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PHARMACEUTICAL MANUFACTURING TECHNICIAN



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ASSESSMENT PACKAGE
National Vocational Certificate Level 3

Version 1 - November, 2019



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ASSESSMENT PACKAGE
National Vocational Certificate Level 3

Version 1 - November, 2019

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

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600606	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Tablets	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"> 1. Assessment Task 1: Mix Raw Materials 2. Assessment Task 2: Perform Slugging (in case of dry granulation) 3. Assessment Task 3: Perform wet mixing 4. Assessment Task 4: Perform wet granulation 5. Assessment Task 5: Collect Wet Granules and Dry 6. Assessment Task 6: Perform Dry Granulation 7. Assessment Task 7: Perform Sieving (Mesh) 8. Assessment Task 8: Perform Final Mixing 9. Assessment Task 9: Shift Material to Compression Room 10. Assessment Task 10: Start Compression Machine 11. Assessment Task 11: Check Weight Variation of Tablets 12. Assessment Task 12: Shift compressed tablets for coating or sorting <p>And complete:</p> <ol style="list-style-type: none"> 1. Knowledge assessment test (Written or Oral) 2. 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 style="padding-left: 40px;">Task 1: Mix raw materials</p> <p style="padding-left: 40px;">Performance Criteria 1: Check identification of materials against manufacturing order Performance Criteria 2: Sieve and add materials as per manufacturing order Performance Criteria 3: Start mixing as per manufacturing order Performance Criteria 4: Record all necessary entries as per manufacturing order Performance Criteria 5: Report to the in-charge about any deviation for quick response</p> <p style="padding-left: 40px;">Task 2: Perform slugging (in case of dry granulation)</p> <p style="padding-left: 40px;">Performance Criteria 1: Install required sieve as per manufacturing order in compactor granulator Performance Criteria 2: Shift materials in compactor granulator as per manufacturing order Performance Criteria 3: Start granulator and adjust rollers for proper flack size as per manufacturing order Performance Criteria 4: Collect dry granules after completion of process as per manufacturing order</p>

Performance Criteria 5: Report to the in-charge about any deviation for quick response

Task 3: Perform wet mixing

Performance Criteria 1: Prepare binder solution as per manufacturing order

Performance Criteria 2: Mix binder solution with powder mixture to form wet mass as per manufacturing order

Performance Criteria 3: Start mixing as per specific mixing time of batch as per manufacturing order

Performance Criteria 4: Check end point of wet mixing properly and report to the in-charge about any deviation

Task 4: Perform wet granulation

Performance Criteria 1: Install required mesh size in the wet granulator as per manufacturing order

Performance Criteria 2: Shift and pass the wet mass through granulator

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

Task 5: Collect wet granules and dry

Performance Criteria 1: Collect wet granules for drying as per specifications given in manufacturing order

Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order

Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process

Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure

Task 6: Perform dry granulation

Performance Criteria 1: Collect dry granules/flacks (in case of slug)

Performance Criteria 2: Shift dry granules/flacks for required sizing as per manufacturing order

Performance Criteria 3: Inform section in-charge for end point confirmation of granulation

Task 7: Perform sieving (mesh)

Performance Criteria 1: Pass material from required sieve size as per manufacturing order

Performance Criteria 2: Record all necessary entries as per requirements of Manufacturing order

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

Task 8: Perform final mixing

Performance Criteria 1: Identity materials for final mixing against manufacturing order

Performance Criteria 2: Add material as per manufacturing order

Performance Criteria 3: Perform final mixing of batch material as per manufacturing order

Performance Criteria 4: Enter all necessary entries as per manufacturing order

Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order

Task 9: Shift material to compression room

Performance Criteria 1: Receive approval from concerned section in-charge.
Performance Criteria 2: Identify trolley for shifting material to compression room for next process
Performance Criteria 3: Perform weight and record of received materials as per specifications
Performance Criteria 4: Place material on pallets using appropriate and safe methods.
Performance Criteria 5: Report any deviations, if any, during shifting process to avoid loss.

Task 10: Start compression machine

Performance Criteria 1: Adjust machine as per manufacturing order using relevant controls
Performance Criteria 2: Add bulk batch material in hopper
Performance Criteria 3: Start and adjust weight and hardness as per manufacturing order
Performance Criteria 4: Perform required in-process tests.
Performance Criteria 5: Operate machine as per job requirements and report deviation, if observed

Task 11: Check weight variation of tablets

Performance Criteria 1: Check calibration status of balance using appropriate method
Performance Criteria 2: Adjust balance using appropriate techniques
Performance Criteria 3: Take tablets for measuring weight variation test as per manufacturing order
Performance Criteria 4: Note in process reading as per procedure in manufacturing order
Performance Criteria 5: Report any deviation to in- charge

Task 12: Shift compressed tablets for coating or sorting

Performance Criteria 1: Shift core tablets after release approval from quality assurance department
Performance Criteria 2: De-dust tablets using relevant tools and appropriate methods
Performance Criteria 3: Prepare coating solution using specified techniques
Performance Criteria 4: Load core tablets in coating pan as per manufacturing order
Performance Criteria 5: Adjust coating machine parameters as per specification.
Performance Criteria 6: Start coating process and check weight gain after specified interval
Performance Criteria 7: Finish coating process, when required weight is achieved
Performance Criteria 8: Polish coated tablets using specified procedure
Performance Criteria 9: Report any deviation

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)

