Co-funded by the European Union

german cooperation
DEUTSCHE ZUSAMMENARBEIT

Norwegian Embassy
Islamabad

PHARMACEUTICAL MANUFACTURING TECHNICIAN

ASSESSMENT PACKAGE

National Vocational Certificate Level 4

Version 1 - November, 2019

NAVTTC

Implemented by
giz Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Published by
National Vocational and Technical Training Commission
Government of Pakistan

Headquarter
Plot 38, Kirthar Road, Sector H-9/4, Islamabad, Pakistan
www.navttc.org

Responsible
Director General Skills Standard and Curricula, National Vocational and Technical Training Commission
National Deputy Head, TVET Sector Support Programme, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH

Layout & design
SAP Communications

Photo Credits
TVET Sector Support Programme

URL links
Responsibility for the content of external websites linked in this publication always lies with their respective publishers. TVET Sector Support Programme expressly dissociates itself from such content.

This document has been produced with the technical assistance of the TVET Sector Support Programme, which is funded by the European Union, the Federal Republic of Germany and the Royal Norwegian Embassy and has been commissioned by the German Federal Ministry for Economic Cooperation and Development (BMZ). The Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH in close collaboration with the National Vocational and Technical Training Commission (NAVTTC) as well as provincial Technical Education and Vocational Training Authorities (TEVTAs), Punjab Vocational Training Council (PVTC), Qualification Awarding Bodies (QABs)s and private sector organizations.

Document Version
November, 2019
Islamabad, Pakistan

PHARMACEUTICAL MANUFACTURING TECHNICIAN

ASSESSMENT PACKAGE

National Vocational Certificate Level 4

Version 1 - November, 2019

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

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600611**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Manufacture Parenterals**	**Assessment Date (DD/MM/YY):**		

Candidate Details	Name…… Registration/Roll Number……
Guidance for Candidate	**To meet this standard, you are required to complete the following tasks within 40 min timeframe:** 1. **Assessment Task 1:** Collect distilled water 2. **Assessment Task 2:** Receive sterile raw materials 3. **Assessment Task 3:** Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottles 4. **Assessment Task 4:** Mix materials 5. **Assessment Task 5:** Control environment of production room 6. **Assessment Task 6:** Transfer product for filling and sealing **And complete:** **1. Knowledge assessment test (Written or Oral)** **2. Portfolios at the time of assessment (if any)**
Minimum Evidence Required	**During a practical assessment, under observation by an assessor, you will complete:** **Task 1: Collect distilled water** Performance Criteria 1: Start double distilled water plant (Water for injection). Performance Criteria 2: Drain water for few minutes as per specification. Performance Criteria 3: Inform section in-charge for further relevant process (e.g. pH, conductivity, sterility & pyrogen) Performance Criteria 4: Receive report from section in-charge. **Task 2: Receive sterile raw materials** Performance Criteria 1: Receive sterile material from pass through window as per specification Performance Criteria 2: Transfer raw material to concerned controlled area as per specifications (i.e. class A, B, C & D) Performance Criteria 3: Report to in-charge about any deviation

Task 3: Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottles

Performance Criteria 1: Select sterilization methods.

a) Filtration: use filtration for heat sensitive products.
i) Select appropriate filter size.

b) Terminal sterilization (autoclave) for heat resistant products.
i) Load product in autoclave. Lock its door properly.
ii) Adjust pressure and temperature as per specifications.

c). Dry heat/chemical Sterilization
i) Sterilize vials/ ampoules/bottles

Performance Criteria 2: Collect product safely for further process.
Performance Criteria 3: Inform to section in-charge about any deviation

Task 4: Mix materials

Performance Criteria 1: Transfer specified volume of water for injection to different manufacturing tanks
Performance Criteria 2: Add and dissolve material as per manufacturing order
Performance Criteria 3: Transfer solution as per specified method to storage tank through filtration
Performance Criteria 4: Report section in-charge about completion of process
Performance Criteria 5: Report any deviation to section in-charge

Task 5: Control environment of production room

Performance Criteria 1: Check environmental control parameters (temperature, humidity & particulate matters) through manufacturing order monometer/ hygrometer/ psychrometer / particle counter.
Performance Criteria 2: Receive area clearance report from section in-charge.
Performance Criteria 3: Report any deviation to section in-charge

