

Qualification Pack



Production Machine Operator-Non-Sterile Formulation

Electives: Hard gelatin Capsule Filling/ Packaging- Tablet & Capsules

QP Code: LFS/Q1202 Instantiated QP Code: LFS/Q1202-SI007

Version: 3.0

NSQF Level: 4

Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar
New Delhi-110057 || email:SHIVI.CHAUDHARY@LSSSDC.IN



Qualification Pack

Contents

LFS/Q1202-SI007: Production Machine Operator-Non-Sterile Formulation	3
<i>Brief Job Description</i>	3
Applicable National Occupational Standards (NOS)	3
<i>Compulsory NOS</i>	3
<i>Elective 1: Hard gelatin Capsule Filling</i>	3
<i>Elective 2: Packaging- Tablet & Capsules</i>	4
<i>Qualification Pack (QP) Parameters</i>	4
LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations	6
LFS/N1201: Prepare machines and perform pre-production check for drug Production	10
LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	15
LFS/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations	21
LFS/N0113: Ensure a hygienic and clean work area to avoid contamination	27
LFS/N0268: Perform Reporting and documentation with Data Integrity	32
LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors	36
DGT/VSQ/N0102: Employability Skills (60 Hours)	42
LFS/N1207: Perform Hard-gelatin Capsule Filling Operations	50
LFS/N1209: Perform blister/ strip packaging of Tablet and Capsules	55
LFS/N1210: Perform dosage container packaging of Tablet and Capsules	62
Assessment Guidelines and Weightage	68
<i>Assessment Guidelines</i>	68
<i>Assessment Weightage</i>	69



Qualification Pack

LFS/Q1202-SI007: Production Machine Operator-Non-Sterile Formulation

Brief Job Description

The production machine operator Non Sterile Formulation program enables the learner to be able to meet the job responsibilities of production machine operator for operating the machines for production and packaging, while following Good Manufacturing Practices for the manufacturing/packaging of non-sterile drug formulations and Nutraceuticals. The program shall be able to develop learner to perform in-process quality checks to verify that the output in batch manufacturing/ continuous manufacturing the quality parameters are met. He/ she shall also be able to generate and maintain the critical records for every activity performed in compliance with data integrity rules. The Program shall also enable engineering skills in the learners to maintain the semi-automated and automated plant equipment and troubleshoot and resolve primary level simple engineering problems to ensure minimal breakdown of the production line.

Personal Attributes

The individual should have good communication skills in the regional language and able to comprehend the instructions and process documents in the English language. He/she should have good analytical skills. The job holder should be able to give attention to detail and understand the criticality of work.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations](#)
2. [LFS/N1201: Prepare machines and perform pre-production check for drug Production](#)
3. [LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area](#)
4. [LFS/N0265: Maintain compliance with current Good Manufacturing Practices \(cGMP\) and other regulations](#)
5. [LFS/N0113: Ensure a hygienic and clean work area to avoid contamination](#)
6. [LFS/N0268: Perform Reporting and documentation with Data Integrity](#)
7. [LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors](#)
8. [DGT/VSQ/N0102: Employability Skills \(60 Hours\)](#)

Electives(mandatory to select at least one):

Elective 1: Hard gelatin Capsule Filling



Qualification Pack

This elective is for operators involved in Hard gelatin Capsule filling

1. [LFS/N1207: Perform Hard-gelatin Capsule Filling Operations](#)

Elective 2: Packaging- Tablet & Capsules

This elective is for operators involved in Packaging of Tablets and Capsules

1. [LFS/N1209: Perform blister/ strip packaging of Tablet and Capsules](#)
2. [LFS/N1210: Perform dosage container packaging of Tablet and Capsules](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
Country	India
NSQF Level	4
Credits	18
Aligned to NCO/ISCO/ISIC Code	NCO-2015/8131.7000, NCO-2015/8131.9900
Minimum Educational Qualification & Experience	12th Class ((Science Subjects Preferred)) OR 10th grade pass plus 2-year NTC (NTC/NAC (engineering Trade)) OR Completed 1st year of diploma (after 12th) (Diploma in Pharmacy) OR Certificate-NSQF (Level 3 (Assistant- Manufacturing and Packaging (Pharma, Biologics and Medical device))) with 3 Years of experience in life sciences sector
Minimum Level of Education for Training in School	10th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA



Qualification Pack

Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	3.0
Reference code on NQR	QG-04-LS-03403-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

Under this program, there are 10 electives. 1. Which have been grouped into 3 groups for possible selection and feasible implementation. 2. Minimum One Elective is MUST to complete program credits 3. Selection of multiple electives from multiple groups is not allowed. 4. A participant can choose maximum two electives from any of the below-listed groups. Group 1 -Blending or Granulation or Compression or Coating or Hard Gelatin Capsule Filling or Packaging- Tablets and Capsules. Group 2- Soft Gelatin Capsules or Hard Gelatin Capsules Manufacturing or Hard Gelatin Capsule Filling or Packaging- Tablets and Capsules Group 3 - Liquid Oral Dosage Manufacturing ,Packaging- Oral Liquid and Nutraceuticals



Qualification Pack

LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations

Description

This NOS unit is related to discussing about Life Sciences Industry and Basics of manufacturing Operations

Scope

The scope covers the following :

- Life Sciences industry and Manufacturing Occupation
- Basics of manufacturing Operations

Elements and Performance Criteria

Life Sciences industry and Manufacturing Occupation

To be competent, the user/individual on the job must be able to:

- PC1.** discuss key insights in the life sciences sector through various market research reports
- PC2.** Identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).
- PC3.** Elaborate importance of a skilled individual in manufacturing Occupation
- PC4.** explain the role of government policies and initiatives in promoting the growth of the life sciences industry in India.

Basics of manufacturing Operations

To be competent, the user/individual on the job must be able to:

- PC5.** Comply with key regulatory requirements for manufacturing facilities (e.g., cGMP, cGLP, cGDP).
- PC6.** Ensure ethical considerations in life sciences manufacturing, including data integrity and patient safety.
- PC7.** Analyze the impact of standard quantity effect on product quality and efficacy.
- PC8.** Analyze the role of each component in ensuring efficient and compliant manufacturing operations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** Understand the Indian Life Sciences industry's key features and challenges.
- KU2.** major segments like pharmaceuticals, biotechnology, and medical devices.
- KU3.** critical role of skilled individuals in ensuring quality and safety in manufacturing.
- KU4.** various guidelines like current Good Manufacturing Practices, current Good Storage Practices, Good Documentation Practices
- KU5.** basics of ALCOA Principles, data integrity and information security rules



Qualification Pack

- KU6.** methods to conserve water and energy
- KU7.** methods to minimize the pollution
- KU8.** how government policies and initiatives drive industry growth.

