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PHARMACEUTICAL MANUFACTURING TECHNICIAN



CBT CURRICULUM

National Vocational Certificate Level 2





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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 detail of the competency standards included in this qualification are given below: National Vocational Certificate level 2, Pharmaceutical Manufacturing Technician

- 1. Comply with Personal Health and Safety Guidelines
- 2. Communicate the Workplace Policy and Procedure
- 3. Perform Basic Communication (Specific)
- 4. Perform Basic Computer Application (Specific)
- 5. Prepare work environment according to manufacturing order
- 6. Receive product raw materials according to manufacturing order
- 7. Adjust machine as per product 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 2, in Pharmaceutical Manufacturing Technician.is given below:

Title	Entry requirements
National Vocational Certificate level 1, 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 1 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 **07** modules that will be covered in **250** hrs. It is proposed that the course may be delivered in a **Three months** period. The distribution of contact hours is given below:

> Theory: (21.60%) Practical (78.40%)

- > Theory: 54 hours
- > Practical: 196 hours
- Total: 250

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
	А	Comply with Personal Health and Safety Guidelines	Generic	06	24	30	03	
	В	Communicate the Workplace Policy and Procedure	Generic	04	16	20	02	
	С	Perform Basic Communication (Specific)	Generic	06	24	30	03	
2	D	Perform Basic Computer Application (Specific)	Generic	08	32	40	04	25
	E	Prepare work environment according to manufacturing order	Technical	10	30	40	04	
	F	Receive product raw material according to manufacturing order	Technical	10	30	40	04	
	G	Adjust machine as per product manufacturing order	Technical	10	40	50	05	
			Total	54	196	250	25	
			Percentage.	21.60%	81.40%			

Summary – Overview of the curriculum

Module Title and Aim	Learning Units	Theory Days/hours	Workplace Days/hours	Timeframe of Modules
Module A: Comply Personal Health and Safety Guidelines	LU1: Identify Personal Hazard at work place	06	24	30
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	 LU2: Apply personal protective and safety equipment (PPE) LU3: Comply with occupational safety and health (OSH) LU4: Dispose of hazardous waste/materials from the 			
Safety and Health (OSH) will be sufficient to provide the basis for the job at workplace.	designated area LU1. Identify workplace communication procedures			
Module B:	LU2. Communicate at workplace			
Communicate the Workplace Policy and Procedure	LU3. Draft Written Information LU4. Review Documents			
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.		04	16	20

 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	30	40
Module G: Adjust machine as per product manufacturing order Nims: 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 LU4: Maintain machine Operation Procedure		10	40	50
	TOTAL	82	328	410



Module-E CBT CURRICULUM National Vocational Certificate Level 2

Module E: Prepare Work Environment according to manufacturing Order

Objectives: After completing this module, the learner will be able to maintain temperature, humidity, air pressure and clean environment at workplace as per procedure.

Duration: Total hours 40	Practical 30	Theory 10	
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Learning Unit	Learning Outcomes	Learning Elements	Duration	Materials (Tools & Equipment) Required	Learning Place
LU1. Maintain temperature and humidity	 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 	2 hours Theory 8 hours Practical Total:10 hours	 Heating ventilation and air conditioning (HVAC) Hygrometer Thermometer Monometer Filters of different types Safety kit 	Class Room and workplace
LU2. Ensure air pressure of specific area/work place	 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 occur, for prompt 	 Explain air pressure variations Know about area specific air pressures 	2 hours Theory 8 hours Practical Total:10	Monometer	Class Room and workplace

	measures		hours		
LU3. Prepare area for swab test	 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 	2 hours Theory 8 hours Practical Total:10 hours	 Sanitizers Disinfectant Detergent Swab 	Class Room and workplace
LU4. Adjust light as per specifications in workplace area	 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 	2 hours Theory 8 hours Practical Total: 10 hours	 Different kinds of lights 	Class Room and workplace



Module-F CBT CURRICULUM National Vocational Certificate Level 2

Module F: Receive product raw material according to 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:	Total hours	50	Practical 4		40	Theory	10
Learning Unit	Learning Outco	omes	Learr	ing Elements	Duration	Materials (Tools & Equipment) Required	Learning Place
LU1. Identify materials according to labels	 against each m order Check the sign 	order e labels of raw er specifications nanufacturing ature of thority on labeled as per order	 (specifications) of raw materials Describe raw materials identification procedure 		3 hours Theory 10 hours Practical Total hours 13	weighing digital balance	Class Room and workplace
LU2. Check weight of rav materials	 Cross check th 	ce e gross weight of ed raw materials	 Exp type l) Des 	scribe calibration and its ortance plain calibration es(internal/externa scribe net weight, gross ght and tare weight	3 hours Theory 10 hours Practical Total hours	Weighing digital balance	Class Room and workplace

			13		
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 	13 2 hours Theory 10 hours Practical Total hours 12	Shifting Trolley	Class Room and workplace
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. 	2 hours Theory 10 hours Practical Total hours 12	shifting trolley	Class Room and workplace



Module-G CBT CURRICULUM National Vocational Certificate Level 2

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:	Total hours 60	Practical 50	Theory 10		
Learning Unit	Learning Outcomes	Learning Elements Oescribe machine electric input	Duration	Materials (Tools & Equipment) Required	Learning Place Class Room
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 	 and output system Importance of instructional manual for machine operating system 	2 hours Theory 10 hours Practical Total hours 12	 Machine manuals Human Machine Interface (HMI) Tool kit 	and workplace

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 	2 hours Theory 10hours Practical Total hours 12	• Different lubricants and its oil pump and other accessories	Class Room and workplace
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	2hours Theory 10 hours Practical Total hours 12	• Machine manuals	Class Room and workplace
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 	 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 	2 hours Theory 10 hours Practical Total	 Log book Register 	

	response during manufacturing processing	 Describe coding system of pharmaceutical products 	hours 12		
LU5. Follow Machine Operation Procedure	 Identify every manufacturing features and notes before start the machine as per manufacturing order Adjust the machine parameters as per product manufacturing order, before operating it Perform in process tests according to product manufacturing order and machine operation procedures Inform to the section in-charge regarding any deviation during process 	 Describe the process of machine operation Describe methods of performing in-process tests correctly Explain possible faults in machine and their repairing Explain the process for maintaining the tools and equipment 	2 hours Theory 10 hours Practical Total hours 12	• Machine manuals	Class Room and workplace

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
16.	Monometer, Hygrometer, pH Meter, Thermometer	1 each
17.	Digital weighing balance	1
18.	Machine tool kit	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.	Compactor granulator	1
16.	Fitz Mills	1
17.	Encapsulation machine	1
18.	Capsule polisher	1
19.	Dry suspension filling and sealing line	1
20.	Blistering/Strip machine	1
21.	Blistering machine molds, sealer and cutter	1
22.	Blister machine code punching digits and alphabets	1
23.	Blister packing Autocartner machine	1
24.	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.	Double distilled water plant	1
15.	Conductivity meter	1
16.	Fogger	1
17.	Autoclave	1
18.	Dry sterilizer	1
19.	Psychrometer	1
20.	Particle counter	1
21.	Autocartner machine (Optional)	1
22.	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	

National Vocational and Technical Training Commission (NAVTTC)

- 🗞 +92 51 9044 322
- info@navttc.org
 www.navttc.org