







PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE

National Vocational Certificate Level 3

Version 1 - November, 2019





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Document Version November, 2019 **Islamabad, Pakistan**

PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE
National Vocational Certificate Level 3

Version 1 - November, 2019

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

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

Candidate Details	NameRegistration/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: Mix Raw Materials 2. Assessment Task 2: Perform Slugging (in case of dry granulation) 3. Assessment Task 3: Perform wet mixing 4. Assessment Task 4: Perform wet granulation 5. Assessment Task 5: Collect Wet Granules and Dry 6. Assessment Task 6: Perform Dry Granulation 7. Assessment Task 7: Perform Sieving (Mesh) 8. Assessment Task 8: Perform Final Mixing 9. Assessment Task 9: Shift Material to Compression Room 10. Assessment Task 10: Start Compression Machine 11. Assessment Task 11: Check Weight Variation of Tablets 12. Assessment Task 12: Shift compressed tablets for coating or sorting 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: Mix raw materials Performance Criteria 1: Check identification of materials against manufacturing order Performance Criteria 2: Sieve and add materials as per manufacturing order Performance Criteria 3: Start mixing as per manufacturing order Performance Criteria 4: Record all necessary entries as per manufacturing order Performance Criteria 5: Report to the in-charge about any deviation for quick response Task 2: Perform slugging (in case of dry granulation) Performance Criteria 1: Install required sieve as per manufacturing order in compactor granulator Performance Criteria 2: Shift materials in compactor granulator as per manufacturing order Performance Criteria 3: Start granulator and adjust rollers for proper flack size as per manufacturing order Performance Criteria 4: Collect dry granules after completion of process as per manufacturing order

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

Task 3: Perform wet mixing

Performance Criteria 1: Prepare binder solution as per manufacturing order Performance Criteria 2: Mix binder solution with powder mixture to form wet mass as per manufacturing order

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

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

Task 4: Perform wet granulation

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

Performance Criteria 2: Shift and pass the wet mass through granulator Performance Criteria 3: Report to the in-charge about any deviation

Task 5: Collect wet granules and dry

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

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

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

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

Task 6: Perform dry granulation

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

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

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

Task 7: Perform sieving (mesh)

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

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

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

Task 8: Perform final mixing

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

Performance Criteria 2: Add material as per manufacturing order

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

Performance Criteria 4: Enter all necessary entries as per manufacturing order Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order

Task 9: Shift material to compression room

Performance Criteria 1: Receive approval from concerned section in-charge.

Performance Criteria 2: Identify trolley for shifting material to compression room for next process

Performance Criteria 3: Perform weight and record of received materials as per specifications

Performance Criteria 4: Place material on pallets using appropriate and safe methods.

Performance Criteria 5: Report any deviations, if any, during shifting process to avoid loss.

Task 10: Start compression machine

Performance Criteria 1: Adjust machine as per manufacturing order using relevant controls

Performance Criteria 2: Add bulk batch material in hopper

Performance Criteria 3: Start and adjust weight and hardness as per manufacturing order

Performance Criteria 4: Perform required in-process tests.

Performance Criteria 5: Operate machine as per job requirements and report deviation, if observed

Task 11: Check weight variation of tablets

Performance Criteria 1: Check calibration status of balance using appropriate method

Performance Criteria 2: Adjust balance using appropriate techniques

Performance Criteria 3: Take tablets for measuring weight variation test as per manufacturing order

Performance Criteria 4: Note in process reading as per procedure in manufacturing order

Performance Criteria 5: Report any deviation to in-charge

Task 12: Shift compressed tablets for coating or sorting

Performance Criteria 1: Shift core tablets after release approval from quality assurance department

Performance Criteria 2: De-dust tablets using relevant tools and appropriate methods

Performance Criteria 3: Prepare coating solution using specified techniques

Performance Criteria 4: Load core tablets in coating pan as per manufacturing order

Performance Criteria 5: Adjust coating machine parameters as per specification. Performance Criteria 6: Start coating process and check weight gain after specified interval

Performance Criteria 7: Finish coating process, when required weight is achieved

Performance Criteria 8: Polish coated tablets using specified procedure

Performance Criteria 9: Report any deviation

Portfolios required at the time of assessment (if any) for Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.

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

		(91600	606 M	anufac	ture T	ablets			
Candidate	Name:						Registr	ation/R	oll Number:	
Details	Candidate Si	gnature	:							
	COMPETENT	COMPETENT ☐ NOT YET COMPETENT ☐								
Assessmer Outcome	nt Name of the	Name of the Assessor:Assessor's code:								
	Assessor's Si	gnature	:							
	Δ	ssessn	nent Si	ımman	v (to be	filled	hy the	25555	sor)	
	Activity	1000001			Metho		by the	100000		sult
Nature of Activity			Written	Oral	Observation	ortfolio	Role Play		Competent	Not Yet Competent
Practical S	skill Demonstratio	n	_>			α_	<u> </u>			2 0
Knowledge	e Assessment									
Another R	equirement									
		Г								
Assessn	nent Task 1		•	of asse aterials	ssmen S	t task :	1			
_	During the practical assessment, candidate demonstrated the following:				ated	Yes	No	Remarks		
				n of						
materials against manufacturing order				20.00=			4			
 Performance Criteria 2: Sieve and add materials as per manufacturing order 				as per						
	-				per			_		
manufacturing order				<u> </u>						
	erformance Criteri		cord all	necessa	ary entr	ies as				
	er manufacturing		no=1 1-	the !=	ob e ====	ob ovit			_	
	erformance Criter		-	uie in-0	marge	auout				
a	any deviation for quick response						ı	ı	I	

Not Yet Competent □

Competent □

Assessment Task 2 Perform Slugging (in case			ing (in case of	dry g	ranula	ition)
During the practical assessment, candidate demonstrated the following:				Yes	No	Remarks
1	Performance Criteria 1: Install required sieve as per manufacturing order in compactor granulator					
2		formance Criteria 2: Shift materials in compactor nulator as per manufacturing order				
3	3 Performance Criteria 3: Start granulator and adjust rollers for proper flack size as per manufacturing order					
4		rformance Criteria 4: Collect dry granules after mpletion of process as per manufacturing order				
5	Performance Criter any deviation for qu	•	n-charge about			
Competent □ Not Yet Com			petent			

