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PHARMACEUTICAL MANUFACTURING TECHNICIAN

LEARNER GUIDE

National Vocational Certificate Level 2

Version 1 - November, 2019

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Contents

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 of your assessment.

Overview of the program

Course: Level 2 Pharmaceutical Manufacturing Technician	**Total Course Duration:** 410 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 Prepare work environment according to manufacturing order, product raw material, adjust machine as per product manufacturing order and maintain workplace safety. 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 Days/hours	Workplace Days/hours	Timeframe of Modules
Module A: Comply Personal Health and Safety Guidelines Aim: This Competency Standard identifies the competencies required to protect/apply occupational Safety, Health and Environment at workplace according to the industry's approved guidelines, procedures and interpret environmental rules/regulations. Trainee will be expected to identify and use Personal Protective Equipment (PPE) according to the work place requirements. The underpinning knowledge regarding Observe Occupational Safety and Health (OSH) will be sufficient to provide the basis for the job at workplace.	**LU1:** Identify Personal Hazard at work place **LU2:** Apply personal protective and safety equipment (PPE) **LU3:** Comply with occupational safety and health (OSH) **LU4:** Dispose of hazardous waste/materials from the designated area	06	24	30
Module B: Communicate the Workplace Policy and	**LU1.** Identify workplace communication procedures **LU2.** Communicate at workplace **LU3.** Draft Written Information	04	16	20

Procedure Aim: This unit describes the performance outcomes, skills and knowledge required to develop communication skills in the workplace. It covers gathering, conveying and receiving information, along with completing assigned written information under direct supervision.	**LU4.** Review Documents			
Module C: Perform Basic Communication (Specific) Aim: This unit describes the skills and knowledge required to assist in the development of communication competence by providing information regarding different forms of communication and their appropriate use.	**LU1.** Communicate in a team to achieve intended outcomes **LU2.** Follow Supervisor's instructions as per organizational SOPs **LU3.** Develop Generic communication skills at workplace `	06	24	30
Module D: Perform Basic Computer Application (Specific) Aim: This unit describes the skills and knowledge required to use spreadsheet to prepare a page of document, develops familiarity with Word, Excel, email, and computer graphics basics.	**LU1.** Create Word Documents **LU2.** Create Excel Documents **LU3.** Use internet for Browsing	08	32	40

Module E: Prepare work environment according to manufacturing order Aim: After completing this module, the learner will be able to maintain temperature, humidity, air pressure and clean environment at workplace as per procedure.	LU1: Maintain temperature and humidity. LU2: Ensure air pressure of specific area/work place. LU3: Prepare area for swab test. LU4: Adjust light as per specifications in workplace area.	10	30	40
Module F: Receive product raw material(s) according to manufacturing order Aim: After completing this module, the learner will be able to identify materials as per labels, shift materials to concerned section and arrange raw materials for mixing as per procedure and protocol of industry.	LU-1: Identify materials according to labels LU-2: Check weight of raw materials LU-3: Shift materials to concerned section LU-4: Arrange Raw Materials for Mixing	10	40	50
Module G: Adjust machine as per product manufacturing order Aims: After completing this module, the learner will be able to identify materials as per labels, shift materials to concerned section and arrange raw materials for mixing as per procedure and protocol of industry.	LU1: Check Electrical and Mechanical parameters of Machine for Proper Functionality LU2: Check Machine Lubrications LU3: Ensure Cleaning of Machine LU4: Maintain machine Log-Book LU5: Follow Machine Operation Procedure	16	44	60
	TOTAL	60	210	270

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Module-E

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Module E: Prepare work environment according to manufacturing order

Objective: This module maintains to workplace lighting, ventilation, proper temperature, humidity, air control and hand washing facilities for workers are ensured for quality products.

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

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
LU1. Maintain temperature and humidity	**Trainee will be able to:** • Inspect work place regularly as per area/product specific requirements • Note current temperature and humidity of workplace as required for manufacturing order • Maintain workplace temperature and humidity as per manufacturing order • Record temperature and humidity as per manufacturing order • Report to in-charge about any deviation if occur, for prompt measures	• Describe Humidity and temperature • Define hygrometer, thermometer as equipment • Explain heating, ventilation, air pressure at workplace • Describe Monometer	• Heating ventilation and air conditioning (HVAC) • Hygrometer, • Thermometer, • Monometer • Filters of different types • Safety kit
LU2. Ensure air pressure of specific area/work place	**Trainee must be able to:** • Note and maintain air pressure of workplace as required for manufacturing order • Record air pressure as per manufacturing order • Report to in-charge about any deviation if	• Explain air pressure variations • Know about area specific air pressures	• Monometer

	occur, for prompt measures		
LU3. Prepare area for swab test	**Trainee must be able to:** • Clean workplace, tools/equipment from dust before swab test • Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications • Report to in-charge about any deviation	• Explain cleaning procedure • Explain swab test • Know the role of detergents & disinfectant in workplace • Define sensitive products and their specifications	• Sanitizers • Disinfectant, Detergent • Swab
LU4. Adjust light as per specifications in workplace area	**Trainee must be able to:** • Identify high-bay and low-bay lights and colors as per manufacturing of sensitive medicine products or task specific lights in workplace • Adjust dust and water resistance lights as required for specific manufacturing tasks	• Explain different types of lights color and specifications	• Different kinds of lights

Examples and illustrations

Humidity: The amount of water vapors presents in moist air per unit mass of the dry air in given volume.

Relative humidity:

The relative humidity is measured using the ambient temperature of the atmosphere, as shown by the 'dry' thermometer and the difference in temperature as shown by the 'wet' thermometer.

Importance of Monitoring Humidity: Many of the ingredients used in pharmaceutical manufacturing are hygroscopic, meaning they can absorb water, even from the air. A high humidity can therefore affect the characteristics of the product and impact the quality of your product. The manufacture of capsules is one situation where a maintaining a low humidity, ideally below 40%, is important due to the hygroscopic nature of gelatin. Hard gelatin capsules and other hygroscopic capsules must be stored in low humidity storage.

Hygrometer:

Hygrometers are devices that measure the relative humidity of the atmosphere. There are several forms that exist, however the wet-dry bulb thermometer hygrometer which is also called a psychrometer is one commonly used variety. Another equipment, used for measurement of temperature and humidity is digital hygrometer.

Heating, Ventilation and Air Conditioning (HVAC) system is a basic requirement of a pharmaceutical manufacturing facility. HVAC is a system that is used to control the air temperature by controlling the air filtration and the moisture in the air.

Thermometer: A thermometer is a device that measures temperature or a temperature gradient.

