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# PHARMACEUTICAL MANUFACTURING TECHNICIAN



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## ASSESSMENT PACKAGE

National Vocational Certificate Level 2

Version 1 - November, 2019



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**Document Version**

November, 2019  
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# PHARMACEUTICAL MANUFACTURING TECHNICIAN



**ASSESSMENT PACKAGE**  
National Vocational Certificate Level 2

**Version 1 - November, 2019**

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

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	<b>CS Code:</b> <b>019600602</b>	<b>Level:</b> 2	<b>Version:</b> 1 (2019)
<b>Competency Standard Title:</b> <b>Prepare work environment according to manufacturing order</b>	<b>Assessment Date (DD/MM/YY):</b>		

<b>Candidate Details</b>	Name.....  Registration/Roll Number.....
<b>Guidance for Candidate</b>	<p><b>To meet this standard, you are required to complete the following tasks within 40 min timeframe:</b></p> <ol style="list-style-type: none"> <li>1. <b>Assessment Task 1:</b> Maintain temperature and humidity</li> <li>2. <b>Assessment Task 2:</b> Ensure air pressure of specific area/work place</li> <li>3. <b>Assessment Task 3:</b> Conduct and verify cleaning and sanitation procedures</li> <li>4. <b>Assessment Task 4:</b> Adjust light as per specifications in workplace area</li> </ol> <p><b>And complete:</b></p> <ol style="list-style-type: none"> <li>1. <b>Knowledge assessment test (Written or Oral)</b></li> <li>2. <b>Portfolios at the time of assessment (if any)</b></li> </ol>
<b>Minimum Evidence Required</b>	<p><b>During a practical assessment, under observation by an assessor, you will complete:</b></p> <p><b>Task 1: Maintain temperature and humidity</b></p> <p>Performance Criteria 1: Inspect work place regularly as per area/product specific requirements</p> <p>Performance Criteria 2: Take note of current temperature and humidity levels at workplace as required by manufacturing order</p> <p>Performance Criteria 3: Maintain workplace temperature and humidity levels as per manufacturing order</p> <p>Performance Criteria 4: Record temperature and humidity as per manufacturing order</p> <p>Performance Criteria 5: Report to in-charge about any deviation if occur, for prompt measures</p> <p><b>Task 2: Ensure air pressure of specific area/work place</b></p> <p>Performance Criteria 1: Note and maintain air pressure of workplace as required for manufacturing order.</p> <p>Performance Criteria 2: Record air pressure as per manufacturing order</p> <p>Performance Criteria 3: Report to in-charge about any deviation if occur, for prompt measures</p>

**Task 3: Conduct and verify cleaning and sanitation procedures**

Performance Criteria 1: Clean workplace, tools/equipment from dust before swab test

Performance Criteria 2: Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications

Performance Criteria 3: Report to in-charge about any deviation

**Task 4: Adjust light as per specifications in workplace area**

Performance Criteria 1: Identify high-bay and low-bay lights and colors as per manufacturing of sensitive medicine products or task specific lights in workplace.

Performance Criteria 2: Adjust dust and water resistance lights as required for specific manufacturing tasks

**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)

**019600602 Prepare work environment according to manufacturing order**

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:..... Signature of the Assessor:.....

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							

<b>Assessment Task 1</b>	Description of assessment task 1 <b>Maintain temperature and humidity</b>				
<b>During the practical assessment, candidate demonstrated the following:</b>					
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>	
1.	Performance Criteria 1: Inspect work place regularly as per area/product specific requirements				
2.	Performance Criteria 2: Take note of current temperature and humidity of workplace as required by manufacturing order				
3.	Performance Criteria 3: Maintain workplace temperature and humidity as per manufacturing order				
4.	Performance Criteria 4: Record temperature and humidity as per manufacturing order				
5.	Performance Criteria 5: Report to in-charge about any deviations, if occurred, for prompt measures				
<b>Competent <input type="checkbox"/></b>		<b>Not Yet Competent <input type="checkbox"/></b>			

<b>Assessment Task 2</b>	<b>Ensure air pressure of specific area/work place</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Note and maintain air pressure of workplace as required for manufacturing order.			
2	Performance Criteria 2: Record air pressure as per manufacturing order			
3	Performance Criteria 3: Report to in-charge about any deviations, if occurred, for prompt measures			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 3</b>	<b>Conduct and verify cleaning and sanitation procedures</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Clean workplace, tools/equipment from dust before swab test			
2	Performance Criteria 2: Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications			
3	Performance Criteria 3: Report to in-charge about any deviation			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 4</b>	<b>Adjust light as per specifications in workplace area</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Identify high-bay and low-bay lights and colors as per manufacturing of sensitive medicine products or tasks specific lights in workplace			
2	Performance Criteria 2: Adjust dust and water resistance lights as required for specific manufacturing tasks			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <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 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"/>			





