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PHARMACEUTICAL MANUFACTURING TECHNICIAN

CBT CURRICULUM

National Vocational Certificate Level 4

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. Contribute to Work Related Health and Safety (WHS) Initiatives
2. Analyze Workplace Policy and Procedures
3. Perform Advanced Communication
4. Develop Advance Computer Application Skills
5. Manage Human Resource Services
6. Develop Entrepreneurial Skills
7. Manufacture of Parenterals
8. Ensure quality product
9. Complete production documentation

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 4, in Pharmaceutical Manufacturing Technician are given below:

Title	Entry requirements
National Vocational Certificate level 4, 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 3, 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 **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:** (23.18%) **Practical** (76.82%)
- **Theory: 102 hours**
- **Practical: 338 hours**
- **Total: 440**

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
4	A	Contribute to Work Related Health and Safety (WHS) Initiatives	Generic	**06**	**24**	**30**	**03**	**44**
	B	Analyze Workplace Policy and Procedures	Generic	**06**	**24**	**30**	**03**	
	C	Perform Advanced Communication	Generic	**06**	**24**	**30**	**03**	
	D	Develop Advance Computer Application Skills	Generic	**08**	**32**	**40**	**04**	
	E	Manage Human Resource Services	Generic	**04**	**16**	**20**	**02**	
	F	Develop Entrepreneurial Skills	Generic	**06**	**24**	**30**	**03**	
	G	Manufacture of Paranterals	Technical	**40**	**140**	**180**	**18**	
	H	Ensure Quality Product	Technical	**10**	**30**	**40**	**04**	
	I	Complete production documentation	Technical	**16**	**24**	**40**	**04**	
			TOTAL	**102**	**338**	**440**	**44**	
			Percentage.	**23.18%**	**76.82%**			

Summary – Overview of the curriculum

Module Title and Aim	Learning Units	Theory Days/hours	Workplace Days/hours	Timeframe of Modules
Module A: **Contribute to Work Related Health and Safety (WHS) Initiatives** **Aim:** This unit describes the skills and knowledge required to manage the identification, review, development, implementation and evaluation of effective participation and consultation processes as an integral part of managing work health and safety (WHS).	**LU1.** Contribute to initiate work-related health and safety measures **LU2.** Contribute to establish work-related health and safety measures **LU3.** Contribute to ensure legal requirements of WHS measures **LU4.** Contribute to review WHS measures **LU5.** Evaluate the organization's WHS system	**06**	**24**	**30**
Module B: **Comply with Workplace Policy and Procedures** **Aim:** This unit describes the skills and knowledge required to 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.** Manage work timeframes **LU2.** Manage to convene meeting **LU3.** Decision making at workplace **LU4.** Set and meet own work priorities at instant **LU5.** Develop and maintain professional competence **LU6.** Follow and implement work safety requirements	**06**	**24**	**30**

Module C: **Perform Advanced Communication** **Aim:** This unit describes the performance outcomes, skills and knowledge required to develop communication skills used professionally. It covers plan and organise work and conduct trainings at workplace, along with demonstrating professional skills independently	**LU1.** Demonstrate professional skills **LU2.** Plan and Organize work **LU3.** Provide trainings at workplace	**06**	**24**	**30**
Module D: **Develop Advance Computer Application Skills** **Aim:** This unit provides an overview of Microsoft Office programs to create personal, academic and business documents following current professional and/or industry standards, i.e. Data Entry, Power Point Presentation and managing data base and graphics for Design. It applies to individuals employed in a range of work environments who need to be able to present a set range of data in a simple and direct forms	**LU1.** Manage Information System to complete a task **LU2.** Prepare Presentation using computers **LU3.** Use Microsoft Access to manage database **LU4.** Develop graphics for Design	**08**	**32**	**40**

Module E: **Manage Human Resource Services** **Aim:** This unit describes the skills and knowledge required to plan, manage and evaluate delivery of human resource services, integrating business ethics. It applies to individuals with responsibility for coordinating a range of human resource services across an organization. They may have staff reporting to them.	**LU1.** Determine strategies for delivery of human resource services **LU2.** Manage the delivery of human resource services **LU3.** Evaluate human resource service delivery **LU4.** Manage integration of business ethics in human resource practices	**04**	**16**	**20**
Module F: Develop Entrepreneurial Skills **Aim:** This Competency Standard identifies the competencies required to develop entrepreneurial skills, in accordance with the organization's approved guidelines and procedures. You will be expected to develop a business plan, collect information regarding funding sources, develop a marketing plan and develop basic business communication skills. Your underpinning knowledge regarding entrepreneurial skills will be sufficient to provide you the basis for your work.	**LU1.** Develop a business plan **LU2.** Collect information regarding funding sources **LU3.** Develop a marketing plan **LU4.** Develop basic business communication skills	**06**	**24**	**30**
Module G: **Manufacture of Paranterlas** **Aim:** After completing this module, the learner will be able to perform manufacturing of parenterals products by involving collection of distal water, sterile raw materials, and sterilization of machine, equipment/tools and packaging materials in accordance with the industry's approved guidelines and procedures.	**LU1.** Collect distal water **LU2.** Receive sterile raw materials **LU3.** Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottle **LU4.** Mix materials **LU5.** Control environment of production room **LU6.** Transfer product for filling and sealing	**50**	**200**	**250**

