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PHARMACEUTICAL MANUFACTURING TECHNICIAN

CBT CURRICULUM

National Vocational Certificate Level 1

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:

- Demonstrate, and apply basic knowledge and concepts in pharmaceutical manufacturing sector
- Develop creative thinking skills and perceptual awareness in pharmaceutical manufacturing sector
- Develop skills necessary for understanding and applying skills during work
- Explore and discuss unique properties and potential of technical work
- Demonstrate techniques and processes for preparation of tablets and capsules
- Communicate and express ideas through a variety of skills and techniques in pharmaceutical manufacturing sector
- Evaluate and select materials, techniques, and processes to prepare tablets/capsules/dry suspension/ parenterals, etc.
- Demonstrate the safe and responsible use of tools and materials at workplace
- Ability to work in a commercial or apprenticeship setup

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 1 , 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 institutes, based on this qualification may require skills and knowledge equivalent to Middle.

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 **05** modules that will be covered in **190** 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%) **Practical** (79%)
- **Theory: 40 hours**
- **Practical: 150 hours**
- **Total: 190**

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
1	A	Comply with Work Health and Safety Policies	Generic	**06**	**24**	**30**	03	**19**
	B	Obey the Workplace Policies and Procedures	Functional	**04**	**16**	**20**	02	
	C	Follow Basic Communication Skills (General)	Technical	**10**	**40**	**50**	05	
	D	Operate Computer Functions(General)	Generic	**10**	**40**	**50**	05	
	E	Adopt Good Manufacturing Practices for Pharmaceutical Production	Technical	**10**	**30**	**40**	04	
			TOTAL	**40**	**150**	**190**	**19**	**19**
			Percentage.	**21%**	**79%**			

Summary – Overview of the curriculum

Module Title and Aim	Learning Units	Theory hours	Workplace hours	Timeframe of Modules
Module A: **Comply with Work Health and Safety Policies** **Aim:** After completing this module, the learner will be able to know skills and knowledge required to apply general work health and safety requirements in the workplace. Communicate work and health safety assess at work place. It describes generic work health and safety responsibilities applicable to employees without managerial or supervisory responsibilities.	**LU-1:** Work safely at work place **LU-2:** Communicate work health and safety (WHS) assess at work place **LU-3:** Minimize risks to personal safety at work place **LU-4:** Minimize risks to public safety	**06**	**24**	**30**
Module B: **Obey the Workplace Policies and Procedures** **Aim:** After completing this module, the learner will be able to obey the workplace personal appearance and hygiene, follow work ethics, Demonstrate the workplace behavior, Communicate the workplace policy and procedure and review the implementation of workplace policy and procedures.	**LU-1:** Obey the workplace personal appearance and hygiene **LU-2:** Follow work ethics **LU-3:** Demonstrate the Work place behaviours **LU-4:** Communicate workplace policy & procedures **LU-5:** Review the implementation of workplace policy & procedures	**04**	**16**	**20**
Module C: **Follow Basic Communication Skills (General).** **Aim:** After completing this module, the learner will be able to listen attentively, develop non-verbal communication, and identify communication barriers, interview preparation for job and	**LU-1:** Adopt Effective listening to Skills **LU-2:** Develop Nonverbal communication with peers **LU-3:** Prepare for Interview to get a job **LU-4:** Use communication platform at workplace **LU-5:** Identify communication barriers to improve interpersonal skills	**10**	**40**	**50**

