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Norwegian Embassy
Islamabad

PHARMACEUTICAL MANUFACTURING TECHNICIAN

LEARNER GUIDE

National Vocational Certificate Level 1

Version 1 - November, 2019

NAVTTC

Implemented by
giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Published by
National Vocational and Technical Training Commission
Government of Pakistan

Headquarter
Plot 38, Kirthar Road, Sector H-9/4, Islamabad, Pakistan
www.navttc.org

Responsible
Director General Skills Standard and Curricula, National Vocational and Technical Training Commission
National Deputy Head, TVET Sector Support Programme, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Layout & design
SAP Communications

Photo Credits
TVET Sector Support Programme

This document has been produced with the technical assistance of the TVET Sector Support Programme, which is funded by the European Union, the Federal Republic of Germany and the Royal Norwegian Embassy and has been commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ). The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH in close collaboration with the National Vocational and Technical Training Commission (NAVTTC) as well as provincial Technical Education and Vocational Training Authorities (TEVTAs), Punjab Vocational Training Council (PVTC), Qualification Awarding Bodies (QABs)s and private sector organizations.

Document Version
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Islamabad, Pakistan

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Introduction

Welcome to your Learner's Guide for the *Pharmaceutical Manufacturing Technician* Program. It will help you to complete the program and to go on to complete further study or go straight into employment.

The *Pharmaceutical Manufacturing Technician* program is to engage young people with a program of development that will provide them with the knowledge, skills and understanding to start this career in Pakistan. The program has been developed to address specific issues, such as the national, regional and local cultures, the manpower availability within the country, and meeting and exceeding the needs and expectations of their customers.

The main elements of your learner's guide are:

- **Introduction:**
  - This includes a brief description of your guide and guidelines for you to use it effectively
- **Modules:**
  - The modules form the sections in your learner's guide
- **Learning Units**:
  - Learning Units are the main sections within each module
- **Learning outcomes**:
  - Learning outcomes of each learning units are taken from the curriculum document
- **Learning Elements:**
  - This is the main content of your learner's guide with detail of the knowledge and skills (practical activities, projects, assignments, practices etc.) you will require to achieve learning outcomes stated in the curriculum
  - This section will include examples, photographs and illustrations relating to each learning outcome

- **Summary of modules**:
    - This contains the summary of the modules that make up your learner's guide
- **Frequently asked questions**:
    - These have been added to provide further explanation and clarity on some of the difficult concepts and areas. This further helps you in preparing for your assessment.
- **Multiple choice questions for self-test**:

These are provided as an exercise at the end of your learner's guide to help you in preparing for your assessment.

Overview of the program

Course: Level 1 Pharmaceutical Manufacturing Technician	**Total Course Duration:** 190 hours
Course Overview:	
This course is aimed at introducing and developing the basic skills and knowledge of pharmaceutical manufacturing sector. The trainee is introduced in a step by step manner to the various elements of the discipline and their implications. Ranging from the knowledge and skills required for the maintaining personal safety and health and adopt basic good manufacturing practices for pharmaceutical production. The students are encouraged to experiment with a focus on acquiring a wide range of new skills. They are also exposed to the commercial market and taught how to deal with clients and their demands in Pharma Sector.	

1. SUMMARY – OVERVIEW OF THE PROGRAM

Module Title and Aim	Learning Units	Theory hours	Workplace hours	Timeframe of Modules
Module A: Comply with Work Health and Safety Policies Aim: After completing this module, the learner will be able to know skills and knowledge required to apply general work health and safety requirements in the workplace. Communicate work and health safety assess at work place. It describes generic work health and safety responsibilities applicable to employees without managerial or supervisory responsibilities.	LU-1: Work safely at work place LU-2: Communicate work health and safety (WHS) assess at work place LU-3: Minimize risks to personal safety at work place LU-4: Minimize risks to public safety	06	24	30
Module B: Obey the Workplace Policies and Procedures Aim: After completing this module, the learner will be able to obey the workplace personal appearance and hygiene, follow work ethics, Demonstrate the workplace behavior, Communicate the workplace policy and procedure and review the implementation of workplace policy and procedures.	LU-1: Obey the workplace personal appearance and hygiene LU-2: Follow work ethics LU-3: Demonstrate the Work place behaviours LU-4: Communicate workplace policy & procedures LU-5: Review the implementation of workplace policy & procedures	04	16	20