Assessment Task 2		Perform Slugging (in case of dry granulation)		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Install required sieve as per manufacturing order in compactor granulator			
2	Performance Criteria 2: Shift materials in compactor granulator as per manufacturing order			
3	Performance Criteria 3: Start granulator and adjust rollers for proper flack size as per manufacturing order			
4	Performance Criteria 4: Collect dry granules after completion of process as per manufacturing order			
5	Performance Criteria 5: Report to the in-charge about any deviation for quick response			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 3		Perform wet mixing		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Prepare binder solution as per manufacturing order			
2	Performance Criteria 2: Mix binder solution with powder mixture to form wet mass as per manufacturing order			
3	Performance Criteria 3: Start mixing as per specific mixing time of batch as per manufacturing order			
4.	Performance Criteria 4: Check end point of wet mixing properly and report to the in-charge about any deviation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 4		Perform wet granulation		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1.	Performance Criteria 1: Install required mesh size in the wet granulator as per manufacturing order			
2	Performance Criteria 2: Shift and pass the wet mass through granulator			
3	Performance Criteria 3: Report to the in-charge about any deviation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 5		Collect Wet Granules and Dry		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Collect wet granules for drying as per specifications given in manufacturing order			
2	Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order			
3	Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process			
4	Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure			
Competent <input type="checkbox"/>				

Assessment Task 6		Perform Dry Granulation		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Collect dry granules/flacks (in case of slug)			
2	Performance Criteria 2: Shift dry granules/flacks for required sizing as per manufacturing order			
3	Performance Criteria 3: Inform section in-charge for end point confirmation of granulation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 7		Perform Sieving (Mesh)		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Pass material from required sieve size as per manufacturing order			
2	Performance Criteria 2: Record all necessary entries as per requirements of Manufacturing order			
3	Performance Criteria 3: Report to the in-charge about any deviation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 8		Perform Final Mixing		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Identify materials for final mixing against manufacturing order			
2	Performance Criteria 2: Add material as per manufacturing order			
3	Performance Criteria 3: Perform final mixing of batch material as per manufacturing order			
4	Performance Criteria 4: Enter all necessary entries as per manufacturing order			
5	Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 9		Shift Material to Compression Room		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Receive approval from concerned section in-charge.			
2	Performance Criteria 2: Identify trolley for shifting material to compression room for next process			
3	Performance Criteria 3: Perform weight and record of received materials as per specifications			
4	Performance Criteria 4: Place material on pallets using appropriate and safe methods.			
5	Performance Criteria 5: Report any deviations, if any, during shifting process to avoid loss.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 10		Start Compression Machine		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Adjust machine as per manufacturing order using relevant controls			
2	Performance Criteria 2: Add bulk batch material in hopper			
3	Performance Criteria 3: Start and adjust weight and hardness as per manufacturing order			
4	Performance Criteria 4: Perform required in-process tests.			
5	Performance Criteria 5: Operate machine as per job requirements and report deviation, if observed			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 11		Check Weight Variation of Tablets		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Check calibration status of balance using appropriate method			
2	Performance Criteria 2: Adjust balance using appropriate techniques			
3	Performance Criteria 3: Take tablets for measuring weight variation test as per manufacturing order			
4	Performance Criteria 4: Take note of process reading as per procedure in manufacturing order			
5	Performance Criteria 5: Report any deviation to in-charge			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 12		Shift compressed tablets for coating or sorting		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Shift core tablets after release approval from quality assurance department			
2	Performance Criteria 2: De-dust tablets using relevant tools and appropriate methods			
3	Performance Criteria 3: Prepare coating solution using specified techniques			
4	Performance Criteria 4: Load core tablets in coating pan as per manufacturing order			
5	Performance Criteria 5: Adjust coating machine parameters as per specification.			
6	Performance Criteria 6: Start coating process and check weight gain after specified interval			
7	Performance Criteria 7: Finish coating process, when required weight is achieved			
8	Performance Criteria 8: Polish coated tablets using specified procedure			
9	Performance Criteria 9: Report any deviation			
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 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"/>		

Knowledge Assessment

091600606 Manufacture Tablets

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600606	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Tablets	Assessment Date (DD/MM/YY): --/--/--		

Guidance for Candidate	To complete your assessment for this Competency Standard, you need to answer the questions on the following pages successfully.
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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.

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

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600606	Level: 3	Version: 1 (2019)
Competency Standard Title: 091600606 Manufacture Tablets	Assessment Date (DD/MM/YY): --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
1. Define sieving process?	
2. Describe different types of sieves?	
3. What are the critical process deviations?	

Question	Candidate's answer
4. What are the different mixing methods?	
5. What is the role of granulators?	
6. What are the different types of wet mixing solution (Aqueous & organic)?	
7. How to check end point of wet mixing properly?	

Question	Candidate's answer
8. Describe different types of dryers?	
9. What are the reasons and procedures for adjusting temperature of dryer?	
10. What is the procedure of adding materials for final mixing?	
11. Define tablet compression?	

Question	Candidate's answer
12. What is a tablet compression machine?	
13. Define tablet coating?	
14. Describe different types of in-process controls?	

