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PHARMACEUTICAL MANUFACTURING TECHNICIAN

CBT CURRICULUM

National Vocational Certificate Level 3

Version 1 - November, 2019

NAVTTC

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Contents

1. Introduction

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, Manufacture tablets, Manufacture capsule and dry suspension, Manufacture liquid dosages, Manufacture of Parenterals and Perform packaging. The trainees 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.

In order to improve the quality of training and to ensure relevance, National Vocational & Technical Training Commission (NAVTTC) through Qualification Development Committee (QDC) developed National Competency Standards for pharmaceutical manufacturing technician. The learning outcomes provided in this curriculum form the basis, which is in accordance with the approved National Competency Standards for pharmaceutical manufacturing technician. The curriculum can be implemented in a variety of pathways and provides flexible learning opportunities.

2. Purpose of the training Programme

In this training program trainee will learn and acquire specialized knowledge and practical skills required to function as a Pharmaceutical Manufacturing Technician both at public and private levels. The specific objectives of developing these qualifications are as under:

- Improve the overall quality of training delivery and setting national benchmarks for training of Pharmaceutical Manufacturing Technician in the country
- Provide flexible pathways and progressions to learners enabling them to receive relevant, up-to-date and current skills
- Provide basis for competency-based assessment which is recognized and accepted by employers
- Establish a standardized and sustainable system of training for Pharmaceutical Manufacturing Technician in the country

3. Overall objectives of training Program

The primary objective of this one year certificate course in Pharmaceutical Manufacturing Technician is to provide the trainees with a comprehensive introduction in Pharma Manufacturing Sector. At present there are no skill standards at national level in Pharma Manufacturing Sector. These standards will develop trainee's abilities and interests and offers outstanding opportunities at different stages of pharmaceutical sector. It will encourage individual to learn knowledge and skills in related field of pharmaceutical manufacturing sector. He/she should have the capability to get job in pharma industry after successful completion of course. Trainees must take part in commercial activities after seeking training in this sector. It will help the trainees to realize to start their commercial activities as an independent skilled worker in pharmaceutical manufacturing industries or an employee in a commercial setup. They are also made aware of the ever changing and evolving demands and challenges of market trends in pharmaceutical industry. This course is open to all science matriculate students for enhancing their capabilities in this field.

4. Competencies to be gained after completion of course

The study of pharmaceutical manufacturing technician enables trainee to develop a range of competencies including, creative thinking, research skills, personal management, presentation skills, communication, negotiation skills and technical competence related to their job assignment. Such competencies acquired and enhanced during the course of study results in highly employable pass outs. In addition, the trainee will be able to acquire the following competencies after completing this course:

1. Apply Work Health and Safety Practices (WHS)
2. Identify and Implement Workplace Policy and Procedures
3. Communicate at Workplace
4. Perform Computer Application Skills
5. Manage Personal Finances
6. Manufacture tablets
7. Manufacture capsules and dry suspensions
8. Manufacture liquid dosages
9. Perform packaging as per manufacturing order

5. Job opportunities available immediately and in the future

The Pass outs of this course may find job / employment opportunities in the following areas:

- Work as pharmaceutical manufacturing Attendant (Level 1)
- Work as pharmaceutical manufacturing Assistant (Level 2)
- Work as pharmaceutical manufacturing Technician (Level 3)
- Work as pharmaceutical manufacturing Supervisor (Level 4)

6. Trainee Entry Level:

The entry for National Vocational Certificate level 3, Pharmaceutical Manufacturing Technician are given below:

Title	Entry requirements
National Vocational Certificate level 3, in Pharmaceutical Manufacturing Technician	Entry for assessment for this qualification is open. However, entry into formal training institute for this qualification is person having National Vocational Certificate level 2 in Pharmaceutical Manufacturing Technician.

7. Minimum Qualification of Trainer

- 2-5 years of professional experience in pharmaceutical industry
- Bachelor's degree (B Pharmacy) / Doctor of Pharmacy (Pharm. D).