Task 6: Transfer product for filling and sealing

Performance Criteria 1: Collect sample report form section in-charge
Performance Criteria 2: Transfer sterilized solution aseptically to filling area
Performance Criteria 3: Start filling and sealing under class A environment
Performance Criteria 4: Perform in-process weight/volume variation & Optical checking
Performance Criteria 5: Shift filled product to quarantine area after terminal sterilization (where required) till approval from Quality Assurance
Performance Criteria 6: Report any deviation 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)

091600611 Manufacture Parenterals

Candidate Details	Name: ……Registration/Roll Number: …… Candidate Signature: …… ……
Assessment Outcome	COMPETENT ☐ NOT YET COMPETENT ☐ 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 **Collect distilled water**

During the practical assessment, candidate demonstrated the following:		**Yes**	**No**	**Remarks**
1.	Performance Criteria 1: Started double distilled water plant (Water for injection).			
2.	Performance Criteria 2: Drained water for few minutes as per specification.			
3.	Performance Criteria 3: Informed section in-charge for further relevant process (e.g. pH, conductivity, sterility & pyrogen)			
4	Performance Criteria 4: Received report from section in-charge.			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 2	Receive sterile raw materials

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Received sterile material from pass through window as per specification			
2	Performance Criteria 2: Transferred raw material to concerned controlled area as per specifications (i.e. class A, B, C & D)			
3	Performance Criteria 3: Reported to in-charge about any deviation			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 3	Perform sterilization of equipment & packing materials i.e. vials/ ampoules/bottles

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Selected sterilization methods. **a) Filtration**: Used filtration for heat sensitive products. i) Selected appropriate filter size. **b)** Terminal sterilization (autoclave) for heat resistant products. i) Load product in autoclave. Lock its door properly. ii) Adjusted pressure and temperature as per specifications. **c)** Dry heat/chemical Sterilization i) Sterilized vials/ ampoules/bottles			
2	Performance Criteria 2: Collected product safely for further process.			
3	Performance Criteria 3: Informed to section in-charge about any deviation			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 4	Mix materials

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Transferred specified volume of water for injection to different manufacturing tanks			
2	Performance Criteria 2: Added and dissolved material as per manufacturing order			
3	Performance Criteria 3: Transferred solution as per specified method to storage tank through filtration			
4	Performance Criteria 4: Reported section in-charge about completion of process			
5	Performance Criteria 5: Reported any deviation to section in-charge			

Competent ☐	Not Yet Competent ☐

Assessment Task 5	Control environment of production room

	During the practical assessment, candidate demonstrated the following:	Yes	No	Remarks
1	Performance Criteria 1: Checked environmental control parameters (temperature, humidity & particulate matters) through manufacturing order monometer/ hygrometer/ psychrometer / particle counter.			
2	Performance Criteria 2: Received area clearance report from section in-charge.			
3	Performance Criteria 3: Reported any deviation to section in-charge			

Competent ☐	Not Yet Competent ☐

Assessment Task 6	Transfer product for filling and sealing

	During the practical assessment, candidate demonstrated the following:	Yes	No	Remarks
1	Performance Criteria 1: Collected sample report form section in-charge			
2	Performance Criteria 2: Transferred sterilized solution aseptically to filling area			
3	Performance Criteria 3: Started filling and sealing under class A environment			
4	Performance Criteria 4: Performed in process weight/volume variation & Optical checking			
5	Performance Criteria 5: Shifted filled product to quarantine area after terminal sterilization (where required) till approval from Quality Assurance			
6	Performance Criteria 6: Reported any deviation to section in-charge			

Competent ☐	Not Yet Competent ☐

Portfolio (if any)	Description of portfolio

Current ☐ Sufficient ☐ Authentic ☐ Valid ☐ Reliable ☐

	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 ☐	Not Yet Competent ☐

Knowledge Assessment

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600611**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Manufacture Parenterals**	**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.**

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 ☐ NOT YET COMPETENT ☐ Name of the Assessor:..... Assessor's code:……. Signature of the Assessor:..... .....

Feedback to the candidate on assessment.

