







PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE

National Vocational Certificate Level 2

Version 1 - November, 2019





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PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE National Vocational Certificate Level 2

Version 1 - November, 2019

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

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 2,	019600602	2	1 (2019)
In Pharmaceutical Manufacturing Technician			
0 1 1 1		. /55/555/5	٠١
Competency Standard Title:	Assessment Da	ate (DD/MM/YY	') :
Prepare work environment according to	Assessment Da	ate (DD/MM/YY	') :
1	Assessment Da	ate (DD/MM/YY	') :

Candidate Details	Name
Details	Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe:
	Assessment Task 1: Maintain temperature and humidity
	2. Assessment Task 2: Ensure air pressure of specific area/work place
	3. Assessment Task 3: Conduct and verify cleaning and sanitation procedures
Guidance for Candidate	4. Assessment Task 4: Adjust light as per specifications in workplace area
	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: Maintain temperature and humidity
	Performance Criteria 1: Inspect work place regularly as per area/product specific
	requirements
	Performance Criteria 2: Take note of current temperature and humidity levels at
	workplace as required by manufacturing order
	Performance Criteria 3: Maintain workplace temperature and humidity levels as per manufacturing order
	Performance Criteria 4: Record temperature and humidity as per manufacturing order
	Performance Criteria 5: Report to in-charge about any deviation if occur, for prompt
Minimum Evidence Required	measures
	Task 2: Ensure air pressure of specific area/work place
	Performance Criteria 1: Note and maintain air pressure of workplace as required for
	manufacturing order.
	Performance Criteria 2: Record air pressure as per manufacturing order
	Performance Criteria 3: Report to in-charge about any deviation if occur, for prompt
	measures

Task 3: Conduct and verify cleaning and sanitation procedures

Performance Criteria 1: Clean workplace, tools/equipment from dust before swab test Performance Criteria 2: Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications

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

Task 4: Adjust light as per specifications in workplace area

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

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

.

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

Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training. **Assessors Judgment Guide** (to be completed by the Assessor and signed both by the assessor and the candidate after the assessment)

019600602 Prepare work environment according to manufacturing order

Candidate Details	Name: Candidate Signature:	•
Assessment Outcome	COMPETENT Name of the Assessor: Signature of the Assessor:	

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

Asses	ssment Task 1	Description of a				
	g the practical assem		,	Yes	No	Remarks
1.	Performance Criteria		•			
2.	Performance Criteria 2: Take note of current temperature and humidity of workplace as required by manufacturing order					
3.	Performance Criteria 3: Maintain workplace temperature and humidity as per manufacturing order					
4.		Performance Criteria 4: Record temperature and humidity as per manufacturing order				
5.		Performance Criteria 5: Report to in-charge about any deviations, if occurred, for prompt measures				
Comp	etent 🗆		Not Yet Comp	etent C]	

Asses	ssment Task 2	Ensure air press	sure of specific	area/w	ork pla	ce
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks	
1		ia 1: Note and maintain air ace as required for manufacturing				
2	Performance Criter manufacturing orde	•				
3	Performance Criter any deviations, if or	•				
Comp	Competent □ Not Yet Con			petent		

Asses	ssment Task 3	Conduct and veri	fy cleaning and	l sanita	tion pr	ocedures
					_	
	•	ssessment, candi	date	Yes	No	Remarks
demo	nstrated the follo	wing:				
1	Performance Crite	ria 1: Clean workpla	ace,			
_	tools/equipment fr	om dust before swa	b test			
	Performance Crite	ria 2: Disinfect man	ufacturing			7
2	area, tools/equipm	nent's before swab to	est as per			
	standard specifica	• •				
2	Performance Criteria 3: Report to in-charge about				1	
3	any deviation					
Comp	etent 🗆		Not Yet Com	petent		

Assessment Task 4 Adjust light as per		specifications in	workpl	ace are	ea	
	ng the practical as onstrated the follo	· ·	date	Yes	No	Remarks
1	Performance Criteria 1: Identify high-bay and low-bay lights and colors as per manufacturing of sensitive medicine products or tasks specific lights in workplace					
2	Performance Criteria 2: Adjust dust and water resistance lights as required for specific manufacturing tasks					_
Competent □		Not Yet Com	petent			

Portfoli	o (if any)	Description of p	ortfolic)	
Current	:□ Sufficient □ Authentic□	│] Valid □		Relia	ble 🗆
Portfoli	o meet the following performance standa	ards:	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 Compet	tent 🗆		