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

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600607	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Capsules and Dry Suspension	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"> 1. Assessment Task 1: Mix raw materials 2. Assessment Task 2: Perform wet granulation 3. Assessment Task 3: Collect wet granules and dry (If required) 4. Assessment Task 4: Perform dry granulation (If required) 5. Assessment Task 5: Perform final mixing 6. Assessment Task 6: Shift material in encapsulation room for filling 7. Assessment Task 7: Start bottle blowing & filling (dry suspension) 8. Assessment Task 8: Capping, optical checking & labeling of bottles <p>And complete:</p> <ol style="list-style-type: none"> 3. Knowledge assessment test (Written or Oral) 4. 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: Mix raw materials</p> <p>Performance Criteria 1: Check identity of materials against manufacturing order Performance Criteria 2: Sieve and add materials as per manufacturing order Performance Criteria 3: Start mixing as per manufacturing order Performance Criteria 4: Record all necessary entries as per manufacturing order Performance Criteria 5: Report to the in-charge about any deviation for quick response</p> <p>Task 2: Perform wet granulation</p> <p>Performance Criteria 1: Install required mesh size in the wet granulator as per manufacturing order Performance Criteria 2: Shift and pass the wet mass through granulator Performance Criteria 3: Report to the in-charge about any deviation</p> <p>Task 3: Collect wet granules and dry</p> <p>Performance Criteria 1: Collect wet granules for drying as per specifications given in manufacturing order Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure</p>

Task 4: Perform dry granulation

Performance Criteria 1: Collect dry granules/flacks (in case of slug)

Performance Criteria 2: Shift dry granules/flacks for required sizing as per manufacturing order

Performance Criteria 3: Inform section in-charge for end point confirmation of granulation

Task 5: Perform final mixing

Performance Criteria 1: Identify materials for final mixing against manufacturing order

Performance Criteria 2: Add material as per manufacturing order

Performance Criteria 3: Perform final mixing of batch material as per manufacturing order

Performance Criteria 4: Enter all necessary entries as per manufacturing order

Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order.

Task 6: Shift material to encapsulation room for filling

Performance Criteria 1: Shift materials to encapsulation area after release approval from quality assurance department

Performance Criteria 2: Adjust machine as per manufacturing order

Performance Criteria 3: Add materials in hopper as per specifications

Performance Criteria 4: Start encapsulation machine

Performance Criteria 5: Perform required in-process tests

Performance Criteria 6: Adjust weight and locking as per manufacturing order

Performance Criteria 7: Make polish and sorting of filled capsules as per process

Performance Criteria 8: Report any deviation to in-charge

Task 7: Start bottle blowing & filling (dry suspension)

Performance Criteria 1: Check approval from Quality Assurance before filling of bottles

Performance Criteria 2: Transfer empty bottles to filling line and place it on the turn table

Performance Criteria 3: Adjust bottle blowing according to the specific bottle size and start blowing process

Performance Criteria 4: Adjust the weight of individual nozzle according to manufacturing order

Task 8: Capping, optical checking & labeling of bottles

Performance Criteria 1: Adjust capping and sealing machine of the lines according to the speed of filling

Performance Criteria 2: Check individual bottle optically in different background for all types of particles

Performance Criteria 3: Adjust labeling machine according to the speed of line

Performance Criteria 4: Perform all required in- process checks as per manufacturing order

Performance Criteria 5: Report any deviation from the standards to section in-charge

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)

091600607 Manufacture Capsules and Dry Suspension

Candidate Details	Name:Registration/Roll Number: Candidate Signature:.....
Assessment Outcome	COMPETENT <input type="checkbox"/> NOT YET COMPETENT <input type="checkbox"/> Assessor Name:..... 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							
Another Requirement							

Assessment Task 1	Description of assessment task 1 Mix Raw Materials			
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1.	Performance Criteria 1: Check identification of materials against manufacturing order			
2.	Performance Criteria 2: Sieve and add materials as per manufacturing order			
3.	Performance Criteria 3: Start mixing as per manufacturing order			
4.	Performance Criteria 4: Record all necessary entries as per manufacturing order			
5.	Performance Criteria 5: Report to the in-charge about any deviation for quick response			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 2		Perform wet granulation		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Install required mesh size in the wet granulator as per manufacturing order			
2	Performance Criteria 2: Shift and pass the wet mass through granulator			
3	Performance Criteria 3: Report to the in-charge about any deviation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 3		Collect Wet Granules and Dry (if Required)		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Collect wet granules for drying as per specifications given in manufacturing order			
2	Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order			
3	Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process			
4	Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure			
Competent <input type="checkbox"/>				

Assessment Task 4		Perform Dry Granulation		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Collect dry granules/flacks (in case of slug)			
2	Performance Criteria 2: Shift dry granules/flacks for required sizing as per manufacturing order			
3	Performance Criteria 3: Inform section in-charge for end point confirmation of granulation			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 5		Perform Final Mixing		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Identity materials for final mixing against manufacturing order			
2	Performance Criteria 2: Add material as per manufacturing order			
3	Performance Criteria 3: Perform final mixing of batch material as per manufacturing order			
4	Performance Criteria 4: Enter all necessary entries as per manufacturing order			
5	Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 6		Shift material to encapsulation room for filling		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Shift materials to encapsulation area after release approval from quality assurance department			
2	Performance Criteria 2: Adjust machine as per manufacturing order			
3	Performance Criteria 3: Add materials in hopper as per specifications			
4	Performance Criteria 4: Start encapsulation machine			
5	Performance Criteria 5: Perform required in-process tests			
6	Performance Criteria 6: Adjust weight and locking as per manufacturing order			
7	Performance Criteria 7: Make polish and sorting of filled capsules as per process			
8	Performance Criteria 8: Report any deviation to person in-charge			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 7		Start bottle blowing & filling (dry suspension)		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Check approval from Quality Assurance before filling of bottles			
2	Performance Criteria 2: Transfer empty bottles to filling line and place it on the turn table			
3	Performance Criteria 3: Adjust bottle blowing according to the specific bottle size and start blowing process			
4	Performance Criteria 4: Adjust the weight of individual nozzle according to manufacturing order			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 8		Capping, optical checking & labeling of bottles		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Adjust capping and sealing machine of the lines according to the speed of filling			
2	Performance Criteria 2: Check individual bottle optically in different background for all types of particles			
3	Performance Criteria 3: Adjust labeling machine according to the speed of line			
4	Performance Criteria 4: Perform all required in-process checks as per manufacturing order.			
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 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"/>		