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications
- GS4.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS5.** use team-building skills while dealing with teammates
- GS6.** apply problem-solving skills to find solutions for deviations found during process-related checks, non-conformities in standards and labeling
- GS7.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and when to deal with a process error individually, depending on the type of concern
- GS8.** apply customer centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate impact of wrongdoings
- GS9.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations



Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Life Sciences industry and Manufacturing Occupation</i>	20	-	5	5
PC1. discuss key insights in the life sciences sector through various market research reports	-	-	-	-
PC2. Identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC3. Elaborate importance of a skilled individual in manufacturing Occupation	-	-	-	-
PC4. explain the role of government policies and initiatives in promoting the growth of the life sciences industry in India.	-	-	-	-
<i>Basics of manufacturing Operations</i>	20	30	10	10
PC5. Comply with key regulatory requirements for manufacturing facilities (e.g., cGMP, cGLP, cGDP).	-	-	-	-
PC6. Ensure ethical considerations in life sciences manufacturing, including data integrity and patient safety.	-	-	-	-
PC7. Analyze the impact of standard quantity effect on product quality and efficacy.	-	-	-	-
PC8. Analyze the role of each component in ensuring efficient and compliant manufacturing operations	-	-	-	-
NOS Total	40	30	15	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0274
NOS Name	Discuss about Life Sciences Industry and Basics of manufacturing Operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	1.00
Version	1.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025



Qualification Pack

LFS/N1201: Prepare machines and perform pre-production check for drug Production

Description

This NOS unit is about a Machine Operator carrying out pre-production checks and trial run for compliance with qualitative and quantitative specifications of drug

Scope

The scope covers the following :

- material check
- pre-production safety check
- prepare machine for production

Elements and Performance Criteria

Material Check

To be competent, the user/individual on the job must be able to:

- PC1.** ensure stocks of required materials are ready and available as per minimum stock required
- PC2.** ensure that critical starting material, raw material, excipients, packing material from a respective batch are analyzed by QC & approved by QA
- PC3.** match the batch code/item code , Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO (First in First Out)
- PC4.** perform visual inspection of material for signs of contamination and bloom
- PC5.** measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size, and weight)
- PC6.** return the unused material to warehouse with the appropriate label

Pre-production Safety check

To be competent, the user/individual on the job must be able to:

- PC7.** follow safe working instructions as per SOP/ batch record and MSDS chemical handling guidelines
- PC8.** use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury
- PC9.** ensure that the lift/ejection/slide/pneumatic valve mechanism of the reactor is properly functioning
- PC10.** ensure that the nozzle/valve mechanism of the utilities are properly functioning
- PC11.** perform job safety analysis in accordance with international/national standards

Prepare Machine for Production

To be competent, the user/individual on the job must be able to:

- PC12.** follow product changeover cleaning procedure
- PC13.** check for any pending preventive maintenance & breakdown work



Qualification Pack

- PC14.** ensure that all instruments/ machines are calibrated & validated
- PC15.** ensure that facilities & equipment are qualified by QA post cleaning validation and equipment validation
- PC16.** keep all the accessories like cleaning sample aids, tool kit available
- PC17.** set critical parameters for the machine based on machine history
- PC18.** perform trial run and random tests to ensure accuracy
- PC19.** maintain electronic documentation for the trial runs and random test along with justifications for any wrong entries as applicable

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** organizational SOPs relevant to machine operations and production process
- KU2.** purpose of in process checks and their procedures
- KU3.** SOP for change request and maintenance of machine
- KU4.** procedures for documentation, reporting and escalation
- KU5.** relevant Data integrity rule, cGMP and ICH GMP guidelines
- KU6.** tools used for broad level checks and their operative procedures
- KU7.** common issues in machine operations and their solutions
- KU8.** procedure for changeover cleaning
- KU9.** equipment calibration process
- KU10.** process for generating electronic records
- KU11.** methods for random tests in pharma production
- KU12.** critical parameters for specific production machines

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** record and communicate details of work done to appropriate people using written report or computer based record/electronic mail
- GS2.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS3.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates
- GS4.** make decisions related to corrective maintenance and troubleshooting
- GS5.** analyse the readings of various operational variables and make informed decisions as per SOP
- GS6.** analyse any situation which needs an immediate escalation or emergency alarm



Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Material Check</i>	10	15	5	5
PC1. ensure stocks of required materials are ready and available as per minimum stock required	-	-	-	-
PC2. ensure that critical starting material, raw material, excipients, packing material from a respective batch are analyzed by QC & approved by QA	-	-	-	-
PC3. match the batch code/item code , Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the planning department, ensuring FIFO (First in First Out)	-	-	-	-
PC4. perform visual inspection of material for signs of contamination and bloom	-	-	-	-
PC5. measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size, and weight)	-	-	-	-
PC6. return the unused material to warehouse with the appropriate label	-	-	-	-
<i>Pre-production Safety check</i>	10	15	5	5
PC7. follow safe working instructions as per SOP/ batch record and MSDS chemical handling guidelines	-	-	-	-
PC8. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury	-	-	-	-
PC9. ensure that the lift/ejection/slide/pneumatic valve mechanism of the reactor is properly functioning	-	-	-	-
PC10. ensure that the nozzle/valve mechanism of the utilities are properly functioning	-	-	-	-
PC11. perform job safety analysis in accordance with international/national standards	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Prepare Machine for Production</i>	10	15	3	2
PC12. follow product changeover cleaning procedure	-	-	-	-
PC13. check for any pending preventive maintenance & breakdown work	-	-	-	-
PC14. ensure that all instruments/ machines are calibrated & validated	-	-	-	-
PC15. ensure that facilities & equipment are qualified by QA post cleaning validation and equipment validation	-	-	-	-
PC16. keep all the accessories like cleaning sample aids, tool kit available	-	-	-	-
PC17. set critical parameters for the machine based on machine history	-	-	-	-
PC18. perform trial run and random tests to ensure accuracy	-	-	-	-
PC19. maintain electronic documentation for the trial runs and random test along with justifications for any wrong entries as applicable	-	-	-	-
NOS Total	30	45	13	12



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1201
NOS Name	Prepare machines and perform pre-production check for drug Production
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4
Credits	1.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area

Description

This NOS unit is about adhering with the rules and regulations related to health, safety, environment, and security in a manufacturing facility or testing/ research laboratory in life sciences sector

Scope

The scope covers the following :

- Follow health and personal hygiene protocols
- Follow safety and security procedures
- Follow emergency procedures

Elements and Performance Criteria

Follow health and personal hygiene protocols

To be competent, the user/individual on the job must be able to:

- PC1.** comply with health and personal hygiene-related protocols as per WHO standards, , revised GMP and ICH GMP guidelines
- PC2.** wash hands before entering in the production area as per SOP
- PC3.** report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person
- PC4.** follow gowning procedures while entering an environment controlled work area

Follow safety and security procedures

To be competent, the user/individual on the job must be able to:

- PC5.** comply with safety and security policies and procedures
- PC6.** use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work
- PC7.** use helmets, ropes, harness, and ladders while working at heights
- PC8.** use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools
- PC9.** report any identified breaches in safety and security policies and procedures to the designated person
- PC10.** segregate material and follow the 5S system at the storage area
- PC11.** adhere to storage and handling guidelines for hazardous material
- PC12.** identify and correct any hazards that one can deal with safely, competently and within the limits of authority
- PC13.** record the details of completed safety drills and training

Follow emergency procedures

To be competent, the user/individual on the job must be able to:



Qualification Pack

- PC14.** raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected
- PC15.** inform the concerned person immediately about every unsafe act/ incident
- PC16.** follow emergency procedures efficiently

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** individual's role and responsibilities in maintaining healthy, hygienic, safe and secure working environment
- KU2.** company's procedures and protocols for the environment, health and safety
- KU3.** relevant legislative requirements as per local laws
- KU4.** implications that any non-compliance with health, safety and security may have on individuals and the organization
- KU5.** workplace hazards in the manufacturing/ research facility in the life sciences sector and reporting procedures for unhealthy/ unsafe act/incidents, hazards and accident as per GMP
- KU6.** limits of individual responsibility for dealing with hazards
- KU7.** chemical substances, their characteristics, and required precaution and safety measures
- KU8.** gowning procedure
- KU9.** the organization's emergency procedures for different emergency situations and the importance of following these
- KU10.** evacuation procedures for employees, contract staff and visitors
- KU11.** procedure to summon medical assistance and the emergency services, where necessary
- KU12.** different types of breaches in the environment, health, safety and security and how and when to report these
- KU13.** WHO guidelines for personal hygiene
- KU14.** types of safety gears and procedure to use them
- KU15.** importance of material segregation and 5S system
- KU16.** WHO guidelines for handling and storing hazardous material