Asses	ssment Task 3	Perform wet mixing				
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks	
1	Performance Crite manufacturing orde	•	ia 1: Prepare binder solution as per r			
2		ria 2: Mix binder solut t mass as per manufa	•			
3		ria 3: Start mixing h as per manufacturi				
4.		ria 4: Check end poi to the in-charge abo				
Comp	etent 🗆		Not Yet Comp	etent		

Asses	ssment Task 4	Perform wet granu	lation			
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks	
1.	Performance Crite	Performance Criteria 1: Install required mesh size in				
	the wet granulator	e wet granulator as per manufacturing order				
2	Performance Crite	ria 2: Shift and pas	s the wet mass			
	through granulator	h granulator				
3	Performance Crite	Criteria 3: Report to the in-charge about				1
	any deviation					
Competent □ Not Yet Com			petent	: 🗆		

Assessn	nent Task 5	Collect Wet Granules and Dry			
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks
1	Performance Criteria 1: Collect wet granules for drying as per specifications given in manufacturing order				
2	Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order				
3	Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process				
4	Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure				
Compete	ent 🗆				

Assess	ment Task 6	Perform Dry Granu	ılation				
_	the practical assestrated the follow	essment, candida ⁄ing:	ite	Yes	No	Remarks	
1.	Performance Crite case of slug)	eria 1: Collect dry granules/flacks (in					
2		Performance Criteria 2: Shift dry granules/flacks for required sizing as per manufacturing order					
3		rformance Criteria 3: Inform section in-charge for d point confirmation of granulation					
Compe	tent 🗆		Not Yet Com	petent			

Assessr	ment Task 7	Perform Sieving (N	lesh)			
		1				
_	the practical asset trated the follow	essment, candida ing:	te	Yes	No	Remarks
1.		eria 1: Pass materia manufacturing order	•			
2		e Criteria 2: Record all necessary entries rements of Manufacturing order				
3	Performance Crite any deviation	ria 3: Report to the i	in-charge about			
Competent ☐ Not Yet Com			petent			

Asses	SSMENT Task 8 Perform Final Mixing			
During the practical assessment, candidate demonstrated the following:			No	Remarks
1	Performance Criteria 1: Identity materials for fin mixing against manufacturing order	al		
2	Performance Criteria 2: Add material as p manufacturing order	er		
3	Performance Criteria 3: Perform final mixing of bate material as per manufacturing order	:h		
4	Performance Criteria 4: Enter all necessary entries a per manufacturing order	ıs		
5 Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order				
Competent □ Not Yet Com			t 🗆	

Asses	ssment Task 9 Shift	: Material to Compression	n Room			
During the practical assessment, candidate demonstrated the following:			,	Yes	No	Remarks
1	Performance Criteria 1	• • • • • • • • • • • • • • • • • • • •	from			
	concerned section in-cha					
2	Performance Criteria 2:		ifting			
	material to compression	ssion room for next process				
3	Performance Criteria 3: F	Perform weight and reco	rd of			
	received materials as per	r specifications				
4	Performance Criteria 4:	Place material on pa	allets			
	using appropriate and sa	nd safe methods.				
5	Performance Criteria 5: F	a 5: Report any deviations, if any,				
	during shifting process to	avoid loss.				
Competent ☐ Not Yet Com			Compe	etent		

Asses	Start Compression	Machine			
•	g the practical assessment, candid nstrated the following:	ate	Yes	No	Remarks
1	Performance Criteria 1: Adjust mac manufacturing order using relevant cont	•			
2	Performance Criteria 2: Add bulk batch hopper	ch material in			
3	Performance Criteria 3: Start and adju- hardness as per manufacturing order	st weight and			
4	Performance Criteria 4: Perform requir tests.	red in-process			
5	Performance Criteria 5: Operate machi requirements and report deviation, if ob-				
Comp	petent	Not Yet Comp	etent		

Asse	ssment Task 11	Check Weig	ght Variation o	f Table	ets		
	ng the practical ass		ındidate		Yes	No	Remarks
demo	onstrated the follow	ving:					
1	Performance Crite	ria 1: Check	calibration sta	tus of			
	balance using appr	opriate method	I				
2	Performance Criter	ia 2: Adjust bal	ance using appro	priate			
	techniques						
3	Performance Crite			suring			
	weight variation tes	-					
4	Performance Criter		•	ing as			
	per procedure in m						
5	Performance Criter	a 5: Report any					
Comp	petent		Not Yet Co	mpete	ent □		
Asse	ssment Task 12	Shift compres	sed tablets for co	ating or	sorting	J	
Durin	a the proptical ac	cocomont ca	didata		Т	I	Ī
	ng the practical ass onstrated the follow	•	nuiuate		Yes	No	Remarks
	Performance Criter		tablata ofter i	-lagge	<u> </u>		
1	approval from quali			eleas c			
2	Performance Crite	•		Navant	1		-
_	tools and appropria		labicis using	Hevan			
3	Performance Crite		coating solution	using	 		-
C	specified technique	•	Coating Co	uo			
4	Performance Criter		e tablets in coati	ng pan	1		-
	as per manufacturii		·	٠٠.			
5	Performance Crit		ust coating m	achine	†		
	parameters as per						
6	Performance Criter	ia 6: Start coat	ting process and	check			
	weight gain after sp						
7	Performance Crite		coating process,	when			
	required weight is a						
8	Performance Crite		coated tablets	using			
	specified procedure				<u> </u>		
9	Performance Criter	ia 9: Report an	 		<u> </u>		
Comp	petent 🗆		Not Yet C	ompet	ent □	_	
tfolio	(if any)		Description of	portfoli	0		
Curren	nt 🗆 Suffi	icient \square	Authentic \Box]	Val	lid 🗆	Reliable 🗖
tfolio r	meet the following pe	erformance sta	ndards:	Vac	NI.O.	Dou	
				Yes	No	Kei	marks
Perfo	ormance criteria for t	the evaluation	of portfolio:				
Subn	nit log book or activi	ty record (pra	ctical journal,				
	ct nictures etc.) cor	•	•				