The temperature and humidity are noted and controlled as per specification according to manufacturing order. HVAC system control and adjust it.

Before staring process, the area should be monitored and adjusted if required as per manufacturing order. Report the incharge of section if any deviations.

Manometer:

A manometer is used to measure the pressure of liquids or gases. A handheld digital manometer commonly is used to measure differential pressure in heating, ventilation and air conditioning (HVAC) systems. Differential pressure references the difference in pressure between two points. Manometer is needed for measuring large gauge pressures [https://en.wikipedia.org/wiki/Pressure_measurement].

Air pressure of workplace is monitored and recorded as per required for manufacturing order. According to WHO guidelines on HVAC (heating, ventilation and air-conditioning) system, 10-15 pascals of differential pressure is maintained between manufacturing and surrounding areas. The aseptic area should always be highly pressurized than the non-aseptic area and air flow should be always from the aseptic to non-aseptic area.

Cascade Airlock: These airlocks are very common having a higher pressure on one side and lower pressure on another side. This prevents to enter dust and contaminants from outside to airlock and from airlock to inner side [https://pharmapathway.com/three-different-types-of-airlock-in-pharmaceuticals/].

Report to in-charge about any deviation if occur, for prompt measures and adjustment prior to processing.

Positive air pressure cleanrooms

This means that the air pressure inside your cleanroom is greater than the pressure outside of it. This is achieved by pumping clean, filtered air into the cleanroom, generally through the ceiling.

Importance of Positive Air Pressure Cleanrooms

Positive pressure is used in cleanrooms where the priority is keeping any possible germs or contaminants out of the cleanroom. In the event that there was a leak, or a door opened, clean air would be forced out of the cleanroom, rather than unfiltered air being allowed into the cleanroom. This works somewhat similarly to deflating a balloon; when you untie a balloon, or pop it, air rushes out because the air pressure in the balloon is higher than the pressure of the ambient air [https://angstromtechnology.com/whats-the-difference-between-positive-and-negative-air-pressure-cleanrooms/].

Cleaning: is the process of removing unwanted substances such as dirt, infectious agents or other impurities from objects, equipment, etc.

Cleaning validation: cleaning process adequately and consistently removes product residues, process residues or environmental contaminants from the manufacturing equipment/system so that this equipment/system can be safely used for the manufacturing of specified subsequent products [https://www.pharmatutor.org/articles/cleaning-validation-pharmaceutical-industry-comprehensive-approach].

Sampling for Cleaning: to evaluate the cleaning effectiveness, it is necessary to take sample of the equipment to establish the level of residue present.

Sampling Methods: There are two methods for sampling

i. Swab sampling

ii. Rinse sampling

Swab test:

Swab sampling shall be considered as the primary criteria for cleaning validation. Swab sampling directly measures surface residues and is a favored method of sampling. Swabbing is the preferred method to validate critical cleaning within pharmaceutical manufacturing environments.

The following steps are involved in carrying out Swab test:

i. A cotton Swab of Johnsons and Johnsons make is moistened with normal saline (0.9 % NaCl) and placed in a suitable test tube or screw cap test tube.

ii. The mouth of the test tube is closed with a cotton plug and rapped with aluminum foil.

iii. The test tube containing the swab is then sterilized by autoclaving at 121°C, 15 psi, pressure for 15 min.

iv. Alternatively, pre-sterilized cotton swab of HI- media make can also be used. In this case, moisten the swab with sterile normal saline before using the swab.

v. Wear gloves and take out the swab carefully from the test tube and swab the surface to be checked.

vi. The area of the swab should be approximately 10 Sq. cm.

vii. Replace the swab immediately in the test tube and close.

FOR MICROBIOLOGICAL TESTING THE FOLLOWING STEPS ARE CARRIED OUT:

viii. Add accurately 10 mL of sterile phosphate buffer pH 7.2 to the test tube containing the Swab aseptically.

ix. Shake well and transfer 1 mL to each of two sterile petri dishes and proceed for test for Total Bacterial Count and yeast and mould as per the respective Standard Testing Procedures.

x. Also determine the presence of pathogens if necessary (E. coli, Salmonella, S. aureus and Pseudomonas) by transferring 1 ml to each of the enrichment medium as per respective Standard Testing Procedures [https://www.dcvmn.org/IMG/pdf/402 cleaning_validation.pdf].

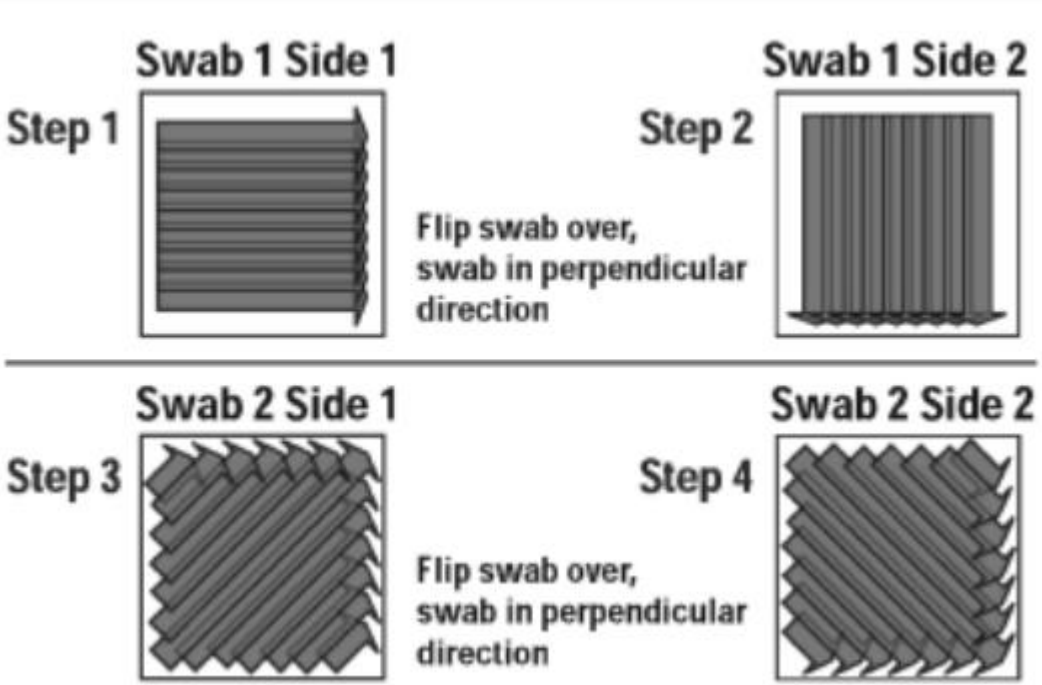

Figure: Proper Swabbing Procedure

[https://pdfs.semanticscholar.org/3445/c83f051af40b4ba4ee28316deedca5c0ab67.pdf]

Detergents & disinfectant in workplace

Cleaning and disinfection of surfaces are essential steps for maintaining the cleanliness of pharmaceutical manufacturing operations.