Knowledge Assessment

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600607	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Capsules and Dry Suspension	Assessment Date (DD/MM/YY): --/--/--		

Guidance for Candidate	To complete your assessment for this Competency Standard, you need to answer the questions on the following pages successfully.
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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"/> Assessor Name:.....Assessor's code:..... Assessor's Signature:

Feedback to the candidate on assessment.

Candidate Signature..... Assessor Signature

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600607	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Capsules and Dry Suspension	Assessment Date (DD/MM/YY): --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
15. Describe Compactor granulator?	
16. Define bulk density and its importance?	
17. What are different types of capsule shell?	

Question	Candidate's answer
18. Describe the weight variation during encapsulation?	
19. Describe the weight variation during the dry powder filling?	
20. Describe the importance of Relative humidity during encapsulation and dry powder filling?	
21. What are different types of mixers?	

Question	Candidate's answer
22. Describe different types of dryers?	
23. What are the reasons and procedures for adjusting temperature of dryer?	
24. What is final mixing and importance of mixing time?	
25. Define encapsulation?	

Question	Candidate's answer
26. What are different types of encapsulation machine?	
27. What are different types of hoppers (powder and empty capsule shells)?	
28. Define different types of capsule polishing machines?	
29. What is the importance of empty bottle blowing?	

Question	Candidate's answer
30. What is the importance of in process controls?	

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

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600608	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Liquid Dosages	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"> 1. Assessment Task 1: Shift the Raw Materials 2. Assessment Task 2: Prepare syrup base 3. Assessment Task 3: Dissolve/ Soak materials in purified water according to procedure 4. Assessment Task 4: Manufacture syrup and suspension 5. Assessment Task 5: Start bottle blowing & filling 6. Assessment Task 6: Capping, optical checking & labeling of bottles <p>And complete:</p> <ol style="list-style-type: none"> 5. Knowledge assessment test (Written or Oral) 6. 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: Shift the raw materials</p> <p>Performance Criteria 1: Transfer batch raw materials to liquid section. Performance Criteria 2: Check the material one by one according to the manufacturing order in the section again prior to mixing. Performance Criteria 3: Segregate each material according to mixing order. Performance Criteria 4: Report any deviation to section in-charge.</p> <p>Task 2: Prepare syrup base</p> <p>Performance Criteria 1: Transfer specified volume of purified water to steam jacketed tank. Performance Criteria 2: Start heating up to the required temperature. Performance Criteria 3: Add preservative(s) as per specification Performance Criteria 4: Add sucrose as per specification and continue heating to required temperature. Performance Criteria 5: Continue mixing until clear base is formed. Performance Criteria 6: Check the cleaning status of filtration assembly. Performance Criteria 7: Filter and transfer the base to the main Mixing tank after cooling. Performance Criteria 8: Report any deviation from the standards to section in-charge.</p>

Task 3: Dissolve/ soak materials in purified water according to procedure

- Performance Criteria 1: Transfer specified volume of purified water to different manufacturing tanks.
- Performance Criteria 2: Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order
- Performance Criteria 3: Report any deviation from the standards to section in-charge.

Task 4: Manufacture syrup and suspension

- Performance Criteria 1: Check the temperature of syrup base in the main mixing tank
- Performance Criteria 2: Add the material one by one to the main mixing tank. In case of syrup the already dissolved material is also added
- Performance Criteria 3: Pass suspension slurry through homogenizer and add it to main mixing tank
- Performance Criteria 4: Make up and record bulk volume of syrup/suspension in main mixing tank
- Performance Criteria 5: Transfer syrup through filtration assembly according to specification and suspension directly to storage tank (through homogenizer if required)
- Performance Criteria 6: Start slow mixer in storage tank in case of suspension
- Performance Criteria 7: Inform section in-charge about process completion
- Performance Criteria 8: Seal storage tank till release from Quality Assurance after sampling
- Performance Criteria 9: Any deviation from the standards must be reported to section in-charge

Task 5: Start bottle blowing & filling

- Performance Criteria 1: Check approval from Quality Assurance before filling of bottles
- Performance Criteria 2: Transfer empty bottles to filling line and place it on the turn table
- Performance Criteria 3: Adjust bottle blowing according to the specific bottle size and start blowing process
- Performance Criteria 4: Adjust the volume of individual nozzle according to manufacturing order

Task 6: Capping, optical checking & labeling of bottles

- Performance Criteria 1: Adjust capping and sealing machine of the lines according to the speed of filling
- Performance Criteria 2: Check individual bottle optically in different background for all types of particles
- Performance Criteria 3: Adjust labeling machine according to the speed of line
- Performance Criteria 4: Perform all required in- process checks as per manufacturing order
- Performance Criteria 5: Report any deviation from the standards to section in-charge

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)