Module C: Follow Basic Communication Skills (General). Aim: After completing this module, the learner will be able to listen attentively, develop non-verbal communication, and identify communication barriers, interview preparation for job and different communication platforms in the workplace and throughout your career.	LU-1: Adopt Effective listening to Skills LU-2: Develop Nonverbal communication with peers LU-3: Prepare for Interview to get a job LU-4: Use communication platform at workplace LU-5: Identify communication barriers to improve interpersonal skills	10	40	50
Module D: Operate Computer Functions (General). Aim: After completing this module, the learner will be able to have skills and knowledge required to setup a computer system, organize files in folders, and shutdown a computer system.	LU1. Set up the computer for use LU2. Organize files in folder LU3. Shut down computer system	10	40	50
Module E: Adopt Good Manufacturing Practices for Pharmaceutical Production. Aim: After completing this module, the learner will be able to know basic current Good Manufacturing Practices (cGMP) at the workplace according to the industry's approved guidelines, procedures and interprets rules/regulations.	LU1.Apply basic GMP requirements in regard to pharmaceutical quality system LU2.Apply basic GMP requirements in regard to personal hygiene measures LU3.Apply basic GMP requirements in regard to premises and equipment LU4.Apply basic GMP requirements in regard to documentation and records LU5. Apply basic GMP requirements in regard to production, and in-process controls LU6. Apply basic GMP requirements in regard to distribution and storage	10	30	40
	TOTAL	40	150	190

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Module-E

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Module E: Adopt current Good Manufacturing Practices for Pharmaceutical Production

Objective: After completing this module, the learner will be able to know basic current Good Manufacturing Practices (cGMP) at the workplace according to the industry's approved guidelines, procedures and interprets rules/regulations.

Duration: 40 Hours **Theory: 10 Hours** **Practice: 30 Hours**

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
LU1. **Apply basic cGMP requirements in regard to pharmaceutical quality system**	• Follow requirements of quality system within the production • Report to in-charge about any deviation if occur, for prompt measures	• Explain safety rules and regulations for the pharmaceutical industry • Know about responsibilities within the quality management system (e.g. production, quality assurance, quality control) • Explain critical deviations during production • Understand system of internal audit and responsibilities for self-inspection	• Safety regulations • Gloves, face mask, Goggles, Caps, Uniform etc.
LU2. **Apply basic cGMP requirements in regard to personal hygiene measures**	• Perform proper hand washing and disinfection procedures before entering production • Report to supervisor in the case of illness • Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area • Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures • Receive visitor following the visitors' policy	• Understand concept of corrective action within the quality system • Understand concept of continual improvement • Know about hygienic measures (GMP) for pharmaceutical production • Explain work place specific guidelines for uniform	• Soaps, disinfectant, Sanitizers. • Gloves, face mask, Goggles, Caps, Uniform etc.

LU3. **Apply basic cGMP requirements in regard to premises and equipment**	• Follow procedures for flow of personnel, material flow and product flow • Fill out specifications, records, batch production records for production under supervision	• Know about cross-contamination in regard to personal hygiene • Explain the use of medical certificates • Know about visitors' policy • Understand clean room concept for pharmaceutical production • Understand system of flow of materials, personnel and product • Understand plant lay-out concepts for pharmaceutical production (e.g. straight-flow)	
LU4. **Apply basic cGMP requirements in regard to documentation and records**	• Interpret laboratory control records • Follow master production instructions • Locate documents of external origin, if needed • Safeguard documents and records appropriately	• Explain control of documents procedure • Explain control of records procedure • Explain distribution procedures • Know about documents of external origin, SOPs, records, specification, master production instructions, batch production and control records, laboratory control records • Know about documentation of completion	