Detergent

Detergents are surfactant or mixture or surfactants which have cleaning properties in dilute solution. All detergents have their specific use due to the nature of surfactant which found in detergents. In pharmaceutical industry nonionic detergents use for cleaning of equipment's to maintain the product quality.

Nonionic detergents are considered to be “mild” detergent. In the comparison of ionic detergent, Nonionic detergent is less likely to denature protein.

This is necessary in order for the disinfectant to work effectively. Furthermore, microorganisms in suspension are easy to remove with rinsing or kill with the disinfectant.

Selection criteria for detergents

Here it is important that the detergent selected will:

i. Work with different types of water (e.g. ‘hard’ and ‘soft’ water)
ii. Be compatible with the disinfectant
iii. Not damage the surfaces
iv. Non-foaming
v. Be effective against different soils e.g. grease, dirt, oil, protein, rust, skin
vi. In general, neutral detergents are ideal. Depending on the area of use, such as aseptic filling areas, detergents may need to be sterile.

Reason of use nonionic detergent

In pharmaceutical industry because they don’t ionize when mix in water. These types of detergent are manufactured to mix the same quantity acid or base. So, that the pH of nonionic detergent remains neutral. These detergents are more effective against the oil surface and generate less foam when mixed in water. Pharmaceutical detergent mainly found in liquid form.

Disinfectant

Disinfectants are antimicrobial agent which may applied on nonliving surface to kill microorganism. It is not compulsory that disinfectant kill all microorganisms. It’s a less effective against bacterial spore. Although some disinfectant such hydrogen peroxide (H_2O_2) applied in high concentration can kill bacterial spores. Antiseptics and antibiotic disinfectant are different from other antimicrobial agents. Antibiotics destroy microorganism within the body and antiseptics destroy microorganism on living tissue. Disinfectants are less effective than sterilization.

There are many different types of disinfectants for use within the pharmaceutical industry, with different spectrums of activity and modes of action. The mechanisms of action are not always completely known and continue to be investigated. A range of different factors needs to be considered as part of the process of selection including the mode of action, and also efficacy, compatibility, cost and with reference to current health and safety standards.

In pharmaceutical industry disinfectant are mainly used for cleaning purpose like floor. Disinfectant should be rotate because they are biocidal. Biocidal activity is measured by the minimum bactericidal concentration (MBC). When a microorganism is first time exposed to disinfectant, sub-culturing is not possible. It means microorganism have been killed. At which concentration microorganism is killed known as biocidal activity. If we expose same disinfectant routinely microorganism develop resistance against particular disinfectant and may alive. Microorganism don't develop resistance against particular disinfectant we need disinfectant rotation.

Some of the more commonly used types of disinfectants. Surface disinfectants can be divided into:

Non-Oxidizing Disinfectants

Alcohols

The effectiveness of alcohols against vegetative bacteria and fungi increases with their molecular weight (therefore ethanol is more effective than methanol and in turn isopropyl alcohols are more effective than ethanol). The advantages of employing alcohols include a relatively low cost, little odour and a quick evaporation

Aldehydes

Aldehydes include formaldehyde and glutaraldehyde. Aldehydes have a non-specific effect in the denaturing of bacterial cell proteins and can cause coagulation of cellular protein. There are some safety concerns about the use of some aldehydes

Phenolics

Synthetic phenols are widely available such as the bis-phenols (triclosan) and halophenols (chloroxylenol). Phenols are bactericidal and antifungal, but are not effective against spores. Some phenols cause bacterial cell damage through disruption of proton motive force, while others attack the cell wall and cause leakage of cellular components and protein denaturation.

Quaternary Ammonium Compounds (QACs)

They are ineffective against bacterial spores. QACs are possibly the most widely used of the non-oxidizing disinfectants within the pharmaceutical industry; examples include cetrimide and benzalkonium chloride.

Oxidizing Disinfectants

This group includes oxygen-releasing compounds (peroxygens) like peracetic acid and hydrogen peroxide. They function by disrupting the cell wall, causing cytoplasm leakage and denature bacterial cell enzymes through oxidation. Oxidizing agents have advantages in that they are clear and colorless, thereby avoiding surface staining

[https://www.researchgate.net/publication/267717115_Selection_of_Disinfectants_for_Use_in_the_Pharmaceutical_Industry].

What Makes a Disinfectant Work Well or Badly?

There are a number of factors that affect whether a selected disinfectant works well or poorly[7]. These are briefly presented below:

i. **Number of microorganisms:** In general disinfectants are more effective against a low number of microorganisms than a higher number.
ii. **Types of microorganisms:** Some microorganisms are more resistant than others. Here, Gram-positive bacteria are generally easier to kill than Gram-negative bacteria; vegetative bacteria are easier to kill than fungi; and endospore forming bacteria are the hardest to kill (for these a disinfectant classed as a sporicide is required).
iii. **Location of microorganisms:** The key issue here is how likely are microorganisms to be fixed to surfaces? The degree of surface attachment can affect the removal and destruction of organisms.

iv. **Contact time:** This is the time taken for a disinfectant to kill the microorganism and the time that the disinfectant must be left in contact with the surface. This will typically be 1 to 5 minutes, although the time can only be assessed through disinfectant efficacy testing.

v. **Disinfection concentration:** Disinfectants are manufactured or validated to be most effective at a set concentration range (the proportion of the chemical to water). Over- or under-dilution will lead to a loss of efficacy.

vi. **Temperature:** The temperature at which the disinfectant is used at influences the rate of reaction. In general, lower temperatures, especially those below the threshold at which the disinfectant has been assessed; mean that the disinfectant may not work. This means that if disinfectants are used in cold storage areas, they should be assessed to see if they remain effective.

vii. **pH:** Like temperature, extremes of pH can influence disinfectant efficacy.

viii. **Soil:** As discussed above, if soil is not effectively removed this can either interfere with the disinfectant or prevent the disinfectant from making contact with the microbial cell wall.

ix. **Type of water:** Hard water can be a problem. The water used to prepare disinfectants in the production facility should be incorporated into disinfectant efficacy studies.

Sensitive products and their specifications

When talking about sensitive products one usually thinks about products that are sensitive to temperature, but other environmental conditions should also be considered, including humidity, light, oxygen, shocks, pressure, vibrations and X-rays encountered during shipment by truck, train, boat, or plane.

