







PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE

National Vocational Certificate Level 4

Version 1 - November, 2019





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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)

CS Code:	Level:	Version:
091600611	4	1 (2019)
Assessment Da	ate (DD/MM/YY	·):
	091600611	

On add dot o	Name
Candidate Details	Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe:
	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
Guidance for	vials/ ampoules/bottles 4. Assessment Task 4: Mix materials
Candidate	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)
	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.
	r enormance officina 4. Neceive report from section in-charge.
	Task 2: Receive sterile raw materials
Minimum Evidence	Performance Criteria 1: Receive sterile material from pass through window a
Required	per specification Performance Criteria 2: Transfer raw material to concerned controlled area a
	per specifications (i.e. class A, B, C & D)
	per specimeations (increases 7, 2, 2 a.2)
	Performance Criteria 3: Report to in-charge about any deviation
	Performance Criteria 3: Report to in-charge about any deviation
	Performance Criteria 3: Report to in-charge about any deviation
	Performance Criteria 3: Report to in-charge about any deviation
	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)

			09	16006	11 N	/lan	ufactu	ure Pa	arente	rals		
Candida Details	ate		Name:Registration/Roll Number:									
COMPETENT Assessment Assessor Name:			NOT YET COMPETENT ☐ Assessor's code:									
Outcon	ne	Assessor's Signature:										
			ecoccn	nont Su	ımm	arv.	(to be	filled	by the	255056	ear)	
	-	Activity	ssessn	nent Su			Vethoo		by the	asses	Res	sult
Nature of Activity			Written	Oral		Observation	Portfolio	Role Play		Competent	Not Yet Competent	
Practica	al Skill I	Demonstration	n					_				
Knowle	dge As	sessment										
Anothe	r Requ	irement										
Assessment Task 1 Description of assessment task 1 Collect distilled water												
During the practical assessment, candidate demonstrated the following: Yes No Remarks												
1.		rmance Criter (Water for inje		arted do	ouble	e dis	stilled v	water				
Performance Criteria 2: Drained water for as per specification.				for f	ew mir	nutes						
3. Performance Criteria 3: Informed section infurther relevant process (e.g. pH, conductiv & pyrogen) A portional section in the process (e.g. pH, conductiv & pyrogen)				_	•							
4		rmance Criter	ia 4: Re	eceived	repo	ort fi	rom se	ection				
Competent □ Not Yet Competent □												

Assessment Task 2 Recei		Receive sterile	ive sterile raw materials				
During the practical assessment, candidate demonstrated the following:					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 Comp	petent			

		Perform sterilizati ampoules/bottles		t & pac	king ma	aterials i.e. vials/
_	he practical asses trated the followir	е	V	.		
			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					
Comp	Competent □			mpete	nt 🗆	

Asses	ssment Task 4	Mix materials			
		•			
	•	ssessment, candidate	Yes	No	Remarks
demo	nstrated the follo	owing:			
1	Performance Crite	eria 1: Transferred specified volume			
	of water for injecti	on to different manufacturing tanks			
2	Performance Crite	eria 2: Added and dissolved			
	material as per m	anufacturing order			
3	Performance Crite	eria 3: Transferred solution as per			
	specified method	to storage tank through filtration			
4	Performance Crite	eria 4: Reported section in-charge			
	about completion	of process			
5	Performance Crite	eria 5: Reported any deviation to]
	section in-charge				