LU5. A **Apply basic cGMP requirements in regard to production, quality control and in-process controls**	• Follow master production instructions • Perform basic in-process control measurements (e.g. pH, weighing) under supervision • Perform basic quality control measure under supervision	• Know about common process deviations • Explain critical steps in production • Explain in-process sampling and controls • Know about contamination controls	
LU6. **Apply basic cGMP requirements in regard to storage and distribution**	• Store materials and end product appropriately • Use appropriate packaging materials for end product	• Know about packaging materials • . Explain warehouse procedures • Explain distribution procedures	• Smoke Detecting Alarm • Fire Extinguisher

Examples and illustrations

Safety and safety rules regarding Pharmaceutical Industry

Safety rules should be followed as per guidelines of the pharmaceutical company. The use of appropriate PPE should be used to minimize the risk of potential at the production.

GMP is that part of Quality assurance which ensures that the products are consistently manufactured and controlled to the Quality standards appropriate to their intended use

– "GMP" is a set of principles and procedures which, when followed by manufacturers for therapeutic goods, helps ensure that the products manufactured will have the required quality.

– It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. Some of the main risks are as following:

– unexpected contamination of products, causing damage to health or even death.

– incorrect labels on containers, which could mean that patients receive the wrong medicine.

– insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

– GMP helps boost pharmaceutical export opportunities:

– Most countries will only accept import and sale of medicines that have been manufactured to internationally recognized GMP.

– Governments seeking to promote their countries export of pharmaceuticals can do so by making GMP mandatory for all pharmaceutical production and by training their inspectors in GMP requirements.

GMP Covers the following:

- ALL aspects of production; from the starting materials, premises and equipment to the training and personal hygiene of staff.
- Detailed, written procedures are essential for each process that could affect the quality of the finished product.
- There must be systems to provide documented proof that correct procedures are consistently followed at each step in the manufacturing process - every time a product is made.

- QC personnel perform the testing and compare the results to the specification requirements. They are contractually responsible for controlling the quality of the work performed. But unless they have authority, as well as first-hand knowledge of the specification requirements and testing procedures, they cannot control quality.
  - Quality Assurance is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.
  - QA personnel check the test procedures used by quality control personnel and verify the accuracy of the data in order to provide confidence in the results. They are ultimately responsible for assuring the quality of the work performed. But unless they have first-hand knowledge of the specification requirements and testing procedures, they cannot assure quality.
  - QC role is to conduct tests and verify by evidence that the product meets the specified requirements. The QA role is to verify the QC tests are conducted in accordance with the appropriate standard.

- Any deviation from limit allowed during processing or in-process control will be reported to relevant section in-charge to overcome the problem on time.

- Internal audit should be carried out to assess the responsibilities fulfilled at specific interval. It will not only enhance the skills of personnel but also motivate the employee to work hard.

Corrective actions within quality system:

Corrective actions are a very important part of pharmaceutical quality systems.
Actions should be taken to correct the existing product nonconformity or quality problems (corrective actions). A Corrective Action may also address a weakness identified in a safety management system. A company's ability to rapidly correct existing problems and implement controls to prevent potential problems is essential to ensure customer satisfaction and achieve operational success. While a corrective action process must meet the necessary industry compliance requirements, it must also be effective.

In simple words, Corrective action is a process of communicating with the employee to improve behavior or performance after other methods such as coaching and performance appraisal have not been successful. All employees are expected to meet performance standards and behave appropriately in the workplace.

Continuous improvement

Continuous improvement, sometimes called continual improvement, is the ongoing improvement of products, services or processes through incremental and breakthrough improvements.

Purpose of Continuous improvement:

Continuous improvement (CI) is an ongoing effort to improve products, processes, or services by reducing waste or increasing quality. This continuous effort drives a competitive advantage for organizations that get it right but, as with many things in life, consistency is not easy to achieve.