8. Recommended Trainer: Trainee ratio

- The recommended trainer and trainee ratio are 1:24 per class

9. Medium of Instruction:

- Urdu, English or Local Language

10. Duration of Course (Total time, theory & practical)

The proposed curriculum is composed of **09** modules that will be covered in **810** hrs. It is proposed that the course may be delivered in a **Six months** period. The distribution of contact hours is given below:

- **Theory:** (21.73%) **Practical** (78.27%)
- **Theory: 176 hours**
- **Practical: 634 hours**
- **Total: 810**

11. Sequence of the modules

Following is the structure of the course:

NVQF Level	Module #	Title	Category	Theory (hours)	Practical (hours)	Total (hour)	Credits hours	Total Credit Hours
3	A	Apply Work Health and Safety Practices (WHS)	Generic	**04**	**16**	**20**	**2**	**81**
	B	Identify and Implement Workplace Policy and Procedures	Generic	**02**	**08**	**10**	**1**	
	C	Communicate at Workplace	Generic	**02**	**08**	**10**	**1**	
	D	Perform Computer Application Skills	Generic	**02**	**08**	**10**	**1**	
	E	Manage Personal Finances	Generic	**02**	**08**	**10**	**1**	
	F	Manufacture tablets	Technical	**50**	**200**	**250**	**25**	
	G	Manufacture capsules and dry suspensions	Technical	**50**	**150**	**200**	**20**	
	H	Manufacture liquid dosages	Technical	**30**	**110**	**140**	**14**	
	I	Perform packaging as per manufacturing order	Technical	**34**	**126**	**160**	**16**	
			TOTAL	**176**	**634**	**810**	**81**	
			Percentage.	**21.73%**	**78.27%**			

Summary – Overview of the curriculum

Overview of the Curriculum for Pharmaceutical Manufacturing Technician:

Module Title and Aim	Learning Units	Theory Days/hours	Workplace Days/hours	Timeframe of Modules
Module A: **Apply Work Health and Safety Practices (WHS)** **Aim:** This unit describes the skills to work with safety and participate in hazard assessment activities, follow emergency procedures and participate OHS practices in process	**LU1.** Implement safe work practices at work place **LU2.** Participate in hazard assessment activities at a work place **LU3.** Follow emergency procedures at workplace **LU4.** Participate in OHS consultative processes	**04**	**16**	**20**
Module B: **Identify and Implement Workplace Policy and Procedures** **Aim:** This unit describes the skills and knowledge required to develop and implement a workplace policy & procedures and to modify the policy to suit changed circumstances. It applies to individuals with managerial responsibilities who undertake work developing approaches to create, monitor and improve strategies and policies within workplaces and engage with a range of relevant stakeholders and specialists.	**LU1.** Identify workplace policy & procedures **LU2.** Implement workplace policy & procedures **LU3.** Communicate workplace policy & procedures **LU4.** Review the implementation of workplace policy & procedures	**02**	**08**	**10**
Module C: **Communicate at Workplace** **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.	**LU-1:** Communicate within the organization **LU-2:** Communicate outside the organization **LU-3:** Communicate effectively in workgroup **LU-4:** Communicate in writing	**02**	**08**	**10**

Module D: **Perform Computer Application Skills** **Aim:** This unit describes the skills and knowledge required to use spreadsheet applications, prepare in page documents, develops familiarity with Word, Excel, Access, PowerPoint, email, and computer graphics basics. It applies to individuals who perform a range of routine tasks in the workplace using a fundamental knowledge of spreadsheets, Microsoft office and computer graphics in under direct supervision or with limited responsibility.	**LU1.** Prepare In-page documents as per required information **LU2.** Prepare Spreadsheets as per required information **LU3.** Use MS Office as per required information **LU4.** Perform computer graphics in basic applications **LU5.** Create Email account for communications	**02**	**08**	**10**
Module E: **Manage Personal Finances** **Aim:** This unit of competency describes the outcomes required to manage develop, implement and monitor a personal budget in order to plan regular savings and manage debt effectively.	**LU1.** Develop a personal budget **LU2.** Develop long term personal budget **LU3.** Identify ways to maximize future finances	**02**	**08**	**10**
Module F. **Manufacture tablets** **Aim:** After completing this module, the learner will be able to perform manufacturing functions by a Pharmaceutical Technician in accordance with the industry's approved guidelines and procedures. This competency covers manufacturing of tablets that includes weighing, milling, sieving, mixing, granulation, compression and coating.	**LU1.** Mix Raw Materials **LU2.** Perform Slugging (in case of dry granulation) **LU3.** Perform wet mixing **LU4**. Perform wet granulation **LU5.** Collect Wet Granules and Dry **LU6.** Perform dry granulation **LU7.** Perform Sieving (Mesh)	**50**	**250**	**300**