Not Yet Competent \Box

Competent \square

Knowledge Assessment

091600606 Manufacture Tablets

Title of Quali	fication:	CS Code:	Version:							
National Voca	ational Certificate level 3,	091600606	3	1 (2019)						
In Pharmaceu	tical Manufacturing Technician									
Competency	Standard Title:	Assessment Date (DD/MM/YY):								
Manufacture		//		·						
Guidance	To complete your assessment for	this Competency St	andard, you	need to answer the						
for	questions on the following pages	successfully.								
Candidate	didate									
-										
ssessors Guid	le (to be completed by the Assesso	r and signed both by	the assessor	and the candidate af						
he assessmen	t)									
	T									
Candidate	Name:	Registrat	ion/Roll Num	ber:						
Details										
	Candidate Signature:									
	COMPETENT	NOT YET	COMPETENT							
Written										
Assessment	Name of the Assessor:									
Outcome										
	Assessor's Signature:									
	Assessor s signature		•••••	••••••						
eedback to t	he candidate on assessment.									

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

WRITTEN ASSESSMENT

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

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

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

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

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

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 3,	091600607	3	1 (2019)
In Pharmaceutical Manufacturing Technician			
	Assessment Da	ite (DD/MM/YY	·)·
Competency Standard Title:	Assessment De	ate (55) ((11))	<i>,</i> ·
Manufacture Capsules and Dry Suspension			

Candidate Details	Name Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe: 1. Assessment Task 1: Mix raw materials
Guidance for Candidate	 Assessment Task 2: Perform wet granulation Assessment Task 3: Collect wet granules and dry (If required) Assessment Task 4: Perform dry granulation (If required) Assessment Task 5: Perform final mixing Assessment Task 6: Shift material in encapsulation room for filling Assessment Task 7: Start bottle blowing & filling (dry suspension) Assessment Task 8: Capping, optical checking & labeling of bottles
	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: Mix raw materials
	Performance Criteria 1: Check identity of materials against manufacturing order Performance Criteria 2: Sieve and add materials as per manufacturing order Performance Criteria 3: Start mixing as per manufacturing order Performance Criteria 4: Record all necessary entries as per manufacturing order Performance Criteria 5: Report to the in-charge about any deviation for quick response
Minimum Evidence Required	Task 2: Perform wet granulation Performance Criteria 1: Install required mesh size in the wet granulator as performance Criteria 2: Shift and pass the wet mass through granulator
	Performance Criteria 3: Report to the in-charge about any deviation Task 3: Collect wet granules and dry
	Performance Criteria 1: Collect wet granules for drying as per specifications give in manufacturing order
	Performance Criteria 2: Transfer wet granulates reliably for completion of dryin process as per manufacturing order Performance Criteria 3: Adjust temperature of dryer as per specifications for
	completion of drying process Performance Criteria 4: Determine end point of drying process and record any

Task 4: Perform dry granulation

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

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

manufacturing order

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

Task 5: Perform final mixing

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

Performance Criteria 2: Add material as per manufacturing order

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

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

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

Task 6: Shift material to encapsulation room for filling

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

Performance Criteria 2: Adjust machine as per manufacturing order

Performance Criteria 3: Add materials in hopper as per specifications

Performance Criteria 4: Start encapsulation machine

Performance Criteria 5: Perform required in-process tests

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

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

Performance Criteria 8: Report any deviation to in-charge

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

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

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

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

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

Task 8: Capping, optical checking & labeling of bottles

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

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

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

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

Performance Criteria 5: Report any deviation from the standards to section incharge

Portfolios required at the time of assessment (if any) for Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.

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

091600607 Manufacture Capsules and Dry Suspension

r	0510	,00007	Marian	uotaic	Capsul	os anc	. D.y C	аэрсп	31011	
Candidate	Name:	Name:Registration/Roll Number:								
Details	Candidate S	ignatur	e:					•••••		
COMPETENT ☐ NOT YET COMPETENT ☐										
Assessmen Outcome	Assessor Na	Assessor Name: Ass						code:		
	Assessor's S	ignatur	e:							
	Α	ssessn	nent Su	ımmaı	ry (to be	filled	by the	assess	sor)	
	Activity				Metho		-		Res	ult
Nature of A	Written	Oral	Observation	Portfolio	Role Play		Competent	Not Yet Competent		
Practical SI	kill Demonstration	n	>	J		4	\ <u>\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\</u>		U	2 0
Knowledge	e Assessment									
_	equirement									
	•									
Assessm	ent Task 1		iption o		essmen s	t task :	1			
During the	e practical asses ing:	sment,	candid	ate de	emonstr	ated	Yes	No	Remarks	
	erformance Crite				ntificatio	n of				
	aterials against merformance Criteri				aterials a	as per			-	
	anufacturing orde		. o and (u III	acondio 6	~0 POI				
3. Pe	erformance Crite	eria 3:	Start	mix	ing as	per			1	
	manufacturing order 4. Performance Criteria 4: Record all necessary entries as								_	
	er manufacturing of		a an i	.55556	Jary Oriti	.50 40				
5. Pe	erformance Criteri	ia 5: Re	-	the in-	-charge	about			1	
an	ny deviation for qu	iick resp	onse	<u> </u>						
Competen	nt 🗆			1	Not Yet	Compe	tent 🗆			

Assessment Task 2 Perfo		Perform wet granul	ation			
During the practical assessment, candidate demonstrated the following:				Yes	No	Remarks
1.		eria 1: Install require as per manufacturin				
2	Performance Criteria 2: Shift and pass the wet mass through granulator					
3	Performance Criteria 3: Report to the in-charge about any deviation					
Competent □			Not Yet Com	petent		