Knowledge Assessment 019600602 Prepare work environment according to manufacturing order

Title of Qualification: National Vocational Certificate level 2, In Pharmaceutical Manufacturing Technician Competency Standard Title: Prepare work environment according to manufacturing order		CS Code: 019600602	Level: 2	Version: 1 (2019)
		Assessment Date (DD/MM/YY)://		
Guidance for Candidate	To complete your assessment for the questions on the following pages so	• •	Standard, yo	ou need to answer the
s essors Guid e assessmen	le (to be completed by the Assessor t)	and signed both	by the assess	sor and the candidate after
Candidate Details	Name: Candidate Signature:		J	
	COMPETENT	NOT Y	ET COMPETE	:NT □
Written Assessment Outcome Name of the Assessor:				essor's code:
	Assessor Signature:			
edback to t	he candidate on assessment.			
Candidate S	Signature	Assessor Sigr	nature	

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 2,	019600602	2	1
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MI	M/YY):

WRITTEN ASSESSMENT

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

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

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

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

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

Task 3: Check weight of raw materials

Performance Criteria 1: Confirm calibration status of weighing balance

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

Task 4: Shift materials to concerned section

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

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

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

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

Task 2: Arrange raw materials for mixing

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

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

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

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

Performance criteria for the evaluation of portfolio:

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

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

-	019600603 Red	eive Pr	oduct	Raw M	aterials	accor	ding to	o manu	tacturing ord	der
Candidate Details	2	Name:Registration/Roll Number: Candidate Signature:								
Assessme Outcome	nt Name of the	COMPETENT NOT YET COMPETENT Name of the Assessor: Assessor's Code: Assessor's Signature:								
	Α	ssessn	nent Sı	ummar	v (to be	e filled	by the	assess	sor)	
	Activity			<u></u>	Metho		<i>by</i> 1110		Res	sult
Nature of Activity			Written	Oral	Observation	Portfolio	Role Play		Competent	Not Yet Competent
Practical S	Skill Demonstration	n							0	2 0
Knowledg	ge Assessment									
Other Red	quirement									
Assessment Task 1 Description of assessment task 1 Receive raw materials & its storage										
During the practical assessment, candidate demonstrated the following: Yes No					Remarks					
2. P	evaluation of raw materials (including packaging materials) 2. Performance Criteria 2: Store raw materials in a manner to prevent degradation, contamination and				in a					
cross-contamination								1		

Not Yet Competent □

Competent □

Asses	Identify materi	als according t	to labe	els	
During the practical assessment, candidate demonstrated the following:				No	Remarks
1	Performance Criteria 1: Identify raw r manufacturing order				
2	Performance Criteria 2: Cross check labels of raw materials as per specifications against each manufacturing order				
3		nce Criteria 3: Check the signature of te authority on labeled raw materials as per uring order			
4	4 Performance Criteria 4: Report to in-charge about any deviation				
Comp	etent 🗆	Not Yet Comp	petent		

Assessment Task 3 Check weight of raw materials						
During the practical assessment, candidate demonstrated the following:				Yes	No	Remarks
1	Performance Crite weighing balance	Performance Criteria 1: Confirm calibration status of weighing balance				
2	Performance Criteria 2: Cross check the gross weight of individual labeled raw materials as per manufacturing order					
Competent □ Not Yet Com			etent			

Assessment Task 4 SI		Shift materials to	Shift materials to concerned section				
During the practical assessment, candidate demonstrated the following:					No	Remarks	
1	Performance Criteria 1: Put the batch materials one by one in dispensing trolley as per manufacturing order for shifting to workplace area						
2		formance Criteria 2: Transfer dispensed materials by to the manufacturing area as per procedure					
3		teria 3: Check the temperature and ial placement area as per procedure					
4		eria 4: Park trolley see as per instruction					
Competent □ Not Yet Competent □							

-								
Asses	ssment Task 5	Mat	erials for Mixing	I				
	g the practical asse nstrated the followi		lidat	e	Yes	No	Remarks	
1	Performance Crite trolley prior to disp							
2	Performance Crite trolley to the produ			•				
3	Performance Crite arrange it according							
Comp	etent 🗆			Not Yet Comp	oetent		1	
Portfoli	o (if any)			Description of p	ortfoli	D		
Curr	rent Suf	ficient \square	А	uthentic \square	thentic □ Valid □ Reliable □			
Portfolio meet the following performance standard			ds:	Yes	No	Remarks		
Performance criteria for the evaluation of portfolog book or activity record (practical journal pictures etc.) completed during the training.			journal, project,					
Compet	ent 🗆			Not Yet Compet	ent 🗆	l		