091600608 Manufacture Liquid Dosages

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							
Another Requirement							

Assessment Task 1	Description of assessment task 1 Shift the Raw Materials			
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1.	Performance Criteria 1: Transfer batch raw materials to liquid section.			
2.	Performance Criteria 2: Check the material one by one according to the manufacturing order in the section again prior to mixing.			
3.	Performance Criteria 3: Segregate each material according to mixing order.			
4.	Performance Criteria 4: Report any deviation to section in-charge.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 2		Prepare syrup base		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Transfer specified volume of purified water to steam jacketed tank.			
2	Performance Criteria 2: Start heating up to the required temperature.			
3	Performance Criteria 3: Add preservative(s) as per specification			
4	Performance Criteria 4: Add sucrose as per specification and continue heating to required temperature.			
5	Performance Criteria 5: Continue mixing until clear base is formed.			
6	Performance Criteria 6: Check the cleaning status of filtration assembly.			
7	Performance Criteria 7: Filter and transfer the base to the main Mixing tank after cooling.			
8	Performance Criteria 8: Report any deviation from the standards to section in-charge.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 3		Dissolve/ Soak materials in purified water according to procedure		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Transfer specified volume of purified water to different manufacturing tanks.			
2	Performance Criteria 2: Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order			
3	Performance Criteria 3: Report any deviation from the standards to section in-charge.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 4		Manufacture syrup and suspension		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Check the temperature of syrup base in the main mixing tank			
2	Performance Criteria 2: Add the material one by one to the main mixing tank. In case of syrup the already dissolved material are also added			
3	Performance Criteria 3: Pass suspension slurry through homogenizer and add it to main mixing tank			
4	Performance Criteria 4: Make up and record bulk volume of syrup/suspension in main mixing tank			
5	Performance Criteria 5: Transfer syrup through filtration assembly according to specification and suspension directly to storage tank (through homogenizer if required)			
6	Performance Criteria 6: Start slow mixer in storage tank in case of suspension			
7	Performance Criteria 7: Inform section in-charge about process completion			
8	Performance Criteria 8: Seal storage tank till release from Quality Assurance after sampling			
9	Performance Criteria 9: Report any deviation from the standards to section in-charge			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 5		Start bottle blowing & filling		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Check approval from Quality Assurance before filling of bottles			
2	Performance Criteria 2: Transfer empty bottles to filling line and place it on the turn table			
3	Performance Criteria 3: Adjust bottle blowing according to the specific bottle size and start blowing process			
4	Performance Criteria 4: Adjust the volume of individual nozzle according to manufacturing order			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 6		Capping, optical checking & labeling of bottles		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Adjust capping and sealing machine of the lines according to the speed of filling			
2	Performance Criteria 2: Check individual bottle optically in different background for all types of particles			
3	Performance Criteria 3: Adjust labeling machine according to the speed of line			
4	Performance Criteria 4: Perform all required in-process checks as per manufacturing order			
5	Performance Criteria 5: Report any deviation from the standards to section in-charge.			
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 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 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600608	Level: 3	Version: 1 (2019)
Competency Standard Title: Manufacture Liquid Dosages	Assessment Date (DD/MM/YY): --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
31. What is the importance of mixing order of materials?	
32. Describe various types of tanks?	
33. What is the importance of temperature in heating process?	

Question	Candidate's answer
34. What is the importance of preservative(s)?	
35. Describe different types of filtration assembly?	
36. What is the importance of volume make up and calibration of mixing tank?	
37. Define the words syrup and suspension?	

Question	Candidate's answer
38. Define the soaking?	
39. Describe different types of homogenizer and its uses?	
40. What is the importance of the slow mixer in suspension?	
41. What is the liquid filling line?	

Question	Candidate's answer
42. Define volume limits?	
43. Define optical checking?	

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

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600609	Level: 3	Version: 1 (2019)
Competency Standard Title: Perform packaging as per manufacturing order	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"> 1. Assessment Task 1: Receive packing materials for product (tablets, capsules & syrups/suspensions/parenteral) 2. Assessment Task 2: Make strip/blister packing 3. Assessment Task 3: Perform over printing 4. Assessment Task 4: Perform aluminum blister foil packaging, strip packaging/ bottle packaging 5. Assessment Task 5: Make tertiary packaging for bulk handling for warehouse storage & shipping/transport <p>And complete:</p> <ol style="list-style-type: none"> 1. Knowledge assessment test (Written or Oral) 2. 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: Receive packing materials for product (tablets, capsules & syrups/suspensions)</p> <p>Performance Criteria 1: Check and receive printed/ unprinted aluminum Foil Roll, Poly Vinyl Chloride (PVC) Roll, bottles, caps, vials, rubber stoppers, flip off seals, ampoules, unit carton, spoons, leaflets, cups, master cartons, labels as per packing order.</p> <p>Performance Criteria 2: Maintain the temperature and humidity of workplace as per requirements of specifications of manufactured product</p> <p>Performance Criteria 3: Check the batch number, manufacturing and expiry date against each labeled packing as per manufacturing order</p> <p>Performance Criteria 4: Ensure all relevant entries manually or electronically as per specifications given in manufacturing order</p> <p>Performance Criteria 5: Inform the section in-charge after completion of task.</p>

Task 2: Make strip/blister packing

Performance Criteria 1: Prepare label area, machines & containers for strip packing correctly as per specifications given in the Packing Order

Performance Criteria 2: Check & sign the "Ready Tag" attached to the machine and make necessary entries in the log book.