Assessment Task 3 Collect Wet Granule		ules and Dry (if Required	d)	
_	the practical assessment, candidatestrated the following:	ate Ye	s No	Remarks
1	Performance Criteria 1: Collect wet gas per specifications given in manufacture.	, ,		
2	Performance Criteria 2: Transfer wet granulates reliably for completion of drying process as per manufacturing order			
3	Performance Criteria 3: Adjust temperature of dryer as per specifications for completion of drying process			
4	Performance Criteria 4: Determine end point of drying process and record any deviation faced during the whole procedure			
Compet	ent 🗆		•	

Asses	ssment Task 4	Perform Dry Gra	nulation				
	41			ı		T	
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks		
1.	Performance Criteria 1: Collect dry granules/flacks (in case of slug)						
2		eria 2: Shift dry gra per manufacturing o					
3		Performance Criteria 3: Inform section in-charge for end point confirmation of granulation					
Competent □ Not Yet Com			petent		•		

Asses	ssment Task 5	Perform Final Mix	ing				
During the practical assessment, candidate demonstrated the following:				Ye	s	No	Remarks
1	Performance Crite mixing against mar	•	terials for	final			
2	Performance Crite manufacturing orde		aterial as	per			
3	Performance Criteria 3: Perform final mixing of batch material as per manufacturing order			atch			
4	Performance Criteria 4: Enter all necessary entries as per manufacturing order			es as			
5	5 Performance Criteria 5: Inform section in-charge about final mixing for next process as per manufacturing order			J			
Comp	etent 🗆		Not Yet	Compete	ent		ı

Assessment Task 6 Shift material to encaps				n roo	m for	filling
During the practical assessment, candidate				Yes	No	Remarks
demoi	nstrated the follow	/ing:				
1	Performance Crite	eria 1: Shift	materials to			
	encapsulation area a	after release appro	val from quality			
	assurance departme	ent				
2	Performance Criter	ria 2: Adjust ma	chine as per			1
	manufacturing order	•				
3	Performance Criteria	a 3: Add materials	s in hopper as			1
	per specifications					
4	Performance Criteria	a 4: Start encapsul	lation machine			
5	Performance Criteria	a 5: Perform requ	ired in-process			
	tests	-				
6	Performance Criteria	a 6: Adjust weight	and locking as			1
	per manufacturing o	rder	_			
7	Performance Criteria 7: Make polish and sorting of		and sorting of			1
	filled capsules as pe	filled capsules as per process				
8	Performance Criter	ia 8: Report an	y deviation to			1
	person in-charge					
Comp	etent 🗆		Not Yet Comp	petent		

Assessi	ment Task 7	Start bottle blo	wing & filling	(dry sı	uspen	sion)	
_	the practical asse strated the followi	•	ate	Yes	No	Remarks	
1	Performance Criter Assurance before fi	lling of bottles					
2	Performance Criter filling line and place	it on the turn table	9				
3	Performance Crite according to the sp process	ecific bottle size ar	nd start blowing				
4	Performance Criteri nozzle according to	•	•				
Compet	ent 🗆		Not Yet Comp	petent			
Assessm	nent Task 8	Capping, optical	checking & label	ing of l	oottles		
•	ne practical asses rated the followin	•	te	Yes	No	Remarks	
1	Performance Criter machine of the lines	s according to the	speed of filling				
2	Performance Criteria 2: Check individual bottle optically in different background for all types of particles						
3	Performance Criteria 3: Adjust labeling machine according to the speed of line						
4	Performance Crite process checks as		•				
Compete	ent 🗆		Not Yet Com	petent			

Ро	rtfolio (if any)		Description of p	ortfolic	•		
	Current	Sufficient	Authentic 🛚		Vali	d 🗆	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 Compet	ent 🗆				

Title of Qua	lification:	CS Code:	Level:	Version:			
National Vo	cational Certificate level 3,	091600607	3	1 (2019)			
In Pharmace	eutical Manufacturing Technician						
Competence	y Standard Title:	Assessment D	Assessment Date (DD/MM/YY):				
-	e Capsules and Dry Suspension	//	ate (DD) IVIIVI	, 11).			
Guidance	To complete your assessment for t	his Competency S	tandard, you	need to answer the			
for	questions on the following pages s	uccessfully.					
Candidate							
	ide (to be completed by the Assessor ant)	and signed both b	y the assessor	and the candidate			
the assessme	,						
he assessme							
the assessme	Name:	Registra	tion/Roll Num	ber:			

Candidate Signature:

Assessor Name:.....Assessor's code:.....

Assessor's Signature:

NOT YET COMPETENT \square

COMPETENT \square

Written Assessment

Outcome

Candi	date Signature Assessor Signature	
Callul	uate signature Assessor signature	

Feedback to the candidate on assessment.

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

WRITTEN ASSESSMENT

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

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

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

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

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

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

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 3,	091600608	3	1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment Da	ate (DD/MM/YY	():
Manufacture Liquid Dosages			

Candidate Details	Name
	Registration/Roll Number
	To meet this standard, you are required to complete the following tasks within 40 min timeframe:
	1. Assessment Task 1: Shift the Raw Materials
	 Assessment Task 2: Prepare syrup base Assessment Task 3: Dissolve/ Soak materials in purified water according to
	procedure
0	Assessment Task 4: Manufacture syrup and suspension
Guidance for Candidate	5. Assessment Task 5: Start bottle blowing & filling
Candidate	6. Assessment Task 6: Capping, optical checking & labeling of bottles
	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: Shift the raw materials
	Performance Criteria 1: Transfer batch raw materials to liquid section. Performance Criteria 2: Check the material one by one according to the manufacturing order in the section again prior to mixing.
	Performance Criteria 3: Segregate each material according to mixing order. Performance Criteria 4: Report any deviation to section in-charge.
Minimum Evidence Required	Task 2: Prepare syrup base Performance Criteria 1: Transfer specified volume of purified water to steam
	jacketed tank.
	Performance Criteria 2: Start heating up to the required temperature.
	Performance Criteria 3: Add preservative(s) as per specification
	Performance Criteria 4: Add sucrose as per specification and continue heating to required temperature.
	Performance Criteria 5: Continue mixing until clear base is formed.
	Performance Criteria 6: Check the cleaning status of filtration assembly.
	Performance Criteria 7: Filter and transfer the base to the main Mixing tank after cooling.
	Performance Criteria 8: Report any deviation from the standards to section incharge.