	LU8. Perform Final Mixing **LU9.** Shift Material to Compression Room **LU10.** Start Compression Machine **LU11.** Check Weight Variation of Tablets **LU12.** Shift compressed tablets for coating or sorting			
Module G. **Manufacture capsule and dry suspension** **Aim:** After completing this module, the learner will be able to weighing, sieving, mixing, granulation, encapsulation and polishing as per industry procedure and process.	**LU1.** Mix Raw Materials **LU2.** Perform wet granulation **LU3.** Collect Wet Granules and Dry (If required) **LU4.** Perform Dry Granulation (If required) **LU5.** Perform Final Mixing **LU6.** Shift material in encapsulation room for filling **LU7.** Start bottle blowing & filling (dry suspension) **LU8.** Capping, optical checking & labeling of bottles	**50**	**250**	**300**
Module H. **Manufacture liquid dosages** **Aim:** After completing this module, the learner will be able to identify materials and to perform manufacturing of syrup, suspension as per manufacturing order, general housekeeping and maintenance of tools/equipment.	**LU1.** Shift the Raw Materials **LU2.** Prepare syrup base **LU3.** Dissolve/ Soak materials in purified water according to procedure **LU4.** Manufacture syrup and suspension **LU5.** Start bottle blowing & filling **LU6.** Capping, optical checking & labeling of bottles	**50**	**150**	**200**

Module I. **Perform packaging as per manufacturing order** **Aim:** After completing this module, the learner will be able to perform packing of manufacturing products as per industry's approved guidelines and procedures. Trainees will be expected to perform packaging of tablets, capsules, bottles, handling for warehouse storage & shipping transport and general housekeeping and maintenance of equipment.	**LU1.** Receive packing materials for product (tablets, capsules & syrups/suspensions) **LU2.** Make strip/blister packing **LU3.** Perform Over printing **LU4.** Perform aluminum blister foil packaging, strip packaging/ bottle packaging **LU5.** Make tertiary packaging for bulk handling for warehouse storage & shipping/transport	**40**	**150**	**190**
	TOTAL	**176**	**634**	**810**

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Module-F

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Module F: Manufacture tablets

Objectives: After completing this module, the learner will be able to perform manufacturing functions by a Pharmaceutical Technician in accordance with the industry's approved guidelines and procedures. This competency covers manufacturing of tablets that includes weighing, milling, sieving, mixing, granulation, compression and coating.

Duration:	**Total hours**	**350**	**Practical**	**300**	**Theory**	**50**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. **Mix Raw Materials**	• Check identification of materials against manufacturing order • Sieve and add materials as per manufacturing order • Start mixing as per manufacturing order • Record all necessary entries as per manufacturing order • Report to the in-charge about any deviation for quick response	• Describe sieving process • and different types of sieves. • Know about deviation process • Explain mixing methods	5 hours Theory 25 hours Practical Total hours: 30	• Stainless-steel high-speed mixing machine • Sieves (different sizes) • Filters of different types • Inactive raw materials for tablet manufacturing	Class Room and workplace

LU2. **Perform Slugging (in case of dry granulation)**	• Install required sieve as per manufacturing order in compactor granulator • Shift materials in compactor granulator as per manufacturing order • Start granulator and adjust rollers for proper flack size as per manufacturing order • Collect dry granules after completion of process as per manufacturing order • Report to the in-charge about any deviation for quick response	• Define granulators • Define pressure of rollers • Describe procedure for sieve in compactor granulator	5 hours Theory 25 hours Practical Total hours: 30	• Compactor granulator	Class Room and workplace
LU3. **Perform wet mixing**	• Prepare binder solution as per manufacturing order • Mix binder solution with powder mixture to form wet mass as per manufacturing order • Start mixing as per specific mixing time of batch as per manufacturing order • Check end point of wet mixing properly and report to the in-charge about any deviation	• Describe types of wet mixing solution (Aqueous & organic) • Describe techniques for mixing • Explain check end point of wet mixing properly	4 hours Theory 25 hours Practical Total hours: 25	• Stainless steel blender • Wet mixer (Gral / sigma mixer) • Oscillator granulator • Stainless-steel high-speed mixing machine • Mixer machine for solution preparation • Stainless steel wet granulation machine	Class Room and workplace

