-model of qualification • User Requirement Specifications (URS) • Design Qualification (DQ) • Installation Qualification (IQ) • Operational Qualification (OQ) • Performance Qualification (PQ) • Terminology used in qualification 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
B.	Hands on Practical	<ul style="list-style-type: none"> • Various guidelines for qualifications (WHO, PIC/S, ISPE, Eu GMP & USP) • Qualification Protocols (like DQ, IQ, OQ & PQ) • URS 	Computer system, Internet, mobile
C.	Self-Learning	<ul style="list-style-type: none"> • Fill the qualification protocols (e.g, URS, DQ, IQ, OQ & PQ) • Read and learn from specific guidelines related Utilities 	Computer system, Internet, mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> • Mock test of all topics covered in the various GMP requirements on: Utilities 	Computer system, Internet, mobile

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Module No.: 5

Various GMP Requirements on: Personnel & their responsibilities

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Review general issues related to personnel Review requirements for key personnel Review the training of personnel Personnel awareness for GMP Role of key Personnel Authorized person Head of Production Head of Quality Unit Responsibilities of key personnel Training of personnel Special training for visitors Entry & exit procedure for Visitors, Consultants & contract staffs 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> Videos and Pictures related to key Personnel/visitors entry & exit procedure in pharmaceutical Industry Formats related to Visitors, Consultants & contract staffs Training Formats designated personnel 	Sample formats of training, Entry & exit formats, Entry & Exit log book, sample format for authorized persons

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
C.	Self-learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related Personnel requirements in pharmaceuticals 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Personnel & their responsibilities 	MCQs paper, Test formats related to personnel

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Module No.: 6

Various GMP Requirements on: R & D

Theory Duration: 05:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Overview of R & D department in pharmaceutical industry • Brief about Formulation & Development • Overall of manufacturing process development • Description of manufacturing process and process control • Selection of starting materials and source materials • Control strategy • Submission of manufacturing process development and related information in common technical documents (CTD) • Brief about Technology Transfer process in R & D • Production Transfer (processing, packaging and cleaning) • Quality control: analytical method transfer • Sending Unit (SU) & Receiving Unit (RU) 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> Information on process and finished pharmaceutical products information Packaging Cleaning Implementation of processing, packaging and cleaning systems Quality control: analytical method transfer Premises and equipment Documentation Qualification and validation 	
B.	Hands on Practical	<ul style="list-style-type: none"> Videos and Pictures related to process development in R & D facility in pharmaceutical Formats related to process validation report Formats related to Qualification protocol and report Formats related to Cleaning validation protocol and report 	Sample formats related to process validation, qualification protocol, cleaning validation and technology transfer
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related pharmaceutical development and technology transfer in pharmaceuticals 	Computer system, Internet, Mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: R & D 	MCQs paper, Test formats of protocol/ Reports

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Module No.: 7

Various GMP Requirements on: Warehouse

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Overview of Warehouse Department in pharmaceutical Industry • Role of warehouse • Storage Condition of materials • Stock Management • Issuance of material • Receipt of Goods • Warehouse staff • Overview of Raw materials, Packing Materials, Solvents, Hazardous Material, Miscellaneous materials, Intermediates and finished product • Good Distribution Practices • Procuring, purchasing, holding, storing, selling, supplying, importing, exporting, or movement of pharmaceutical products, with the exception of the dispensing or providing pharmaceutical products directly to a patient or his or her agent • Vehicles and equipment 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> • Dispatch • Transportation and products in transit • Documentation • Repackaging and relabeling • Complaints • Recalls • Returned products • Counterfeit pharmaceutical products • Contract activities • Self-inspection 	
B.	Hands on Practical	<ul style="list-style-type: none"> • Videos and Pictures related to warehouse in pharmaceutical industry • Formats related to issuance of materials, Receipt of goods, Temperature monitoring of storage areas, Distribution of RM/PM/FG etc 	Sample formats related to issuance of materials, temperature monitoring of storage areas or other related
C.	Self-Learning	<ul style="list-style-type: none"> • Read and learn from specific guidelines related Raw materials, packaging materials and intermediate materials and its distribution practices 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> • Mock test of all topics covered in the various GMP requirements on: Warehouse 	MCQs paper, Test formats of protocol/ Reports