Com	Competent □ Not Yet Competent □							
Asse	ssment Task 5	Control environmen	nt of product	ion ro	om			
		1						
	ng the practical as	ssessment, candida owing:	ite	Yes	No	Rei	marks	
1	control paramet	iteria 1: Checked enters (temperature, ers) through manufactrometer/ psychromete	humidity & turing order					
	counter.	rometen psychiomete	n / particio					
2	Performance Crit report from sectio	teria 2: Received are n in-charge.	ea clearance					
3	Performance Crit section in-charge	eria 3: Reported any	deviation to					
Com	petent 🗆	N	lot Yet Com	peten	t 🗆			
		<u>'</u>						
Asse	ssment Task 6	Transfer product	for filling ar	nd sea	alina			
		Transiti product			9			
	ng the practical as	ssessment, candida	ite	Yes	No	Rei	marks	
1		eria 1: Collected sample	e report form					
•	section in-charge	· · · · · · · · · · · · · · · · · · ·	1 (22 1					
2	Performance Cr solution aseptical	riteria 2: Transferre ly to filling area	d sterilized					
3	-	eria 3: Started filling	and sealing					
	under class A env							
4		iteria 4: Performed	•					
5		riation & Optical checki teria 5: Shifted filled						
Ü		after terminal steriliza	•					
		oval from Quality Assura						
6		eria 6: Reported any	deviation to					
Com	section in-charge		lot Yet Com	noton	<u> </u>			
COIII	petent L	18	iot ret com	peteri				
Portf	olio (if any)		Description	of po	rtfolio			
C	urrent \square	Sufficient \square	Authentic			Valid []	Reliable 🗖
Portf	olio meet the follow	ing performance stand	ards:	١	⁄es	No	Remarks	
1	Performance criteria for the evaluation of portfolio Submit log book or activity record (practical journ project, pictures etc.) completed during the training			ıl,				
Comp	etent 🗆		Not Yet Cor	npete	nt 🗆			

Knowledge Assessment

Title of Quali	ificat	ion:	CS Code:	Level:	Version:			
		nal Certificate level 4,	091600611	4	1 (2019)			
In Pharmaceutical Manufacturing Technician								
Competency	Stan	ndard Title:	Assessment Date (DD/MM/YY):					
Manufacture Parenterals			//	• •				
Guidance for		complete your assessment for t estions on the following pages s		tandard, you	need to answer the			
Candidate								
Assessors Gu the assessme	-	(to be completed by the Assesso	or and signed both b	oy the assesso	or and the candidate aft			
Candidate		Name:	Regis	stration/Roll N	Number:			
Details		Candidate Signature:						
		COMPETENT ☐ NOT YET COMPETENT ☐						
Written								
Assessment Outcome		Name of the Assessor: Assessor's code:						
		Signature of the Assessor:						
Feedback to	the	e candidate on assessment.						
Candidate Si	gnat	ure	. Assessor Signatu	ıre				

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

WRITTEN ASSESSMENT

Que	stion	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 inprocess controls?	

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

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

Candidate Details	Name Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe:
Guidance for Candidate	 Assessment Task 1: Ensure quality raw materials. Assessment Task 2: Check production equipment as per industry standards. Assessment Task 3: Give suggestions for process improvements. 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)

			910000		isure Q	uanty	1 1001	<u>uct</u>		
Candidate	Name:			,			Regis	tration,	/Roll Number	r:
Details	Candidate Si	gnature	:			<u>.</u>				
	COMPETENT	· 🗖				NOT	YET CO	OMPETE	ENT 🗖	
Assessment Outcome	Assessor Nar	Assessor Name:Assessor's code:								
	Assessor's Si	gnature	::							
		Assessr	ment Si	ımmar	y (to be	filled	by the	35565!	eor)	
	Activity	133000	Terr Ca		Method		Jy	<u>assect</u>	<u> </u>	sult
	Activity				TVICTION	л Т				Juit
Nature of Act	tivity		Written	Oral	Observation	Portfolio	Role Play		Competent	Not Yet Competent
Practical Skill	l Demonstratio	n								
Knowledge As	ssessment									
Another Requ	uirement									
							_			
Assessmen	nt Task 1		•		essment w mate					
During the po the following	oractical asses g:	sment,	candid	ate de	monstra		Yes	No	Remarks	
	ormance Crite erials as per th		: Rece		quality nanufact	raw turing				
ident	ormance Cri tification labels ufacturing orde	ls as p		nsured e spec		erials ns of				
	ormance Criteri led raw materia					each				
Competent D			•		Not Yet C	Compe	tent □	1	<u> </u>	

Assessr	nent Task 2	Check producti	on equipment	as pe	r indu	stry standards
•	he practical asse trated the followi	•	te	Yes	No	Remarks
1		ria 1: Enlisted equi s per specificatio er	•			
2		eria 2: Identified to k as per Manufactur				7
Compete	ent 🗆		Not Yet Com	petent	: 🗆	

Asses	Ssment Task 3 Give suggest	ions for process	impr	oveme	ents
During	g the practical assessment, can	didate	Yes	No	Remarks
demo	nstrated the following:		163	110	Kemarks
1	Performance Criteria 1: Identific	ed problems on			
	quality issues during completion	of manufacturing			
	order				
2	Performance Criteria 2: Observed	quality issues			
	during manufacturing process				
3	Performance Criteria 3: Ide	ntified objective			
	measures for quality system	effectiveness at			
	manufacturing sites				
4	Performance Criteria 4: Submitted	report to section			
	in-charge	_			
Comp	etent 🗆	Not Yet Comp	etent		