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

Performance Criteria 1: Transfer specified volume of purified water to different manufacturing tanks.

Performance Criteria 2: Soak material in case of suspension and dissolve material in case of solution separately as per

manufacturing order

Performance Criteria 3: Report any deviation from the standards to section in-

charge.

Task 4: Manufacture syrup and suspension

Performance Criteria 1: Check the temperature of syrup base in the main mixing tank

Performance Criteria 2: Add the material one by one to the main mixing tank. In case of syrup the already dissolved material is also added

Performance Criteria 3: Pass suspension slurry through homogenizer and add it to main mixing tank

Performance Criteria 4: Make up and record bulk volume of syrup/suspension in main mixing tank

Performance Criteria 5: Transfer syrup through filtration assembly according to specification and suspension directly to storage tank (through homogenizer if required)

Performance Criteria 6: Start slow mixer in storage tank in case of suspension

Performance Criteria 7: Inform section in-charge about process completion

Performance Criteria 8: Seal storage tank till release from Quality Assurance after sampling

Performance Criteria 9: Any deviation from the standards must be reported to section in-charge

Task 5: Start bottle blowing & filling

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

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

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

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

Task 6: Capping, optical checking & labeling of bottles

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

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

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

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

Performance Criteria 5: Report any deviation from the standards to section incharge

Portfolios required at the time of assessment (if any) for Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.

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

091600608 Manufacture Liquid Dosages

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

Assessment Summary (to be filled by the assessor)								
Activity			Method	ł		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 Shift the Raw Materials				1		
During the practical assessment, candidate demonstrated the following:				Yes	No	Remarks
1.	Performance Criteria 1: Transfer batch raw materials to liquid section.					
2.	·					
3.						
4. Performance Criteria 4: Report any deviation to section in-charge.						
Competent □ Not Yet Comp			tent 🗆	1		

Assessr	nent Task 2	Prepare syrup bas	se			
During t	he practical asse	ssment, candidat	е	Yes	No	Remarks
demons	trated the following	ng:		163	110	Remarks
1	Performance Criter	ria 1: Transfer speci	fied volume of			
	purified water to sto	eam jacketed tank.				
2	Performance Crite	eria 2: Start heatir	ng up to the			
	required temperatu	ıre.				
3	Performance Crite	ria 3: Add preserva	tive(s) as per			
	specification					
4	Performance Crit	eria 4: Add sucı	rose as per			
	specification and	continue heating	to required			
	temperature.					
5	Performance Crite	ria 5: Continue mix	ing until clear			
	base is formed.					
6	Performance Criter	ria 6: Check the clea	aning status of			
	filtration assembly.					
7	7 Performance Criteria 7: Filter and transfer the base to					
	the main Mixing tank after cooling.					
8	8 Performance Criteria 8: Report any deviation from the					
standards to section in-charge.						
Compete	ent 🗆		Not Yet Comp	oetent		

Assessment Task 3 Dissolve/ Soak materials in purified water according to procedure					
During the practical assessment, candidate demonstrated the following:				No	Remarks
1	Performance Criteria 1: Transfer specified volume of purified water to different manufacturing tanks.				
Performance Criteria 2: Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order					
3 Performance Criteria 3: Report any deviation from the standards to section in-charge.					
Comp	etent 🗆	Not Yet Co	mpete	nt 🗆	

Asses	Assessment Task 4 Manufacture syrup and suspension				
_	g the practical assessment, cand	date	'es	No	Remarks
demonstrated the following:		•			rtoma no
1	Performance Criteria 1: Check the	temperature of			
	syrup base in the main mixing tank				
2	Performance Criteria 2: Add the mate	rial one by one			
	to the main mixing tank. In case of sy	rup the already			
	dissolved material are also added				
3	Performance Criteria 3: Pass sus	pension slurry			
	through homogenizer and add it to ma	ain mixing tank			
4	Performance Criteria 4: Make up a	nd record bulk			
	volume of syrup/suspension in main r	nixing tank			
5	Performance Criteria 5: Transfer	syrup through			
	filtration assembly according to sp				
	suspension directly to storage	tank (through			
	homogenizer if required)				
6	Performance Criteria 6: Start slow n	nixer in storage			
	tank in case of suspension				
7	Performance Criteria 7: Inform se	ction in-charge			
	about process completion				
8	Performance Criteria 8: Seal storage	tank till release			
	from Quality Assurance after sampling	9			
9	Performance Criteria 9: Report any de	viation from the		_	
	standards to section in-charge				
Comp	etent □	Not Yet Compe	tent		

Asses	Start bottle blowing & filling			
	g the practical assessment, candidate nstrated the following:	Yes	No	Remarks
1	Performance Criteria 1: Check approval from Quality Assurance before filling of bottles			
2	Performance Criteria 2: Transfer empty bottles to filling line and place it on the turn table			
3	Performance Criteria 3: Adjust bottle blowing according to the specific bottle size and start blowing process			
4	Performance Criteria 4: Adjust the volume of individual nozzle according to manufacturing order			
Comp	etent □ Not Yet Con	petent	: 🗆	

Asses	Sament Task 6 Capping, optical of	checking & labeli	ing of b	ottles	
Duraina	the amostical accessment condi	alata			1
•	g the practical assessment, candi nstrated the following:	date	Yes	No	Remarks
1	Performance Criteria 1: Adjust cappi machine of the lines according to the				
2	Performance Criteria 2: Check in optically in different background for particles				
3	Performance Criteria 3: Adjust lab according to the speed of line	peling machine			
4	Performance Criteria 4: Perform a process checks as per manufacturing	•			
5	Performance Criteria 5: Report any de standards to section in-charge.	viation from the			
Co	ompetent □	Not Yet Co	mpet	ent 🗆	İ

Ро	rtfolio (if any)		Description of p	ortfolio)		
	Current \square	Sufficient \square	Authentic 🗆		Valid		Reliable 🗆
Ро	rtfolio meet the follov	wing performance sta	ndards:	Yes	No	Remarks	
1	Submit log book or	ria for the evaluation r activity record (pra c.) completed durin	ectical journal,				
Со	mpetent		Not Yet Compet	ent 🗆			