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Module No.: 8

Various GMP Requirements on: Production & Process

Theory Duration: 16:00

Practical Duration: 04:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Know about Quality Management System for Production in Industry including its introduction and importance, QC and QA Systems. Learn about Deviation, incident and change control procedure and Required Documentation practices by QMS, and implementation Know the documentation practices required by cGMP and implement these learnings at shop floor <p>Production Process for API</p> <ul style="list-style-type: none"> Know and follow Production Process of API with an in-detail understanding Upstream processes of production process Downstream processes like Filtration, Centrifugation, Extraction, Evaporation, Crystallization, Drying and Size reduction 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<p>Production Process for Formulations</p> <ul style="list-style-type: none"> • Basics of Formulations including Route of Drug Administration and Various Dosage Forms like Oral Solid Dosage, Liquid Oral Dosage, Sterile Dosage, Dermatological Dosage and their relevant benefits and practice Assay calculation procedure and assay role in formulation, Standard weight procedure or standard quantity effect in formulation • Learn conceptual and practical skills about Production process of Oral Solid Dosage including Process of Granulation, Compression, Coating, Capsule Filling • Apply the conceptual and practical skills about Production process of Liquid Oral Dosage covering aspects like: <ul style="list-style-type: none"> • Types of Oral liquid • Types of liquid dosage forms • Theoretical aspects of vehicles and additives for Monophasic liquid oral dosage forms & Mixing processes • Filtration: Definition, theory, filter media, selection of the filter media and filter aid 	

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> • Operation, cleaning and maintenance of filter press • Processing of Liquid Orals • Operation, cleaning and maintenance of Filling Lines • Cleaning of manufacturing tanks and validation of cleaning process. • To learn the conceptual and practical skills about Production process of Sterile Dosage covering aspects like: • Definition and scope of Aseptic and terminally sterilized processing • WFI production, testing and maintenance • Gowning procedures • Good aseptic techniques • Microbiology and environmental monitoring • Sterilization techniques and sterilization qualification • Operation and maintenance of autoclave • Liquid Filtration and filter integrity testing • Lyophilization processes • SIP and CIP processes • Components preparations 	

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> • Operation and maintenance of LAF • Equipment handling skills used in sterile dosage production 	
B.	Hands on Practical	<ul style="list-style-type: none"> • Videos and Pictures related to production processes in pharmaceutical industry • Formats related to production of API & Formulation processes like: MFR, BMR, BPR • Protocol of Process validation • Protocol of cleaning validation • Equipment qualification 	Sample formats related to MFR, BMR, BPR or related formats
C.	Self-Learning	<ul style="list-style-type: none"> • Read and learn from specific guidelines related Production processes for API & Formulation 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> • Mock test of all topics covered in the various GMP requirements on: Production & Process 	MCQs paper, Test formats/reports of Production process

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Module No.: 9

Various GMP Requirements on: Engineering and Maintenance

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Brief about Workflow in Engineering • Role of maintenance and preventive maintenance (PM) in pharmaceutical industry • Checking, repairing and servicing machinery, equipment, systems and infrastructures • Types of maintenance in the industry • Preventive maintenance in department • Maintenance of premises and equipment • Design of facilities • Validation and qualification of equipment and facilities • Management of calibration programme • Control and operation of site services • Control of engineering spares/ equipment spares • Control of engineering contractors 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
B.	Hands on Practical	<ul style="list-style-type: none"> Videos and Pictures related to maintenance activity in pharmaceuticals Reports related to qualification & validation protocols DQ, IQ, OQ, PQ protocols & reports Learn from ISPE guidelines 	Sample formats related to maintenance, Qualification reports, Validation reports
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related engineering & maintenance, ISPE, WHO guidelines 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Engineering & Maintenance 	MCQs paper, Test formats/reports of qualification & validation