LU4. **Perform wet granulation**	• Install required mesh size in the wet granulator as per manufacturing order • Shift and pass the wet mass through granulator • Report to the in-charge about any deviation	• Describe different types of granules • Explain types of granulators and deviation in wet granulation process	4 hours Theory 25 hours Practical Total hours: 29	• Stainless steel wet granulation machine • Stainless-steel high-speed mixing machine	Class Room and workplace
LU5. **Collect Wet Granules and Dry**	• Collect wet granules for drying as per specifications given in manufacturing order • Transfer wet granules for completion of drying process as per manufacturing order • Adjust temperature of dryer as per specifications for completion of drying process • Determine end point of drying process and record any deviation faced during the whole procedure	• Explain types of dryers • Describe process of drying based on solvent used (Aqueous/ Organic) • Describe thermostat role in drying process • Explain reasons and procedure for adjusting temperature of dryer	4 hours Theory 25 hours Practical Total hours: 29	• Dryers • Thermostat	Class Room and workplace
LU6. **Perform Dry Granulation**	• Collect dry granules/flacks (in case of slug) • Shift dry granules/flacks for required sizing as per manufacturing order • Inform section in-charge for end point confirmation of granulation.	• Describe processes of dry granulation • Describe types of dry granulators • Describe different types of granules sizes	4 hours Theory 25 hours Practical Total hours: 29	• Hammer mill / Fitz mill	Class Room and workplace

LU7. **Perform Sieving (Mesh)**	• Pass material from required sieve size as per manufacturing order • Record all necessary entries as per requirements of Manufacturing order • Report to the in-charge about any deviation	• Describe procedure of sieving (Mesh)	4 hours Theory 25 hours Practical Total hours: 29	• sizes of sieves • sieve shaker	Class Room and workplace
LU8. **Perform Final Mixing**	• Identify materials for final mixing against manufacturing order • Add material as per manufacturing order • Perform final mixing of batch material as per manufacturing order • Enter all necessary entries as per manufacturing order • Inform section in-charge about final mixing for next process as per manufacturing order	• Describe process of adding materials for final mixing • Describe critical points of blending/mixing • Describe different types of mixers	4 hours Theory 25 hours Practical Total hours: 29	• Cone mixer / V- mixer	Class Room and workplace
LU9. **Shift Material to Compression Room**	• Receive approval from concerned section in-charge. • Identify trolley for shifting material to compression room for next process • Perform weight and record of received materials as per specifications • Place material on pallets using	• Explain safety concerns while shifting materials to compression room • Describe quarantine and released labels • Explain different types of staking pallets	4 hours Theory 25 hours Practical Total hours: 29	• Quarantine register • Balances	Class Room and workplace

	appropriate and safe methods. • Report any deviations, if any, during shifting process to avoid loss.				
LU10. **Start Compression Machine**	• Adjust machine as per manufacturing order using relevant controls • Add bulk batch material in hopper • Start and adjust weight and hardness as per manufacturing order • Perform required in-process tests. • Operate machine as per job requirements and report deviation, if observed	• Describe compression process and different types of compression machine • Describe in- process control	4 hours Theory 25 hours Practical Total hours: 29	• Compression machine	Class Room and workplace
LU11. **Check Weight Variation of Tablets**	• Check calibration status of balance using appropriate method • Adjust balance using appropriate techniques • Take tablets for measuring weight variation test as per manufacturing order • Note in process reading as per procedure in manufacturing order • Report any deviation to in- charge	• Describe procedure of checking calibration status of balance	4 hours Theory 25 hours Practical Total hours: 29	• Digital Balance • Calibrated weights	Class Room and workplace

LU12. **Shift compressed tablets for coating or sorting**	• Shift core tablets to the coating/ sorting area after release/ approval from quality assurance department • De-dust tablets using relevant tools and appropriate methods • Prepare coating solution using specified techniques • Load core tablets in coating pan as per manufacturing order • Adjust coating machine parameters as per specification. • Start coating process and check weight gain after specified interval • Finish coating process, when required weight is achieved • Polish coated tablets using specified procedure • Report any deviation.	• Describe coating solution based on aqueous /organic • Describe coating processes based on conventional and automatic • Describe end point of coating	4 hours Theory 25 hours Practical Total hours: 29	• Conventional and automatic coating systems	Class Room and workplace

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Module-G

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Module G: Manufacture Capsules and Dry Suspension

Objectives: After completing this module, the learner will be able to weighing, sieving, mixing, granulation, encapsulation and polishing as per industry procedure and process.