_____

_____

_____

_____

Candidate Signature…….. Assessor Signature ……

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600611**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Manufacture Parenterals**	**Assessment Date (DD/MM/YY):** --/--/--		

WRITTEN ASSESSMENT

Question	**Candidate's answer**
1. What is the importance of sterile water for injection?	
2. What are the different types of controlled areas e.g. class A, B, C & D?	
3. Define sterile material(s)?	

Question	Candidate's answer
4. List down different types of sterilization and filters?	
5. What is sterilization?	
6. What is the importance of the order of mixing?	

Question	Candidate's answer
7. What is the importance of monometer, hygrometer, psychrometer and particle counter	
8. Differentiate between vials and ampoule?	
9. 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 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**Assessment Date (DD/MM/YY):**		

Candidate Details	Name……..…… Registration/Roll Number……..……
Guidance for Candidate	**To meet this standard, you are required to complete the following tasks within 40 min timeframe:** 1. **Assessment Task 1:** Ensure quality raw materials. 2. **Assessment Task 2:** Check production equipment as per industry standards. 3. **Assessment Task 3:** Give suggestions for process improvements. 4. **Assessment Task 4:** Inspect production process. **And complete:** **3. Knowledge assessment test (Written or Oral)** **4. Portfolios at the time of assessment (if any)**
Minimum Evidence Required	**During a practical assessment, under observation by an assessor, you will complete:** **Task 1: Ensure quality raw materials** Performance Criteria 1: Receive quality raw materials as per the specifications of manufacturing order Performance Criteria 2: Ensure materials identification labels as per the specifications of manufacturing order Performance Criteria 3: Check expiry date on each labeled raw material as per specifications **Task 2: Check production equipment as per industry standards** Performance Criteria 1: Enlist equipment relevant to the task as per specifications given in manufacturing order. Performance Criteria 2: Identify tools/equipment relevant to the task as per Manufacturing order.

Task 3: Give suggestions for process improvements

Performance Criteria 1: Identify problems on quality issues during completion of manufacturing order
Performance Criteria 2: Observe quality issues during manufacturing process
Performance Criteria 3: Identify objective measures for quality system effectiveness at manufacturing sites
Performance Criteria 4: Submit report to section in-charge

Task 4: Inspect production process

Performance Criteria 1: Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry
Performance Criteria 2: Reduce defect rate and waste of product by applying rules & regulations of industry for quality product
Performance Criteria 3: Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry

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)

091600612 Ensure Quality Product

Candidate Details	Name: ……Registration/Roll Number: ……. Candidate Signature: ……. …….
Assessment Outcome	COMPETENT ☐ NOT YET COMPETENT ☐ 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 **Ensure quality raw materials**

During the practical assessment, candidate demonstrated the following:		**Yes**	**No**	**Remarks**
1.	Performance Criteria 1: Received quality raw materials as per the specifications of manufacturing order			
2.	Performance Criteria 2: Ensured materials identification labels as per the specifications of manufacturing order			
3.	Performance Criteria 3: Checked expiry date on each labeled raw material as per specifications			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 2	Check production equipment as per industry standards

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Enlisted equipment relevant to the task as per specifications given in manufacturing order			
2	Performance Criteria 2: Identified tools/equipment relevant to the task as per Manufacturing order			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 3	Give suggestions for process improvements

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Identified problems on quality issues during completion of manufacturing order			
2	Performance Criteria 2: Observed quality issues during manufacturing process			
3	Performance Criteria 3: Identified objective measures for quality system effectiveness at manufacturing sites			
4	Performance Criteria 4: Submitted report to section in-charge			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 4	Inspect production process

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Ensured manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry			
2	Performance Criteria 2: Reduced defect rate and waste of product by applying rules & regulations of industry for quality product			
3	Performance Criteria 3: Ensured the availability of safe and effective drugs through Standard Operating Procedures of industry			
Competent ☐		**Not Yet Competent ☐**		

Portfolio (if any)	**Description of portfolio**

Current ☐ Sufficient ☐ Authentic ☐ Valid ☐ Reliable ☐

	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 ☐	**Not Yet Competent ☐**

Knowledge Assessment

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**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.**

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 ☐ NOT YET COMPETENT ☐ 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 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**Assessment Date (DD/MM/YY):** --/--/--		

WRITTEN ASSESSMENT

Question	Candidate's answer
10. What is the importance of physical aspects of raw materials?	
11. Define operation qualifications?	
12. What are acceptance criteria?	