Temperature is the main focus for testing because almost all pharmaceutical products are sensitive to temperature.

A drop/rise in *pressure* can damage products if packaging has not been tested for deformation or leakage under high/low pressure. Blisters and sprays are examples of sensitive packaging.

Shocks can damage products if packaging has not been tested for shock resistance. Shock might damage solid dosage forms (tablets) during transport if they are friable.

Specifications are critical quality standards that are proposed and justified by the manufacturer and approved by regulatory authorities as conditions of approval. Specifications are one part of a total control strategy for the drug substance and drug product designed to ensure product quality and consistency.

Photo-sensitive drugs: Exposure to light is a concern with numerous medications due to the potential for photo-degradation or other chemical reactions that affect drug stability. Many pharmaceutical products are sensitive to light and it is therefore crucial that they are protected from direct sunlight and certain spectrums of artificial light. One way to do this is by using brown colored light, especially during the manufacturing process. here are many different chemicals that are sensitive to light and can degrade if exposed to certain light spectrums. Not only can this lead to the product being less effective, the degradation of the chemicals can lead to impurities in the product and result in the product failing quality standards. More importantly, these impurities may also have negative effects on a patient's health. Throughout the manufacturing process, light-sensitive drugs must be protected. Longer wavelength light, above 500 nm, is recommended for granulation, compression and packaging areas. For this, the best option is brown colored light, which has wavelengths of between 500 nm and 800 nm.

[https://www.americanpharmaceuticalreview.com/Featured-Articles/184449-Pharmaceutical-Facility-Sanitization-Best-Practices-Considered/]

Bay lighting:

High Bay and Low Bay are lighting terms used to describe the correct bay lights needed for the appropriate ceiling height. Typically, High Bay Lights apply to any large area with a ceiling height greater than 20 ft. In return, Low Bay Fixtures are used in large rooms with a ceiling height between 12 and 20 feet.[https://www.homelectrical.com/what-difference-between-high-bay-and-low-bay-light.6.html]

Heavy duty lighting projects, like those often done in large buildings such as warehouses, factories, and processing plants, typically require high bay or low bay lights. These high lumen output lights are designed to provide well distributed and uniform light in open areas.

In general, each functional areas of pharmaceutical industry are large, and the rational selection of lighting fixtures has a great impact on the maintenance of cleanliness and energy saving. This also contributes to create a clean and tidy environment for pharmaceutical factory where has strict requirement to its environment.

An appropriate lighting intensity for office is 300-500 lux. It should be about 400 lux in all production areas and above 300 lux in sampling center and dispensing center.

Figure: Lux meter (for measuring light intensity)

https://www.globalmediapro.com/dp/A2H3G1/Victor-1010A-Digital-Lux-Meter/

The following two videos are very helpful to know about how to use Lux meter:

https://www.youtube.com/watch?v=dYkX0EKP9pk

https://www.youtube.com/watch?v=YfLV14LFFfI

Test Yourself (Multiple Choice Questions)

Module E Prepare work environment according to manufacturing order

Please mark the correct one from the given options.

QNO1: Which one of the following equipment is used to measure intensity of light?

A. Hygrometer
B. Manometer
C. Barometer
D. Lux meter

QNO2: What does HVAC stand for?

A. Heating, ventilation and air conditioning
B. Heating and alternate current
C. Heating versus air conditioning
D. Heating, ventilation and air control

QNO3: What is considered as the primary criteria for cleaning validation?

A. Dusting removal
B. The likelihood of something going wrong
C. Where an accident is likely to cause harm
D. Swab sampling

QNO4: Which one of the following is best description of disinfectant?

A. applied on living to kill microorganism
B. applied on both living and nonliving surfaces to kill microorganism
C. applied on nonliving surface to kill microorganism
D. applied on nonliving surface to stop only growth of microorganism

QNO5: What is meant by positive pressure inside cleanroom?

A. the air pressure inside cleanroom is less than the pressure outside of it
B. the air pressure inside cleanroom is greater than the pressure outside of it
C. the air pressure inside cleanroom is equal to the pressure outside of it
D. e air pressure outside cleanroom is greater than the pressure inside of it

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

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Module-F

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Module F: Receive product raw material according to manufacturing order

Objective: After completing this module, the learner will be able to identify materials as per labels, shift materials to concerned section and arrange raw materials for mixing as per procedure and protocol of industry.-

Duration: 50 Hours **Theory: 10 Hours** **Practice: 40 Hours**

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
LU1. **Identify materials according to labels**	• Identify raw materials as per manufacturing order • Cross check the labels of raw materials as per specifications against each manufacturing order • Check the signature of appropriate authority on labeled raw materials as per manufacturing order • Report to in-charge about any deviation	• Describe manufacturing order • Describe different types (specifications) of raw materials • Describe raw materials identification procedure	
LU2. **Check weight of raw materials**	• Confirm calibration status of weighing balance • Cross check the gross weight of individual labeled raw materials as per manufacturing order	• Describe calibration and its importance • Explain calibration types(internal/external) • Describe net weight, gross weight and tare weight •	• Weighing digital balance

LU3. **Shift materials to concerned section**	• Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area • Transfer dispensed materials trolley to the manufacturing area as per procedure • Check the temperature and humidity of material placement area as per procedure • Park trolley safely and lock it at appropriate place as per instructions	• Describe safe shifting of materials • Describe different methods of arranging batch materials as per job order	Shifting Trolley
LU4. **Arrange Raw Materials for Mixing**	• Check the batch material trolley prior to dispatch to mixing area as per procedure • Transfer dispensing material trolley to the production area as per instructions • Check the batch material and arrange it according to mixing order as per set procedure	• Describe mixing procedure of individual dosage form	shifting trolley

Examples and illustrations

Manufacturing order

A manufacturing order is an order issued within a pharmaceutical company to produce a specific quantity of material product in a certain timeframe.

Different types (specifications) of raw materials

The learner must ensure the physical aspects of raw materials. The physical aspects may include the following:

i. Nature of raw materials (fine or granular forms, flow properties)
ii. Visual inspection of raw materials (color)
iii. Odor

The following procedure should be followed for raw materials identification

i. Identify raw materials as per manufacturing order
ii. Cross check the labels of raw materials as per specifications against each manufacturing order
iii. Check the signature of appropriate authority on labeled raw materials as per manufacturing order
iv. Report to in-charge about any deviation

Besides the above, the following informations should be checked on the label of the raw materials.

i. Name of raw material
ii. Code of material
iii. Manufacturer/Supplier Lot Number
iv. Internal Lot Number
v. Batch Number
vi. Manufacturing date
vii. Date of Expiry
viii. Retest date
ix. Quantity (weight/volume)
x. Signature of the authorized person
xi. The name and the batch number of the product for which the materials have been dispensed

Calibration and its importance

Calibration is a process of ensuring and maintaining the accuracy of a weighing instrument in alignment with a standard or accepted range of results. Therefore, weighing scale calibration is considered the process of correcting, determining and checking the scale is meeting its known or assigned accuracy.