Duration:	**Total hours**	**300**	**Practical**	**250**	**Theory**	**50**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. **Mix Raw Materials**	• Check identity of materials against manufacturing order • Sieve and add materials as per manufacturing order • Start mixing as per manufacturing order • Record all necessary entries as per manufacturing order • Report to the in-charge about any deviation for quick response	• Describe sieving process • and different types of sieves • Know about deviation process • Explain mixing methods	7 hours Theory 32 hours Practical Total hours: 39	• Stainless-steel high-speed mixing machine/ groove mixer • Sieves (different sizes) • Inactive • Raw materials for manufacturing of capsules • Gelatine capsule shells of different sizes (00-5) • Containers of different types	Class Room and workplace

LU2. **Perform wet granulation**	• Install required mesh size in the wet granulator as per manufacturing order • Shift and pass the wet mass through granulator • Report to the in-charge about any deviation	• Describe different types of granules • Explain types of granulators and deviation in wet granulation process	7 hours Theory 32 hours Practical Total hours: 39	• Stainless steel wet granulation machine • Stainless-steel high-speed mixing machine	Class Room and workplace
LU3. **Collect Wet Granules and Dry (If required)**	• Collect wet granules for drying as per specifications given in manufacturing order • Transfer wet granulates reliably for completion of drying process as per manufacturing order • Adjust temperature of dryer as per specifications for completion of drying process • Determine end point of drying process and record any deviation faced during the whole procedure	• Explain types of dryers • Describe process of drying based on solvent used (Aqueous/ Organic) • Describe thermostat role in drying process • Explain reasons and procedure for adjusting temperature of dryer	6 hours Theory 31 hours Practical Total hours: 37	• Dryers • Thermostat	
LU4. **Perform Dry Granulation (If required)**	• Collect dry granules/flacks (in case of slug) • Shift dry granules/flacks for required sizing as per manufacturing order • Intimate section in-charge for end point confirmation of granulation.	• Describe processes of dry granulation • Describe types of dry granulators • Describe different types of granules sizes	6 hours Theory 31 hours Practical Total hours: 37	• Hammer mill / Fitz mill	Class Room and workplace

LU5. **Perform Final Mixing**	• Identity materials for final mixing against Manufacturing Order • Add material as per manufacturing order • Perform final mixing of batch material as per manufacturing order • Enter all necessary entries as per manufacturing order • Inform section in-charge about final mixing for next process as per manufacturing order	• Describe process of adding materials for final mixing • Describe critical points of blending/mixing • Describe different types of mixers	6 hours Theory 31 hours Practical Total hours: 37	• Cone mixer/ V-mixer	
LU6. **Shift material in encapsulation room for filling**	• Shift materials to encapsulation area after release approval from quality assurance department • Adjust machine as per manufacturing order • Add materials in hopper as per specifications • Start encapsulation machine • Perform required in-process tests • Adjust weight and locking as per manufacturing order • Make polish and sorting of filled	• Describe types of hoppers (powder and empty capsule shells) • Describe different types of encapsulation machine • Define types of capsule polishing machines	6 hours Theory 31 hours Practical	• Encapsulation machine • Capsule polisher • Digital balance	Class Room and workplace

	capsules as per process • Report any deviation to in-charge				
LU7. **Start bottle blowing & filling (dry suspension)**	• Check approval from Quality Assurance before filling of bottles • Transfer empty bottles to filling line and place it on the turn table • Adjust bottle blowing according to the specific bottle size and start blowing process • Adjust the weight of individual nozzle according to manufacturing order.	• Describe types of blowing machine and mechanism • Describe filling machine • Describe weight variation of filled bottles (empty and filled)	6 hours Theory 31 hours Practical Total hours: 37	• Bottle blower • Bottle filling machine • Digital balance	
LU8. **Capping, optical checking & labeling of bottles**	• Adjust capping and sealing machine of the lines according to the speed of filling • Check individual bottle optically in different background for all types of particles • Adjust labeling machine according to the speed of line • Perform all required in- process checks as per manufacturing order • Report any deviation from the standards to section in-	• Describe Optical checking • Describe Labelling process • Describe physical parameters of capping & leakage	6 hours Theory 31 hours Practical Total hours: 37	• Bottle capping and sealing machine • Labelling machine	Class Room and workplace

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Module-H

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Module H: Manufacture Liquid Dosages

Objectives: After completing this module, the learner will be able to identify materials and to perform manufacturing of syrup, suspension as per manufacturing order, general housekeeping and maintenance of tools/equipment.

