







PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE

National Vocational Certificate Level 1

Version 1 - November, 2019





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PHARMACEUTICAL MANUFACTURING TECHNICIAN



ASSESSMENT PACKAGE
National Vocational Certificate Level 1

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 1,	091600735	1	1 (2019)		
In Pharmaceutical Manufacturing Technician					
	Assessment Date (DD/MM/YY):				
Competency Standard Title:	Assessment Da	ate (DD/MM/YY	') :		
Competency Standard Title: Adopt Good Manufacturing Practices for	Assessment Da	ate (DD/MM/YY	') :		
_ · · · · · · · · · · · · · · · · · · ·	Assessment Da	ate (DD/MM/YY	') :		

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: Apply basic GMP requirements in regard to pharmaceutical quality system 2. Assessment Task 2: Apply basic GMP requirements in regard to personal hygiene measures 3. Assessment Task 3: Apply basic GMP requirements in regard to premises and equipment 4. Assessment Task 4: Apply basic GMP requirements in regard to documentation and records 5. Assessment Task 5: Apply basic GMP requirements in regard to production, and inprocess controls 6. Assessment Task 6: Apply basic GMP requirements in regard to distribution and storage 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: Apply basic GMP requirements in regard to pharmaceutical quality system Performance Criteria 1: Follow requirements of quality system within the production Performance Criteria 2: Report to in-charge about any deviation if occur, for promp measures Task 2: Apply basic GMP requirements in regard to personal hygiene measures Performance Criteria 1: Perform proper hand washing and disinfection procedures
	before entering production. Performance Criteria 2: Report to supervisor in the case of illness. Performance Criteria 3: Remove personal articles (jewelry, watch, cell phone, etc.) before entering work area.

Performance Criteria 4: Wear Personal Protective Equipment (PPE) as per SOPs regarding hygienic measures.

Performance Criteria 5: Receive visitor following the visitors' policy.

Task 3: Apply basic GMP requirements in regard to premises and equipment Performance Criteria 1: Follow procedures for flow of personnel, material flow

and product flow

Performance Criteria 2: Fill out specifications, records, batch production records for production under supervision.

Task 4: Apply basic GMP requirements in regard to documentation and records

Performance Criteria 1: Interpret laboratory control records

Performance Criteria 2: Follow master production instructions

Performance Criteria 3: Locate documents of external origin, if needed

Performance Criteria 4: Safeguard documents and records appropriately

Task 5: Apply basic GMP requirements in regard to production, and inprocess controls

Performance Criteria 1: Follow master production instructions

Performance Criteria 2: Perform basic in-process control measurements (e.g. pH, weighing) under supervision

Performance Criteria 3: Perform basic quality control measure under supervision

Task 6: Apply basic GMP requirements in regard to distribution and storage

Performance Criteria 1: Store materials and end product appropriately

Performance Criteria 2: Use appropriate packaging materials for end product.

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)

091600735 A	dopt Good I	vianut	acturi	ng Pra	actices	tor P	harma	ceutic	al Produc	tion
Candidate Details	Name: Registration/Roll Number:									
	COMPETEN	т 🗆				N	OT YET	СОМРЕ	ETENT 🗖	
Assessment Outcome		Name of the Assessor:								
		ssess	ment S		ry (to k		by the	asses		
Α	ctivity			1	Metho	d			R	esult
Nature of Acti	Nature of Activity Observation Portfolio			Portfolio	Role Play		Competent	Not Yet Competent		
Practical Skill	Demonstratio	n								
Knowledge As	sessment									
Other Require										
Assessment Task 1 Assessment Task 1 Apply basic GMP requirements in regard to pharmaceutical quality system										
During the pridemonstrate			t, cano	lidate			Yes	No	Remarks	
	rmance Criter			requirer	ments of	quality				
	n within the pro								_	
Perfo	mance Criteria 2: Report to in-charge about any									

Not Yet Competent □

deviation if occur, for prompt measures

Competent □

Asses	sment Task 2	Apply basic GMF	P requirements	in rega	ırd to p	personal hygiene measures
During the practical assessment, candidate demonstrated the following:					No	Remarks
1	Performance Criteri washing and disinfe production.					
2	Performance Criteria 2: Report to supervisor in the case of illness					
3						
4						
5	Performance Criteria 5: Receive visitors following the visitors' policy					
Comp	etent 🗆		Not Yet Com	petent		

Asses	ssment Task 3	Apply basic GN	IP requirements	in reg	ard to	premises and equipment
During the practical assessment, candidate demonstrated the following:			Yes	No	Remarks	
1		formance Criteria 1: Follow procedures for flow of sonnel, material flow and product flow.				
2		teria 2: Fill out specifications, records, ecords for production under supervision.				
Competent □ Not Yet Com		petent				