Performance Criteria 3: Receive approval from section in-charge before start packing of manufactured products

Performance Criteria 4: Start strip/blistering operation and perform the following checks:

- a) Set Batch No., Manufacturing & expiry dates
- b) Count of unit dose per blister/strip
- c) Alignment of blister/ strip
- d) Check release label on the buckets /drums.

Performance Criteria 5: Inform the section in-charge to take empty blisters/strips for leak test.

Performance Criteria 6: Start the blistering/stripping operation, only after passing the leak test for empty & filled.

Performance Criteria 7: Check the completion of blistering/stripping process and shift the blisters/strips to packing hall for packaging as per specifications

Task 3: Perform over printing

Performance Criteria 1: Remove all printed packaging material like labels, unit cartons, blisters/strips etc. of the previous product

Performance Criteria 2: Check that the correct packaging material as per packaging order for printing

Performance Criteria 3: Check Batch no. expiry, manufacturing date, pack size against packaging order for printing on the carton or labels

Performance Criteria 4: Perform in-process checks to avoid any wastages

Task 4: Perform aluminum blister foil packaging, strip packaging/ bottle packaging

Performance Criteria 1: Remove all printed packaging material like labels, unit cartons, blisters/strips etc. of the previous product

Performance Criteria 2: Check correct packaging material as per packing order is received for concerned batch

Performance Criteria 3: Receive blisters/strips, bottles, printed cartons, printed labels of product

Performance Criteria 4: Check batch. no. manufacturing date, expiry and pack size

Performance Criteria 5: Take approval for product to be packed

Performance Criteria 6: Check labels, cartons blister/blisters etc. for proper printing

Performance Criteria 7: Removed defective printed materials immediately

Performance Criteria 8: Bring the cartons, labels, blisters for sorting in a tray & label it as "**For Sorting**"

Performance Criteria 9: Collect all the rejected cartons, labels, blisters in a tray, and label it as "**REJECTED**"

Performance Criteria 10: Collect cartons, labels, blisters/strips in a separate tray and label it as "**Ready for use**"

Performance Criteria 11: Shift only ready for use cartons, labels for packaging on belt

Performance Criteria 12: Take blisters/strips, bottle, ampoule, and vial according to the unit carton and insert pack.

Task 5: Make tertiary packaging for bulk handling for warehouse storage & shipping/transport

Performance Criteria 1: Place required number of packs in the master carton as per packing order.

Performance Criteria 2: Seal each master carton properly with sealing carton tape.

Performance Criteria 3: Check each master carton label before pasting it on each sealed master carton for its product name, manufacturing date, expiry date, master cartons no., quantity of units & packaging date.

Performance Criteria 4: Arrange each outer carton properly on staking pallet

Performance Criteria 5: Deliver batch to finish goods store after release from Quality Assurance

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)

091600609 Perform packaging as per manufacturing order

Candidate Details	Name:Registration/Roll Number: Candidate Signature:
Assessment Outcome	COMPETENT <input type="checkbox"/> NOT YET COMPETENT <input type="checkbox"/> Assessor Name:.....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							
Another Requirement							

Assessment Task 1	Description of assessment task 1 Receive packing materials for product (tablets, capsules & syrups/suspensions)			
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1.	Performance Criteria 1: Checked and received printed/unprinted aluminum Foil Roll, Poly Vinyl Chloride (PVC) Roll, bottles, caps, vials, rubber stoppers, flip off seals, ampoules, unit carton, spoons, leaflets, cups, master cartons, labels as per packing order.			
2.	Performance Criteria 2: Maintained the temperature and humidity of workplace as per requirements of specifications of manufactured product			
3.	Performance Criteria 3: Checked the batch number, manufacturing and expiry date against each labeled packing as per manufacturing order			
4.	Performance Criteria 4: Ensured all relevant entries manually or electronically as per specifications given in manufacturing order			
5.	Performance Criteria 5: Informed the section in-charge after completion of task			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 2		Make strip/blister packing		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Prepared label area, machines & containers for strip packing correctly as per specifications given in the packing order			
2	Performance Criteria 2: Checked & signed the "Ready Tag" attached to the machine and make necessary entries in the log book.			
3	Performance Criteria 3: Received approval from section in-charge before start packing of manufactured products			
4	Performance Criteria 4: Started strip/blistering operation and perform the following checks: a) Set Batch No., Manufacturing & expiry dates b) Count of unit dose per blister/strip c) Alignment of blister/ strip d) Check release label on the buckets /drums.			
5	Performance Criteria 5: Informed the section in-charge to take empty blisters/strips for leak-test.			
6	Performance Criteria 6: Started the blistering/striping operation, only after passing the leak test for empty & filled.			
7	Performance Criteria 7: Checked the completion of blistering/striping process and shift the blisters/strips to packing hall for packaging as per specifications			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 3		Perform Over printing		
During the practical assessment, candidate demonstrated the following:				
		Yes	No	Remarks
1	Performance Criteria 1: Removed all printed packaging material like labels, unit cartons, blisters/strips etc. of the previous product			
2	Performance Criteria 2: Checked that the correct packaging material as per packaging order for printing			
3	Performance Criteria 3: Checked batch no. expiry, manufacturing date, pack size against packaging order for printing on the carton or labels			
4	Performance Criteria 4: Performed in process checks to avoid any wastage			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 4		Perform aluminum blister foil packaging, strip packaging/ bottle packaging		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Removed all printed packaging material like labels, unit cartons, blisters/strips etc. of the previous product			
2	Performance Criteria 2: Checked correct packaging material as per packing order is received for concerned batch			
3	Performance Criteria 3: Received blisters/strips, bottles, printed cartons, printed labels of product			
4	Performance Criteria 4: Check batch. no. manufacturing date, expiry and pack size			
5	Performance Criteria 5: Took approval for product to be packed			
6	Performance Criteria 6: Checked labels, cartons blister/blisters etc. for proper printing			
7	Performance Criteria 7: Removed defective printed materials immediately			
8	Performance Criteria 8: Brought the cartons, labels, blisters for sorting in a tray & labelled it as "For Sorting"			
9	Performance Criteria 9: Collected all the rejected cartons, labels, blisters in a tray, and labelled it as "REJECTED"			
10	Performance Criteria 10: Collect cartons, labels, blisters/strips in a separate tray and label it as "Ready for use"			
11	Performance Criteria 11: Shifted only ready for use cartons, labels for packaging on belt			
12	Performance Criteria 12: Took blisters/strips, bottle, ampoule, and vial according to the unit carton and inserted pack.			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Assessment Task 5		Make tertiary packaging for bulk handling for warehouse storage & shipping/transport		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Placed required number of packs in the master carton as per packing order.			
2	Performance Criteria 2: Sealed each master carton properly with sealing carton tape.			
3	Performance Criteria 3: Checked each master carton label before pasting it on each sealed master carton for its product name, manufacturing date, expiry date, master cartons no., quantity of units & packaging date			
4	Performance Criteria 4: Arranged each outer carton properly on staking pallet			
5	Performance Criteria 5: Delivered batch to finish goods store after release from Quality Assurance			
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 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"/>			

