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PHARMACEUTICAL MANUFACTURING TECHNICIAN



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ASSESSMENT PACKAGE

National Vocational Certificate Level 1

Version 1 - November, 2019



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November, 2019
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PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE
National Vocational Certificate Level 1

Version 1 - November, 2019

Instructions for Candidate (to be given by the Assessor before Assessment)

Title of Qualification: National Vocational Certificate level 1, In Pharmaceutical Manufacturing Technician	CS Code: 091600735	Level: 1	Version: 1 (2019)
Competency Standard Title: Adopt Good Manufacturing Practices for Pharmaceutical Production	Assessment Date (DD/MM/YY):		

Candidate Details	Name..... Registration/Roll Number.....
Guidance for Candidate	<p>To meet this standard, you are required to complete the following tasks within 40 min timeframe:</p> <ol style="list-style-type: none"> Assessment Task 1: Apply basic GMP requirements in regard to pharmaceutical quality system Assessment Task 2: Apply basic GMP requirements in regard to personal hygiene measures Assessment Task 3: Apply basic GMP requirements in regard to premises and equipment Assessment Task 4: Apply basic GMP requirements in regard to documentation and records Assessment Task 5: Apply basic GMP requirements in regard to production, and in-process controls Assessment Task 6: Apply basic GMP requirements in regard to distribution and storage <p>And complete:</p> <ol style="list-style-type: none"> Knowledge assessment test (Written or Oral) Portfolios at the time of assessment (if any)
Minimum Evidence Required	<p>During a practical assessment, under observation by an assessor, you will complete:</p> <p>Task 1: Apply basic GMP requirements in regard to pharmaceutical quality system</p> <p>Performance Criteria 1: Follow requirements of quality system within the production</p> <p>Performance Criteria 2: Report to in-charge about any deviation if occur, for prompt measures</p> <p>Task 2: Apply basic GMP requirements in regard to personal hygiene measures</p> <p>Performance Criteria 1: Perform proper hand washing and disinfection procedures before entering production.</p> <p>Performance Criteria 2: Report to supervisor in the case of illness.</p> <p>Performance Criteria 3: Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area.</p>

Performance Criteria 4: Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures.

Performance Criteria 5: Receive visitor following the visitors' policy.

Task 3: Apply basic GMP requirements in regard to premises and equipment

Performance Criteria 1: Follow procedures for flow of personnel, material flow and product flow

Performance Criteria 2: Fill out specifications, records, batch production records for production under supervision.

Task 4: Apply basic GMP requirements in regard to documentation and records

Performance Criteria 1: Interpret laboratory control records

Performance Criteria 2: Follow master production instructions

Performance Criteria 3: Locate documents of external origin, if needed

Performance Criteria 4: Safeguard documents and records appropriately

Task 5: Apply basic GMP requirements in regard to production, and in-process controls

Performance Criteria 1: Follow master production instructions

Performance Criteria 2: Perform basic in-process control measurements (e.g. pH, weighing) under supervision

Performance Criteria 3: Perform basic quality control measure under supervision

Task 6: Apply basic GMP requirements in regard to distribution and storage

Performance Criteria 1: Store materials and end product appropriately

Performance Criteria 2: Use appropriate packaging materials for end product.

Portfolios required at the time of assessment (if any) for

Performance criteria for the evaluation of portfolio:

Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.

Assessors Judgment Guide (to be completed by the Assessor and signed both by the assessor and the candidate after the assessment)

091600735 Adopt Good Manufacturing Practices for Pharmaceutical Production

Candidate Details	Name: Registration/Roll Number: Candidate Signature:
Assessment Outcome	COMPETENT <input type="checkbox"/> NOT YET COMPETENT <input type="checkbox"/> Name of the Assessor:..... Assessor's code:..... Assessor's Signature:.....

Assessment Summary (to be filled by the assessor)							
Activity	Method					Result	
Nature of Activity	Written	Oral	Observation	Portfolio	Role Play	Competent	Not Yet Competent
Practical Skill Demonstration							
Knowledge Assessment							
Other Requirement							

Assessment Task 1	Description of assessment task 1 Apply basic GMP requirements in regard to pharmaceutical quality system					
During the practical assessment, candidate demonstrated the following:						
1.	Performance Criteria 1: Followed requirements of quality system within the production.					
2.	Performance Criteria 2: Report to in-charge about any deviation if occur, for prompt measures					
Competent <input type="checkbox"/>			Not Yet Competent <input type="checkbox"/>			

Assessment Task 2		Apply basic GMP requirements in regard to personal hygiene measures		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Perform proper hand washing and disinfection procedures before entering production.			
2	Performance Criteria 2: Report to supervisor in the case of illness			
3	Performance Criteria 3: Remove personal accessories (jewelry, watch, cell phone, etc.) before entering work area			
4	Performance Criteria 4: Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures			
5	Performance Criteria 5: Receive visitors following the visitors' policy			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 3		Apply basic GMP requirements in regard to premises and equipment		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Follow procedures for flow of personnel, material flow and product flow.			
2	Performance Criteria 2: Fill out specifications, records, batch production records for production under supervision.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 4		Apply basic GMP requirements in regard to documentation and records		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Interpret laboratory control records			
2	Performance Criteria 2: Follow master production instructions			
3	Performance Criteria 3: Locate documents of external origin, if needed			
4	Performance Criteria 4: Safeguard documents and records appropriately			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 5		Apply basic GMP requirements in regard to production, and in-process controls		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Follow master production instructions			
2	Performance Criteria 2: Perform basic in-process control measurements (e.g. pH, weighing) under supervision			
3	Performance Criteria 3: Perform basic quality control measure under supervision			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 6		Apply basic GMP requirements in regard to distribution and storage		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Store materials and end product appropriately			
2	Performance Criteria 2: Use appropriate packaging materials for end product			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Portfolio (if any)		Description of portfolio		
Current <input type="checkbox"/>	Sufficient <input type="checkbox"/>	Authentic <input type="checkbox"/>	Valid <input type="checkbox"/>	Reliable <input type="checkbox"/>
Portfolio meet the following performance standards:		Yes	No	Remarks
1	Performance criteria 1 for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Title of Qualification: National Vocational Certificate level 1, In Pharmaceutical Manufacturing Technician	CS Code: 091600735	Level: 1	Version: 1 (2019)
Competency Standard Title: Adopt Good Manufacturing Practices for Pharmaceutical Production	Assessment Date (DD/MM/YY): --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
1. What are the responsibilities of the quality management system?	
2. Describe some critical deviations during production process?	
3. How to control cross-contamination in regard to personal hygiene?	
4. What is the importance of medical certificates?	