Hygienic measures (GMP) for pharmaceutical production:

The following key points should be considered to know about hygienic measure (GMP) for pharmaceutical production

i. Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area

ii. Wash hands before entering production areas, also use disinfectants

iii. All personnel, prior to and during employment, as appropriate, should undergo health examinations. Personnel conducting visual inspections should also undergo periodic eye examinations

iv. All personnel should be trained in the practices of personal hygiene. A high level of personal hygiene should be observed by all those concerned with manufacturing processes. In particular, personnel should be instructed to wash their hands before entering production areas. Signs to this effect should be posted and instructions observed.

v. Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle starting materials, packaging materials, in-process materials or medicines products until the condition is no longer judged to be a risk.

vi. All employees should be instructed and encouraged to report to their immediate supervisor any conditions (relating to plant, equipment or personnel) that they consider may adversely affect the products.

vii. Direct contact should be avoided between the operator's hands and starting materials, primary packaging materials and intermediate or bulk product.

viii. To ensure protection of the product from contamination, personnel should wear clean body coverings appropriate to the duties they perform, including appropriate hair covering. Used clothes, if reusable, should be stored in separate closed containers until properly laundered and, if necessary, disinfected or sterilized.

ix. Smoking, eating, drinking, chewing, and keeping plants, food, drink, smoking material and personal medicines should not be permitted in production, laboratory and storage areas, or in any other areas where they might adversely influence product quality.

Personal hygiene procedures including the use of protective clothing should apply to all persons entering production areas, whether they are temporary or full-time employees or nonemployees, e.g. contractors' employees, visitors, senior managers and inspectors.

Cross-Contamination:

Contamination of a starting material, intermediate product, or finished product with another starting material or product during production.

Do not process more than one product in the same area during production. Check that every material is free from microbial or any other form of contamination. Before using, remove the outer wrapping of the packaging material to help reduce contamination. Before filling, visually check to see if the containers are clean. The following points should be considered in regard to personal hygiene:

i. All personnel, prior to and during employment, as appropriate, should undergo health examinations. Personnel conducting visual inspections should also undergo periodic eye examinations. It will be better to submit the medical report prior to employment.

ii. All personnel should be trained in the practices of personal hygiene. A high level of personal hygiene should be observed by all those concerned with manufacturing processes. In particular, personnel should be instructed to wash their hands before entering production areas. Signs to this effect should be posted and instructions observed.

iii. Any person shown at any time to have an apparent illness or open lesions that may adversely affect the quality of products should not be allowed to handle starting materials, packaging materials, in-process materials or drug products until the condition is no longer judged to be a risk.

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viii. Personal hygiene procedures including the use of protective clothing should apply to all persons entering production areas, whether they are temporary or full-time employees or non-employees, e.g. contractors' employees, visitors, senior managers, and inspectors.

Clean Room:

A clean environment designed to reduce the contamination of processes and materials. This is accomplished by removing or reducing contamination sources.

"British Standard" defines a clean room as a room with control of particulate contamination, constructed and used in such a way as to minimize the introduction, generation and retention of particles inside the room and in which the temperature, humidity, airflow patterns, air motion and pressure are controlled.

A cleanroom or clean room is a laboratory facility ordinarily utilized as a part of specialized industrial production, including the manufacture of pharmaceutical product.

A cleanroom is any given contained space where provisions are made to reduce particulate contamination and control other environmental parameters such as temperature, humidity and pressure. The key component is the High Efficiency Particulate Air (HEPA) filter that is used to trap particles that are 0.3 micron and larger in size. All of the air delivered to a cleanroom passes through HEPA filters, and in some cases where stringent cleanliness performance is necessary, Ultra Low Particulate Air (ULPA) filters are used.

Personnel selected to work in cleanrooms undergo extensive training in contamination control theory. They enter and exit the cleanroom through airlocks, air showers and/or gowning rooms, and they must wear special clothing designed to trap contaminants that are naturally generated by skin and the body.

Cleanroom clothing is used to prevent substances from being released off the wearer's body and contaminating the environment. The cleanroom clothing itself must not release particles or fibers to prevent contamination of the environment by personnel. This type of personnel contamination can degrade product performance in the semiconductor and pharmaceutical industries and it can cause cross-infection between medical staff and patients in the healthcare industry for example.