Question	Candidate's answer
13. How can you address quality issues in manufacturing process?	

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

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**Assessment Date (DD/MM/YY):**		

Candidate Details	Name……..…… Registration/Roll Number……..……
Guidance for Candidate	**To meet this standard, you are required to complete the following tasks within 40 min timeframe:** 5. **Assessment Task 1:** Ensure quality raw materials. 6. **Assessment Task 2:** Check production equipment as per industry standards. 7. **Assessment Task 3:** Give suggestions for process improvements. 8. **Assessment Task 4:** Inspect production process. **And complete:** **5. Knowledge assessment test (Written or Oral)** **6. Portfolios at the time of assessment (if any)**
Minimum Evidence Required	**During a practical assessment, under observation by an assessor, you will complete:** **Task 1: Ensure quality raw materials** Performance Criteria 1: Receive quality raw materials as per the specifications of manufacturing order Performance Criteria 2: Ensure materials identification labels as per the specifications of manufacturing order Performance Criteria 3: Check expiry date on each labeled raw material as per specifications **Task 2: Check production equipment as per industry standards** Performance Criteria 1: Enlist equipment relevant to the task as per specifications given in manufacturing order. Performance Criteria 2: Identify tools/equipment relevant to the task as per Manufacturing order.

Task 3: Give suggestions for process improvements

Performance Criteria 1: Identify problems on quality issues during completion of manufacturing order
Performance Criteria 2: Observe quality issues during manufacturing process
Performance Criteria 3: Identify objective measures for quality system effectiveness at manufacturing sites
Performance Criteria 4: Submit report to section in-charge

Task 4: Inspect production process

Performance Criteria 1: Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry
Performance Criteria 2: Reduce defect rate and waste of product by applying rules & regulations of industry for quality product
Performance Criteria 3: Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry

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)

091600612 Ensure Quality Product

Candidate Details	Name: ……Registration/Roll Number: ……. Candidate Signature: ……. …….
Assessment Outcome	COMPETENT ☐ NOT YET COMPETENT ☐ 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 **Ensure quality raw materials**

During the practical assessment, candidate demonstrated the following:		**Yes**	**No**	**Remarks**
1.	Performance Criteria 1: Received quality raw materials as per the specifications of manufacturing order			
2.	Performance Criteria 2: Ensured materials identification labels as per the specifications of manufacturing order			
3.	Performance Criteria 3: Checked expiry date on each labeled raw material as per specifications			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 2	Check production equipment as per industry standards

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Enlisted equipment relevant to the task as per specifications given in manufacturing order			
2	Performance Criteria 2: Identified tools/equipment relevant to the task as per Manufacturing order			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 3	Give suggestions for process improvements

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Identified problems on quality issues during completion of manufacturing order			
2	Performance Criteria 2: Observed quality issues during manufacturing process			
3	Performance Criteria 3: Identified objective measures for quality system effectiveness at manufacturing sites			
4	Performance Criteria 4: Submitted report to section in-charge			
Competent ☐		**Not Yet Competent ☐**		

Assessment Task 4	Inspect production process

During the practical assessment, candidate demonstrated the following:		Yes	No	Remarks
1	Performance Criteria 1: Ensured manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of industry			
2	Performance Criteria 2: Reduced defect rate and waste of product by applying rules & regulations of industry for quality product			
3	Performance Criteria 3: Ensured the availability of safe and effective drugs through Standard Operating Procedures of industry			
Competent ☐		**Not Yet Competent ☐**		

Portfolio (if any)	**Description of portfolio**

Current ☐ Sufficient ☐ Authentic ☐ Valid ☐ Reliable ☐

	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 ☐	**Not Yet Competent ☐**

Knowledge Assessment

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**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.**

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 ☐ NOT YET COMPETENT ☐ 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 4, In Pharmaceutical Manufacturing Technician	CS Code: **091600612**	Level: 4	Version: 1 (2019)
Competency Standard Title: **Ensure Quality Product**	**Assessment Date (DD/MM/YY):** --/--/--		

WRITTEN ASSESSMENT

Question	**Candidate's answer**
14. What is the importance of physical aspects of raw materials?	
15. Define operation qualifications?	
16. What are acceptance criteria?	