Knowledge Assessment

091600608 Manufacture Liquid Dosages

Title of Quali	fication:	CS Code:	Level:	Version:			
National Voca	ational Certificate level 3,	091600608	3	1 (2019)			
In Pharmaceu	itical Manufacturing Technician						
Competency	Standard Title:	Assessment Date (DD/MM/YY):					
•	Liquid Dosages	//					
Guidance	To complete your assessment for	this Competency St	andard, you	need to answer the			
for	questions on the following pages successfully.						
Candidate							
Assessors Guio	de (to be completed by the Assessor	and signed both by	the assessor	and the candidate af			
he assessmen							
	Name:	Registrat	ion/Roll Num	her:			
Candidate	No.		ion, non nam	DC1			
Details	Candidate Signature:						
	COMPETENT	NOT YET	COMPETENT				
Written							
Assessment	Assessor Name:Assessor's code:						
Outcome							
	Assessor Name:						
andhack to t	the candidate on assessment.						
-eeuback to t	ine candidate on assessment.						
							
							
Candidata Sia	nature	Assessor Signatu	re				

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 3,	091600608	3	1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MN	//YY):
Competency Standard Title: Manufacture Liquid Dosages	Assessment D	ate (DD/MN	//YY):
• •		ate (DD/MN	л/YY):

WRITTEN ASSESSMENT

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

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

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

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

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

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

Candidate	Name
Details	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: Receive packing materials for product (tablets, capsules & syrups/suspensions/parenteral) 2. Assessment Task 2: Make strip/blister packing 3. Assessment Task 3: Perform over printing 4. Assessment Task 4: Perform aluminum blister foil packaging, strip packaging/bottle packaging 5. Assessment Task 5: Make tertiary packaging for bulk handling for warehouse storage & shipping/transport
	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: Receive packing materials for product (tablets, capsules & syrups/suspensions)
	Performance Criteria 1: Check and receive printed/ unprinted aluminum Foil Roll, Pol- Vinyl Chloride (PVC) Roll, bottles, caps, vials, rubbe stoppers, flip off seals, ampoules, unit carton, spoons leaflets, cups, master cartons, labels as per packing order. Performance Criteria 2: Maintain the temperature and humidity of workplace as per requirements of specifications of manufactured product
Minimum Evidence Required	Performance Criteria 3: Check the batch number, manufacturing and expiry date against each labeled packing as per manufacturing order

Task 2: Make strip/blister packing

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

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

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

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

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

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

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

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

Task 3: Perform over printing

Performance Criteria 1: Remove all printed packaging material like labels, unit

cartons, blisters/strips etc. of the previous product

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

packaging order for printing

Performance Criteria 3: Check Batch no. expiry, manufacturing date, pack

size against packaging order for printing on the carton

or labels

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

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

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

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

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

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

Performance Criteria 5: Take approval for product to be packed

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

for proper printing

Performance Criteria 7: Removed defective printed materials immediately

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

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

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

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

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

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

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

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

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

Performance Criteria 4: Arrange each outer carton properly on staking pallet Performance Criteria 5: Deliver batch to finish goods store after release from Quality Assurance

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

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

091600609 Perform packaging as per manufacturing order					
Candidate Details		Registr			
Assessment Outcome		NOT YET COI	essor's code:		
	Assessment Summary (to be filled by the assessor)				
	A	8.6.11	5 !!		

Assessi	nent Sເ	ımmary	/ (to be	filled b	y the a	ssessor)	
Activity			Method	ł		Res	sult
Nature of Activity	Written	Oral	Observation	Portfolio	Role Play	Competent	Not Yet Competent
Practical Skill Demonstration							
Knowledge Assessment							
Another Requirement							

Asses	sment Task 1	Description of as Receive packing r syrups/suspension	materials for prod		ablets, o	capsules &
_	the practical asses owing:	sment, candidate	demonstrated	Yes	No	Remarks
1.	Performance Criteri unprinted aluminur (PVC) Roll, bottles, seals, ampoules, u master cartons, lab	m Foil Roll, Poly caps, vials, rubber init carton, spoons	Vinyl Chloride stoppers, flip off , leaflets, cups,			
2.	Performance Criter and humidity of was specifications of ma	orkplace as per r	requirements of			
3.	Performance Criter manufacturing and packing as per mar	expiry date agains	•			
4.	Performance Criter manually or electron manufacturing orde	nically as per specif				
5.	Performance Criterial after completion of		ection in-charge			
Compe	etent 🗆		Not Yet Compe	etent 🗆	l	

Assessn	nent Task 2	Make strip/blister	packing			
During t	he practical asses	ssment, candida	te	Yes	No	Remarks
demons	trated the following	ng:		163	NO	Remarks
1	Performance Crit	eria 1: Prepared	l label area,			
		ners for strip packi	,			
		given in the packing				
2		ria 2: Checked & sigi	•			
	•	he machine and m	ake necessary			
	entries in the log bo					
3		eria 3: Received	• •			
	section in-charge		packing of			
	manufactured prod					
4	Performance Crit					
	•	orm the following ch				
	,	No., Manufacturing				
	•	nit dose per blister/s	strip			
	,	of blister/ strip				
	,	ase label on the bu				
5		eria 5: Informed th				
	,	oty blisters/strips for				
6		ria 6: Started the bli				
		er passing the leak to	est for empty &			
	filled.					
7		ria 7: Checked the	•			
		process and shift the	•			
		packaging as per sp				
Compete	ent 🗆		Not Yet Comp	petent		

Assess	ment Task 3	Perform Over prir	nting			
_	the practical asses	•	e	Yes	No	Remarks
				103	140	Kemarks
1		ria 1: Removed all pr s, unit cartons, bliste ct				
2		eria 2: Checked th I as per packaging o				
3		eria 3: Checked ba e, pack size against p carton or labels	• •			
4	Performance Crite to avoid any wasta	ria 4: Performed in ge	process checks			
Com	petent 🗆		Not Yet Co	mpete	nt 🗆	