<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>019600602</b>	Level: 2	Version: 1
<b>Competency Standard Title:</b> <b>Prepare work environment according to manufacturing order</b>	<b>Assessment Date (DD/MM/YY):</b> --/--/--		

**WRITTEN ASSESSMENT**

Question	Candidate's answer
1. Define humidity and temperature?	
2. Why do we use hygrometer, thermometer, monometer and psychrometer as equipment?	

Question	Candidate's answer
3. Define heating, ventilation, air pressure (HVAC)?	
4. Define air pressure variations?	
5. Define cleaning procedures at workplace?	
6. Define Types and role of detergents & disinfectants used at the workplace?	

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

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>019600603</b>	Level: 2	Version: 1 (2019)
<b>Competency Standard Title:</b> Receive Product Raw Materials according to manufacturing order	<b>Assessment Date (DD/MM/YY):</b>		

<b>Candidate Details</b>	Name.....  Registration/Roll Number.....
<b>Guidance for Candidate</b>	<p><b>To meet this standard, you are required to complete the following tasks within 40 min timeframe:</b></p> <p align="center"> <b>Assessment Task 1:</b> Receiving of raw materials &amp; storage  <b>Assessment Task 2:</b> Identify materials according to labels  <b>Assessment Task 3:</b> Check weight of raw materials  <b>Assessment Task 4:</b> Shift materials to concerned section  <b>Assessment Task 5:</b> Arrange raw materials for mixing                 </p> <p><b>And complete:</b></p> <p align="center"> <b>3. Knowledge assessment test (Written or Oral)</b>  <b>4. Portfolios at the time of assessment (if any)</b> </p>
<b>Minimum Evidence Required</b>	<p><b>During a practical assessment, under observation by an assessor, you will complete:</b></p> <p><b>Task 1: Receive raw materials &amp; its storage</b></p> <p>Performance Criteria 1: Perform sensory (visual) evaluation of raw materials (including packaging materials)                  Performance Criteria 2: Store raw materials in a manner to prevent degradation, contamination and cross-contamination</p> <p><b>Task 2: Identify materials according to labels</b></p> <p>Performance Criteria 1: Identify raw materials as per manufacturing order                  Performance Criteria 2: Cross check labels of raw materials as per specifications against each manufacturing order                  Performance Criteria 3: Check the signature of appropriate authority on labeled raw materials as per manufacturing order                  Performance Criteria 4: Report to in-charge about any deviation</p>

**Task 3: Check weight of raw materials**

Performance Criteria 1: Confirm calibration status of weighing balance

Performance Criteria 2: Cross check the gross weight of individual labeled raw materials as per manufacturing order

**Task 4: Shift materials to concerned section**

Performance Criteria 1: Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area

Performance Criteria 2: Transfer dispensed materials trolley to the manufacturing area as per procedure

Performance Criteria 3: Check the temperature and humidity of material placement area as per procedure

Performance Criteria 4: Park trolley safely and lock it at appropriate place as per instructions

**Task 2: Arrange raw materials for mixing**

Performance Criteria 1: Check the batch material trolley prior to dispatch to mixing area as per procedure.

Performance Criteria 2: Transfer dispensing material trolley to the production area as per instructions

Performance Criteria 3: Check the batch material and arrange it according to mixing order as per set procedure

**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.



<b>Assessment Task 2</b>		<b>Identify materials according to labels</b>		
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Identify raw materials as per manufacturing order			
2	Performance Criteria 2: Cross check labels of raw materials as per specifications against each manufacturing order			
3	Performance Criteria 3: Check the signature of appropriate authority on labeled raw materials as per manufacturing order			
4	Performance Criteria 4: Report to in-charge about any deviation			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 3</b>		<b>Check weight of raw materials</b>		
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Confirm calibration status of weighing balance			
2	Performance Criteria 2: Cross check the gross weight of individual labeled raw materials as per manufacturing order			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 4</b>		<b>Shift materials to concerned section</b>		
<b>During the practical assessment, candidate demonstrated the following:</b>				
		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area			
2	Performance Criteria 2: Transfer dispensed materials trolley to the manufacturing area as per procedure			
3	Performance Criteria 3: Check the temperature and humidity of material placement area as per procedure			
4	Performance Criteria 4: Park trolley safely and lock it at appropriate place as per instruction			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 5</b>		<b>Arrange Raw Materials for Mixing</b>		
<b>During the practical assessment, candidate demonstrated the following:</b>		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Check the batch material trolley prior to dispatch to mixing area as per procedure			
2	Performance Criteria 2: Transfer dispensing material trolley to the production area as per instructions			
3	Performance Criteria 3: Check the batch material and arrange it according to mixing order as per procedure			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