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Module No.: 10

Various GMP Requirements on: Quality Control

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • GLP in Quality Control • Management and infrastructure • Activities of Quality control Laboratory • Role of Personnel & their training • Brief about Materials, equipment, instruments and devices used in quality laboratory • Storage facility of laboratory • Purchasing services and supplies • Working procedures, documents and safety • Control of documentation & records • Inspecting the laboratory • Quality Management System (QMS) • Quality Manual for quality control laboratory • Sops for quality control laboratory for all testing procedures & equipment used • Calibration & Qualification of instruments & equipment 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> Policy for handling of OOS and OOL results Handling of Deviation & change control Specifications 	
B.	Hands on Practical	<ul style="list-style-type: none"> Videos and Pictures related to instruments & equipment used in quality control laboratory Equipment used in chemical, Microbiology & analytical quality control laboratory Reports & formats of testing procedures and other quality control activities (e.g., analytical requisition form (ARF), temperature monitoring, cleaning records, Sample receiving and testing reports, OOS, OOL etc.) Qualification & validation reports 	Sample formats of quality control activities (e.g, ARF, temperature monitoring, calibration of instruments, cleaning records of laboratory instruments etc)
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related to Good Laboratory Practices in quality control 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Quality control 	MCQs paper, Test formats/reports of calibration, qualification & validation

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Module No.: 11

Various GMP Requirements on: Quality Assurance

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Role of Quality Assurance in pharmaceuticals • Document management • Change control • Deviation management/CAPA • Quality Risk management • Staff training • Qualification / Validation • Appraisal of suppliers and third-party service providers • Hygiene programs and environmental monitoring • Release of materials / premises / equipment for use, execution of IPCs • Batch record review • Complaints handling • Self-inspections • Product quality review 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> Ongoing stability Program Documentation cell QMS Training & Development Role of IPQA Data integrity Documentation and data control Authorized signatory 	
B.	Hands on Practical	<ul style="list-style-type: none"> Reports & protocols used in quality assurance department (e.g., issuance of daily formats, data storage & retrieval etc. SOP distribution log BMR, BPR issuance record Delay justification form for change control & QMS Form of OOS, OOT Logbooks & formats of data Issuance of calibration & qualification reports Document destruction Record Investigation reports Guidelines related to deviation, CAPA, QMS, QRM, Data integrity, cleaning & process validation, qualification of instruments etc. 	Sample formats /reports of qualification, issuance of reports, logbooks, validation protocols, SOP training formats, deviation, change control, OOS, OOT etc,

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related to QA (e.g., QMS, QRM) 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Quality Assurance 	MCQs paper, Test formats/reports related quality assurance

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Module No.: 12

Various GMP Requirements on: Stability

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Brief about stability & ICH guidelines Q1A- Q1E Stability Definition of stability Types of stability study Brief about Long-term stability Brief about accelerated stability Brief about intermediate stability Sampling of stability samples for different dosage forms Storage condition of stability samples Testing frequency of stability samples Evaluation of stability data Documentation 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> Reports & formats used in stability study Learn to fill Sample formats of stability for long term, accelerated & intermediate etc 	Stability Sample formats /reports of different dosage forms

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific ICH guidelines related to Stability 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the various GMP requirements on: Stability 	MCQs paper , Test formats/reports related stability

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Module No.: 13

Various GMP Requirements on: Information Technology & Computer system validation

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Apply Basic Computer Skills (Ms Office, Internet) at Work Software Validation Hardware Validation SCADA System Validation Controlled System validation Need identification for validation Brief about 21 CFR Part 11 rules IQ, OQ, PQ protocol, report preparation, execution and compilation of data 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> Reports & formats related to computer system validation Learn to fill formats related to validation 	Sample formats /reports of computer system validation
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related to computer system validation 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in the IT & CSV 	MCQs paper, Test formats/reports of IT & CSV

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Module No.: 14

Workflow of warehouse management: Finished Goods

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Brief about Finished goods Overview of Packing, Labelling, Storage, and distribution of finished goods in pharmaceuticals Packaging and identification of APIs, intermediates & Finished goods Receipt, Label issuance and control of finished goods Importance of Packaging & Labelling operations Storage of finished goods & its distribution 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> Reports and formats related to finished goods in pharmaceuticals (e.g., packaging, labelling, storage and distribution) Learn to fill formats of Packaging, labelling, storage and distribution of finished goods in pharmaceuticals 	Sample formats /reports related to packing, labelling, storage and distribution