Asse	ssment Task 4	Apply basic GMF	sic GMP requirements in regard to documentation and records				
Durin	g the practical as	ssessment, candi	date				
	onstrated the follo			Yes	No	Remarks	
1	Performance Crite records	eria 1: Interpret labora	tory control				
2	Performance Criteria 2: Follow master production instructions					-	
3	Performance Criteria 3: Locate documents of external origin, if needed						
4	Performance Criteria 4: Safeguard documents and records appropriately						
Comp	petent 🗆	_	Not Yet Con	npetent			

Assessment Task 5 Apply basic GM controls			requirements	in rega	rd to p	roduction, and in-process
During the practical assessment, candidate demonstrated the following:					No	Remarks
1	Performance Criteria 1: Follow master production instructions					
2	Performance Criteria 2: Perform basic in-process control measurements (e.g. pH, weighing) under supervision					
Performance Criteria 3: Perform basic quality control measure under supervision						
Competent □ Not Yet Competent □						

Asses	Assessment Task 6 Apply basic GMP requirements in regard to distribution and storage					istribution and storage
•	During the practical assessment, candidate demonstrated the following:					
1	Performance Criteria 1: Store materials and end product appropriately					
2	Performance Crite materials for end pro	ance Criteria 2: Use appropriate packaging sfor end product				
Competent □			Not Yet Com	petent		

Portfoli	o (if any)	Description of I	portfolic)	
Current	□ Sufficient □ Authentio	c□ Valid □		Relia	ble 🗆
Portfolio meet the following performance standards:			Yes	No	Remarks
Performance criteria 1 for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.					
Compet	tent \square	Not Yet Compe	tent 🗆	•	

Knowledge Assessment

		T-				
Title of Quali	fication:	CS Code:	Level:	Version:		
National Voc	ational Certificate level 1,	091600735	1	1 (2019)		
In Pharmaceu	utical Manufacturing Technician					
Competency	Standard Title:	Assessment D	ate (DD/MM/Y	Y):		
Adopt Good	d Manufacturing Practices for	//				
Pharmaceu	tical Production					
Guidance for	To complete your accessment for th	ria Campatana.	Ctondoud vo	and to one way the		
Candidate	To complete your assessment for the questions on the following pages su	•	standard, you r	ieed to answer the		
Candidate	questions on the following pages st	accessiumy.				
Assessors G the assessm	guide (to be completed by the Assessor anent)	and signed both	by the assessor	and the candidate after		
Candidate						
Details	Name:	Registratio	n/Roll Number	·		
	Candidate Signature:					
	COMPETENT ☐ NOT YET COMPETENT ☐					
Written						
Assessment						
Outcome	Assessor Name:	Assessor's	code:			
	Assessor signature:					
Feedback t	to the candidate on assessment.					
Candidate S	ignature A	ssessor Signatu	re			

Title of Qualification:	CS Code:	Level:	Version:
National Vocational Certificate level 1,	091600735	1	1 (2019)
In Pharmaceutical Manufacturing Technician			
Competency Standard Title:	Assessment D	ate (DD/MM	/YY):
Adopt Good Manufacturing Practices for Pharmaceutical	//		
Production			

WRITTEN ASSESSMENT

Que	stion	Candidate's answer
1.	What are the responsibilities of the quality management system?	
2.	Describe some critical deviations during production process?	
3.	How to control cross- contamination in regard to personal hygiene?	
4.	What is the importance of medical certificates?	

Question		Candidate's answer
5.	What is the significance of documentation and records?	
6.	What is a clean room in pharmaceutical manufacturing?	
7.	Define the significance of materials & personnel flow?	
8.	What is the significance of in process checks?	

Title of Qualific	ation:	CS Code:	Level: 1	Version:			
-	onal Certificate level 1,	0916PHR02		1 (2019)			
In Pharmaceution	cal Manufacturing Technician						
Competency Sta	andard Title:	Assessment Da	ate (DD/MM/Y	Y):			
National Vocati	onal Certificate Level – 1 in Pharmaceutical						
Manufacturing Attendant							
Candidate							
Details	Name:						
	Registration/Roll Number:						
	To meet this standard, you are required to	complete the fo	llowing within	03 Hours (for			
	practical demonstration & assessment):						
	1. Assessment Task: In a given situation t	0					
Guidance for	"Apply basic cGMP requirements in regard to	o the pharmaceu	ıtical quality sys	stem, personal			
Candidate	hygiene measures, premises and equipmer						
carraidate	observing personal safety"						
	And complete:						
	3. Knowledge assessment test (Writte	-					
	4. Portfolios at the time of assessmen						
	During a practical assessment, under observ	ation by an asse	ssor, you are re	equired to			
	Apply basic cGMP requirements in regard to the pharmaceutical quality system,						
	personal hygiene measures, premises and equipment, quality control and in-process						
	controls by observing personal safety"						
	demonstrating the following criteria:						
Minimum	Performance Criteria 1: Wear gown and Personal Protective Equipment (PPE) as per job description						
Evidence	Performance Criteria 2: Deal with problems which are within your control,						
Required	and report those that cannot be resolved to safety officer						
	3. Performance Criteria 3: Keep wo						
	store tools or equipment as per incident	procedure of th	e industry to av	old any			
	4. Performance Criteria 4: Follow r	equirements of	the quality syst	em within the			
	production						
	5. Performance Criteria 5: Perform	•	ashing and disir	nfection			
	procedures before entering pro 6. Performance Criteria 6: Follow p		ow of nersonne	el material			
	flow and product flow	J. J. C. C. G. 101 11	ow or personne	.i, iliaccital			
	·						