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



## Knowledge Assessment

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	<b>CS Code:</b> <b>019600603</b>	<b>Level:</b> 2	<b>Version:</b> 1 (2019)
<b>Competency Standard Title:</b> <b>Receive Product Raw Materials according to manufacturing order</b>	<b>Assessment Date (DD/MM/YY):</b> --/--/--		

Guidance for Candidate	<b>To complete your assessment for this Competency Standard, you need to answer the questions on the following pages successfully.</b>
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**Assessors Guide** (to be completed by the Assessor and signed both by the assessor and the candidate after the assessment)

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

**Feedback to the candidate on assessment.**

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Candidate Signature..... Assessor Signature .....

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>019600603</b>	Level: 2	Version: 1
<b>Competency Standard Title:</b> <b>Receive Product Raw Materials according to manufacturing order</b>	<b>Assessment Date (DD/MM/YY):</b> --/--/--		

## WRITTEN ASSESSMENT

Question	Candidate's answer
2. What is a manufacturing order?	
7. How to identify the raw materials used in manufacturing order?	
8. What is the importance of calibration?	
9. What is the safe shifting of materials according to the manufacturing order?	

Question	Candidate's answer
10. Describe different methods of arranging batch materials as per manufacturing order?	
11. What is gross weight, net weight and tare weight?	
12. What is a lot number?	

Question	Candidate's answer
13. What is a batch number?	
14. What is the significance of a product code?	

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

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>019600604</b>	Level: 2	Version: 1 (2019)
<b>Competency Standard Title:</b> <b>Adjust machine according to manufacturing order</b>	<b>Assessment Date (DD/MM/YY):</b>		

<b>Candidate Details</b>	Name.....  Registration/Roll Number.....
<b>Guidance for Candidate</b>	<p><b>To meet this standard, you are required to complete the following tasks within 40 min timeframe:</b></p> <p align="center"> <b>Assessment Task 1:</b> Check electrical and mechanical parameters of machine for proper functionality  <b>Assessment Task 2:</b> Check machine lubrications  <b>Assessment Task 3:</b> Ensure cleaning of machine  <b>Assessment Task 4:</b> Maintain machine Log-book  <b>Assessment Task 5:</b> Follow machine operation procedure                 </p> <p><b>And complete:</b></p> <p align="center"> <b>5. Knowledge assessment test (Written or Oral)</b>  <b>6. Portfolios at the time of assessment (if any)</b> </p>
<b>Minimum Evidence Required</b>	<p><b>During a practical assessment, under observation by an assessor, you will complete:</b></p> <p><b>Task 1: Check electrical and mechanical parameters of machine for proper functionality</b></p> <p>Performance Criteria 1: Check machine electric input and output as per instructions given in machine manual</p> <p>Performance Criteria 2: Check machine mechanically fit for operation as per manufacturing order</p> <p>Performance Criteria 3: Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order</p> <p><b>Task 2: Check machine lubrications</b></p> <p>Performance Criteria 1: Check gauge of lubricants as per machine manual.</p> <p>Performance Criteria 2: Verify proper lubrication of machinery as per maintenance schedule</p> <p>Performance Criteria 3: Report to in-charge about any deviation.</p>

**Task 3: Ensure cleaning of machine**

Performance Criteria 1: Check the cleanliness status of machine after completion of each batch as per the instructions given in manual.