Question	Candidate's answer
17. How can you address quality issues in manufacturing process?	

Title of Qualification: National Vocational Certificate level 4, In Pharmaceutical Manufacturing Technician	CS Code: **0916PHR05**	Level: 4	Version: 1 (2019)
Competency Standard Title: **National Vocational Certificate Level – 4 in Pharmaceutical Manufacturing Technician**	**Assessment Date (DD/MM/YY):**		

Candidate Details	Name: ..... Registration/Roll Number: .....
Guidance for Candidate	**To meet this standard, you are required to complete the following activities within 04 Hrs. time frame (for practical demonstration & assessment):** Complete project of manufacture parenterals as per standardized criteria keeping in view the quality product and documentation as per manufacturing order. During demonstration also focus on occupational health and safety **And complete:** **1. Knowledge assessment test (Written or Oral).** **2. Portfolios at the time of assessment (if any).**

Minimum Evidence Required	During a practical assessment, under the observation by an assessor, you are required to **Complete project of manufacturing Parenterals as per standardized criteria considering the quality of the product and documentation as per manufacturing order. During demonstration also focus on occupational health and safety** D**emonstrating the following criteria**: 1. Performance Criteria 1: Start double distilled water plant (Water for injection). 2. Performance Criteria 2: Receive sterile material from pass through window as per specification 3. Performance Criteria 3: Transfer raw material to the corresponding controlled area as per specifications (i.e. class A, B, C & D) 4. Performance Criteria 4: Transfer specified volume of water for injection to different manufacturing tanks 5. Performance Criteria 5: Add and dissolve materials separately as per manufacturing order 6. Performance Criteria 6: Transfer solution as per specified method to storage tank through filtration 7. Performance Criteria 7: Check environmental control parameters (temperature, humidity, air pressure & particulate matters) using monometer/ hygrometer/ psychrometer /particle counter. 8. Performance Criteria 8: Transfer sterilized solution aseptically to filling area 9. Performance Criteria 9: Start filling and sealing under class “A” environment 10. Performance Criteria 10: Perform all in-process controls as per manufacturing order 11. Performance Criteria 11: Shift filled product to quarantine area after final sterilization (where required) till approval from Quality Assurance 12. Performance Criteria 12: Ensure materials identification labels as per specifications of manufacturing order 13. Performance Criteria 13: Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of the industry 14. Performance Criteria 14: Reduce defect rate and waste of product by applying rules & regulations of the industry for quality product 15. Performance Criteria 15: Ensure the availability of safe and effective drugs through Standard Operating Procedures of the industry 16. Performance Criteria 16: Ensure documentation after completion of each batch. 17. Maintain standard operating procedures and fill all the log books and documents.

	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.

Self-Assessment Checklist

Candidate Name	
Registration No.	
Qualification	**National Vocational Certificate Level – 4 in Pharmaceutical Manufacturing Technician**
Purpose of Assessment	**Summative Assessment**
Assessment Task	**Complete project of manufacturing Parenterals as per standardized criteria considering the quality of the product and documentation as per manufacturing order. During demonstration also focus on occupational health and safety** • Knowledge Assessment

I can…

……

…….

Performance Criteria	**Yes**	**No**
P1. Start double distilled water plant (water for injection).	☐	☐
P2. Receive sterile material from pass through window as per specification	☐	☐
P3. Transfer raw material to corresponding controlled area as per specifications (i.e. class A, B, C & D)	☐	☐
P4. Transfer specified volume of water for injection to different manufacturing tanks	☐	☐
P5. Add and dissolve materials separately as per manufacturing order	☐	☐
P6. Transfer solution as per specified method to storage tank through filtration	☐	☐
P7. Check environmental control parameters (temperature, humidity, air pressure & particulate matters) using monometer/ hygrometer/ psychrometer / particle counter	☐	☐
P8. Transfer sterilized solution aseptically to filling area	☐	☐
P9. Start filling and sealing under class "A" environment	☐	☐
P10. Perform all in process controls as per manufacturing order	☐	☐
P11. Shift filled product to quarantine area after final sterilization (where required) till approval from Quality Assurance	☐	☐
P12. Ensure materials identification labels as per the specifications of manufacturing order	☐	☐
P13. Ensure manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of the industry	☐	☐
P14. Reduce defect rate and waste of product by applying rules & regulations of the industry for quality products	☐	☐
P15. Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry	☐	☐
P16. Ensure documentation after completion of each batch	☐	☐
P17. Maintain standard operating procedures and fill all the log books and documents	☐	☐