Asses	ssment Task 4	Inspect product	on process			
	g the practical as	ssessment, candic	late	Yes	No	Remarks
1	Performance Crite packed products manufacturing or Operating Procedule	eria 1: Ensured man s are manufactur der, batch records	red as per and Standard			
2		by applying rules &				
3		eria 3: Ensured the drugs through Stand ustry	•			
Comp	etent 🗆		Not Yet Com	petent		

Po	rtfolio (if any)		Description of p	ortfolio)		
	Current \square	Sufficient \square	Authentic 🛚		Valid		Reliable 🗖
Ро	rtfolio meet the follow	ving performance sta	ndards:	Yes	No	Remarks	
1		ia for the evaluation activity record (pra	ctical journal,				
Со	mpetent 🗆		Not Yet Compet	ent 🗆			

Knowledge Assessment

Title of Quali	fication:	CS Code:	Level:	Version:			
	ational Certificate level 4,	091600612	4	1 (2019)			
In Pharmaceutical Manufacturing Technician							
Competency	Standard Title:	Assessment Date (DD/MM/YY):					
Ensure Qua	ality Product	//					
Guidance	To complete your assessment for		tandard, you	need to answer the			
for Candidate	questions on the following pages	successfully.					
Assessors Gu	ide (to be completed by the Assesso	or and signed both b	ov the assesso	or and the candidate aft			
the assessme		,	y				
	T						
	Name:	Registrat	ion/Roll Num	her:			
Candidate Details	Numer						
Details	Securio						
	Candidate Signature:		•••••				
	COMPETENT	NOT YET	COMPETENT				
Written Assessment	Assessor Name:	Ass	sessor's code:				
Outcome							
	Assessor's Signature:						
Feedback to	the candidate on assessment.						
	THE Canadace on assessment.						
							
							
	-						
Candidate Sig	gnature	. Assessor Signatu	re				

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 4,	091600612	4	1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MN	//YY):
Competency Standard Title: Ensure Quality Product	Assessment D	ate (DD/MN	/I/YY):
		ate (DD/MN	/I/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:	CS Code:	Level:	Version:
National Vocational Certificate level 4,	091600612	4	1 (2019)
In Pharmaceutical Manufacturing Technician			
Compositionary Standard Title	Accessment De	ate (DD/MM/YY	١.
Competency Standard Title:	Assessment Da	ite (DD) iviivi) i i)·
Ensure Quality Product	Assessment Da).
1	Assessment Da	ite (DD) iviivi) i i	<i>j</i> .

NameRegistration/Roll Number
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)
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)

			910000		isure Q	uanty	1 1001	<u>uct</u>		
Candidate	Name:	Name:Registration/Roll Number:					r:			
Details	Candidate Si	Candidate Signature:								
	COMPETENT	· 🗖				NOT	YET CO	OMPETE	ENT 🗖	
Assessment Outcome	Assessor Nar	me:				Asse	ssor's (code:		
	Assessor's Si	gnature	::							
		Assessr	ment Si	ımmar	y (to be	filled	by the	35565!	eor)	
	Activity	133000	Terr Ca		Method		Jy	<u>assect</u>	<u> </u>	sult
	Activity				TVICTION	л Т				Juit
Nature of Activity		Written	Oral	Observation	Portfolio	Role Play		Competent	Not Yet Competent	
Practical Skill	l Demonstratio	n								
Knowledge As	ssessment									
Another Requ	uirement									
							_			
Assessmen	nt Task 1		•		essment w mate					
During the practical assessment, candidate demonstrated the following:					Yes	No	Remarks			
Performance Criteria 1: Received quality raw materials as per the specifications of manufacturing order										
Performance Criteria 2: Ensured materials identification labels as per the specifications of manufacturing order										
	ormance Criteri led raw materia					each				
labeled raw material as per specifications										