Feedback to the candidate on assessment.

Candidate Signature..... Assessor Signature

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 091600609	Level: 3	Version: 1 (2019)
Competency Standard Title: Perform packaging as per manufacturing order	Assessment Date (DD/MM/YY): --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
44. Explain different types of packing material?	
45. Describe batch number, manufacturing and expiry date correctly as per packaging order?	
46. Explain specific temperature and humidity requirements of the workplace for each product?	

Question	Candidate's answer
47. How to fill out specifications record and data correctly?	
48. Describe the importance of leak test?	
49. Describe the importance of packaging order for overprinting?	
50. Explain different types of printing machines?	

Question	Candidate's answer
51. Describe different types of packaging machines?	
52. Describe proper and safe methods of arranging carton on staking pallet?	
53. Explain the method of sealing carton using carton tape?	

Title of Qualification: National Vocational Certificate level 3, In Pharmaceutical Manufacturing Technician	CS Code: 0916PHR04	Level: 3	Version: 1 (2019)
Competency Standard Title: National Vocational Certificate Level – 3 in Pharmaceutical Manufacturing Technician	Assessment Date (DD/MM/YY):		

Candidate Details	Name: Registration/Roll Number:
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Minimum Evidence Required	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.
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Guidance for Candidate	<p>To meet this standard, you are required to complete the following activities within 04 Hrs. time frame (for practical demonstration & assessment):</p> <ul style="list-style-type: none"> Complete project of manufacturing of oral dosage forms (tablets, capsule, dry suspension and liquids) as per standardized criteria keeping considering workplace place safety and taking appropriate measures. <p>And complete:</p> <ol style="list-style-type: none"> Knowledge assessment test (Written or Oral). Portfolios at the time of assessment (if any). <p>During a practical assessment, under the observation by an assessor, you are required to</p> <p>Complete project of manufacturing of oral dosage forms (tablets, capsule, dry suspension and liquids) as per standardized criteria keeping considering workplace place safety and taking appropriate measures</p> <p>Demonstrating the following criteria:</p> <ol style="list-style-type: none"> Performance Criteria 1: Check identification of materials against manufacturing order Performance Criteria 2: Sieve and add materials as per manufacturing order Performance Criteria 3: Prepare binder solution as per manufacturing order Performance Criteria 4: Mix binder solution with powder mixture to form wet mass as per manufacturing order and check end point Performance Criteria 5: Install required mesh size in the granulator as per manufacturing order Performance Criteria 6: Adjust temperature of dryer as per specifications for completion of drying process
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	<p>7. Performance Criteria 7: Determine end point of drying process</p> <p>8. Performance Criteria 8: Perform final mixing of batch material as per manufacturing order</p> <p>9. Performance Criteria 9: Enter all necessary entries as per manufacturing order</p> <p>10. Performance Criteria 10: Adjust machine as per manufacturing order using relevant control measures</p> <p>11. Performance Criteria 11: Start tablet compression machine and adjust weight and hardness as per manufacturing order</p> <p>12. Performance Criteria 12: Start coating process and check weight gain after specified interval</p> <p>13. Performance Criteria 13: Start encapsulation machine</p> <p>14. Performance Criteria 14: Adjust bottle-filling, capping and sealing machine of the production according to speed of filling.</p> <p>15. Performance Criteria 15: Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order</p> <p>16. Performance Criteria 16: Start slow mixer in storage tank in case of suspension.</p> <p>17. Performance Criteria 17: Perform required in-process controls as per manufacturing order of the product.</p> <p>18. Performance Criteria 18: Start strip/blistering operation and perform the following checks:</p> <p style="margin-left: 20px;">e) Set Batch No., Manufacturing & expiry dates</p> <p style="margin-left: 20px;">f) Count of unit dose per blister/strip.</p> <p style="margin-left: 20px;">g) Alignment of blister/ strip</p>
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Self-Assessment Checklist

Candidate Name	
Registration No.	
Qualification	National Vocational Certificate Level – 3 in Pharmaceutical Manufacturing Technician
Purpose of Assessment	Summative Assessment
Assessment Task	<ul style="list-style-type: none"> • Complete project of manufacture tablets as per standardized criteria keeping in view workplace safety by taking appropriate measures • Knowledge Assessment

can.....