Why does a balance need to be calibrated?

It is essential that balances and weighing instruments are regularly calibrated to ensure that weighing results are consistent.

How is a weighing scale or balance calibrated?

There are several ways in which to calibrate a balance or scale, however it is most common to use approved **calibration weights** or test weights. There are wide varieties of calibration weights available which range from 1g up to large kilogram increments. When testing your balance, it is best weighing practice to use a full set of weights that are comparable with your scale or balance's weight capacity and level of accuracy.

Types calibration (internal/external)

External calibration:

External calibration means that the calibration process is manual. To calibrate a balance or scale externally, the user must have a set of approved calibration weights that should be kept in top condition.

The weights are put on the balance or scale and their mass or weight set as the standard. So, if your weight is 1kg, you would set the weight on the scale as 1kg. It is important that the weights are bought from a trusted source (scale and balance manufacturers usually have an accessory tab on the website with a set of weights being one of the options). The weights should be maintained with care to ensure they do not lose or gain mass, which would render them invalid [https://www.inscale-scales.co.uk/blog/internal-or-external-calibration].

Internal calibration:

Internal calibration allows the weighing scale or balance to calibrate itself, often automatically without needing manual input from its users or calibration weight sets. There are various degrees and technologies used to ensure precision that change depending on model, make and price range. Some balances even allow you to set calibration at specific times or intervals (for example, during lunch or in the morning before people come to work, or even every couple of hours). They also allow for the scale or balance to be calibrated with a single button press. These balances have built-in calibration weights, often motor driven [https://www.inscale-scales.co.uk/blog/internal-or-external-calibration].

Net weight, gross weight and tare weight

Net weight: It refers to the weight of the raw product and does not include the weight of the products packaging or container. The net weight is equal to the gross weight minus the tare weight. Net weight can also refer to the weight of products/materials that have been packed into a container but do not include the container's weight [http://www.differencebetween.net/science/difference-between-gross-weight-and-net-weight/].

Gross weight: The word gross means total. Thus, gross weight means total weight.

Tare weight: Tare weight is the weight of the packaging or container in which materials are shipped. Tare weight forms the basic difference between the gross weight and net weight of a shipment [http://www.differencebetween.net/science/difference-between-gross-weight-and-net-weight/].

The Net weight is the amount of weight added to the scale since the last "TARE" command was done. Doing a "TARE" command will cause the Net weight to equal zero.

Safe shifting of materials

Procedure for Safe shifting of materials:

The following steps are taken for “Safe Shifting of Materials”:

i. Check and verify all the detail of materials (name of materials, code, approved label, Batch number, manufacturing date, expiry date, retest date) one by one as per manufacturing order
ii. Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area
iii. High potency drugs such as steroids and alkaloids should be weighed in separate room equipped with absolute filters to avoid even minimal cross contamination
iv. Transfer dispensed materials trolley to the manufacturing area as per procedure
v. Check the temperature and humidity of material placement area as per procedure
vi. Park trolley safely and lock it at appropriate place as per instructions/guidelines
vii. The production person should check all the materials dispensed as per manufacturing order prior to processing. I case of any problem consult the section incharge.

Different methods of arranging batch materials as per job order

The following steps are taken to minimize the errors:

i. The materials should be arranged as per mixing order in the manufacturing procedure
ii. Verify the quantity and product tag of the materials and cross check as per manufacturing order

Mixing: is defined as shuffling type unit operation process involving both large and small particle groups.

Types of Mixtures: Mixtures may be classified as follows:

1. **Positive mixtures –** These types of mixtures are formed when two or more than two gases or miscible liquids are mixed together by means of diffusion process. In this case no energy is required provided the time allowed for solution formation is sufficient. These types of materials do not create any problem in mixing.

2. **Negative mixtures –** These types of mixtures are formed when insoluble solids are mixed with a vehicle to form a suspension or when two immiscible liquids are mixed to form an emulsion. These mixtures are more difficult to prepare and require a higher degree of mixing with external force as there is tendency of the components of these mixtures separate out unless they are continuously stirred

3. **Neutral mixtures –** Many pharmaceutical products such as pastes, ointments and mixed powders are the examples of neutral mixtures. They are static in their behavior. The components of such products do not have any tendency to mix spontaneously but once mixed, they do not separate out easily.

Standard operating procedures are used for mixing process of any dosage form. The order of mixing, mixing time, appropriate selection of mixer is the basic considerations.

Some of the examples of large-scale mixing practiced in pharmacy are:

i. Mixing of powders in varying proportions prior to granulation or tableting

ii. Dry mixing of the materials for direct compression in tablets

iii. Dry blending of powders in capsules and compound powders (insufflations).

iv. Blending of powders in cosmetics in the preparation of face powders, tooth powders

v. Dissolution of soluble solids in viscous liquids for dispensing in soft capsules and in the preparation of syrups

vi. Mixing of two immiscible liquids for preparation of emulsions.

Conditions for mixing of Powder: The theory of mixing shows four conditions that should be observed in the mixing operation.

i. **Mixer volume:** The mixer must allow sufficient space for dilation of the bed. Overfilling reduces the efficiency and may prevent mixing entirely.

ii. **Mixing mechanism:** The mixer must apply suitable shear forces to bring about local mixing and a convective movement to ensure that the bulk of the material passes through this area.

iii. **Mixing time:** Mixing must be carried out for an appropriate time, since the degree of mixing will approach its limiting equilibrium value asymptotically. Hence, there is an optimum time for mixing for any particular situation, one should also note that the equilibrium condition may not represent the best mixing if segregation has occurred.

iv. **Handling the mixed powder:** When the mixing operation is completed, the mixer should stop and the powder should be handled in such a way that segregation is minimized. The vibration caused by subsequent manipulation, transport, handling or use is likely to cause segregation. Therefore, a bulk powder that has been stored or transported should be re-mixed before removing a part of the contents [https://www.pharmatutor.org/pharmaceutics/mixing-of-pharmaceuticals-mechanism.html].