Performance Criteria 2: Proper tagging of machine as per procedure

Performance Criteria 3: Inform the area in-charge about completion of each batch as well as for next process as per manufacturing order

**Task 4: Maintain machine log-book**

Performance Criteria 1: Make entries in machine log book as per instructions

Performance Criteria 2: Check log book periodically for effective and smooth running of machine functions

Performance Criteria 3: Report to in-charge for any unusual response during manufacturing processing

**Task 5: Follow machine operation procedure**

Performance Criteria 1: Identify every manufacturing features and notes before start the machine as per manufacturing order

Performance Criteria 2: Adjust the machine parameters as per product manufacturing order, before operating it

Performance Criteria 3: Perform in process tests according to product manufacturing order and machine operation procedures

Performance Criteria 4: Inform to the section in-charge regarding any deviation during process

**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)

**019600604 Adjust machine as per product manufacturing order**

Candidate Details	Name: ..... Registration/Roll Number: ..... Candidate Signature:.....
Assessment Outcome	COMPETENT <input type="checkbox"/> <span style="margin-left: 200px;">NOT YET COMPETENT <input type="checkbox"/></span>  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							

<b>Assessment Task 1</b>	Description of assessment task 1 <b>Check electrical and mechanical parameters of machine for proper functionality</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
		Yes	No	Remarks
1.	Performance Criteria 1: Check machine electric input and output as per instruction given in machine manual			
2.	Performance Criteria 2: Check, if machine mechanically fit for operation as per manufacturing order			
3.	Performance Criteria 3: Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order			
<b>Competent <input type="checkbox"/></b>		<b>Not Yet Competent <input type="checkbox"/></b>		



<b>Assessment Task 2</b>	<b>Check machine lubrications</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
1	Performance Criteria 1: Check gauge of lubricants as per machine manual	Yes	No	Remarks
2	Performance Criteria 2: Verify proper lubrication of machinery as per maintenance schedule			
3	Performance Criteria 3: Report to in-charge about any deviation			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 3</b>	<b>Ensure cleaning of machine</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
1	Performance Criteria 1: Check the cleanliness status of machine after completion of each batch as per instruction given in the manual	Yes	No	Remarks
2	Performance Criteria 2: Proper tagging of machine as per procedure			
3	Performance Criteria 3: Inform the area in-charge about completion of each batch as well as for next process as per manufacturing order			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 4</b>	<b>Maintain machine log-book</b>			
<b>During the practical assessment, candidate demonstrated the following:</b>				
1	Performance Criteria 1: Make entries in machine log book as per instruction	Yes	No	Remarks
2	Performance Criteria 2: Check log book periodically for effective and smooth running of machine functions			
3	Performance Criteria 3: Report to in-charge for any unusual response during manufacturing processing			
<b>Competent</b> <input type="checkbox"/>		<b>Not Yet Competent</b> <input type="checkbox"/>		

<b>Assessment Task 5</b>		<b>Arrange Raw Materials for Mixing</b>		
<b>During the practical assessment, candidate demonstrated the following:</b>		<b>Yes</b>	<b>No</b>	<b>Remarks</b>
1	Performance Criteria 1: Identify every manufacturing feature and notes before the start of the machine as per manufacturing order			
2	Performance Criteria 2: Adjust the machine parameters as per product manufacturing order, before operating it			
3	Performance Criteria 3: Perform in process tests according to product manufacturing order and machine operation procedures			
4	Performance Criteria 4: Inform to the section in-charge regarding any deviation during process			
<b>Competent <input type="checkbox"/></b>		<b>Not Yet Competent <input type="checkbox"/></b>		

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

## Knowledge Assessment



<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>019600604</b>	Level: 2	Version: 1
<b>Competency Standard Title:</b> Adjust machine as per product manufacturing order	<b>Assessment Date (DD/MM/YY):</b> --/--/--		

**WRITTEN ASSESSMENT**

Question	Candidate's answer
3. Define the electric input and output system of the machine?	
4. Define SOP's of the machine?	
5. What are the critical checks of the mechanical system of the machine?	

Question	Candidate's answer
6. How to check machine gauge for lubrication?	
7. What is the role of machine lubrication?	
8. Define logbook of machine?	
9. How to maintain logbooks of machine?	
10. What is the unusual machine response?	

Question	Candidate's answer
11. What are the different parts of machine?	

<b>Title of Qualification:</b> National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician	CS Code: <b>0916PHR03</b>	Level: 2	Version: 1 (2019)
<b>Competency Standard Title:</b> <b>National Vocational Certificate Level – 2 in  Pharmaceutical Manufacturing Assistant</b>	<b>Assessment Date (DD/MM/YY):</b>		

Candidate Details	Name: .....  Registration/Roll Number: .....
Guidance for Candidate	<p><b>To meet this standard, you are required to complete the following within the given time frame (for practical demonstration &amp; assessment):</b></p> <p style="text-align: center;"><b>Assessment Task:</b> In a given situation to  “Prepare work environment before receiving product raw materials and adjust machines as per manufacturing order keeping in view the workplace safety.”</p> <p><b>And complete:</b></p> <ol style="list-style-type: none"> <li><b>1. Knowledge assessment test (Written or Oral).</b></li> <li><b>2. Portfolios at the time of assessment (if any).</b></li> </ol>