Assessr	nent Task 2	Check producti	on equipment	as pe	r indu	stry standards
•	he practical asse trated the followi	•	te	Yes	No	Remarks
1	Performance Criteria 1: Enlisted equipment relevant to the task as per specifications given in manufacturing order					
Performance Criteria 2: Identified tools/equipment relevant to the task as per Manufacturing order				7		
Compete	ent 🗆		Not Yet Com	petent	: 🗆	

Assessment Task 3 Give suggestion		ions for process	impr	oveme	ents
During	g the practical assessment, can	didate	Yes	No	Remarks
demo	nstrated the following:		163	110	Kemarks
1	Performance Criteria 1: Identific	ed problems on			
	quality issues during completion	of manufacturing			
	order				
2	Performance Criteria 2: Observed	quality issues			
	during manufacturing process				
3	Performance Criteria 3: Ide	ntified objective			
	measures for quality system	effectiveness at			
	manufacturing sites				
4	Performance Criteria 4: Submitted	report to section			
	in-charge	_			
Comp	etent 🗆	Not Yet Comp	etent		

Asses	ssment Task 4	Inspect product	on process			
	g the practical as	ssessment, candic	late	Yes	No	Remarks
1	Performance Crite packed products manufacturing or Operating Procedule	eria 1: Ensured man s are manufactur der, batch records ures of industry	red as per and Standard			
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					
Comp	etent 🗆		Not Yet Com	petent		

Po	rtfolio (if any)		Description of p	ortfolio)		
	Current \square	Sufficient \square	Authentic 🛚		Valid		Reliable 🗖
Ро	rtfolio meet the follow	ving performance sta	ndards:	Yes	No	Remarks	
1		ia for the evaluation activity record (pra	ctical journal,				
Со	mpetent 🗆		Not Yet Compet	ent 🗆			

Knowledge Assessment

Title of Quali	fication:	CS Code:	Level:	Version:				
	ational Certificate level 4,	091600612	4	1 (2019)				
In Pharmaceı	utical Manufacturing Technician							
Competency	Standard Title:	Assessment Date (DD/MM/YY):						
	ality Product	//						
Guidance	To complete your assessment for	this Competency S	tandard, you	need to answer the				
for	questions on the following pages s	successfully.						
Candidate								
	•• G. L	C. Control Lands I		Lulia de dialega de				
Assessors Gu the assessme	uide (to be completed by the Assesso ent)	r and signed both t	by the assesso	or and the candidate aft				
Candidate	Name:Registration/Roll Number:							
Details								
	Candidata Signaturo:							
	Candidate Signature:							
	COMPETENT	NOT YET	COMPETENT	П				
Written								
Assessment	Assessor Name:	Ass	sessor's code:					
Outcome								
	Assessor's Signature:							
	1							
Feedback to	the candidate on assessment.							
`andidate Sic	gnature	Assessor Signatu	re					

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 4,	091600612	4	1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MM	I/YY):
Competency Standard Title: Ensure Quality Product	Assessment D	ate (DD/MM	I/YY):
• •		ate (DD/MM	I/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:	CS Code:	Level: 4	Version:
National Vocational Certificate level 4,	0916PHR05		1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment Da	te (DD/MM/YY):	
National Vocational Certificate Level – 4 in			
Pharmaceutical Manufacturing Technician			

Candidate	
Details	Name:
	Registration/Roll Number:
	To meet this standard, you are required to complete the following activities within 04
	Hrs. time frame (for practical demonstration & assessment):
Guidance for Candidate	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:
	 Knowledge assessment test (Written or Oral). Portfolios at the time of assessment (if any).

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

Demonstrating 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.

Minimum Evidence Required

Self-Assessment Checklist

I

can...

Candidate Name						
Registration No.						
Qualification	National Vocational Certificate Level – 4 in Pharmac Technician	ceutical Manu	facturing			
Purpose of Assessment Summative Assessment						
Assessment Task	Complete project of manufacturing Parenterals a considering the quality of the product and manufacturing order. During demonstration also for and safety	documenta	ntion as per			
	Knowledge Assessment					
Performance Criteria		Yes	No			
P1. Start double dis	tilled water plant (water for injection).					
P2. Receive sterile specification	material from pass through window as per					
	aterial to corresponding controlled area as per .e. class A, B, C & D)					
P4. Transfer specifi manufacturing	ed volume of water for injection to different tanks					
	re materials separately as per manufacturing order					
P6. Transfer solution						
P7. Check environmental control parameters (temperature, humidity, air pressure & particulate matters) using monometer/ hygrometer/ psychrometer / particle counter						
	ed solution aseptically to filling area					
P9. Start filling and	sealing under class "A" environment					
P10. Perform all in p	rocess controls as per manufacturing order					
P11. Shift filled product to quarantine area after final sterilization (where required) till approval from Quality Assurance						
P12. Ensure materia	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						
	rate and waste of product by applying rules & he industry for quality products					
P15. Ensure the availability of safe and effective drugs through Standard Operating Procedures of industry						
P16. Ensure docume						
P17. Maintain standa and documents	ard operating procedures and fill all the log books					
Candidate's Signature	e 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		Registration/Roll Number:				
Assessment Outcome	COMPETENT Assessor Name: 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								