Table: Mixing Equipment used for Dosage forms

S. No	Type of Mixing	Name of Mixer	Uses
1.	Liquid-liquid mixing	• Shaker mixers • Propeller mixers • Paddle mixers • Turbine mixers • Sonic and ultrasonic devices such as Rapisonic homogenizer	Used in the preparation of emulsions, antacid suspensions, mixtures such as anti-diarrhoeal bismuth-kaolin mixtures etc. Rapisonic homogenizer is particularly used in the mixing of immiscible liquids i.e. preparation of emulsions.
2.	Solid-solid mixing	• Agitator mixers • Tumbling mixers • Double-cone mixers • V-blenders	Used for the mixing of dry powders.
3.	Semi-solid mixing	• Agitator mixers like sigma mixers and Planetary mixers • Shear mixers like colloidal mills and triple roller mills	Sigma mixers can also be used for solid-solid mixing.

[https://www.pharmatutor.org/pharmaceutics/mixing-of-pharmaceuticals-mechanism.html]

Test Yourself (Multiple Choice Questions)

MODULE	F	Receive Raw Material according to Manufacturing Order

Please mark the correct one from the given options.

QNO1: Why calibration of weighing balance is done?		
A. to maintain the quality of weighing balance	C.	to maintain the accuracy of weighing balance with standard
B. to maintain the accuracy of weighing balance with market	D.	to maintain the quality of weighing balance with standard
QNO2: What is Net weight?		
A. the weight of the raw product and include the weight of container	C.	the weight of the raw product and include the weight of the products packaging or container
B. the weight of the raw product and include the weight of the products packaging	D.	the weight of the raw product and does not include the weight of the products packaging or container
QNO3: What is meant by Gross weight?		
A. Net weight	C.	Total weight
B. Tared weight	D.	Weight of container
QNO4: What is the equipment used for liquid-liquid mixing?		
A. Propeller and double cone mixers	C.	Agitator and Turbine mixers
B. Shaker and paddle mixers	D.	Tumbling and Propeller mixers
QNO5: What are the four conditions that should be observed in the mixing of powder operation?		
A. Mixing volume, mechanism, efficiency and handling of mixed powder	C.	Air pressure, mechanism, efficiency and handling of mixed powder
B. temperature, mechanism, efficiency and handling of mixed powder	D.	Theory, mechanism, efficacy and handling of mixed powder

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

PHARMACEUTICAL MANUFACTURING TECHNICIAN

Module-G

LEARNER GUIDE

National Vocational Certificate Level 2

Version 1 - November, 2019

Module G: Adjust machine as per product manufacturing order

Objectives: After completing this module, the learner will be able to identify materials as per labels, shift materials to concerned section and arrange raw materials for mixing as per procedure and protocol of industry.

Duration: 60 Hours **Theory: 10 Hours** **Practice: 50 Hours**

Learning Unit	Learning Outcomes	Learning Elements	Materials Required
LU1. **Check Electrical and Mechanical parameters of Machine for Proper functionality**	• Check machine electric input and output as per instructions given in machine manual • Check machine mechanically fit for operation as per manufacturing order • Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order	• Describe machine electric input and output system • Importance of instructional manual for machine operating system • Describe machine Program Logic Control (PLC), Human Machine Interface (HMI) and how it works • Describe types and functions of machine • Explain different parts of machine • Describe abnormal functions of machine during processing	• Machine manuals • Human Machine Interface (HMI) • Tool kit
LU2. **Check Machine Lubrications**	• Check gauge of lubricants as per machine manual • Verify proper lubrication of machinery as per maintenance schedule • Report to in-charge about any deviation.	• Describe importance and different types of lubricants • Describe the process of machine lubrication	• Different lubricants and its oil pump and other accessories

LU3. **Ensure Cleaning of Machine**	• Check the cleanliness status of machine after completion of each batch as per the instructions given in manual • Proper tagging of machine as per procedure • Inform the area in-charge about completion of each batch as well as for next process as per manufacturing order	• Describe cleaning methods of machine	• Machine manuals
LU4. **Maintain machine Log-Book**	• Make entries in machine log book as per instructions • Check log book periodically for effective and smooth running of machine functions • Report to in-charge for any unusual response during manufacturing processing	• Describe types of log book • Describe procedure of maintaining of log-book • Define tags and product name and codes • Describe tagging and assigning codes to the products • Describe coding system of pharmaceutical products	• Log book

Examples and illustrations

Machine electric input and output system

Power adapters convert the electricity from one voltage to another voltage, and sometimes between AC and DC. The INPUT is what sort of electrical system you need to supply to the adapter (i.e. what your power company supplies). The OUTPUT is what is supplied to your device. Input Power is the power, which is required by the appliance at its input i.e., from the plug point. Power at the load is the output power, which can be delivered by the appliance. It is always less than Input power. Using a digital multimeter, the INPUT is measured.

Importance of instructional manual for machine operating system

The operations **manual** is the documentation by which an organization provides guidance for members and employees to perform their functions correctly and reasonably efficiently. It documents the approved standard procedures for performing operations safely to produce goods and provide services. It includes the functions of various parts of machine, its operation, safety instructions while operating the machine, maintenance instructions in case of any problem in proper functioning.

Machine Program Logic Control (PLC), Human Machine Interface (HMI) and how it works

Most modern control systems employ a PLC (Programmable Logic Controller) as a means to control motors, pumps, valves and various other equipment used in a process. Computer based HMI (Human Machine Interface) products provide the means by which process personnel interact with the PLC control system. These operator devices are designed to monitor and control the system. Operators can tell the system's status, adjust application parameters, input and output positions, or run master programs.

How do PLCs Work?

The first step in the process is called an Input Scan. As its name implies, the PLC detects the state of all input devices hooked up to the PLC. After that, the second step is the Program Scan, which scans the program that the user created and then executes it. The next step is the Output Scan. As its name implies, it scans the output devices connected to the PLC and either energize or de-energize them.

Finally, the last step is Housekeeping. This step is more like a safety step in which the PLC communicates with internal diagnostics, programming terminals, etc. If the last step is done correctly and everything is under control, the PLC starts from the beginning until the loop is finished.

Abnormal functions of machine during processing

The abnormal functions of machine may not only affect the efficiency of machine but also *deteriorate* the product. These functions may include:

i. Noisy
ii. Speed may be reduced
iii. Sometimes parts of machine are broken down

Lubricants: are substances that reduce friction, heat, and wear when introduced as a film between solid surfaces. Using the correct lubricant helps maximize the life of your bearings and machinery, therefore saving money, time, and manpower, thus making operations more efficient and more reliable.

Importance of Lubrication of machines:

It is beneficial to lubricate pharmaceutical machinery from time to time. Lubrication during manufacturing minimizes the friction between different parts of the machines. This is important as friction can cause heating which may adversely affect the pharmaceutical product. Lubrication also helps reduce the tendency of parts to rust and decreases load in the machine. The lubricants for pharmaceutical machinery are generally made of natural organic oils as synthetic ones can cause reaction with products and are therefore not permitted.