Module H: **Ensure Quality Product** **Aim:** After completing this module, the learner will be able to check quality raw materials in accordance with the Current Good Manufacturing Practices (cGMP) as well as industry's approved guidelines and procedures. Quality assurance and control play an essential role in the pharmaceutical manufacturing process, by ensuring that patients are provided with medications that are safe, effective, and produced at a high level of quality.	**LU1.** Ensure quality raw materials **LU2.** Check production equipment as per industry standards **LU3.** Give suggestions for process improvements **LU4.** Inspect production process	**40**	**160**	**200**
Module I: **Complete Production Documentation** **Aim:** After completing this module, the learner will be able to apply communication skills, knowledge and understanding to maintain documentations of all manufacturing raw materials and products in accordance with the industry's approved guidelines and procedure.	**LU1.** Maintain documentation of production **LU2.** Prepare reports and data base **LU3.** Maintain all packaging record **LU4.** Maintain record of equipment and batches	**16**	**64**	**80**
	Total Hours	**102**	**338**	**440**

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Module-G

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Module G: Manufacture Parenterals

Objectives: After completing this module, the learner will be able to perform manufacturing of parenterals products by involving collection of distal water, sterile raw materials, and sterilization of machine, equipment/tools and packaging materials in accordance with the industry's approved guidelines and procedures.

Duration:	**Total hours**	**180**	**Practical**	**140**	**Theory**	**40**

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. Collect distal water	• Start double distal water plant (Water for injection). • Drain water for few minutes as per specification. • Inform section in-charge for further relevant process (e.g. pH, conductivity, sterility & pyrogen) • Receive report from section in-charge.	• Describe specification sterile water for injection • Describe different types of distal water plants • Describe operating procedure of distal water plant	8 hours Theory 24 hours Practical Total hours: 32	• Double distilled water plant • pH meter • Conductivity meter • Filters of different sizes • Fogger • Disinfectant • Dedicated parenterals safety kit	Class Room and workplace
LU2. Receive sterile raw materials	• Receive sterile material from pass through window as per specification • Transfer raw material to concerned	• Describe types of controlled area e.g. Class A, B, C & D	8 hours Theory 24 hours	• Autoclave • Dry Sterilizer	Class Room and workplace

	controlled area as per specifications (i.e. class A, B, C & D) • Report to in-charge about any deviation	• Describe sterile material(s)	Practical Total hours: 32		
LU3. Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottles	• Select sterilization methods. **a)** Filtration: use filtration for heat sensitive products. **i)** Select appropriate filter size. **b)** Terminal sterilization (autoclave) for heat resistant products. **i)** Load product in autoclave. Lock its door properly. **ii)** Adjust pressure and temperature as per specifications. **c)** Dry heat/chemical Sterilization **i)** Sterilize vials/ ampoules/bottles • Collect product safely for further process. • Inform to section in-charge about any deviation	• Describe types of sterilization and filters • Describe autoclave and dry heat sterilizers • Describe types of chemical sterilization and equipment.	6 hours Theory 23 hours Practical Total hours: 29	• Filtration Assembly • Nominal filters • Mixers • Autoclave • Dry heat sterilizer	Class Room and workplace
LU4. Mix materials	• Transfer specified volume of water for injection to different manufacturing tanks • Add and dissolve material as per manufacturing order • Transfer solution as per specified method to storage tank through filtration	• Describe order of mixing • Describe mixers	6 hours Theory 23 hours Practical Total	• Mixers • Manufacturing tanks • Filtration assembly	Class Room and workplace