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to read instructions, guidelines, procedures, rules, and signages
- GS2.** use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the language prescribed by the company's SOP
- GS3.** apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements
- GS4.** use critical thinking skills to ascertain the breach/ compliance of EHS protocols



Qualification Pack

- GS5.** apply customer centricity to remain compliant with data integrity rules, GMP guidelines and to evaluate impact of wrongdoings
- GS6.** apply decision-making skills to make balanced judgments within the authority in different situations while dealing with hazards and breaches
- GS7.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS8.** use verbal communication skills to communicate with supervisor/ manager/ EHS Incharge or any other concerned authority clearly for escalating any emergency situation or hazard

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Follow health and personal hygiene protocols</i>	10	10	5	5
PC1. comply with health and personal hygiene-related protocols as per WHO standards, , revised GMP and ICH GMP guidelines	-	-	-	-
PC2. wash hands before entering in the production area as per SOP	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. follow gowning procedures while entering an environment controlled work area	-	-	-	-
<i>Follow safety and security procedures</i>	10	20	5	5
PC5. comply with safety and security policies and procedures	-	-	-	-
PC6. use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work	-	-	-	-
PC7. use helmets, ropes, harness, and ladders while working at heights	-	-	-	-
PC8. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
PC9. report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
PC10. segregate material and follow the 5S system at the storage area	-	-	-	-
PC11. adhere to storage and handling guidelines for hazardous material	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. identify and correct any hazards that one can deal with safely, competently and within the limits of authority	-	-	-	-
PC13. record the details of completed safety drills and training	-	-	-	-
<i>Follow emergency procedures</i>	10	10	5	5
PC14. raise the alarm and report any hazards that one is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may be affected	-	-	-	-
PC15. inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
PC16. follow emergency procedures efficiently	-	-	-	-
NOS Total	30	40	15	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0112
NOS Name	Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations

Description

This NOS unit is about maintaining compliance with current Good Manufacturing Practices (cGMP) and other regulations

Scope

The scope covers the following :

- GMP compliance in production process
- GMP compliance in waste management
- GMP compliance in machine maintenance
- GMP compliance in documentation
- Environment sustainability

Elements and Performance Criteria

GMP compliance in production process

To be competent, the user/individual on the job must be able to:

- PC1.** perform the cleaning of machine in compliance with cGMP guidelines and SOP
- PC2.** monitor environmental conditions in production area as per SOP and cGMP guidelines
- PC3.** perform and record pre-production checks, job safety analysis
- PC4.** ensure adherence to Good Manufacturing Practices related to equipment operations
- PC5.** perform the specific in-process production checks as directed in SOPs
- PC6.** comply with the appropriate cGMP rules for the batch change over procedure

GMP Compliance in waste management

To be competent, the user/individual on the job must be able to:

- PC7.** comply with the appropriate environmental rules and organizational SOP for the waste management and disposal
- PC8.** perform waste segregation and generate record for the same
- PC9.** perform waste disposal under supervision and ensure Effluent treatment and solvent recycling procedures under supervision

GMP compliance in equipment maintenance

To be competent, the user/individual on the job must be able to:

- PC10.** perform the general routine maintenance of equipment and maintain semi-automated and automated plant equipment and troubleshoot of machine as per schedule
- PC11.** perform the calibration of equipment under supervision as per SOP

GMP compliance in documentation

To be competent, the user/individual on the job must be able to:

- PC12.** adhere to ALCOA principles during documentation of the activities performed



Qualification Pack

- PC13.** secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity
- PC14.** ensure Audit trail of every document generated by oneself
- PC15.** ensure that only authorized user ID is used to enter the record entries in an automated system
- PC16.** file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager
- PC17.** correct the wrong entries, using ALCOA principles
- PC18.** perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer

Environment Sustainability

To be competent, the user/individual on the job must be able to:

- PC19.** ensure energy conservation by switching off the machine and equipment post operations
- PC20.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes
- PC21.** ensure energy conservation by optimizing the machine/ equipment performance
- PC22.** apply environment-friendly methods given in SOPs for waste disposal
- PC23.** ensure no leakage of water in the plant
- PC24.** follow organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution.

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** organizational SOPs relevant to machine operations and production processes
- KU2.** SOP for entry and exit from GMP area
- KU3.** rules of WHO and ICH-GMP relevant to roles and responsibility of Machine Operator
- KU4.** Good Manufacturing Practices, Good Storage Practices, Good Documentation Practices
- KU5.** machine operation manual and troubleshooting of the machines available in assigned section
- KU6.** procedures for documentation, reporting and escalation
- KU7.** basics of ALCOA Principles, data integrity and information security rules
- KU8.** methods to conserve water and energy
- KU9.** methods to minimize the pollution

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and cGMP guidelines
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages



Qualification Pack

- GS3.** use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications
- GS4.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS5.** use team-building skills while dealing with teammates
- GS6.** apply problem-solving skills to find solutions for deviations found during process-related checks, non-conformities in standards and labeling
- GS7.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and when to deal with a process error individually, depending on the type of concern
- GS8.** apply customer centricity to remain compliant with data integrity rules, cGMP/GLP guidelines and to evaluate impact of wrongdoings
- GS9.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>GMP compliance in production process</i>	7	8	5	5
PC1. perform the cleaning of machine in compliance with cGMP guidelines and SOP	-	-	-	-
PC2. monitor environmental conditions in production area as per SOP and cGMP guidelines	-	-	-	-
PC3. perform and record pre-production checks, job safety analysis	-	-	-	-
PC4. ensure adherence to Good Manufacturing Practices related to equipment operations	-	-	-	-
PC5. perform the specific in-process production checks as directed in SOPs	-	-	-	-
PC6. comply with the appropriate cGMP rules for the batch change over procedure	-	-	-	-
<i>GMP Compliance in waste management</i>	5	7	5	3
PC7. comply with the appropriate environmental rules and organizational SOP for the waste management and disposal	-	-	-	-
PC8. perform waste segregation and generate record for the same	-	-	-	-
PC9. perform waste disposal under supervision and ensure Effluent treatment and solvent recycling procedures under supervision	-	-	-	-
<i>GMP compliance in equipment maintenance</i>	7	8	5	5
PC10. perform the general routine maintenance of equipment and maintain semi-automated and automated plant equipment and troubleshoot of machine as per schedule	-	-	-	-
PC11. perform the calibration of equipment under supervision as per SOP	-	-	-	-
<i>GMP compliance in documentation</i>	7	8	5	5

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. adhere to ALCOA principles during documentation of the activities performed	-	-	-	-
PC13. secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity	-	-	-	-
PC14. ensure Audit trail of every document generated by oneself	-	-	-	-
PC15. ensure that only authorized user ID is used to enter the record entries in an automated system	-	-	-	-
PC16. file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager	-	-	-	-
PC17. correct the wrong entries, using ALCOA principles	-	-	-	-
PC18. perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer	-	-	-	-
<i>Environment Sustainability</i>	1	2	1	1
PC19. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC20. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
PC21. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC22. apply environment-friendly methods given in SOPs for waste disposal	-	-	-	-
PC23. ensure no leakage of water in the plant	-	-	-	-
PC24. follow organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution.	-	-	-	-
NOS Total	27	33	21	19