Performance Criteria	Yes	No
P1. Check identification of materials against manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P2. Sieve and add materials as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P3. Prepare binder solution as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P4. Mix binder solution with powder mixture to form wet mass as per manufacturing order and check end point	<input type="checkbox"/>	<input type="checkbox"/>

P5. Install required mesh size in the granulator as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P6. Adjust temperature of dryer as per specifications for completion of drying process	<input type="checkbox"/>	<input type="checkbox"/>
P7. Determine end point of drying process	<input type="checkbox"/>	<input type="checkbox"/>
P8. Perform final mixing of batch material as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P9. Enter all necessary entries as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P10. Adjust machine as per manufacturing order using relevant controls	<input type="checkbox"/>	<input type="checkbox"/>
P11. Start tablet compression machine and adjust weight and hardness as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P12. Start coating process and check weight gain after specified interval	<input type="checkbox"/>	<input type="checkbox"/>
P13. Start encapsulation machine	<input type="checkbox"/>	<input type="checkbox"/>
P14. Adjust bottle filling, capping and sealing machine according to speed of filling	<input type="checkbox"/>	<input type="checkbox"/>
P15. Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P16. Start slow mixer in storage tank in case of suspension	<input type="checkbox"/>	<input type="checkbox"/>
P17. Perform required in-process controls as per manufacturing order	<input type="checkbox"/>	<input type="checkbox"/>
P18. Start strip/blistering operation and perform the following checks: a) Set Batch No., Manufacturing & expiry dates b) Count of unit dose per blister/strip c) Alignment of blister/ strip	<input type="checkbox"/>	<input type="checkbox"/>

Candidate's Signature _____ Assessor's Signature _____

Date: _____

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

National Vocational Certificate Level – 3 in Pharmaceutical Manufacturing Technician

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

Assessment Summary (to be filled by the assessor)

Activity	Method	Result
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Nature of Activity	Written	Oral	Observation	Portfolio	Role Play	Competent	Not Yet Competent
Practical Skill Demonstration							
Knowledge Assessment							
Other Requirement							

Each Assessment Task (with performance criteria)				
Assessment Task		Description of assessment task		
		Complete project of manufacture tablets as per standardized criteria keeping in view workplace place safety by taking appropriate measures		
During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Checked identification of materials against manufacturing order			
2	Performance Criteria 2: Sieved and add materials as per manufacturing order			
3	Performance Criteria 3: Prepared binder solution as per manufacturing order			
4	Performance Criteria 4: Mixed binder solution with powder mixture to form wet mass as per manufacturing order and check end point			
5	Performance Criteria 5: Installed required mesh size in the granulator as per manufacturing order			
6	Performance Criteria 6: Adjusted temperature of dryer as per specifications for completion of drying process			
7	Performance Criteria 7: Determined end point of drying process			
8	Performance Criteria 8: Performed final mixing of batch material as per manufacturing order			
9	Performance Criteria 9: Entered all necessary entries as per manufacturing order			
10	Performance Criteria 10: Adjusted machine as per manufacturing order using relevant control			
11	Performance Criteria 11: Started tablet compression machine and adjust weight and hardness as per manufacturing order			
12	Performance Criteria 12: Started coating process and check weight gain after specified interval			
13	Performance Criteria 13: Started encapsulation machine			
14	Performance Criteria 14: Adjusted bottle filling, capping and sealing machine according to speed of filling			
15	Performance Criteria 15: Soaked material in case of suspension and dissolved material in case of solution separately as per manufacturing order			
16	Performance Criteria 16: Started slow mixer in storage tank in case of suspension.			
17	Performance Criteria 17: Performed required in-process controls as per manufacturing order			

18	Performance Criteria 18: Started strip/blistering operation and perform the following checks: <ul style="list-style-type: none"> a. Set Batch No., Manufacturing & expiry dates b. Count of unit dose per blister/strip c. Alignment of blister/ strip 			
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>		

Knowledge Assessment

Qualification	National Vocational Certificate Level – 3 in Pharmaceutical Manufacturing Technician
Purpose of Assessment	Summative Assessment
Candidate Details	Name: _____ Registration Number: _____ Signature: _____
Assessment Outcome	COMPETENT <input type="checkbox"/> NOT YET COMPETENT <input type="checkbox"/> Name of the Assessor _____ Assessor's code: _____ Signature: _____

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
1	Performance criteria for the evaluation of portfolio: Submitted log book or activity record (practical journal, project, pictures etc.) completed during the training.		
Competent <input type="checkbox"/>		Not Yet Competent <input type="checkbox"/>	

<h2 style="margin: 0;">Feedback to the Candidate</h2>

<p>Candidate's Signature _____ Assessor's Signature _____</p>

Questions (Candidate confidently answered questions correctly and demonstrated understanding of the topics and their application)	Satisfactory	Not Satisfactory
<p>What is the importance of the sieving process?</p>		
<p>What is the importance of the mixing order?</p>	Satisfactory	Not Satisfactory

			Enlist different types of granulators?	Satisfactory	Not Satisfactory
			How the end-point of wet mixing will be determined?	Satisfactory	Not Satisfactory