Asses	Sement Task 4 Perform aluminum blister fo	il packaging	, strip	packaging/ bottle packaging
During	g the practical assessment, candidate	Yes	No	Remarks
demoi	nstrated the following:	163	140	Kemarks
1	Performance Criteria 1: Removed all prin	nted		
	packaging material like labels, unit cart	ons,		
	blisters/strips etc. of the previous product			
2	Performance Criteria 2: Checked correct packa			
	material as per packing order is received	for		
	concerned batch			_
3	Performance Criteria 3: Received blisters/st	rips,		
	bottles, printed cartons, printed labels of product			
4	Performance Criteria 4: Check batch.	no.		
	manufacturing date, expiry and pack size			_
5	Performance Criteria 5: Took approval for produc	ct to		
	be packed	,		_
6	Performance Criteria 6: Checked labels, car	tons		
	blister/blisters etc. for proper printing	0 t 0 d		4
7	Performance Criteria 7: Removed defective print materials immediately	ntea		
8	Performance Criteria 8: Brought the cartons, lab	oolo		_
٥	blisters for sorting in a tray & labelled it as	*		
	Sorting"	1 01		
9	Performance Criteria 9: Collected all the reje	cted		-
	cartons, labels, blisters in a tray, and labelled i			
	"REJECTED"			
10	Performance Criteria 10: Collect cartons, lab	pels,		
	blisters/strips in a separate tray and label it as "Re	-		
	for use"			
11	Performance Criteria 11: Shifted only ready for	use		1
	cartons, labels for packaging on belt			
12	Performance Criteria 12: Took blisters/strips, bo	ottle,		
	ampoule, and vial according to the unit carton	and		
	inserted pack.			
Comp	etent Not Yet 0	Competent		

Asses	Ssment Task 5 Make tertiary pack	kaging for bulk har	ndling fo	or warel	nouse storage & shipping/transport
	g the practical assessment, candidat	е	Yes	No	Remarks
demo	nstrated the following:				
1	Performance Criteria 1: Placed required n	umber of packs			
	in the master carton as per packing order.				
2	Performance Criteria 2: Sealed each	master carton			
	properly with sealing carton tape.				
3	Performance Criteria 3: Checked each mas	ster carton label			
	before pasting it on each sealed maste	r carton for its			
	product name, manufacturing date, expir	ry date, master			
	cartons no., quantity of units & packaging	date			
4	Performance Criteria 4: Arranged each	n outer carton			
	properly on staking pallet				
5	Performance Criteria 5: Delivered batch	to finish goods			
	store after release from Quality Assurance	•			
Comp	etent □	Not Yet Comp	petent		

Ро	rtfolio (if any)		Description of p	ortfolio)		
	Current \square	Sufficient \square	Authentic \Box		Valid		Reliable 🗆
Ро	rtfolio meet the fo	llowing performance sta	ndards:	Yes	No	Remarks	
1	Submit log book	iteria for the evaluatior k or activity record (pra s etc.) completed durin	ctical journal,				
Со	mpetent 🗆		Not Yet Compet	ent 🗆	_		

Knowledge Assessment

for

Candidate

Title of Quali	fication:	CS Code:	Level:	Version:
National Voca	ational Certificate level 3,	091600609	3	1 (2019)
In Pharmaceu	itical Manufacturing Technician			
Competency	Standard Title:	Assessment Da	te (DD/MM/YY):	
Perform pag	rm packaging as per manufacturing//			
order				
Guidance	To complete your assessment for this	Competency Sta	andard, you need	to answer the

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

questions on the following pages successfully.

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

-		
-		
-		
_		
Candid	late Signature Assessor Signature	

Feedback to the candidate on assessment.

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

WRITTEN ASSESSMENT

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

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

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

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

Candidate	
Details	Name:
	Registration/Roll Number:

	Portfolios required at the time of assessment (if any) for
Minimum	Performance criteria for the evaluation of portfolio:
Evidence	Submit log book or activity record (practical journal, project, pictures etc.)
Required	completed during the training.

To meet this standard, you are required to complete the following activities within 04 Hrs. time frame (for practical demonstration & assessment):

• Complete project of manufacturing of oral dosage forms (tablets, capsule, dry suspension and liquids) as per standardized criteria keeping considering workplace place safety and taking appropriate measures.

And complete:

- 1. Knowledge assessment test (Written or Oral).
- 2. Portfolios at the time of assessment (if any).

Guidance for Complete

Candidate

During a practical assessment, under the observation by an assessor, you are required to

Complete project of manufacturing of oral dosage forms (tablets, capsule, dry suspension and liquids) as per standardized criteria keeping considering workplace place safety and taking appropriate measures

Demonstrating the following criteria:

- 1. Performance Criteria 1: Check identification of materials against manufacturing order
- 2. Performance Criteria 2: Sieve and add materials as per manufacturing order
- 3. Performance Criteria 3: Prepare binder solution as per manufacturing order
- 4. Performance Criteria 4: Mix binder solution with powder mixture to form wet mass as per manufacturing order and check end point
- 5. Performance Criteria 5: Install required mesh size in the granulator as per manufacturing order
- 6. Performance Criteria 6: Adjust temperature of dryer as per specifications for completion of drying process

- Performance Criteria 7: Determine end point of drying process
 Performance Criteria 8: Perform final mixing of batch material as per manufacturing order
 Performance Criteria 9: Enter all necessary entries as per manufacturing order
- 9. Performance Criteria 9: Enter all necessary entries as per manufacturing orde
- 10. Performance Criteria 10: Adjust machine as per manufacturing order using relevant control measures
- 11. Performance Criteria 11: Start tablet compression machine and adjust weight and hardness as per manufacturing order
- 12. Performance Criteria 12: Start coating process and check weight gain after specified interval
- 13. Performance Criteria 13: Start encapsulation machine
- 14. Performance Criteria 14: Adjust bottle-filling, capping and sealing machine of the production according to speed of filling.
- 15. Performance Criteria 15: Soak material in case of suspension and dissolve material in case of solution separately as per manufacturing order
- 16. Performance Criteria 16: Start slow mixer in storage tank in case of suspension.
- 17. Performance Criteria 17: Perform required in-process controls as per manufacturing order of the product.
- 18. Performance Criteria 18: Start strip/blistering operation and perform the following checks:
 - e) Set Batch No., Manufacturing & expiry dates
 - f) Count of unit dose per blister/strip.
 - g) Alignment of blister/ strip