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 – 4 in Pharmaceutical Manufacturing Technician

Candidate Details	Name: .....Registration/Roll Number: ……. .. Candidate's Signature: .....
Assessment Outcome	COMPETENT☐ NOT YET COMPETENT☐ Assessor Name:.....Assessor's code:..... Assessor 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							

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: Started double distilled water plant (Water for injection).			
2	Performance Criteria 2: Received sterile material from pass through window as per specification			
3	Performance Criteria 3: Transferred raw material to concerned controlled area as per specifications (i.e. class A, B, C & D)			
4	Performance Criteria 4: Transferred specified volume of water for injection to different manufacturing tanks			
5	Performance Criteria 5: Added and dissolved material separately as per manufacturing order			
6	Performance Criteria 6: Transferred solution as per specified method to storage tank through filtration			
7	Performance Criteria 7: Checked environmental control parameters (temperature, humidity, air pressure & particulate matters) using monometer/ hygrometer/ psychrometer / particle counter.			
8	Performance Criteria 8: Transferred sterilized solution aseptically to filling area			
9	Performance Criteria 9: Started filling and sealing under class “A” environment			
10	Performance Criteria 10: Performed all in process controls as per manufacturing order			
11	Performance Criteria 11: Shifted filled product to quarantine area after final sterilization (where required) till approval from Quality Assurance			
12	Performance Criteria 12: Ensured materials identification labels as per the specifications of manufacturing order			
13	Performance Criteria 13: Ensured that manufactured and packed products are manufactured as per manufacturing order, batch records and Standard Operating Procedures of the industry			
14	Performance Criteria 14: Reduced defect rate and waste of product by applying rules & regulations of industry for quality product			
15	Performance Criteria 15: Ensured the availability of safe and effective drugs through Standard Operating Procedures of industry			
16	Performance Criteria 16: Ensured documentation after completion of each batch			
17	Performance Criteria 17: Maintained standard operating procedures and filled all the log books and other related documentation			

Competent ☐	Not Yet Competent ☐

Knowledge Assessment

Qualification	**National Vocational Certificate Level – 4 in Pharmaceutical Manufacturing Technician**
Purpose of Assessment	**Summative Assessment**
Candidate Details	Name: _____ Registration Number: _____Signature: _____
Assessment Outcome	**COMPETENT** ☐ **NOT YET COMPETENT** ☐ **Name of the Assessor**_____ **Assessor's code:** _____ **Signature:** _____

Portfolio (if any)	Description of portfolio
Current☐ Sufficient☐ Authentic☐ Valid☐ Reliable ☐	

Portfolio meet the following performance standards:		Yes	No	Remarks
1	Performance criteria for the evaluation of portfolio: Submitted log book or activity record (practical journal, project, pictures etc.) completed during the training.			
Competent ☐		Not Yet Competent ☐		

Feedback to the Candidate
Candidate's Signature_____ **Assessor's Signature** _____

Questions (Candidate confidently answered questions correctly and demonstrated understanding of the topics and their application)		**Satisfactory**	**Not Satisfactory**
1.	Describe types of clean rooms.?		
2.	What is the importance of sterilization?	**Satisfactory**	**Not Satisfactory**

3.	What is the importance of a Laminar flow?	**Satisfactory**	**Not Satisfactory**
4.	Define autoclave?	**Satisfactory**	**Not Satisfactory**
5	Define sterilization methods?	**Satisfactory**	**Not Satisfactory**

National Vocational and Technical Training Commission (NAVTTC)

Plot 38, Kirthar Road, Sector H-9/4, Islamabad, Pakistan
+92 51 9044 322
+92 51 9044 322
info@navttc.org
www.navttc.org