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Module No.: 15

Workflow in HR & Admin

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Role of HR in pharmaceuticals • Strategic management • Workflow planning and employment (recruitment and selection) • Induction and orientation • Human Resource Development (Training & Development) • Medical check-ups of employees- for new joined employees & for existing employees annual medical check-up • Policy formulation • Employee and labour relations • Risk management • Pest control within and surrounding of plant premises • Role of Admin in pharmaceuticals 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
B.	Hands on Practical	<ul style="list-style-type: none"> • Formats related to HR activities (e.g., Application form, call letter, self-declaration form, interview evaluation form, procedure for medical check-ups , procedure for pest control, cleaning records of drain, daily monitoring record of rodent box • Learn to fill this format for better understanding 	Sample formats /reports related to HR, Camera
C.	Self-Learning	<ul style="list-style-type: none"> • Read and learn from specific guidelines related to HR & Admin 	Computer system, Internet, Mobile
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> • Mock test of all topics covered in workflow of HR & Admin 	MCQs paper, Test formats/reports related to HR & admin

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Module No.: 16

Workflow in EHS

Theory Duration: 06:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Role EHS department in pharmaceuticals • Brief about Environmental management system • Brief about Effluent Treatment Plant (ETP) for treatment of industrial waste water or safe disposal to the environment • Health management in pharmaceuticals • Safety management system (SMS) in pharmaceuticals • General safety guidelines & basic rules of safety in pharmaceuticals • Learn the Basic Concepts of Safety including Hazards, Accidents, Safety Signs and Signals and practice same • No harm to employees 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> Use Material Data Safety Sheet, and follow the Process of Safety Analysis. Know and follow the Fire Safety concepts and prepare oneself to act in case of Fire Emergency at workplace. Know about various PPEs used in different production operations and do Job Safety Analysis for Various production machines/ equipment and provide this critical information to concerned team members Follow the Basic Concepts and practical skills for managing Emergency Procedures and how to do first aid 	
B.	Hands on Practical	<ul style="list-style-type: none"> Read the guidelines and understand the basic requirements of EHS in pharmaceuticals Learn to fill formats related to Environmental, Health and safety management 	Sample formats /reports related to Environmental, Health and safety management
C.	Self-Learning	<ul style="list-style-type: none"> Read and learn from specific guidelines related to EHS (e.g., EHS –policy the company 	Computer system, Internet, Mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
D.	Continuous Evaluation Assessment	<ul style="list-style-type: none"> Mock test of all topics covered in Environmental, Health and Safety management 	MCQs paper, Test formats related to EHS

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Module No.: 17

Soft Skill Development

Theory Duration: 02:00

Practical Duration: 02:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> • Self-Grooming and Effective communication • Email Etiquettes and Business English • Power Point Presentation Skills and Workplace Skills • Group Discussion • Group Activity and Role Plays • Personality Development • Resume Building • Interview skills and Mock Interview Practice 	Computer system, Internet, mobile
B.	Hands on Practical	<ul style="list-style-type: none"> • Power point presentation (Allocated topics) • Extempore • Group Discussion (any topic) • Group Activity and Role Plays • Personality Development • Real time Resume development • Mock Interview Practice 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
C.	Self-learning	<ul style="list-style-type: none"> Detailed learning on different aspects of soft skills Learn to be Self –disciplined & work independently Learn to Self-evaluation & self-reflection 	Computer system, internet, mobile

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Module No.: 18

Analytical Training

Theory Duration: 04:00

Practical Duration: 04:00

Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
A.	Theory	<ul style="list-style-type: none"> Theoretical training on Chromatography Demonstration on various models of HPLC Basics of HPLC & UHPLC Instrumentation & troubleshooting of HPLC & UHPLC Method development, Column care & maintenance Overview on LC- MS and LC-MS-MS 	Computer system, Internet, mobile
B.	Hands on Practical	Lab Solutions software training <ul style="list-style-type: none"> Real-time analysis Batch creation Method creation Audit Trial Security Policy, Project administration Smart Automation Workflow System configuration Batch creation, submission, queue 	Computer system, Internet, mobile

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Category	Division	Key Learning Outcomes	Equipment Required/Virtual Training
		<ul style="list-style-type: none"> • Method creation, submission • Algorithm for Integration (I-Peak Finder) • Quant browser for data reporting • Post run for data reporting • Column manager usage • Sample treatment & handling • Queries & questions for users 	Computer system, Internet, mobile
C.	Self-Learning	<ul style="list-style-type: none"> • Detailed process of LC- MS and LC-MS-MS 	Computer system, Internet, Mobile

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