Cleanroom garments include boots, shoes, aprons, beard covers, bouffant caps, coveralls, face masks, frocks/lab coats, gowns, glove and finger cots, hairnets, hoods, sleeves and shoe covers. The type of cleanroom garments used should reflect the cleanroom and product specifications. Low-level cleanrooms may only require special shoes having completely smooth soles that do not track in dust or dirt. However, shoe bottoms must not create slipping hazards since safety always takes precedence. A cleanroom suit is usually required for entering a cleanroom. Class 10,000 clean rooms may use simple smocks, head covers, and booties. For Class 10 clean rooms, careful gown wearing procedures with a zipped cover all, boots, gloves and complete respirator enclosure are required.

Material flow

Material flow refers to the interlinking of all operations relevant to sourcing, processing and treatment, as well as the distribution of material goods within specified areas. This specifically involves: processing, handling, transportation, testing, stopovers and storage. Material flow is the sequence of individual manufacturing and storage steps, starting with the raw material and ending with the finished product. In addition to economic considerations, the material flow has a particular significance in terms of Good Manufacturing Practice.

Personnel flow:

Many characteristics and functions of material flow also apply to personnel flow. Most importantly, logical organization of the personnel flow serves to protect the product in addition to considerations of economy and labour legislation. The functions of Personal flow include:

- Support of zonal concept
- Prevention of cross-contamination
- Product and personnel protection
- Economic efficiency

To optimize the material flow, the appropriate number of persons required to operate, monitor and maintain the machines and facilities must be determined. The functions of individual person must then be described and the routes transferred to the layout.

Objective of plant layout

The primary objective of plant layout is to maximize production at minimum cost. The layout should be designed in such a way that it is flexible to change according to new processes and production techniques.

Plant layout can affect the total operation of a company, including the production processes, equipment, storage, dispatch and administration. It has a direct effect upon production efficiency and economics of the operation, the morale of employees and can affect the physical health of operatives.

Plant layout has to be reviewed for operation, maintenance, construction, safety, emergency, insurance, and regulatory purposes at frequent intervals during design.

Four main types of Plant lay-out

i. Product or Line Layout: If all the processing equipment and machines are arranged according to the sequence of operations of the product, the layout is called product type of layout.

ii. Process or Functional Layout

iii. Fixed Position Layout

iv. Combination Type of Layout

Control of Documentation

Documentation is the key to GMP compliance and ensures traceability of all development, manufacturing, and testing activities. Documentation provides the route for auditors to assess the overall quality of operations within a company and the final product. Documents are typically used and

completed by the quality control (QC) department.

Test methods documentation provide step-by-step instructions for testing supplies, materials, products, and other production-related tasks and activities, e.g., environmental monitoring of the GMP facility.

Test methods typically contain forms that have to be filled in at the end of the procedure; this is for documenting the testing and the results of the testing.

All the records (documentations) from starting dispensing of raw materials to finished products should be maintained.

The following documents (not limited to it):

i. Records

ii. Labels

iii. Specifications and Testing Procedures

iv. Master Formulae

v. Packaging Instructions

vi. Batch Manufacturing Records (BMR)

vii. Batch Packaging Records (BPR)

viii. Standard Operating Procedures (SOPs)

Complete batch history should be documented for each batch including all the documents from dispensing to processing of finished products.

Deviation

A deviation may occur during sampling and testing, raw materials- and finished product acceptance and manufacturing.

It is important to manage any deviations in expected standards in the development, manufacturing and distribution processes of pharmaceutical products.

Deviations are measured differences between observed value and expected or normal value for a process or product condition, or a departure from a documented standard or procedure. A deviation may occur during sampling and testing, raw materials- and finished product acceptance and manufacturing. There are three types of deviations:

1. **Critical deviation:** A Critical Deviation is an unplanned event that affects a quality attributes a critical process parameter, an equipment or instrument critical for process control and has an immediate patient safety risk, life threatening situations.

2. **Major deviation:** A Major Deviation is an unplanned event that potentially affects a product's quality, safety or efficacy or its ability to meet specification, or regulatory or documentation requirements which may not have direct impact on patient.