Duration:	**Total hours**	**140**	**Practical**	**110**	**Theory**	**30**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. **Shift the Raw Materials**	• Transfer batch raw materials to liquid section. • Check the material one by one according to the manufacturing order in the section again prior to mixing. • Segregate each material according to mixing order. • Report any deviation to section in charge.	• Describe mixing order of materials	5 hours Theory 19 hours Practical Total hours: 24	• Batch shifting trolley • Staking pallets • Inactive raw materials for syrup • Bottles of different capacity with caps	Class Room and workplace
LU2. **Prepare syrup base**	• Transfer specified volume of purified water to steam jacketed tank. • Start heating up to the required temperature.	• Describe types of tanks • Describe importance of temperature in heating process • Know about color and solubility of material	5 hours Theory 19 hours Practical	• Reverse osmosis plant • Stainless steel jacketed tank	Class Room and workplace

	• Add preservative(s) as per specification • . • Add sucrose as per specification and continue heating to required temperature. • Continue mixing until clear base is formed. • Check the cleaning status of filtration assembly. • Filter and transfer the base to the main Mixing tank after cooling. • Report Any deviation from the standards to section in-charge.	• Describe importance of preservative(s) • Describe types of filtration assembly and technique. • Describe volume making and calibration of mixing tank.	Total hours: 24	• Filtration assembly	
LU3. **Dissolve/ Soak materials in purified water according to procedure**	• Transfer specified volume of purified water to different manufacturing tanks. • Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order • Report any deviation from the standards to section in-charge.	• Describe syrup and suspension • Describe soaking • Describe wetting process	5 hours Theory 18 hours Practical Total hours: 23	• Mixer	Class Room and workplace
LU4. **Manufacture syrup and suspension**	• Check the temperature of syrup base in the main mixing tank	• Describe types of homogenizer and its uses	5 hours Theory	• Silver son mixer	

	• Add the material one by one to the main mixing tank. In case of syrup the already dissolved material is also added • Pass suspension slurry through homogenizer and add it to main mixing tank • Make up and record bulk volume of syrup/suspension in main mixing tank • Transfer syrup through filtration assembly according to specification and suspension directly to storage tank (through homogenizer if required) • Start slow mixer in storage tank in case of suspension • Intimate section in-charge about process completion • Seal storage tank till release from Quality Assurance after sampling • Any deviation from the standards must be reported to section in-charge	• Describe types of filtration assembly and technique • Describe types of transfer pump involved in the process • Describe importance of temperature in mixing process	18 hours Practical Total hours: 23	• Colloidal mill • Transfer pump	
LU5. **Start bottle blowing & filling**	• Check approval from Quality Assurance before filling of bottles • Transfer empty bottles to filling line and place it on the turn table	• Describe importance of slow mixer in suspension • Describe types of liquid filling line • Describe types of nozzles and	5 hours Theory 18 hours Practical	Liquid filling line	

	• Adjust bottle blowing according to the specific bottle size and start blowing process • Adjust the Volume of individual nozzle according to manufacturing order •	method of adjusting volume of each nozzle • Describe volume limits	Total hours: 23		
LU6. Capping, optical checking & labeling of bottles	• Adjust capping and sealing machine of the lines according to the speed of filling • Check individual bottle optically in different background for all types of particles • Adjust labeling machine according to the speed of line • Perform all required in- process checks as per manufacturing order • Report any deviation from the standards to section in-charge	• Describe Optical checking • Describe Labelling process • Describe physical parameters of capping & leakage	5 hours Theory 18 hours Practical Total hours: 23	• Bottle capping and sealing machine • Labelling machine	Class Room and workplace

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Module-I

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Module I: Perform Packaging as per Manufacturing Order

Objectives: After completing this module, the learner will be able to perform packing of manufacturing products as per industry's approved guidelines and procedures. Trainees will be expected to perform packaging of tablets, capsules, bottles, handling for warehouse storage & shipping transport and general housekeeping and maintenance of equipment.