Knowledge Assessment

Title of Qualification:

ritle of Qualit	iication:	CS Code:	Levei:	version:			
National Voca	ational Certificate level 2,	019600603	2	1 (2019)			
In Pharmaceu	tical Manufacturing Technician						
Competency	Standard Title:	Assessment D	 ate (DD/MM,	/YY):			
Receive Proc manufacturin	duct Raw Materials according to ng order	//					
	To complete your assessment for the	•	tandard, you	need to answer the			
Guidance for	questions on the following pages s	successfully.					
Candidate							
Assessors Gui the assessmen	de (to be completed by the Assessor nt)	and signed both by	the assessor	and the candidate after			
Candidate	Name:	Registratio	an/Rall Numh	ner:			
Details	Name: Registration/Roll Number:						
	Candidate Signature:						
	COMPETENT	NOT YET (COMPETENT [
Written							
Assessment			_				
Outcome	Name of the Assessor:	Assessor's	code:				

Candidate Signature Assessor Signature Assessor Signature	
Carridate Signature	

Feedback to the candidate on assessment.

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 2,	019600603	2	1
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MN	M/YY):

WRITTEN ASSESSMENT

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

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

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

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

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

	Name
Candidate Details	Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe:
Guidance for	Assessment Task 1: Check electrical and mechanical parameters of machine for proper functionality Assessment Task 2: Check machine lubrications Assessment Task 3: Ensure cleaning of machine Assessment Task 4: Maintain machine Log-book
Candidate	Assessment Task 5: Follow machine operation procedure
	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: Check electrical and mechanical parameters of machine for proper functionality
	Performance Criteria 1: Check machine electric input and output as per instructions given in machine manual
	Performance Criteria 2: Check machine mechanically fit for operation as pe
Minimum Evidence Required	Performance Criteria 3: Check all parameters according to Program Logic Contro (PLC) system/Human Machine Interface (HMI) as pe manufacturing order
	Task 2: Check machine lubrications
	Performance Criteria 1: Check gauge of lubricants as per machine manual.
	Performance Criteria 2: Verify proper lubrication of machinery as per maintenance
	schedule

Task 3: Ensure cleaning of machine

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

Performance Criteria 2: Proper tagging of machine as per procedure

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

Task 4: Maintain machine log-book

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

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

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

Task 5: Follow machine operation procedure

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

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

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

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

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

Performance criteria for the evaluation of portfolio:

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

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

019600604 Adjust machine as per product manufacturing order

Candidate Details	Name: Registration/Roll Number:
	COMPETENT ☐ NOT YET COMPETENT ☐
Assessment Outcome	Name of the Assessor:

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

Asses	ssment Task 1	chine for proper functionality				
_	the practical asses lowing:	sment, candidate	demonstrated	Yes	No	Remarks
1.	Performance Crit input and output machine manual					
2.	Performance Cr mechanically fi manufacturing ord	t for operation	•			
Performance Criteria 3: Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order						
Competent □			Not Yet Compe	etent 🗆	I	

Asses	ssment Task 2	Check machine	lubrications			
During the practical assessment, candidate				Yes	No	Remarks
aemo	nstrated the follow	wing:				
1	Performance Cr	iteria 1: Ched	ck gauge of			
	lubricants as per	machine manual				
2	Performance Crite	eria 2: Verify prop	per lubrication			
	of machinery as p	oer maintenance s	schedule			
3	Performance Cri	teria 3: Report	to in-charge]
	about any deviation	on				
Comp	etent 🗆		Not Yet Com	petent		

Asses	ssment Task 3	Ensure cleaning o	e cleaning of machine					
•	g the practical ass	sessment, candida wing:	ate	Yes	No	Remarks		
1	Performance Criteria 1: Check the cleanliness status of machine after completion of each batch as per instruction given in the manual							
2	Performance Crit as per procedure	riteria 2: Proper tagging of machine re						
3	about completion	teria 3: Inform the and of each batch as we hand acturing order						
Comp	etent 🗆		Not Yet Comp	etent				

Asses	ssment Task 4 Maintain machine log-book			
	'			
1	g the practical assessment, candidate nstrated the following:	Yes	No	Remarks
1	Performance Criteria 1: Make entries in mach log book as per instruction	ine		
2	Performance Criteria 2: Check log be periodically for effective and smooth running machine functions	ook J of		
3	Performance Criteria 3: Report to in-charge any unusual response during manufactur processing			
Comp	etent Not Yet C	ompeten	t 🗆	