Performance criteria for the evaluation of portfolio: Submit log book or activity record (practical journal, project, pictures etc.) completed during the training.

Self-Assessment Checklist

Cand	lidate Name					
Regis	stration No.					
Qual	ification	National Vocational Certificate Level – 1 in Pharmac Attendant	ceutical Manu	facturing		
· ·	ose of ssment	Summative Assessment				
Assessment Task		Apply basic cGMP requirements in regard to the pharmaceutical quality system, personal hygiene measures, premises and equipment, quality control and inprocess controls by observing personal safety • Knowledge Assessment				
l can						
Perf	ormance Criteria	a .	Yes	No		
		-				
P1.	Wear gown an description	d Personal Protective Equipment (PPE) as per job				
P2.	•	lems which are within your control, and report those resolved to safety officer				
P3.	•	a clean and clear of obstructions and store tools or per industry procedure to avoid any incident				
P4.	Follow require	ments of quality system within the production				
P5.	Perform prope entering produ	r hand washing and disinfection procedures before action				
P6.	Follow procedu					
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 – 1 in Pharmaceutical Manufacturing Attendant

Candidate Details	Name: Candidate's Signature:	
Assessment Outcome	COMPETENT Assessor Name:	NOT YET COMPETENT□Assessor's code:
	Assessor's Signature:	

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

Each	Assessment Task (with performance criteria)					
Assessment Task		Description of assessment task				
		Apply basic GMP requirements in regard to the				
		pharmaceutica	al qua	lity s	ystem, personal hygiene	
		measures, premises and equipment by observing				
		personal safet	y.			
Durir	ng the practical assessment, candidate demor	nstrated the				
follo	wing:		Yes	No	Remarks	
4	Performance Criteria 1: Worn gown and Personal					
1	Protective Equipment (PPE) as per job					
	Performance Criteria 2: Dealt with problems which are					
2	within your control, and reported those that cannot be					
	resolved to safety officer					
	Performance Criteria 3: Kept work area clean and clear of					
3	obstructions and stored tools or equipment as per industry					
	procedure to prevent any incident					
4	Performance Criteria 4: Followed requirements of quality					
4	system within the production					
5	Performance Criteria 5: Performed proper hand washing					
5	and disinfection procedures before entering	gproduction				
6	Performance Criteria 6: Followed procedures for flow of					
0	personnel, material flow and product flow					
Competent □		Not Yet Compe	tent 🗆			

Knowledge Assessment

Qualification	National Vocational Certi Attendant	National Vocational Certificate Level – 1 in Pharmaceutical Manufacturing Attendant				
Purpose of Assessment	Summative Assessment	Summative Assessment				
Candidate Details	Name:	Name:				
	Registration Number:	Registration Number:Signature:				
	COMPETENT	COMPETENT NOT YET COMPETENT				
Assessment Outco	Assessor Name					
	Assessor's code:	Sign	nature:			
Portfolio (if any)		Description of	portfoli	0		
Current□	Sufficient□ Authentic□	Valid□		Reliable	e 🗆	
Portfolio meet the	following performance standar	ds:	Yes	No	Remarks	
Performance criteria for the evaluation Submitted log book or activity rejournal, project, pictures etc.) complete training.		record (practical				
Competent		Not Yet Compe	tent 🗆			
	Feedba	ick to the Can	ndida	te		
Candidate's Signature		Assessor's S	Signatu	re		

 $\textbf{Questions} \ (\textbf{Candidate confidently answered questions correctly and demonstrated}$

understanding of the topics and their application)

Not

Satisfactory

Satisfactory

1.	Name any three safe working conditions?		
2.	List down Good attitudes that may contribute to good practices at the work environment?	Satisfactory	Not Satisfactory
3.	Name and explain three common hazards found at the workplace?	Satisfactory	Not Satisfactory
4.	List any three precautions to follow when working with dangerous substances?	Satisfactory	Not Satisfactory

5.	Name any three general duties that employees have to comply regarding health and safety?	Satisfactory	Not Satisfactory

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