Duration:	**Total hours**	**190**	**Practical**	**150**	**Theory**	**40**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. **Receive packing materials for product (tablets, capsules & syrups/suspensions)**	• Check and receive printed/ unprinted aluminum Foil Roll, Poly Vinyl Chloride (PVC) Roll, bottles, caps, vials, rubber stoppers, flip off seals, ampoules, unit carton, spoons, leaflets, cups, master cartons, labels as per packing order. • Maintain the temperature and humidity of workplace as per requirements of specifications of manufactured product • Check the Batch Number, manufacturing and expiry date against each labeled packing as per manufacturing order	• Explain types of packing material • Describe batch number, manufacturing and expiry date correctly as per packaging order • Explain specific requirements of temperature and humidity of workplace for each product	8 hours Theory 30 hours Practical Total hours: 38	• Containers • Printed/ unprinted aluminium Foil Roll • Poly Vinyl Chloride (PVC) Roll • Bottles • Bottles Caps • Vials • Rubber stoppers, • Flip off seals • Ampoules	Class Room and workplace

	• Ensure all relevant entries manually or electronically as per specifications given in manufacturing order • Inform the section in-charge after completion of task			• Unit carton • Spoons • Leaflets • Cup • Master cartons	
LU2. **Make strip/blister packing**	• Prepare label area, machines & containers for strip packing correctly as per specifications given in the Packing Order • Check & sign the "Ready Tag" attached to the machine and make necessary entries in the log book. • Receive approval from section in-charge before start packing of manufactured products • Start strip/blistering operation and perform the following checks: **a)** Set Batch No., Manufacturing & expiry dates **b)** Count of unit dose per blister/strip **c)** Alignment of blister/ strip **d)** Check release label on the buckets /drums. • Inform the section in-charge to take empty blisters/strips for leak-test. • Start the Blistering/striping Operation, only after passing the Leak Test for empty & filled.	• Record and enlisting specifications and data correctly. • Describe importance of Leak test	10 hours Theory 30 hours Practical Total hours: 40	• Packaging machine • . Printing machine	Class Room and workplace

	• Check the completion of blistering/striping process and shift the blisters/strips to packing hall for packaging as per specifications				
LU3. **Perform Over printing**	• Remove all printed packaging material like Labels, unit cartons, Blisters/strips etc. of the previous product • Check that the correct packaging material as per Packaging order for printing • Check Batch No. expiry, manufacturing date, pack size against packaging order for printing on the carton or labels • Perform in process checks to avoid any wastages	• Describe importance of packaging order for overprinting • Explain types of printing machine	8 hours Theory 30 hours Practical	• Printing Machine	Class Room and workplace
LU4.Perform aluminum blister foil packaging, strip packaging/ bottle packaging	• Remove all printed packaging material like labels, unit cartons, Blisters/strips etc. of the previous product • Check correct packaging material as per packing order is received for concerned batch • Received blisters/strips, bottles, printed cartons, printed labels of product	• Describe types of packaging machine	8 hours Theory 30 hours Practical Total hours: 38	• Blister packing materials	Class Room and workplace

	• Check Batch. No. manufacturing date, expiry and pack size • Take approval for product to be packed • Check labels, cartons blister/blisters etc. • for proper printing • Remanufacturing ordered defective printed materials immediately • Bring the cartons, Labels, Blisters for sorting in a Tray & Label it as "**For Sorting**" • Collect all the rejected cartons, Labels, Blisters • in a tray, and label it as "**REJECTED**" • Collect Cartons, Labels, Blisters/strips in a separate tray and label it as "**Ready for use**" • Shift only ready for use Cartons, Labels for packaging on belt • Take blisters/strips, bottle, ampoule, and vial according to the unit carton and insert pack.				
LU5. **Make tertiary packaging for bulk handling for warehouse storage & shipping/transport**	• Place required number of packs in the master carton as per packing order. • Seal each master carton properly with sealing carton Tape. • Check each master carton label before pasting it on each sealed master carton for	• Describe proper and safe methods of arranging carton on staking pallet • Explain method of sealing	8 hours Theory 30 hours Practical Total hours: 38	• Tertiary packing machine	Class Room and workplace

	its product name, Manufacturing date, expiry date, master cartons No., quantity of units & packaging date • Arrange each outer carton properly on staking pallet • Deliver batch to finish goods store after release from Quality Assurance	carton using carton tape			

Supportive notes:

Assessment context, Critical aspects, Assessment conditions

Formative assessment: The specification of the expected performance demonstrated by the trainee at the conclusion of the learning experiences in a particular module or course. It is used to assess the necessary knowledge, skills and attitudes, reflecting the performance standard in the relevant industry or competency standards. Formative assessment may include observation, simulation, questioning, presentation/ demonstration and written assessment at the end of each module. The various methods or techniques used to gather evidence of sufficiency and quality in which to make a sound judgment on the competency of a learner

Summative assessment: Assessors need to plan in advance how they will conduct summative assessments covering all modules. There must be a maximum of 6-8 trainees per assessor and if there are two assessors than 12 students can be assessed within a day and 24 students in 2 days. The entire course can be tested in the summative assessment covering all 16 modules. Direct observation is an important approach in assessing the attitude of the students toward work, observance of safety rules and regulations, and how they interact and relate with other trainees and instructor. Training providers need to decide ways to combine modules into a cohesive two-day final assessment programme for each group of 6-8 trainees. Assessment methods may include observation, simulation, questioning, presentation/ demonstration and written assessment. The various methods or techniques used to gather evidence of sufficiency and quality in which to make a sound judgment on the competency student or learner. Training providers must agree the settings for practical assessments in advance.

Sr. No	List of Tools and Equipment	Quantity (24 students)
	(A) Liquid Manufacturing Section Tools and Machines	
1.	Stainless steel tanks of different capacities	5
2.	Stainless steel spoons and scope	5
3.	Stainless steel transfer pumps	10
4.	PVC pipes	1 of each type
5.	Filtration assembly	2
6.	Silver son mixer	1
7.	Homogenizer	1
8.	Slow mixer	1
9.	Stainless steel buckets	3
10.	Bottles blowing machine	1
11.	Bottles filling machine	1
12.	Bottles caps sealing machine	1
13.	Bottles labeling machine	1
14.	Autocartner packing machine	1
15.	Labels and unit carton printing machines	1
	(B) Solids Manufacturing Section Tools and Machines	
1.	Stainless-steel high-speed mixing machine	1
2.	Mixer machine for solution preparation	1
3.	Stainless steel wet granulation machine	1
4.	Fluidize bed dryer	1
5.	Tray dryer	1
6.	Stainless steel granulator	1
7.	Stainless steel blender	1

8.	Stainless steel buckets	1
9.	Stainless steel mesh of different sizes	1 each of different sizes
10.	Compression machines	1
11.	Punches and dies	1
12.	Tablets De-dusting machine	1
13.	Coating assembly	1
14.	Tablets polisher	1
15.	Encapsulation machine	1
16.	Capsule polisher	1
17.	Dry suspension filling and sealing line	1
18.	Blistering/Strip machine	1
19.	Blistering machine molds, sealer and cutter	1
20.	Blister machine code punching digits and alphabets	1
21.	Blister packing Autocartner machine	1
22.	Unit carton printing machine	1
	(C) Parenterals Manufacturing Section Tools and Machines	
1.	Stainless steel tanks of different capacities	1
2.	Stainless steel spoons and scoop.	5
3.	Stainless steel transfer pipes.	5
4.	Filtration assembly	1
5.	Silver son mixer	1
6.	Transfer pumps	1
7.	Vials and ampoules washing and sterilizer	1
8.	Autoclaves	1
9.	Filling machines	1
10.	Ampoules or vials sealing machine	1
11.	Labeling machine	1
12.	Blister machines	1
13.	Blistering machine molds, sealer and cutter	1
14.	Autocartner machine (Optional)	1
15.	Unit carton and ampoules or vials printing machine	1

LIST OF CONSUMABLE SUPPLIES

Sr. No.	Name of Consumable Supplies	Quantity (24 students)
1.	Soaps	
2.	Disinfectant	
3.	Sanitizers	
4.	Gloves	
5.	Filters of different types	
6.	Inactive raw materials for tablet manufacturing	
7.	Inactive Raw materials for manufacturing of capsules	
8.	Inactive raw materials for syrup	
9.	Containers	
10.	Printed/ unprinted aluminium Foil Roll	
11.	Poly Vinyl Chloride (PVC) Roll	
12.	Bottles	
13.	Caps	
14.	Vials	
15.	Rubber stoppers	
16.	Flip off seals	
17.	Ampoules	
18.	Unit carton	
19.	Spoons	
20.	Leaflets	
21.	Cups	
22.	Master cartons	

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