3. **Minor deviation:** A Minor deviation is an unplanned event that potentially has GMP impact (e.g. an event affecting a utility, equipment, materials, components environment or documentation) but does not affect product quality and / or the physical state of the product, intermediate or component, or its labeling.

How to note and action taken on the deviations:

- A person identifying the deviation (observer) shall inform to initiator for documenting the deviation details in the deviation form with the description of the deviation, Batch no., name of the product / Material. date, time and other details related to deviation as per deviation form

- Observer/Initiator shall take immediate actions in consultation with QA and head of responsible department to contain the deviation.

- Initiator shall address all immediate actions taken in deviation form and shall analyze the risk and evaluate impact of deviation in consultation with HOD of responsible department and subsequently mention it in the deviation form. After completion of details initiator shall submit deviation form to QA for review, evaluation and login.

- The products intended for the regulatory dossier preparation / submission purpose; the overall risk as a concept must be considered differently for the following reasons like Products considered at the development stage, Product knowledge is under development phase and the products are not intended for commercial purpose at this stage till approved by the respective regulatory authorities.

- Wherever applicable, quality risk assessment shall be performed for suspected product defects, potential impact on other batches or on other products etc.

- QA shall review & evaluate details of deviation mentioned in deviation for correctness & completeness along with the immediate actions taken, risk & impact assessment of deviation and supporting documents (if any). Additional supportive data and documents can be requested from responsible department for evaluation.

- After review and evaluation, QA shall assign unique reference number to the deviation form and update the deviation number in the deviation log book.

- After evaluation of details mentioned in deviation form, risk, impact assessment of deviation, QA shall categorize the deviation in to Critical, major or minor as per nature of deviation.

- QA shall also check whether similar type of deviation was happened in past one year.

- Investigation of Critical, major deviations and minor deviations which are repetitive in nature shall be performed using investigation report and deviations which are minor in nature or deviations having obvious or known root cause, investigation shall be performed as per deviation approval form.

- The responsible department head/designee shall initiate the investigation as per the SOP for Investigations as applicable, considering history & trending, root cause evaluation, risk and impact assessment and comments from other departments within the site along with QA department.

- The cross functional investigation team shall be formed for the investigation of deviations and shall consist of Head of the department or designee where deviation has occurred and members with sufficient knowledge on current matter for investigation.

- The investigators must have appropriate knowledge and training to perform an investigation.

- The team shall include members (depend upon nature and Applicability) from QA, QC, Manufacturing, Packaging, Regulatory, Engineering, Safety and Warehouse etc.

- If actual root cause is not identified, potential root cause shall be identified based on history of repetitive deviation, deviation trends, vendor assessment, scientific knowledge and actions shall be taken to prevent the potential from occurring.

- Investigations where human error is suspected or identified as a root cause shall be justified. The procedural or systems-based errors must be thoroughly reviewed before concluding for human errors.

In-process Quality Control tests:

In-process quality control (IPQC) **tests** are strongly related to final products **quality** because checks performed during production in order to monitor and if necessary, to adjust the **process** to ensure that the product conforms to its specification are the key for good **quality** pharmaceutical products.

The tests for liquids include

- Content Uniformity
- pH
- Viscosity
- Volume check

The tests for tablets include

- Weight variation
- Friability
- Content Uniformity
- Hardness
- Thickness

Pharmaceutical Packaging

Pharmaceutical packaging (or drug packaging) is the packages and the packaging processes for pharmaceutical preparations. It involves all of the operations from production through drug distribution channels to the end consumer. Packaging is often involved in dispensing, dosing, and use of the pharmaceutical product

The pharmaceuticals (raw and finished products) are to be stored under conditions that prevent contamination and, as far as possible, deterioration. The stability of product retains within the specified limit, throughout its period of storage and use.

High temperature and relative humidity (RH) are the most important factors involved in drug degradation. For many products requiring storage in cool conditions, refrigeration plant is widely used, which needs to be carefully monitored to ensure that the correct temperatures are maintained. Stock must be stored in appropriate and auditable environmental conditions.