<p>Minimum Evidence Required</p>	<p>During a practical assessment, under the observation by an assessor, you are required to</p> <p><b>“Prepare work environment before receiving product raw materials and adjust machines as per manufacturing order keeping in mind workplace safety”</b></p> <p><b>Demonstrating the following criteria:</b></p> <ol style="list-style-type: none"> <li>1. Performance Criteria 1: Inspect work place as per area/product specific requirements</li> <li>2. Performance Criteria 2: Take note of current temperature and humidity levels at workplace as required by manufacturing order</li> <li>3. Performance Criteria 3: Take note of air pressure levels at workplace as required by manufacturing order</li> <li>4. Performance Criteria 4: Clean workplace, tools/equipment from dust before swab test</li> <li>5. Performance Criteria 5: Disinfect manufacturing area, tools/equipment’s before swab test as per standard specifications</li> <li>6. Performance Criteria 6: Identify and check weight of raw materials as per manufacturing order</li> <li>7. Performance Criteria 7: Confirm calibration status of weighing balance</li> <li>8. Performance Criteria 8: Check machine electric input and output as per instructions given in the machine manual</li> <li>9. Performance Criteria 9: Check if machine is mechanically fit for operation as per manufacturing order</li> <li>10. Performance Criteria 10: Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order</li> <li>11. Performance Criteria 11: Check the status cleanliness of the machine after completion of each batch as per the instructions given in the manual.</li> </ol>
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	<p><b>Portfolios required at the time of assessment (if any) for</b></p> <p>Performance criteria for the evaluation of portfolio:  Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.</p>
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## Self-Assessment Checklist

<b>Candidate Name</b>	
<b>Registration No.</b>	
<b>Qualification</b>	<b>National Vocational Certificate Level – 2 in Pharmaceutical Manufacturing Assistant</b>
<b>Purpose of Assessment</b>	<b>Summative Assessment</b>
<b>Assessment Task</b>	<b>Prepare work environment before receiving product raw materials and adjust machines as per manufacturing order keeping in view the workplace safety.</b> <ul style="list-style-type: none"> <li>• Knowledge Assessment</li> </ul>

I can.....

Performance Criteria	Yes	No
<b>P1.</b> Inspect work place as per area/product specific requirements.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P2.</b> Take note of current temperature and humidity levels at the workplace as required by manufacturing order.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P3.</b> Take note of air pressure levels at workplace as required by manufacturing order.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P4.</b> Clean workplace, tools/equipment from dust before swab test.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P5.</b> Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P6.</b> Identify and check weight of raw materials as per manufacturing order.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P7.</b> Confirm calibration status of weighing balance.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P8.</b> Check machine electric input and output as per instructions given in the machine manual.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P9.</b> Check if machine is mechanically fit for operation as per manufacturing order.	<input type="checkbox"/>	<input type="checkbox"/>
<b>P10.</b> Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
<b>P11.</b> Check the status of cleanliness of machine after completion of each batch as per the instructions given in the manual.	<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		
		<b>Prepare work environment before receiving product raw materials and adjust machines as per manufacturing order (1000 batch) keeping in view the workplace safety</b>		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Inspected work place as per area/product specific requirements.			
2.	Performance Criteria 2: Took note of current temperature and humidity levels at workplace as required by manufacturing order			
3.	Performance Criteria 3: Took note of air pressure levels at workplace as required by manufacturing order			
4.	Performance Criteria 4: Cleaned workplace, tools/equipment from dust before swab test			
5.	Performance Criteria 5: Disinfected manufacturing area, tools/equipment's before swab test as per standard specifications			
6.	Performance Criteria 6: Identified and checked weight of raw materials as per manufacturing order			
7.	Performance Criteria 7: Confirmed calibration status of weighing balance			
8.	Performance Criteria 8: Checked machine electric input and output as per instructions given in machine manual			
9.	Performance Criteria 9: Checked if machine is mechanically fit for operation as per manufacturing order			
10.	Performance Criteria 10: Checked all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order			
11.	Performance Criteria 11: Checked the status of cleanliness of machine after completion of each batch as per the instructions given in manual.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		





	What is the role of lubrication for smooth functioning of machine?		
5.	Define Machine Gauge?	<b>Satisfactory</b>	<b>Not Satisfactory</b>
6	What is the importance of safe disposal of pharmaceutical waste?	<b>Satisfactory</b>	<b>Not Satisfactory</b>