Eacl	n Assessment Task (with performance criteria)					
Asse	essment Task	Description	of asse	essmen	t task	
Complete				t of	manufacture	tablets as per
						workplace place
		safety by ta	king a	ppropri	iate measures	
	ing the practical assessment, candidate demons	strated the	Yes	No	Remarks	
follo	owing:				neman.	
1	Performance Criteria 1: Started double dis	tilled water				
	plant (Water for injection).				<u></u>	
2	Performance Criteria 2: Received sterile ma	aterial from				
	pass through window as per specification				<u></u>	
	Performance Criteria 3: Transferred raw					
3	concerned controlled area as per specificatio	ns (i.e. class				
	A, B, C & D)				<u></u>	
4	Performance Criteria 4: Transferred specified	d volume of				
	water for injection to different manufacturing	tanks				
5	Performance Criteria 5: Added and dissolv	ed material				
,	separately as per manufacturing order					
6	Performance Criteria 6: Transferred solut	ion as per				
U	specified method to storage tank through filtr	ation				
	Performance Criteria 7: Checked environme	ntal control				
7	parameters (temperature, humidity, air	pressure &				
,	particulate matters) using monometer/	nygrometer/				
	psychrometer / particle counter.					
8	Performance Criteria 8: Transferred steriliz	ed solution				
0	aseptically to filling area					
9	Performance Criteria 9: Started filling and se	ealing under				
9	class "A" environment					
Performance Criteria 10: Performed all in process						
10	controls as per manufacturing order					
	Performance Criteria 11: Shifted filled	product to				
11	quarantine area after final sterilization (whe	re required)				
	till approval from Quality Assurance					
42	Performance Criteria 12: Ensured materials id	dentification				
12	labels as per the specifications of manufacturi	ng order				
	Performance Criteria 13: Ensured that manufa	ctured and				
4.0	packed products are manufactured as per ma	nufacturing				
13	order, batch records and Standard Operating	Procedures				
	of the industry					
	Performance Criteria 14: Reduced defect rate	e and waste				
14	of product by applying rules & regulations of	industry for				
	quality product					
	Performance Criteria 15: Ensured the availab	oility of safe			_	
15 and effective drugs through Standard Operating						
	Procedures of industry	. 3				
Performance Criteria 16: Ensured documentation af		tation after			1	
16	completion of each batch					
	Performance Criteria 17: Maintained standard	operating			1	
17	procedures and filled all the log books and oth					
	documentation					

Competent \square	1	Not Yet Compe	tent \square			
	Knov	vledge Ass	essm	ent		
Qualification	National Vocational Certificate	Level – 4 in Ph	armaceu	tical N	Nanufacturing Technicia	n
Purpose of Assessment	Summative Assessment					
Candidate Details		Signature:				
Assessment Outcome	COMPETENT	_				
		Signature:				
ortfolio (if any)		Description of	portfoli	0		
Current 🗆	Sufficient□ Authentic□	 Valid□	R	eliable	e 🗆	
ortfolio meet th	e following performance standards:		Yes	No	Remarks	
S	erformance criteria for the evaluation ubmitted log book or activity reconstruction project, pictures etc.) comples aining.	cord (practical				
ompetent 🗆		Not Yet Comp	etent \square			
	Feed	dback to t	ne Cai	ndida	ate	
Cand	idate's Signature	Assessor's	Signatu	re		

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

3.	What is the importance of a Laminar flow?	Satisfactory	Not Satisfactory
	Define a hada a		- No.
4.	Define autoclave?	Satisfactory	Not Satisfactory
5	Define sterilization methods?	Satisfactory	Not Satisfactory

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