Appropriate conditions of light, humidity, ventilation, temperature and security should be ensured. All medicinal products must be stored in accordance with the manufacturer's directions and within the terms of product authorizations

Pharmaceutical products should be packed in a well closed container that protects the contents from contamination by extraneous solids, liquids or vapors and the loss of the products under normal conditions of handling and storage. The following factors to be taken in consideration for proper storage:

- Sanitation
- Temperature
- Light
- Moisture
- Ventilation
- Segregation

All freezer rooms, cold rooms and temperature-controlled storage, packing and staging areas must be equipped with continuous temperature and/or humidity monitoring equipment as described in the companion supplement: Temperature and humidity monitoring systems for fixed storage areas.

Test Yourself (Multiple Choice Questions)

MODULES E Module E: Adopt current Good Manufacturing Practices for Pharmaceutical Production

Please mark the correct one from the given options.

QNO1: GMP covers all the following, except:

A. All aspects of production
C. Premises
B. Workload efficiency
D. Personal hygiene of staff

QNO2: What are the factors to be taken in consideration for proper storage?

A. Temperature, light
C. Temperature, light, moisture
B. Weight and volume
D. Light and equipment

QNO3: Cleanroom garments include all the following except?

A. Beard cover
C. face mask, gowns
B. Fan
D. Shoes covers, lab coats

QNO4: Do not process more than one product in the same area during production to avoid which of the below phenomenon to occur:

A. Contamination
C. Over crowed
B. Waste of money
D. none of them

QNO5: Material flow refers to the interlinking of all operations relevant to which one of the following?

A. Only for processing

C. Sourcing, processing and treatment

B. Sourcing and treatment

D. None of them

Answers Key	
Number	Correct Answer
1	B
2	C
3	B
4	A
5	C

FREQUENTLY ASKED QUESTIONS (FAQs)

1. What is Competency Based Training (CBT) and how is it different from currently offered trainings in institutes?	Competency-based training (CBT) is an approach to vocational education and training that places emphasis on what a person can do in the workplace as a result of completing a program of training. Compared to conventional programs, the competency-based training is not primarily content based; it rather focuses on the competence requirement of the envisaged job role. The whole qualification refers to certain industry standard criterion and is modularized in nature rather than being course oriented.
2. What is the passing criterion for CBT certificate?	You shall be required to be declared “Competent” in the summative assessment to attain the certificate.
3. What is the examination / assessment system in this program?	Competency based assessments are organized by training institutes during the course which serve the purpose of assessing the progress and preparedness of each student. Final / summative assessments are organized by the relevant qualification awarding bodies at the end of the certificate program. You shall be required to be declared “Competent” in the summative assessment to attain the certificate.
4. What are the entry criteria for enrollment in this program?	Matric science or equivalent, preferably F.Sc.
5. What is medium of instructions for this program?	The medium of instructions for this program are Urdu, English or Local Language
6. How can I progress in my educational career after attaining this certificate?	You shall be eligible to take admission in the National Vocational Certificate Level-2 in Pharmaceutical Manufacturing Technician. You shall be able to progress further to National Vocational Certificate Level-3 and Level-4 after completing Level-2 and Level-3 respectively.
7. If I have the experience and skills mentioned in the competency standards, do I still need to attend	You can opt to take part in the Recognition of Prior Learning (RPL) program by contacting the relevant training institute and getting assessed by providing the required evidences.

the course to attain this certificate?	
8. What is the entry requirement for Recognition of Prior Learning program (RPL)?	There is no general entry requirement. The institute shall assess you, identify your competence gaps and offer you courses to cover the gaps; after which you can take up the final assessment.
9. Is there any age restriction for entry in this course or Recognition of Prior Learning program (RPL)?	There are no age restrictions to enter this course or take up the Recognition of Prior Learning program
10. What is the total duration of this course?	The duration of the whole course work is 1,600 hrs.
11. How much salary can I get on job after attaining this certificate?	The minimum wages announced by the Government of Pakistan in 2019 are PKR 17,500. This may vary in subsequent years and different regions of the country. Progressive employers may pay more than the mentioned amount.

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