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0265
NOS Name	Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	4.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N0113: Ensure a hygienic and clean work area to avoid contamination

Description

This NOS unit is about maintaining hygienic and clean work area to avoid contamination

Scope

The scope covers the following :

- Sanitation activities before starting the work
- Sanitation activities during work
- Sanitation activities post completion of work

Elements and Performance Criteria

sanitation activities before starting the work

To be competent, the user/individual on the job must be able to:

- PC1.** inspect the area and machine, taking into account various surfaces
- PC2.** check for cleaning validation tag on machines and accessories
- PC3.** ensure to clean the area or machine part as per SOP, in case of any stain on floor or machine
- PC4.** perform the cleaning validation in the presence of authorized personnel or QA inspector
- PC5.** ensure that there is adequate ventilation for the work being carried out
- PC6.** handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method
- PC7.** segregate and store the chemicals/ material with an appropriate label in designated places to avoid contamination

Sanitation activities during work

To be competent, the user/individual on the job must be able to:

- PC8.** deal with accidental spillage, if any, caused while carrying out the work and clean as per SOP
- PC9.** segregate and store the intermediate material with an appropriate label in designated places to avoid contamination
- PC10.** report any additional cleaning requirement that is outside one's purview, to the appropriate person
- PC11.** segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel

Sanitation activities after completion of work

To be competent, the user/individual on the job must be able to:

- PC12.** ensure that there is no oily substance on the floor to avoid slippage
- PC13.** ensure that no scrap material is lying around
- PC14.** perform the cleaning of the equipment after every batch production as per SOP
- PC15.** perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector



Qualification Pack

- PC16.** ensure that, on completion of the work, the area is left clean and dry and meets WHO and cGMP requirements of sanitized premises
- PC17.** place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored
- PC18.** dispose of the waste garnered from the activity as per SOP
- PC19.** dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** levels of hygiene required by production area and the importance of maintaining the same
- KU2.** methodology for production area inspection with methods and materials required for cleaning a variety of surfaces and equipment
- KU3.** the method to check the treated surface and equipment on completion of cleaning
- KU4.** procedures for reporting any unidentified soiling or any deviation for cleaning validation
- KU5.** role of different materials, chemicals, and equipment in cleaning and sanitation of production area
- KU6.** current Good Manufacturing Practices (cGMP) and WHO guidelines for cleaning/ sanitation activity and maintaining hygiene
- KU7.** cleaning validation process
- KU8.** waste disposal guidelines as per WHO and cGMP and relevant organizational SOPs

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use written communication skills to record and communicate details of work done to appropriate people using written/typed report and electronic mail
- GS2.** use verbal communication skills to communicate with supervisor, cross-functional teams and auditors effectively
- GS3.** use critical thinking skills to interpret the various coding systems as per company norms and in identifying the non-compliance while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>sanitation activities before starting the work</i>	10	10	5	5
PC1. inspect the area and machine, taking into account various surfaces	-	-	-	-
PC2. check for cleaning validation tag on machines and accessories	-	-	-	-
PC3. ensure to clean the area or machine part as per SOP, in case of any stain on floor or machine	-	-	-	-
PC4. perform the cleaning validation in the presence of authorized personnel or QA inspector	-	-	-	-
PC5. ensure that there is adequate ventilation for the work being carried out	-	-	-	-
PC6. handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
PC7. segregate and store the chemicals/ material with an appropriate label in designated places to avoid contamination	-	-	-	-
<i>Sanitation activities during work</i>	10	20	5	5
PC8. deal with accidental spillage, if any, caused while carrying out the work and clean as per SOP	-	-	-	-
PC9. segregate and store the intermediate material with an appropriate label in designated places to avoid contamination	-	-	-	-
PC10. report any additional cleaning requirement that is outside one's purview, to the appropriate person	-	-	-	-
PC11. segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel	-	-	-	-
<i>Sanitation activities after completion of work</i>	10	10	5	5



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. ensure that there is no oily substance on the floor to avoid slippage	-	-	-	-
PC13. ensure that no scrap material is lying around	-	-	-	-
PC14. perform the cleaning of the equipment after every batch production as per SOP	-	-	-	-
PC15. perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector	-	-	-	-
PC16. ensure that, on completion of the work, the area is left clean and dry and meets WHO and cGMP requirements of sanitized premises	-	-	-	-
PC17. place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored	-	-	-	-
PC18. dispose of the waste garnered from the activity as per SOP	-	-	-	-
PC19. dispose of used and un-used solutions according to manufacturer's instructions, and clean the equipment thoroughly	-	-	-	-
NOS Total	30	40	15	15



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0113
NOS Name	Ensure a hygienic and clean work area to avoid contamination
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N0268: Perform Reporting and documentation with Data Integrity

Description

This NOS unit is about a machine operator performing reporting and documentation with data integrity

Scope

The scope covers the following :

- Reporting and escalation of deviation
- Documentation

Elements and Performance Criteria

Reporting and escalation of deviations

To be competent, the user/individual on the job must be able to:

- PC1.** identify non-conformities according to quality assurance standards and product specifications during in-process checks
- PC2.** identify potential causes of non-conformities to quality assurance standards with the help of a production chemist
- PC3.** report and escalate the deviations as per the escalation matrix
- PC4.** implement the corrective and preventive actions as guided by the production chemist and quality assurance team

Documentation

To be competent, the user/individual on the job must be able to:

- PC5.** identify documentation to be completed as per SOP, GMP and data integrity rules
- PC6.** record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and cGMP guidelines
- PC7.** maintain records (both electronic and manual) in the log books
- PC8.** maintain documentation for breakdown time, daily manufacturing record, yield report, etc. as per SOP, cGMP and data integrity rules

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** procedures for documentation, reporting, and escalation of incidents and deviations
- KU2.** procedure for generating electronic records
- KU3.** ALCOA plus principles
- KU4.** ALCOA Principles, Data integrity, and information security rules
- KU5.** procedure for line clearance

Generic Skills (GS)



Qualification Pack

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages
- GS3.** use verbal communication skills to interact with teammates, and during interaction with regulatory inspectors and other people
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify what and when to report an issue to the concerned supervisor and to deal with a colleague individually, depending on the type of concern
- GS6.** use critical thinking skills in analyzing the impact of deviations, wastage, and rejects to the safety, environment and efficiency, compliance, and cost
- GS7.** apply customer-centricity to remain compliant with data integrity rules, and while responding to auditors and QA personnel

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Reporting and escalation of deviations</i>	10	10	5	5
PC1. identify non-conformities according to quality assurance standards and product specifications during in-process checks	-	-	-	-
PC2. identify potential causes of non-conformities to quality assurance standards with the help of a production chemist	-	-	-	-
PC3. report and escalate the deviations as per the escalation matrix	-	-	-	-
PC4. implement the corrective and preventive actions as guided by the production chemist and quality assurance team	-	-	-	-
<i>Documentation</i>	15	25	15	15
PC5. identify documentation to be completed as per SOP, GMP and data integrity rules	-	-	-	-
PC6. record the required information of all significant activities, incidents, and deviations as per recording formats in compliance with SOP and cGMP guidelines	-	-	-	-
PC7. maintain records (both electronic and manual) in the log books	-	-	-	-
PC8. maintain documentation for breakdown time, daily manufacturing record, yield report, etc. as per SOP, cGMP and data integrity rules	-	-	-	-
NOS Total	25	35	20	20



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0268
NOS Name	Perform Reporting and documentation with Data Integrity
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	4
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors

Description

This NOS unit is about coordinating with supervisor/ production chemist, teams, and auditors.