Self-Assessment Checklist

Candidate Name			
Registration No.			
Qualification	National Vocational Certificate Level – 3 in Pharmac Technician	ceutical Manu	ıfacturing
Purpose of Assessment	Summative Assessment		
Assessment Task	 Complete project of manufacture tablets as keeping in view workplace place safety by takin Knowledge Assessment 	•	
can			
Porformanco Critoria		V	A1 -

Perf	ormance Criteria	Yes	No
P1.	Check identification of materials against manufacturing order		
P2.	Sieve and add materials as per manufacturing order		
P3.	Prepare binder solution as per manufacturing order		
P4.	Mix binder solution with powder mixture to form wet mass as per manufacturing order and check end point		

P5. Install req	uired mesh size in the granulator as per manufacturing					
	nperature of dryer as per specifications for completion of					
	e end point of drying process					
P8. Perform fi	nal mixing of batch material as per manufacturing order					
	ecessary entries as per manufacturing order					
	chine as per manufacturing order using relevant controls					
_	et compression machine and adjust weight and hardness					
as per ma	nufacturing order					
P12. Start coat	ng process and check weight gain after specified interval					
P13. Start enca	psulation machine					
P14. Adjust bot speed of f	tle filling, capping and sealing machine according to illing					
P15. Soak mate	erial in case of suspension and dissolve material in case of eparately as per manufacturing order					
	mixer in storage tank in case of suspension					
	equired in-process controls as per manufacturing order					
	/blistering operation and perform the following checks:					
•	et Batch No., Manufacturing & expiry dates					
	ount of unit dose per blister/strip					
	ignment of blister/ strip					
Date:	Assessor's Signature ent Guide (to be completed by the Assessor and signed bot	h by the asses:	sor and the cand			
after the assessm	ent)					
National Vocatio	nal Certificate Level – 3 in Pharmaceutical Manufacturing	Technician				
Candidate	Name: Registration	n/Roll Number	:			
Details	Candidate's Signature:					
	COMPETENT□ NOT YET CO	OMPETENT				
Assessment	Name of the Assessor: Assessor's code:					
Outcome	Signature of the					
1	Assessor:	• • • • • • • • • • • • • • • • • • • •				

Assessm	Assessment Summary (to be filled by the assessor)						
Activity		I	Method	i		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)				
Asse	ssessment Task Description of assessment task			t task	
Complete				t of	manufacture tablets as per
standardized criteria keepi					eping in view workplace place
safety by taking appropriate measures					ate measures
Duri	ng the practical assessment, candidate demons	strated the	Yes	No	Remarks
follo	owing:		163	INO	Remarks
1	Performance Criteria 1: Checked identification	of materials			
_	against manufacturing order				
2	Performance Criteria 2: Sieved and add mate	erials as per			
2	manufacturing order				
3	Performance Criteria 3: Prepared binder solu	ution as per			
,	manufacturing order				
	Performance Criteria 4: Mixed binder so	lution with			
4	powder mixture to form wet mass as per ma	nufacturing			
	order and check end point				
5	Performance Criteria 5: Installed required mes	sh size in the			
5	granulator as per manufacturing order				
6	Performance Criteria 6: Adjusted temperature	e of dryer as			
Ü	per specifications for completion of drying pro	cess			
7	Performance Criteria 7: Determined end point	nt of drying			
,	process				
8	Performance Criteria 8: Performed final mixi	ng of batch			
Ū	material as per manufacturing order				
9	Performance Criteria 9: Entered all necessar	y entries as			
_	per manufacturing order				
10	Performance Criteria 10: Adjusted machi	ne as per			
	manufacturing order using relevant control				
	Performance Criteria 11: Started tablet of	•			
11	machine and adjust weight and hardne	ess as per			
	manufacturing order				
12	Performance Criteria 12: Started coating p	process and			
	check weight gain after specified interval				
13	Performance Criteria 13: Started encapsulation				
14	Performance Criteria 14: Adjusted bottle filling, capping				
	and sealing machine according to speed of filli				
	Performance Criteria 15: Soaked material				
15	suspension and dissolved material in case	of solution			
	separately as per manufacturing order				
16	Performance Criteria 16: Started slow mixer	r in storage			
tank in case of suspension.					
17	Performance Criteria 17: Performed required	ın-process			
	controls as per manufacturing order				

		Criteria 18: Started strip/blistering perform the following checks:					
18	a. Set Ba	atch No., Manufacturing & expiry dates of unit dose per blister/strip					
		nent of blister/ strip					
on	npetent 🗆	Not Ye	t Compe	tent l			
		Knowledge					
_	lification	National Vocational Certificate Level -	- 3 in Ph	arma	ceutical N	/lanufa	cturing Technician
	pose of essment	Summative Assessment					
Can	didate	Name:					
	ails	Registration Number:		Sig	nature:		
۸		COMPETENT NO	T YET CO	ОМРЕ	TENT		
	essment come	Name of the Assessor					
		Assessor's code:	Signa	ture:			
Ī	Portfolio (if any	у)	Descrip	otion (of portfoli	io	
	Current□	Sufficient□ Authentic□	Valid		R	Reliable	
	Portfolio meet	the following performance standards:			Yes	No	Remarks
	1	Performance criteria for the evaluation Submitted log book or activity red journal, project, pictures etc.) complet training.	cord (p	ractic	al		
	Competent \square		Not Ye	t Com	petent \square]	
		Feedback to	the C	Cano	lidate		
\mid							

date's Signature Assessor's Signature		
derstanding of the topics and their application)	Satisfactory	Not Satisfact
What is the importance of the sieving process?		
What is the importance of the mixing order?	Satisfactory	Not
	Satisfactory	Satisfact

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

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