Different Lubricants Approved for Pharmaceutical Machine Use:

There are several machines that are commonly used by in pharmaceutical industry that have moving parts that require regular lubrication. Examples Food grade lubricant, Amber Grease include the colloid mill, coating machine, tablet press, packing machine and rapid mixer granulator. A common issue is that lubricants can leak and ultimately may inadvertently come into contact with the product and cause contamination. In sterile environments, the lubricant can be a source of microbial contamination, and if such lubricant infiltrates the product there is a high probability that it will compromise both its quality and efficacy.

In order to prevent risk of compromising pharmaceutical products, lubricants used in machinery must meet the necessary regulatory guidelines -- only food-grade lubricant oil is permitted, and it must have ISO21469 certification. Manufacturers are also required to have their products pass the National Sanitation Foundation (NSF) H1 registration. The H1 category is one of three categories of lubricant:

i. **H1 Lubricant – food grade lubricants** used for equipment with high chance of contact or mixing with the food or drug product. It must contain ingredients that are listed in the 21CFR part 178:3570.
ii. **H2 Lubricant –** these lubricants are used for parts that are not exposed to the product. The lubricants must not contain any heavy metal like arsenic, lead or cadmium.
iii. **H3 Lubricant –** lubricants that are edible and soluble and are usually used in transportation equipment.

Synthetic food grade lubricants that contain polyalphaolefin or polyalkylene oils may be used when manufacturing at an extreme temperature. **Polyalphaolefin** is by far the most common major synthetic base oil used in industrial and automotive lubricants. Silicon oil that has high viscosity may also be used.

Process of machine lubrication

Lubrication is the process or technique of using a lubricant to reduce friction and/or wear in a contact between two surfaces. Adequate lubrication allows smooth, continuous operation of machine elements, reduces the rate of wear, and prevents excessive stresses or seizures at bearings. The fraction may cause the heating of the moving parts. There are several **machines** that are commonly used by in **pharmaceutical** industry that have moving parts that require regular **lubrication**. Examples include the colloid mill, coating **machine**, tablet press, packing **machine** and rapid mixer granulator. The below video is an illustration of ways of lubrication of tablet press machine:

https://www.youtube.com/watch?v=yxgvMj178Ik

Cleaning methods of machine

Manual, ultrasonic, spray, machine and automated systems are all used for cleaning pharmaceutical equipment. The type of cleaning method used will impact your choice of detergent. Automatic parts cleaners and high-pressure washers require low foaming detergents.

Importance of Pharmaceutical processing equipment:

i. Maintain product quality.

ii. Remove all trace ingredients to prevent the transfer of ingredients from one product to the next. This is especially important when multiple products are produced on the same equipment.

iii. Prevent equipment malfunctions that may lead to product contamination.

iv. Provide a clean surface for disinfection. Surfaces cannot be properly sanitized or disinfected if they are not thoroughly cleaned first.

v. Comply with local and international standards and regulations to ensure consumer safety and avoid legal issues.

vi. Increase plant performance and productivity by diminishing waste, maintaining equipment and preserving product quality.

vii. Enhance worker safety by providing a clean working environment and smoothly functioning equipment.

Very specific description of each step is cleaning procedure must be considered and the following details should be documented:

a. Frequency of cleaning – including time requirements between processing products and cleaning
b. Cleaning tools used – any sponges, brushes, scrapers, sprayers, wipes or equipment used to aid the cleaning process
c. Establishment and sequence of each cleaning step
d. Identification of each specific piece of equipment to be cleaned, including instructions for cleaning between batches of the same or different products
e. Cleaning method – clean-in-place (CIP) or clean-out-of-place (COP)
f. Detailed instructions for any required disassembly and re-assembly of equipment if COP methods are used. Instructions should specify the parts to be removed and any assembly aids used during this process.
g. Identification of all cleaning detergents and detailed instructions for their use. Usage instructions should include amounts, concentration, temperature, dwell time and application method.
h. Type of water – deionized, distilled or tap

i. Number of rinse steps required

j. Drying and storage guidelines

k. Instructions for visual inspection after cleaning

l. Cleaning validation methods

How to Clean?

Several factors must be taken into consideration to set up an effective cleaning process and remain in compliance with federal regulations.

Soils

Soils found on pharmaceutical processing equipment may be traces of the various ingredients used in production or soils from the actual manufacturing process such as oil, grease, dust or minerals. Understanding the soils that are present will guide your choice of cleaning detergent.

Gels, polyethylene glycol, oils, titanium dioxide, dyes, silicon, flavorings, petrolatum, paraffin, proteins, steroids, sugars, alcohol, stearates, and cornstarch are some of the typical foulants that are often found on pharmaceutical processing equipment.

Each type of soil is unique and requires the proper detergent to thoroughly clean the surface. Choose a cleaner that will best attack the soils you are trying to remove. Alkaline cleaners are the best choice for cleaning soils such as gels, dyes and petrolatum, while citric acid-based cleaners are better suited for removing titanium dioxide. Protein or starch-based soils may require the use of an enzyme cleaner. Use the table below to help match the most effective type of cleaner to each kind of soil.

Soil	Cleaner
Gels	Micro-90, Micro Green Clean, LF-2100, Zymit Pro, Zymit Low Foam
Polyethylene glycol	Micro-90, Micro Green Clean, LF-2100
Edible Oils	Micro-90, Micro Green Clean, LF-2100
Titanium dioxide	Micro A07
Dyes	Micro-90, Micro Green Clean, LF-2100, Micro A07
Silicon	Micro-90, Micro Green Clean, LF-2100
Flavorings	Micro-90, Micro Green Clean, LF-2100
Petrolatum	Micro-90, Micro Green Clean, LF-2100
Paraffin	Micro-90, Micro Green Clean, LF-2100
Protein	Zymit Pro, Zymit Low Foam
Steroids	Micro-90, Micro Green Clean, LF-2100
Sugars	Micro-90, Micro Green Clean, LF-2100
Alcohol	Micro-90, Micro Green Clean, LF-2100
Stearates	Micro-90, Micro Green Clean, LF-2100
Cornstarch	Zymit Low Foam

Type of Equipment

Mixing tanks, tablet presses, capsule fillers, centrifuges, granulators, filling lines, mixers, conveyors, filters, fluid lines, batch process tanks, tubes and flasks all need to be thoroughly cleaned. The design of the equipment must be taken into consideration. By nature of its construction, some types of equipment will be more difficult to clean than others. Hidden parts and blind holes present unique challenges.