Scope

The scope covers the following :

- Coordination with supervisor/ production chemist
- Coordination with cross-functional teams
- Coordination with auditors
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Supervisor / production chemist

To be competent, the user/individual on the job must be able to:

- PC1.** work as per instructions given by reporting supervisor
- PC2.** seek guidance/advice from supervisor on production plan for meeting the timelines
- PC3.** communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist
- PC4.** ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention
- PC5.** coordinate with supervisor on work-related and behavioral feedback

Coordination with cross-functional teams

To be competent, the user/individual on the job must be able to:

- PC6.** support team members and colleagues of other departments in work
- PC7.** take handover from previous shift operator and give handover to next shift operator as per SOP
- PC8.** guide manufacturing and packaging assistants during production process
- PC9.** coordinate with warehouse team for material dispensing and issuance
- PC10.** coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors
- PC11.** coordinate with quality control team for sample collection and batch release
- PC12.** coordinate with QA for machine/ equipment validation at a routine interval as per SOP
- PC13.** provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance
- PC14.** coordinate with EHS team for any safety incident, accident and emergency

Coordination with auditors

To be competent, the user/individual on the job must be able to:

- PC15.** provide clear answers to the auditor's queries



Qualification Pack

PC16. provide the required documents of performed activities and operations to auditors on time

PC17. maintain data integrity while responding to auditors and regulatory inspectors

Sensitivity towards all genders and people with disability

To be competent, the user/individual on the job must be able to:

PC18. respect all genders, religions, and caste

PC19. empathize with people with disability

PC20. offer support or help to a person with disability only when asked

PC21. Adhere to the guidelines laid in POSH Act

PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the company's policies on the preferred language of communication, reporting and escalation policy

KU2. the reporting structure of the organization

KU3. types of audits in the life sciences sector for the manufacturing operations

KU4. the required regulatory and statutory compliance-related documentation

KU5. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU6. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU7. the methods of workplace communication

KU8. importance of team coordination

KU9. the types of possible disabilities among people with disability (PwD)

KU10. the challenges faced by PwD

KU11. the importance of displaying empathy towards PwD

KU12. the right way to use the laws, acts, and provisions defined for PwD by the statutory bodies

KU13. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU14. importance of respecting all gender identities, religion, caste, and culture

KU15. method to receive the performance feedback

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. use reading and comprehension skills to gauge the relevant information manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/ comments

GS2. use written communication skills to record and communicate details of work done to appropriate stakeholders by using written or computer-based record/ electronic mail in a given format and compliant with ALCOA principle



Qualification Pack

- GS3.** use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates
- GS4.** use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** apply customer-centricity skills while responding to auditors and QA personnel

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with Supervisor / production chemist</i>	10	10	5	5
PC1. work as per instructions given by reporting supervisor	-	-	-	-
PC2. seek guidance/advice from supervisor on production plan for meeting the timelines	-	-	-	-
PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist	-	-	-	-
PC4. ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
PC5. coordinate with supervisor on work-related and behavioral feedback	-	-	-	-
<i>Coordination with cross-functional teams</i>	10	10	5	5
PC6. support team members and colleagues of other departments in work	-	-	-	-
PC7. take handover from previous shift operator and give handover to next shift operator as per SOP	-	-	-	-
PC8. guide manufacturing and packaging assistants during production process	-	-	-	-
PC9. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
PC10. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-
PC11. coordinate with quality control team for sample collection and batch release	-	-	-	-
PC12. coordinate with QA for machine/ equipment validation at a routine interval as per SOP	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
PC14. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
<i>Coordination with auditors</i>	10	10	5	5
PC15. provide clear answers to the auditor's queries	-	-	-	-
PC16. provide the required documents of performed activities and operations to auditors on time	-	-	-	-
PC17. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	3	3	2	2
PC18. respect all genders, religions, and caste	-	-	-	-
PC19. empathize with people with disability	-	-	-	-
PC20. offer support or help to a person with disability only when asked	-	-	-	-
PC21. Adhere to the guidelines laid in POSH Act	-	-	-	-
PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	33	33	17	17



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0104
NOS Name	Coordinate and communicate with Supervisor/ production chemist, teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	4
Credits	1.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

DGT/VSQ/N0102: Employability Skills (60 Hours)

Description

This unit is about employability skills, Constitutional values, becoming a professional in the 21st Century, digital, financial, and legal literacy, diversity and Inclusion, English and communication skills, customer service, entrepreneurship, and apprenticeship, getting ready for jobs and career development.

Scope

The scope covers the following :

- Introduction to Employability Skills
- Constitutional values - Citizenship
- Becoming a Professional in the 21st Century
- Basic English Skills
- Career Development & Goal Setting
- Communication Skills
- Diversity & Inclusion
- Financial and Legal Literacy
- Essential Digital Skills
- Entrepreneurship
- Customer Service
- Getting ready for Apprenticeship & Jobs

Elements and Performance Criteria

Introduction to Employability Skills

To be competent, the user/individual on the job must be able to:

- PC1.** identify employability skills required for jobs in various industries
- PC2.** identify and explore learning and employability portals

Constitutional values – Citizenship

To be competent, the user/individual on the job must be able to:

- PC3.** recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.
- PC4.** follow environmentally sustainable practices

Becoming a Professional in the 21st Century

To be competent, the user/individual on the job must be able to:

- PC5.** recognize the significance of 21st Century Skills for employment
- PC6.** practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life

Basic English Skills

To be competent, the user/individual on the job must be able to:



Qualification Pack

- PC7.** use basic English for everyday conversation in different contexts, in person and over the telephone
- PC8.** read and understand routine information, notes, instructions, mails, letters etc. written in English
- PC9.** write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

To be competent, the user/individual on the job must be able to:

- PC10.** understand the difference between job and career
- PC11.** prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

To be competent, the user/individual on the job must be able to:

- PC12.** follow verbal and non-verbal communication etiquette and active listening techniques in various settings
- PC13.** work collaboratively with others in a team

Diversity & Inclusion

To be competent, the user/individual on the job must be able to:

- PC14.** communicate and behave appropriately with all genders and PwD
- PC15.** escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

To be competent, the user/individual on the job must be able to:

- PC16.** select financial institutions, products and services as per requirement
- PC17.** carry out offline and online financial transactions, safely and securely
- PC18.** identify common components of salary and compute income, expenses, taxes, investments etc
- PC19.** identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

To be competent, the user/individual on the job must be able to:

- PC20.** operate digital devices and carry out basic internet operations securely and safely
- PC21.** use e- mail and social media platforms and virtual collaboration tools to work effectively
- PC22.** use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

To be competent, the user/individual on the job must be able to:

- PC23.** identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research
- PC24.** develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
- PC25.** identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

To be competent, the user/individual on the job must be able to:

- PC26.** identify different types of customers
- PC27.** identify and respond to customer requests and needs in a professional manner.



Qualification Pack

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

To be competent, the user/individual on the job must be able to:

PC29. create a professional Curriculum vitae (Résumé)

PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC31. apply to identified job openings using offline /online methods as per requirement

PC32. answer questions politely, with clarity and confidence, during recruitment and selection

PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills and different learning and employability related portals

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

KU4. Twenty first (21st) century skills and their importance

KU5. how to use English language for effective verbal (face to face and telephonic) and written communication in formal and informal set up

KU6. importance of career development and setting long- and short-term goals

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

KU10. different types of financial institutes, products, and services

KU11. how to compute income and expenditure

KU12. importance of maintaining safety and security in offline and online financial transactions

KU13. different legal rights and laws

KU14. different types of digital devices and the procedure to operate them safely and securely

KU15. how to create and operate an e- mail account and use applications such as word processors, spreadsheets etc.