Question	Candidate's answer
5. What is the significance of documentation and records?	
6. What is a clean room in pharmaceutical manufacturing?	
7. Define the significance of materials & personnel flow?	
8. What is the significance of in process checks?	

Title of Qualification: National Vocational Certificate level 1, In Pharmaceutical Manufacturing Technician		CS Code: 0916PHR02	Level: 1	Version: 1 (2019)
Competency Standard Title: National Vocational Certificate Level – 1 in Pharmaceutical Manufacturing Attendant		Assessment Date (DD/MM/YY):		
Candidate Details	Name:			
	Registration/Roll Number:			
Guidance for Candidate	<p>To meet this standard, you are required to complete the following within 03 Hours (for practical demonstration & assessment):</p> <p>1. Assessment Task: In a given situation to</p> <p>“Apply basic cGMP requirements in regard to the pharmaceutical quality system, personal hygiene measures, premises and equipment, quality control and in-process controls by observing personal safety”</p> <p>And complete:</p> <p>3. Knowledge assessment test (Written or Oral).</p> <p>4. Portfolios at the time of assessment (if any).</p>			
Minimum Evidence Required	<p>During a practical assessment, under observation by an assessor, you are required to</p> <p>Apply basic cGMP requirements in regard to the pharmaceutical quality system, personal hygiene measures, premises and equipment, quality control and in-process controls by observing personal safety”</p> <p>demonstrating the following criteria:</p> <ol style="list-style-type: none"> 1. Performance Criteria 1: Wear gown and Personal Protective Equipment (PPE) as per job description 2. Performance Criteria 2: Deal with problems which are within your control, and report those that cannot be resolved to safety officer 3. Performance Criteria 3: Keep work area clean and clear of obstructions and store tools or equipment as per procedure of the industry to avoid any incident 4. Performance Criteria 4: Follow requirements of the quality system within the production 5. Performance Criteria 5: Perform proper hand washing and disinfection procedures before entering production 6. Performance Criteria 6: Follow procedures for flow of personnel, material flow and product flow 			

	<p>Portfolios required at the time of assessment (if any) for</p>
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Performance criteria for the evaluation of portfolio:

Submit log book or activity record (practical journal, project, pictures etc.)
completed during the training.

Self-Assessment Checklist

Candidate Name	
Registration No.	
Qualification	National Vocational Certificate Level – 1 in Pharmaceutical Manufacturing Attendant
Purpose of Assessment	Summative Assessment
Assessment Task	Apply basic cGMP requirements in regard to the pharmaceutical quality system, personal hygiene measures, premises and equipment, quality control and in-process controls by observing personal safety <ul style="list-style-type: none"> • Knowledge Assessment

I can.....

Performance Criteria	Yes	No
P1. Wear gown and Personal Protective Equipment (PPE) as per job description	<input type="checkbox"/>	<input type="checkbox"/>
P2. Deal with problems which are within your control, and report those that cannot be resolved to safety officer	<input type="checkbox"/>	<input type="checkbox"/>
P3. Keep work area clean and clear of obstructions and store tools or equipment as per industry procedure to avoid any incident	<input type="checkbox"/>	<input type="checkbox"/>
P4. Follow requirements of quality system within the production	<input type="checkbox"/>	<input type="checkbox"/>
P5. Perform proper hand washing and disinfection procedures before entering production	<input type="checkbox"/>	<input type="checkbox"/>
P6. Follow procedures for flow of personnel, material flow and product flow	<input type="checkbox"/>	<input type="checkbox"/>

Candidate's Signature _____ Assessor's Signature _____

Date: _____

Each Assessment Task (with performance criteria)				
Assessment Task		Description of assessment task		
		Apply basic GMP requirements in regard to the pharmaceutical quality system, personal hygiene measures, premises and equipment by observing personal safety.		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Worn gown and Personal Protective Equipment (PPE) as per job			
2	Performance Criteria 2: Dealt with problems which are within your control, and reported those that cannot be resolved to safety officer			
3	Performance Criteria 3: Kept work area clean and clear of obstructions and stored tools or equipment as per industry procedure to prevent any incident			
4	Performance Criteria 4: Followed requirements of quality system within the production			
5	Performance Criteria 5: Performed proper hand washing and disinfection procedures before entering production			
6	Performance Criteria 6: Followed procedures for flow of personnel, material flow and product flow			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

1. Name any three safe working conditions?		
2. List down Good attitudes that may contribute to good practices at the work environment?	Satisfactory	Not Satisfactory
3. Name and explain three common hazards found at the workplace?	Satisfactory	Not Satisfactory
4. List any three precautions to follow when working with dangerous substances?	Satisfactory	Not Satisfactory

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5. Name any three general duties that employees have to comply regarding health and safety?	Satisfactory	Not Satisfactory

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