Another important factor to consider is the how the equipment is used. Are you cleaning a dedicated production system or equipment that is used to produce a range of products? Processing equipment used to produce multiple products has a greater chance of cross contamination of ingredients.

It's also important to select a cleaner that is compatible with the surface of the equipment you are cleaning.

CLEANING METHOD AND LOCATION

Clean-in-place (CIP) or Clean-out-of-place (COP)?

CIP is generally used for large systems and components that cannot easily be taken apart. CIP often results in less downtime since it eliminates the need to take apart or move the equipment. Automated systems, spray systems and immersion are all examples of CIP operations.

COP is most often used for smaller pieces of equipment or smaller parts of larger equipment that can be removed and re-assembled after cleaning. COP can involve either manual washing or use of machine washers. Specific instructions for disassembling and re-assembling equipment must be followed.

SELECTION OF CLEANING METHOD:

Manual, ultrasonic, spray, machine and automated systems are all used for cleaning pharmaceutical equipment. The type of cleaning method used will impact your choice of detergent. Automatic parts cleaners and high-pressure washers require low foaming detergents. An example of low foaming detergent is LF2100®. LF2100® is a powerful, low-foaming alkaline cleaner. Excellent for removing oil, grease, wax, tar, flux and biological debris from manufacturing and food-processing equipment, tanks, instruments, lab ware, and many other surfaces. The low-foam formulation makes it suitable for use in lab washers, power sprayers and industrial sized washers. Registered with NSF as an A1 cleaner and can be validated in FDA processes.

Temperature

In most cases, increasing the temperature is one of the best ways to speed up or improve the cleaning action. The temperature parameters that should be used for any individual cleaning application will depend upon the equipment and the soils that are present, as well as your choice of detergent and wash method. Check with the manufacturer for the maximum suggested operating temperature for your detergent.

Dwell Time

The length of the cleaning cycle contributes to the effectiveness of your cleaning application. In most cases, a longer dwell time will improve the results. However, all factors – soils, temperature, substrate, detergent and cleaning method must be taken into consideration.

Rinse Step

Thorough rinsing should follow cleaning. Rinsing removes any excess detergent left on the item. For critical cleaning applications, it is best to use deionized or distilled water, as rinsing with ordinary water may introduce new contaminants.

Cleaning Validation

Cleaning validation is a part of the regulatory compliance process for cleaning pharmaceutical processing equipment. Validation ensures that all equipment is washed according to previously determined standards and that all traces of soil and detergent are removed. Validation methods are unique to each detergent and should be available from most cleaner manufacturers.

Equipment logs/log books

Logbooks are basically documenting that are used in different purposes and for different functions with regards to equipment handling, maintenance, and usage. The following points are considered while keeping the log book of machine/equipment:

1. All the equipment must have an individual log book.

2. The log book for any equipment shall be contain the following parameters:

    i. Equipment Name
    ii. Equipment Identification Number.
    iii. Department
    iv. Location
    v. Date
    vi. Name of the product
    vii. Batch Number
    viii. Mfg. date
    ix. Exp. date
    x. Batch Size
    xi. Operational activity (Procedure time)
    xii. Done by.
    xiii. Checked By
    xiv. Verified By
    xv. Remarks

3. Any break down in equipment must be recorded. The log book for break down contain the following points:

    a) Date
    b) Details of break down
    c) Corrective action taken
    d) Rectified by
    e) Checked by
    f) Remarks

Tags and product name and codes

Product tags are descriptors assigned to specific products to organize, document and track their progress. If two products share the same size and color type, product tags must be used to display them correctly online.

Drug nomenclature is the systematic naming of drugs, especially pharmaceutical drugs. In the majority of circumstances, drugs have 3 types of names:

Chemical names: The chemical names are the scientific names, based on the molecular structure of the drug. There are various systems of chemical nomenclature and thus various chemical names for any one substance. The IUPAC name of Paracetamol/Acetaminophen is *N*-(4-hydroxyphenyl) acetamide.

Nonproprietary (generic) names: During development, the company will apply for regulatory approval of the drug by the relevant national regulatory agency such as the U.S. Food and Drug Administration (FDA); and it will apply for a generic (nonproprietary) name for that country, such as the United States Adopted Name (USAN) or Japanese Accepted Name (JAN). It will also apply for an International Nonproprietary Name (INN) through the World Health Organization (WHO).

Brand names: For drugs that make it all the way through development, testing, and regulatory acceptance, the pharmaceutical company then gives the drug a trade name, which is a standard term in the pharmaceutical industry for a brand name or trademark name. For example, Panadol is one of GSK (GlaxoSmithKline's) trade names for paracetamol or acetaminophen.

Pharmaceutical codes are used in medical classification to uniquely identify medication. They may uniquely identify an active ingredient, drug system (including inactive ingredients and time-release agents) in general, or a specific pharmaceutical product from a specific manufacturer. Describe tagging and assigning codes to the products. Product code may also refer to: Universal Product Code, common barcode used to identify packaged products.

Coding system of pharmaceutical products

The coding system of pharmaceutical products may vary from company to company. The mostly used are bar code, Batch number, Manufacturing date, expiry date.

Process of machine operation

For any machine, the standard operating procedures are followed. These are available in the form of “SOP” of machine or may be consulted from “manual”.

Test Yourself (Multiple Choice Questions)

MODULE G Adjust machine as per product manufacturing order

Please mark the correct one from the given options.

QNO1: What is equipment used for checking of electrical parameters of machine?

A. Ampere meter and volt meter

C. Voltmeter and Thermometer

B. Hygrometer and ampere meter

D. Ampere meter and Barometer

QNO2: What are the main points for the log book for breakdown of a machine?

A. Date, detail of breakdown and purchase

C. Date, detail of supplier and purchase

B. Date, detail of breakdown, corrective action taken

D. Date of manufacturing and corrective action taken

QNO3: What is meant Scientific name of drug?

A. Trade name

C. Brand name

B. Non-proprietary name

D. Chemical name

QNO4: What is the equipment used for liquid-liquid mixing?

A. Propeller and double cone mixers

C. Agitator and Turbine mixers

B. Shaker and paddle mixers

D. Tumbling and Propeller mixers

QNO5: PLC is the abbreviation of which one of the following?

A. Power logic control

C. Program logic control

B. Program logic customer

D. Power logic carrier

Answers Key	
Number	Correct Answer
1	A
2	B
3	D
4	B
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 enrolment 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-3 in Pharmaceutical Manufacturing Technician. You shall be able to progress further to National Vocational Certificate Level-4 after completing Level-3.
7. If I have the experience and skills mentioned in the competency	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

standards, do I still need to attend the course to attain this certificate?	required evidences.
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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