KU16. how to identify business opportunities

KU17. types and needs of customers

KU18. how to apply for a job and prepare for an interview

KU19. apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

User/individual on the job needs to know how to:

GS1. read and write different types of documents/instructions/correspondence

GS2. communicate effectively using appropriate language in formal and informal settings



Qualification Pack

- GS3.** behave politely and appropriately with all
- GS4.** how to work in a virtual mode
- GS5.** perform calculations efficiently
- GS6.** solve problems effectively
- GS7.** pay attention to details
- GS8.** manage time efficiently
- GS9.** maintain hygiene and sanitization to avoid infection

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC3. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc.	-	-	-	-
PC4. follow environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	2	4	-	-
PC5. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC6. practice the 21st Century Skills such as Self-Awareness, Behaviour Skills, time management, critical and adaptive thinking, problem-solving, creative thinking, social and cultural awareness, emotional awareness, learning to learn for continuous learning etc. in personal and professional life	-	-	-	-
<i>Basic English Skills</i>	2	3	-	-
PC7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
<i>Career Development & Goal Setting</i>	1	2	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. understand the difference between job and career	-	-	-	-
PC11. prepare a career development plan with short- and long-term goals, based on aptitude	-	-	-	-
<i>Communication Skills</i>	2	2	-	-
PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
PC13. work collaboratively with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	2	-	-
PC14. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
<i>Financial and Legal Literacy</i>	2	3	-	-
PC16. select financial institutions, products and services as per requirement	-	-	-	-
PC17. carry out offline and online financial transactions, safely and securely	-	-	-	-
PC18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
<i>Essential Digital Skills</i>	3	4	-	-
PC20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-
PC22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Entrepreneurship</i>	2	3	-	-
PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
<i>Customer Service</i>	1	2	-	-
PC26. identify different types of customers	-	-	-	-
PC27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
PC28. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	2	3	-	-
PC29. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC33. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0102
NOS Name	Employability Skills (60 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	4
Credits	2
Version	1.0
Last Reviewed Date	08/05/2025
Next Review Date	08/05/2028
NSQC Clearance Date	08/05/2025



Qualification Pack

LFS/N1207: Perform Hard-gelatin Capsule Filling Operations

Description

This NOS unit is about a machine operator performing filling process for empty hard-gelatin capsule

Scope

The scope covers the following :

- Capsule filling operations
- In-process checks
- Post-production critical activities

Elements and Performance Criteria

Capsule filling operations

To be competent, the user/individual on the job must be able to:

- PC1.** perform sanitization and gowning procedures as per clean room guidelines
- PC2.** wear personal protective equipment(PPE) before entering into the production area
- PC3.** load empty capsules in machine capsule hopper
- PC4.** operate sorter cum elevator to sortout diametrically defective capsules
- PC5.** adjust capsule orientation and loading
- PC6.** load filling powder/ filling pellets into drug filling hopper
- PC7.** set the parameters in the control panel for capsule filling machine as per batch manufacturing record (BMR)
- PC8.** operate semi automatic or fully automatic hard geletain capsule filling machine to fill the capsules as per BMR
- PC9.** perform inspection of filled capsules through capsule sorter machine
- PC10.** store the filled and inspected hard gelatin capsule shells in a container with lid, lined with double poly-bag
- PC11.** minimize waste/ rejections during entire production operation

In-process checks

To be competent, the user/individual on the job must be able to:

- PC12.** perform total range of in-process checks specified to be performed as per SOP
- PC13.** use appropriate measuring instruments, equipment, tools, accessories etc. as required for carrying out in-process checks
- PC14.** confirm that the intermediate/final product meet the specifications

Post-production critical activities

To be competent, the user/individual on the job must be able to:

- PC15.** weigh the filled hard gelatin capsules and record in BMR
- PC16.** carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs
- PC17.** segregate waste and perform disposal under supervision



Qualification Pack

PC18. provide support for line clearance before the next batch is produced

PC19. handover the work/ equipment to colleague in next shift in adherence with the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** clean room behaviour practices and gowning procedures
- KU2.** SOP for entry and exit from GMP area
- KU3.** PPE used in hard gelatin capsule manufacturing and their work instructions
- KU4.** material, segregation, handling and Storage guidelines of WHO
- KU5.** types of machines for each step in hard gelatin capsule filling process, their operating process and critical parameters
- KU6.** utilities in Non sterile formulation manufacturing plant
- KU7.** in process checks for every stage in hard gelatin capsule filling process
- KU8.** labeling guidelines as per GMP
- KU9.** procedures for documentation, reporting and escalation of incidents and deviations
- KU10.** procedure for generating electronic records
- KU11.** ALCOA Principles, data integrity and information security rules
- KU12.** procedure for line clearance
- KU13.** procedure for handover and takeover

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS4.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** use critical thinking skills in analyzing the impact of deviations, wastage, and rejects to the environment and efficiency, compliance, and cost
- GS8.** apply decision making while making necessary adjustments in parameters to achieve quality specifications
- GS9.** apply customer-centricity while responding to auditors and QA personnel

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Capsule filling operations</i>	20	25	5	10
PC1. perform sanitization and gowning procedures as per clean room guidelines	-	-	-	-
PC2. wear personal protective equipment(PPE) before entering into the production area	-	-	-	-
PC3. load empty capsules in machine capsule hopper	-	-	-	-
PC4. operate sorter cum elevator to sortout diametrically defective capsules	-	-	-	-
PC5. adjust capsule orientation and loading	-	-	-	-
PC6. load filling powder/ filling pellets into drug filling hopper	-	-	-	-
PC7. set the parameters in the control panel for capsule filling machine as per batch manufacturing record (BMR)	-	-	-	-
PC8. operate semi automatic or fully automatic hard geletain capsule filling machine to fill the capsules as per BMR	-	-	-	-
PC9. perform inspection of filled capsules through capsule sorter machine	-	-	-	-
PC10. store the filled and inspected hard gelatin capsule shells in a container with lid, lined with double poly-bag	-	-	-	-
PC11. minimize waste/ rejections during entire production operation	-	-	-	-
<i>In-process checks</i>	4	8	4	4
PC12. perform total range of in-process checks specified to be performed as per SOP	-	-	-	-
PC13. use appropriate measuring instruments, equipment, tools, accessories etc. as required for carrying out in-process checks	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. confirm that the intermediate/final product meet the specifications	-	-	-	-
<i>Post-production critical activities</i>	4	8	4	4
PC15. weigh the filled hard gelatin capsules and record in BMR	-	-	-	-
PC16. carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs	-	-	-	-
PC17. segregate waste and perform disposal under supervision	-	-	-	-
PC18. provide support for line clearance before the next batch is produced	-	-	-	-
PC19. handover the work/ equipment to colleague in next shift in adherence with the shift schedule	-	-	-	-
NOS Total	28	41	13	18



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1207
NOS Name	Perform Hard-gelatin Capsule Filling Operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4
Credits	3.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N1209: Perform blister/ strip packaging of Tablet and Capsules

Description

This NOS unit is about a machine operator performing blister/ strip primary & secondary packing operations of tablets and capsules

Scope

The scope covers the following :

- Primary packaging
- In-process checks
- Secondary packaging
- Post-packaging critical activities

Elements and Performance Criteria

Primary Packaging

To be competent, the user/individual on the job must be able to:

- PC1.** perform sanitization and gowning procedures as per SOP and cleanroom guidelines
- PC2.** wear Personal Protective Equipment (PPE) before entering into the production area
- PC3.** ensure availability of QA approved packaging material
- PC4.** record the environmental variables like temperature and humidity
- PC5.** set the strip packaging/ blister packaging machine variables as per batch manufacturing record (BMR)
- PC6.** set the overprinting matter received from production chemist, on the overprint unit
- PC7.** fill the QA approved tablets/ capsules in the filling line/ sorter with care to minimize material overflow/ wastage/ excess flash/ spill
- PC8.** operate strip packing/blister packing machine to start the primary packaging
- PC9.** operate filling and packaging line in the correct pattern as per the SOP
- PC10.** monitor the packaging line for empty pockets, pocket cut disintegrated tablet/ capsules during primary packaging operation
- PC11.** segregate the defective strips/ blisters in a labeled container
- PC12.** minimize waste/ rejections during entire packaging operation

In-process checks

To be competent, the user/individual on the job must be able to:

- PC13.** perform a total range of in-process checks specified for strip/ blister packaging
- PC14.** use appropriate measuring instruments, equipment, tools for carrying out in-process checks
- PC15.** confirm that packaged tablet/ capsule strips/ blisters meet the specifications for packaging, storage conditions, and labeling

Secondary packaging

To be competent, the user/individual on the job must be able to:

- PC16.** ensure QA and production chemist provides the line clearance



Qualification Pack

- PC17.** ensure pre-printed over packing material is available near the packaging belt
- PC18.** perform carton filling, leaflet insertion, and carton closing
- PC19.** perform weighing of each carton and segregate cartons with varying weight
- PC20.** perform shipper packing of every weighed and approved carton
- PC21.** ensure specimen on shipper is approved by authorized personnel
- PC22.** seal with approved BOPP tape, label, and weigh the shipper box

Post-packaging critical activities

To be competent, the user/individual on the job must be able to:

- PC23.** segregate batchwise packaged and sealed shippers on pallets for storage and transportation in the warehouse
- PC24.** segregate packaging waste and perform disposal under supervision
- PC25.** sort the approved good tablets/ capsules from the defective packing for repacking
- PC26.** provide support for line clearance before the next batch is processed for packaging
- PC27.** handover the work/ equipment to colleague in next shift in adherence of the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** cleanroom behavior practices and gowning procedures
- KU2.** SOP for entry and exit from GMP area
- KU3.** PPE used during blister/ strip packaging for tablet and capsules and their work instructions
- KU4.** material, segregation, handling, and Storage guidelines of WHO
- KU5.** types of machines for blister/ strip packaging for tablet and capsules, their operating process, and critical parameters
- KU6.** calibration process of machines
- KU7.** utilities in blister/ strip packaging for tablet and capsules
- KU8.** in-process checks for blister/ strip packaging for tablet and capsules
- KU9.** labeling guidelines as per GMP
- KU10.** procedures for documentation, reporting, and escalation of incidents and deviations
- KU11.** procedure for generating electronic records
- KU12.** ALCOA Principles, data integrity and information security rules
- KU13.** procedure for line clearance
- KU14.** procedure for handover and takeover

Generic Skills (GS)

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments



Qualification Pack

- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS6.** use critical thinking skills in analyzing the impact of deviations, wastage, and rejects to the environment and efficiency, compliance, and cost
- GS7.** apply decision making while making necessary adjustments in parameters to achieve quality specifications
- GS8.** apply customer-centricity while responding to auditors and QA personnel

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Primary Packaging</i>	10	12	4	4
PC1. perform sanitization and gowning procedures as per SOP and cleanroom guidelines	-	-	-	-
PC2. wear Personal Protective Equipment (PPE) before entering into the production area	-	-	-	-
PC3. ensure availability of QA approved packaging material	-	-	-	-
PC4. record the environmental variables like temperature and humidity	-	-	-	-
PC5. set the strip packaging/ blister packaging machine variables as per batch manufacturing record (BMR)	-	-	-	-
PC6. set the overprinting matter received from production chemist, on the overprint unit	-	-	-	-
PC7. fill the QA approved tablets/ capsules in the filling line/ sorter with care to minimize material overflow/ wastage/ excess flash/ spill	-	-	-	-
PC8. operate strip packing/blister packing machine to start the primary packaging	-	-	-	-
PC9. operate filling and packaging line in the correct pattern as per the SOP	-	-	-	-
PC10. monitor the packaging line for empty pockets, pocket cut disintegrated tablet/ capsules during primary packaging operation	-	-	-	-
PC11. segregate the defective strips/ blisters in a labeled container	-	-	-	-
PC12. minimize waste/ rejections during entire packaging operation	-	-	-	-
<i>In-process checks</i>	4	8	4	4
PC13. perform a total range of in-process checks specified for strip/ blister packaging	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC14. use appropriate measuring instruments, equipment, tools for carrying out in-process checks	-	-	-	-
PC15. confirm that packaged tablet/ capsule strips/ blisters meet the specifications for packaging, storage conditions, and labeling	-	-	-	-
<i>Secondary packaging</i>	10	12	4	4
PC16. ensure QA and production chemist provides the line clearance	-	-	-	-
PC17. ensure pre-printed over packing material is available near the packaging belt	-	-	-	-
PC18. perform carton filling, leaflet insertion, and carton closing	-	-	-	-
PC19. perform weighing of each carton and segregate cartons with varying weight	-	-	-	-
PC20. perform shipper packing of every weighed and approved carton	-	-	-	-
PC21. ensure specimen on shipper is approved by authorized personnel	-	-	-	-
PC22. seal with approved BOPP tape, label, and weigh the shipper box	-	-	-	-
<i>Post-packaging critical activities</i>	4	8	4	4
PC23. segregate batchwise packaged and sealed shippers on pallets for storage and transportation in the warehouse	-	-	-	-
PC24. segregate packaging waste and perform disposal under supervision	-	-	-	-
PC25. sort the approved good tablets/ capsules from the defective packing for repacking	-	-	-	-
PC26. provide support for line clearance before the next batch is processed for packaging	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC27. handover the work/ equipment to colleague in next shift in adherence of the shift schedule	-	-	-	-
NOS Total	28	40	16	16



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1209
NOS Name	Perform blister/ strip packaging of Tablet and Capsules
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4
Credits	2.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

LFS/N1210: Perform dosage container packaging of Tablet and Capsules

Description

This NOS unit is about a machine operator performing primary and secondary container packaging operations of tablets and capsules

Scope

The scope covers the following :

- Filling and primary packaging
- In-process checks
- Secondary packaging
- Post-packaging critical activities

Elements and Performance Criteria

Filling and primary packaging

To be competent, the user/individual on the job must be able to:

- PC1.** perform sanitization and gowning procedures as per SOP and cleanroom guidelines
- PC2.** wear personal protective equipment(PPE) before entering into the production area
- PC3.** ensure availability of QA approved containers, caps and self adhesive labels
- PC4.** record the environmental variables like temperature and humidity
- PC5.** set the semi-automatic/ automatic containerization machine variables as per batch manufacturing record (BMR)
- PC6.** set the overprinting matter, received from production chemist, on the self-adhesive labeling machine
- PC7.** load the containers and caps in the respective feeders
- PC8.** charge the QA approved tablets/ capsules in the filling line/ sorter with care to minimize material overflow/ wastage/ excess flash/ spill
- PC9.** operate counting and container filling machine to start the primary packaging
- PC10.** operate filling and packaging line in the correct pattern as per the SOP
- PC11.** monitor the packing belt, air jets, tablet/ capsule counter, cotton inserter, cap feeder, induction sealer, and rejection sensor for optimal operations
- PC12.** ensure detection and segregation of empty containers, a container with cross/ no cap / no aluminum cap
- PC13.** operate the self-adhesive labelling machine for labelling each container as per SOP
- PC14.** minimize waste/ rejections during the entire packaging operation