Asses	Assessment Task 5 Arrange Raw Materials for Mixing						
During the practical assessment, candidate demonstrated the following:			te	Yes	No	Remarks	
Performance Criteria 1: Identify every manufacturing feature and notes before the start of the machine as per manufacturing order			efore the start				
2		iteria 2: Adjust er product manuf it					
3	Performance Criteria 3: Perform in process tests according to product manufacturing order and machine operation procedures						
4 Performance Criteria 4: Inform to the section incharge regarding any deviation during process							
Comp	petent		Not Yet Comp	oetent			
Portfoli	o (if any)		Description of p	cription of portfolio			
Curr	rent Suff	icient 🗆 🏻 A	authentic 🗆	,	Valid □	I	Reliable 🗆
Portfolio meet the following performance standards:			ds:	Yes	No	Remarks	
Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.							
Compet	ent П		Not Vet Compe	tent Π			

Title of Qua	lification:	CS Code:	Level:	Version:				
National Vocational Certificate level 2,		019600604	2	1 (2019)				
In Pharmac	eutical Manufacturing Technician							
-	y Standard Title:		ate (DD/MM/YY	') :				
_	chine as per product manufacturing	//						
order								
Guidance	To complete your assessment for thi	is Competency St	tandard, you ne	ed to answer the				
for	questions on the following pages successfully.							
Candidate								
Carialaate								
Assessors Gu	lide (to be completed by the Assessor ar	nd signed both by	the assessor an	d the candidate after				
the assessme								
	•							
Candidate	Name:	Registratio	n/Roll Number:					
Details								
Details	Candidate Signature:							
	COMPETENT	NOT VET CO	OMPETENT					
	COMPETENT	NOTTETE	SIVIFETEINT L					
Written								
Assessmen								
t Outcome	Name of the Assessor:		Assessor's code:					
	Assessor's Signature:							
Feedback to	the candidate on assessment.							
Candidata	Ganaturo ^	ccoccor Cianati	ro					
Candidate S	Candidate Signature Assessor Signature							

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

WRITTEN ASSESSMENT

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

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

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

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

Candidate	
Details	Name:
	Registration/Roll Number:
	To meet this standard, you are required to complete the following within the given
	time frame (for practical demonstration & assessment):
	Assessment Task: In a given situation to
Guidance	"Prepare work environment before receiving product raw materials and adjust
for	machines as per manufacturing order keeping in view the workplace safety."
Candidate	
	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

"Prepare work environment before receiving product raw materials and adjust machines as per manufacturing order keeping in mind workplace safety"

Demonstrating the following criteria:

- **1.** Performance Criteria 1: Inspect work place as per area/product specific requirements
- 2. Performance Criteria 2: Take note of current temperature and humidity levels at workplace as required by manufacturing order
- 3. Performance Criteria 3: Take note of air pressure levels at workplace as required by manufacturing order
- 4. Performance Criteria 4: Clean workplace, tools/equipment from dust before swab test
- 5. Performance Criteria 5: Disinfect manufacturing area, tools/equipment's before swab test as per standard specifications
- 6. Performance Criteria 6: Identify and check weight of raw materials as per manufacturing order
- 7. Performance Criteria 7: Confirm calibration status of weighing balance
- 8. Performance Criteria 8: Check machine electric input and output as per instructions given in the machine manual
- 9. Performance Criteria 9: Check if machine is mechanically fit for operation as per manufacturing order
- Performance Criteria 10: Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order
- 11. Performance Criteria 11: Check the status cleanliness of the machine after completion of each batch as per the instructions given in the manual.