	• Report section in-charge about completion of process • Report any deviation to section in-charge		hours: 29		
LU5. Control environment of production room	• Check environmental control parameters (temperature, humidity & particulate matters) through manufacturing order monometer/ hygrometer/ psychrometer / particle counter. • Receive area clearance report from section in-charge. • Report any deviation to section in-charge	• Describe method of checking different types of environmental parameters • Define monometer/ hygrometer/ psychrometer / particle counter	6 hours Theory 23 hours Practical Total hours: 29	• Hygrometer • Psychrometer • Monometer • Particle counter	Class Room and workplace
LU6. Transfer product for filling and sealing	• Collect sample report form section in-charge • Transfer sterilized solution aseptically to filling area • Start filling and sealing under class A environment • Perform in process weight/volume variation & Optical checking • Shift filled product to quarantine area after terminal sterilization (where required) till approval from Quality Assurance • Report any deviation to section in-	• Describe vials and ampoule • Explain weight/ volume variation	6 hours Theory 23 hours Practical Total hours: 29	• Transfer pump • Filtration Assembly • Filling and sealing machine • Volumetric cylinder • digital balance	Class Room and workplace

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Module-H

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Module H: Ensure Quality Product

Objectives: After completing this module, the learner will be able to check quality raw materials in accordance with the Current Good Manufacturing Practices (cGMP) as well as industry's approved guidelines and procedures. Quality assurance and control play an essential role in the pharmaceutical manufacturing process, by ensuring that patients are provided with medications that are safe, effective, and produced at a high level of quality.

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

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. Ensure quality raw materials	• Receive quality raw materials as per the specifications of manufacturing order • Ensure materials identification labels as per the specifications of manufacturing order • Check expiry date on each labeled raw material as per specifications	• Describe physical aspects of raw materials	3 hours Theory 8 hours Practical Total hours: 11	Materials identification labels	Class Room and workplace
LU2. Check production equipment as per industry standards	• Enlist equipment relevant to the task as per specifications given in manufacturing order • Identify tools/equipment relevant to the task as per Manufacturing order	• Explain quality standards as per specification	3 hours Theory 8 hours Practical Total hours: 11	Production Equipment	Class Room and workplace

LU3. **Give suggestions for process improvements**	• Identify problems on quality issues during completion of manufacturing order • Observe quality issues during manufacturing process • Identify objective measures for quality system effectiveness at manufacturing sites • Submit report to section in-charge	• Define operation qualifications • Explain acceptance criteria • Explain quality issues in manufacturing process	2 hours Theory 7hours Practical Total hours: 9	• Manufacturing Order • Reporting Document	Class Room and workplace
LU4. **Inspect production process**	• Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry • Reduce defect rate and waste of product by applying rules & regulations of industry for quality product • Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry	• Define techniques for solving issues in manufacturing process • Elaborate how defect rates can be reduced in production	2 hours Theory 7hours Practical Total hours: 9		Class Room and workplace

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Module-I

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Module I: Complete Production Documentation

Objectives: After completing this module, the learner will be able to apply communication skills, knowledge and understanding to maintain documentations of all manufacturing raw materials and products in accordance with the industry's approved guidelines and procedure.

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

Learning Unit	**Learning Outcomes**	**Learning Elements**	**Duration**	**Materials (Tools & Equipment) Required**	**Learning Place**
LU1. Maintain documentation of production	• Ensure documentation after completion of each batch • Maintain standard operating procedures and fill all the log books and other related Performa • Collect analysis reports and data sheet and handover to the person concerned after proper authentication, if required.	• Read industry related policy matters • Explain job related standard operating procedures	3 hours Theory 8 hours Practical Total hours: 11	• Analysis Report • Data Sheet • Log Book	Class Room and workplace
LU2. Prepare reports and data base	• Summarize information in proper format for decision making. • Select appropriate record source that is authentic and relevant. • Follow instructions of the management for preparing reports and database.	• Describe procedure of maintaining log books and another related Performa • Explain procedure of maintain documentation • Elaborate information on	3 hours Theory 8 hours Practical Total hours: 11	• Reporting Document	Class Room and workplace

	• Submit report to the management timely to make decisions	database • Know database on website			
LU3. **Maintain all packaging record**	• Perform manual inspections of packaging as per procedure • Assist physical inventory cycle counts accordingly • Communicate to upper management	• Explain data sources • Explain method of recording data and summarizing meaningful information for management.	2 hours Theory 7hours Practical Total hours: 9		Class Room and workplace
LU4. **Maintain record of equipment and batches**	• Perform routine inspection as per procedure of industry • Ensure that each machine is in tip-top shape before putting them to work • Maintain document after every repair or maintenance work • Keep record of maintenance work as per procedure	• Describe process of record keeping • Define importance of equipment • Explain types of maintenance work	2 hours Theory 7hours Practical Total hours: 9	• Maintenance Log Book	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	

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