different communication platforms in the workplace and throughout your career.				
Module D: **Operate Computer Functions (General).** **Aim:** After completing this module, the learner will be able to have skills and knowledge required to setup a computer system, organize files in folders, and shutdown a computer system.	**LU1.** Set up the computer for use **LU2.** Organize files in folder **LU3.** Shut down computer system	**10**	**40**	**50**
Module E: **Adopt Good Manufacturing Practices for Pharmaceutical Production.** **Aim:** After completing this module, the learner will be able to know basic current Good Manufacturing Practices (cGMP) at the workplace according to the industry's approved guidelines, procedures and interprets rules/regulations.	**LU1.**Apply basic GMP requirements in regard to pharmaceutical quality system **LU2.**Apply basic GMP requirements in regard to personal hygiene measures **LU3.**Apply basic GMP requirements in regard to premises and equipment **LU4**.Apply basic GMP requirements in regard to documentation and records **LU5**. Apply basic GMP requirements in regard to production, and in-process controls **LU6**. . Apply basic GMP requirements in regard to distribution and storage	**10**	**30**	**40**
	TOTAL	**40**	**150**	**190**

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Module-E

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Module E: Adopt current Good Manufacturing Practices for Pharmaceutical Production

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

Duration:	**Total hours**	**40**	**Practical**	**30**	**Theory**	**10**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. **Apply basic cGMP requirements in regard to pharmaceutical quality system**	• Follow requirements of quality system within the production. • Report to in-charge about any deviation if occur, for prompt measures	• Explain safety rules and regulations for the pharmaceutical industry • Know about responsibilities within the quality management system (e.g. production, quality assurance, quality control). • Explain critical deviations during production. • Understand system of internal audit and responsibilities for self-inspection	2 hours Theory 5 hours Practical Total:7 hours	• Gloves • face mask • Goggles, • Caps • Uniform etc.	Class Room and workplace
LU2. **Apply basic cGMP**	• Perform proper hand washing and disinfection procedures before entering production	• Understand concept of corrective action within the quality system • Understand concept of continual	2 hours Theory	• Soaps • Disinfectant • Sanitizers	Class Room and workplace

requirements in regard to personal hygiene measures	• Report to supervisor in the case of illness • Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area • Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures • Receive visitor following the visitors' policy	improvement. • Know about hygienic measures (GMP) for pharmaceutical production. • Explain work place specific guidelines for uniform	5 hours Practical Total:7 hours	• Gloves • Face mask, Goggles • Caps • Uniform etc.	
LU3. **Apply basic cGMP requirements in regard to premises and equipment**	• Follow procedures for flow of personnel, material flow and product flow • Fill out specifications, records, batch production records for production under supervision	• Know about cross-contamination in regard to personal hygiene. • Explain the use of medical certificates. • Know about visitors' policy. • Understand clean room concept for pharmaceutical production. • Understand system of flow of materials, personnel and product. • Understand plant lay-out concepts for pharmaceutical production (e.g. straight-flow).	1 hours Theory 5 hours Practical Total:6 hours		Class Room and workplace
LU4. **Apply basic cGMP requirements in regard to documentation and records**	• Interpret laboratory control records • Follow master production instructions • Locate documents of external origin, if needed	• Explain control of documents procedure • Explain control of records procedure • Explain distribution procedures • Know about documents of external origin, SOPs, records, specification, master production instructions, batch production and	1 hours Theory 5 hours Practical Total:6 hours		Class Room and workplace

	• Safeguard documents and records appropriately	control records, laboratory control records • Know about documentation of completion			
LU5. **Apply basic cGMP requirements in regard to production, quality control and in-process controls**	• Follow master production instructions • Perform basic in-process control measurements (e.g. pH, weighing) under supervision • Perform basic quality control measure under supervision	• Know about common process deviations • Explain critical steps in production • Explain in-process sampling and controls • Know about contamination controls	2 hours Theory 5 hours Practical Total:7 hours	• First Aid Box • Maintenance box	
LU6. **Apply basic cGMP requirements in regard to storage and distribution**	• Store materials and end product appropriately • Use appropriate packaging materials for end product	• Know about packaging materials • Explain warehouse procedures • Explain distribution procedures	2 hours Theory 5 hours Practical Total:7 hours	• Smoke Detecting Alarm • Fire Extinguisher	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
	(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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