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

		Sen-Assessment Checklist				
Cand	lidate Name					
Regis	stration No.					
0 1	• • • • • • •	National Vocational Certificate Level – 2 in Pharma	ceutical Manu	facturing		
Quai	ification	Assistant				
_	ose of ssment	Summative Assessment				
Asse	Assessment Task Prepare work environment before receiving product raw materials and adjusted the product raw materials and adjusted to the product raw mate					
71330	osinent rusk	machines as per manufacturing order keeping in vie	ew the workpl	ace safety.		
		Knowledge Assessment				
I can						
Perf	ormance Criteria		Yes	No		
P1.	Inspect work pl	ace as per area/product specific requirements.				
P2.		rrent temperature and humidity levels at the				
		quired by manufacturing order.				
Р3.	P3. Take note of air pressure levels at workplace as required by manufacturing order.					
P4.		e, tools/equipment from dust before swab test.				
P5.	Disinfect manuf as per standard	facturing area, tools/equipment's before swab test specifications.				
P6.	Identify and che order.	eck weight of raw materials as per manufacturing				
P7.	Confirm calibra	tion status of weighing balance.				
P8.	Check machine the machine ma	electric input and output as per instructions given in anual.				
	manufacturing					
P10	P10. Check all parameters according to Program Logic Control (PLC) system/Human Machine Interface (HMI) as per manufacturing order					
P11	P11. Check the status of cleanliness of machine after completion of each batch as per the instructions given in the manual.					
Candio		Assessor's Signature				

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 – 2 in Pharmaceutical Manufacturing Assistant

Candidate Details	Name: Candidate's Signature:	
Assessment Outcome	COMPETENT Assessor Name: Assessor Signature:	

Assessment Summary (to be filled by the assessor)							
Activity		Method				Res	sult
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)						
Assess	sessment Task Description of assessment task					
Prepare work environment before receiving pro-						
		raw materia	ls an	d adj	ust machines as per	
		manufacturing	order	(1000	batch) keeping in view the	
		workplace safe	ety			
Durin	g the practical assessment, candidate de	monstrated	Yes	No	Remarks	
the fo	llowing:		103	140	Remarks	
			1	ı		
1.	Performance Criteria 1: Inspected wor	rk place as per				
	area/product specific requirements.					
	Performance Criteria 2: Took not					
2.	temperature and humidity levels at	workplace as				
	required by manufacturing order					
	Doute was a Cuite via 2. To also at a ef air					
3.	Performance Criteria 3: Took note of air	•				
	at workplace as required by manufactured Performance Criteria 4: Cleaner	_				
4		• •				
4.	tools/equipment from dust before swa	n test				
	Performance Criteria 5: Disinfected	manufacturing				
5.	area, tools/equipment's before swa	_				
J.	standard specifications	b test as per				
	Performance Criteria 6: Identified and o	rhecked weight				
6.	of raw materials as per manufacturing	_				
	Performance Criteria 7: Confirmed calib					
7.	weighing balance					
	Performance Criteria 8: Checked ma	achine electric				
8.	input and output as per instructions gi					
	manual					
	Performance Criteria 9: Checked	if machine is				
9.	mechanically fit for operation as per	manufacturing				
	order					
	Performance Criteria 10: Checked a	all parameters				
10.	according to Program Logic (Control (PLC)				
10.	system/Human Machine Interface (HMI) as per					
	manufacturing order					
	Performance Criteria 11: Checked	the status of				
11.	cleanliness of machine after completion	n of each batch				
11.	as per the instructions given in manual.					
Comp	etent 🗆	Not Yet Compe	tent 🗖			

Knowledge Assessment

Qualification	National Vocational Certificate Level – 2 in Pharmaceutical Manufacturing Assistant					
Purpose of Assessment	Summative Assessment					
Candidate	Name:					
Details	Registration Number:Signature:					
COMPETENT NOT YET COMPETENT					٦	
Outcome	Assessor Name					
	Assessor's code:	Signature: _				
Portfolio (if any)	Description of p	portfoli	0		
Current□	Sufficient□ Authentic□	Valid□	R	eliable		
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 \square		Not Yet Compe	tent 🗆			
	Feedback to	the Candia	Jata			
	reeuback to	the Candic	aate			
Candidate's Sign	natureAssesso	or's Signature				

	cions (Candidate confidently answered questions correctly and demonstrated tanding of the topics and their application)	Satisfactory	Not Satisfactory
1.	What are the different functions of a hygrometer, thermometer and monometer?		
2.	What is the importance of HVAC in pharmaceutical industry?	Satisfactory	Not Satisfactory
		<u> </u>	
		Ι	
3.	What is the procedure to clean and disinfect the workplace?	Satisfactory	Not Satisfactory
		I	
		I	No.
4.		Satisfactory	Not Satisfactory

	What is the role of lubrication for smooth functioning of		
	machine?		
5.	Define Machine Gauge?		Not
3.	Define Waterine Gaage.	Satisfactory	Satisfactory
			,
6	What is the importance of safe disposal of pharmaceutical waste?	Satisfactory	Not
		Satisfactory	Satisfactory

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