In-process checks

To be competent, the user/individual on the job must be able to:

- PC15.** perform a total range of in-process checks specified for container packaging
- PC16.** use appropriate measuring instruments, equipment, tools for carrying out in-process checks



Qualification Pack

- PC17.** confirm that packaged tablet/ capsule container meet the specifications for packaging, storage conditions, and labeling

Secondary packaging

To be competent, the user/individual on the job must be able to:

- PC18.** ensure QA and production chemist provides the line clearance
- PC19.** ensure pre-printed over packing material is available near packaging belt
- PC20.** perform carton filling, leaflet insertion, and carton closing
- PC21.** perform weighing of each carton and segregate cartons with varying weight
- PC22.** perform shipper packing of every weighed and approved carton
- PC23.** ensure specimen on shipper is approved by authorized personnel
- PC24.** seal with approved BOPP tape, label, and weigh the shipper box

Post packaging critical activities

To be competent, the user/individual on the job must be able to:

- PC25.** segregate batchwise packaged and sealed shippers on pallets for storage and transportation in the warehouse
- PC26.** segregate packaging waste and perform disposal under supervision
- PC27.** secure the approved good tablets/ capsules from the defective packing for repacking
- PC28.** provide support for line clearance before the next batch is processed for packaging
- PC29.** handover the work/ equipment to colleague in next shift in adherence of the shift schedule

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** cleanroom behavior practices and gowning procedures
- KU2.** SOP for entry and exit from GMP area
- KU3.** PPE used during container packaging for tablet and capsules and their work instructions
- KU4.** material, segregation, handling, and storage guidelines of WHO
- KU5.** types of machines for container packaging for tablet and capsules, their operating process and critical parameters
- KU6.** calibration process of machines
- KU7.** utilities in container packaging for tablet and capsules
- KU8.** in-process checks for container packing for tablet and capsules
- KU9.** labeling guidelines as per GMP
- KU10.** procedures for documentation, reporting, and escalation of incidents and deviations
- KU11.** procedure for generating electronic records
- KU12.** ALCOA Principles, data integrity, and information security rules
- KU13.** procedure for line clearance
- KU14.** procedure for handover and takeover

Generic Skills (GS)



Qualification Pack

User/individual on the job needs to know how to:

- GS1.** use reading and comprehension skills to extract the relevant information from manuals, SOPs, health and safety instructions, memos, reports, job cards, and notes/comments
- GS2.** use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
- GS3.** use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams
- GS4.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS5.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS6.** use critical thinking skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, compliance and cost
- GS7.** apply decision making while making necessary adjustments in parameters to achieve quality specifications
- GS8.** apply customer-centricity while responding to auditors and QA personnel

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Filling and primary packaging</i>	8	12	4	6
PC1. perform sanitization and gowning procedures as per SOP and cleanroom guidelines	-	-	-	-
PC2. wear personal protective equipment(PPE) before entering into the production area	-	-	-	-
PC3. ensure availability of QA approved containers, caps and self adhesive labels	-	-	-	-
PC4. record the environmental variables like temperature and humidity	-	-	-	-
PC5. set the semi-automatic/ automatic containerization machine variables as per batch manufacturing record (BMR)	-	-	-	-
PC6. set the overprinting matter, received from production chemist, on the self-adhesive labeling machine	-	-	-	-
PC7. load the containers and caps in the respective feeders	-	-	-	-
PC8. charge the QA approved tablets/ capsules in the filling line/ sorter with care to minimize material overflow/ wastage/ excess flash/ spill	-	-	-	-
PC9. operate counting and container filling machine to start the primary packaging	-	-	-	-
PC10. operate filling and packaging line in the correct pattern as per the SOP	-	-	-	-
PC11. monitor the packing belt, air jets, tablet/ capsule counter, cotton inserter, cap feeder, induction sealer, and rejection sensor for optimal operations	-	-	-	-
PC12. ensure detection and segregation of empty containers, a container with cross/ no cap / no aluminum cap	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. operate the self-adhesive labelling machine for labelling each container as per SOP	-	-	-	-
PC14. minimize waste/ rejections during the entire packaging operation	-	-	-	-
<i>In-process checks</i>	4	8	4	4
PC15. perform a total range of in-process checks specified for container packaging	-	-	-	-
PC16. use appropriate measuring instruments, equipment, tools for carrying out in-process checks	-	-	-	-
PC17. confirm that packaged tablet/ capsule container meet the specifications for packaging, storage conditions, and labeling	-	-	-	-
<i>Secondary packaging</i>	8	12	4	6
PC18. ensure QA and production chemist provides the line clearance	-	-	-	-
PC19. ensure pre-printed over packing material is available near packaging belt	-	-	-	-
PC20. perform carton filling, leaflet insertion, and carton closing	-	-	-	-
PC21. perform weighing of each carton and segregate cartons with varying weight	-	-	-	-
PC22. perform shipper packing of every weighed and approved carton	-	-	-	-
PC23. ensure specimen on shipper is approved by authorized personnel	-	-	-	-
PC24. seal with approved BOPP tape, label, and weigh the shipper box	-	-	-	-
<i>Post packaging critical activities</i>	4	8	4	4
PC25. segregate batchwise packaged and sealed shippers on pallets for storage and transportation in the warehouse	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC26. segregate packaging waste and perform disposal under supervision	-	-	-	-
PC27. secure the approved good tablets/ capsules from the defective packing for repacking	-	-	-	-
PC28. provide support for line clearance before the next batch is processed for packaging	-	-	-	-
PC29. handover the work/ equipment to colleague in next shift in adherence of the shift schedule	-	-	-	-
NOS Total	24	40	16	20



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1210
NOS Name	Perform dosage container packaging of Tablet and Capsules
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)
2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.
3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.
4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.
5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and viva for every student at each examination/training center based on this criterion.
6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied



Qualification Pack

assessment component.

7. To pass the Qualification Pack, every trainee should score a minimum of 50%-70% of marks in each NOS (depending on NSQF Level) to successfully clear the assessment. In the case of a Govt funded program, the program guidelines will be overarching on the pass percentage rules.

8. In case of unsuccessful completion, the trainee may seek re-assessment on the Qualification Pack.

Minimum Aggregate Passing % at QP Level : 70

(Please note: Every Trainee should score a minimum aggregate passing percentage as specified above, to successfully clear the Qualification Pack assessment.)

Minimum Passing % at NOS Level: 70

(Please note: A Trainee must score the minimum percentage for each NOS separately as well as on the QP as a whole.)

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0274.Discuss about Life Sciences Industry and Basics of manufacturing Operations	40	30	15	15	100	6.15
LFS/N1201.Prepare machines and perform pre-production check for drug Production	30	45	13	12	100	7.69
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	6.15
LFS/N0265.Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations	27	33	21	19	100	7.69
LFS/N0113.Ensure a hygienic and clean work area to avoid contamination	30	40	15	15	100	6.15

Qualification Pack

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0268.Perform Reporting and documentation with Data Integrity	25	35	20	20	100	7.69
LFS/N0104.Coordinate and communicate with Supervisor/ production chemist, teams and auditors	33	33	17	17	100	6.15
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	6.15
Total	235	286	116	113	750	53.82

Elective: 1 Hard gelatin Capsule Filling

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1207.Perform Hard-gelatin Capsule Filling Operations	28	41	13	18	100	23.08
Total	28	41	13	18	100	23.08

Elective: 2 Packaging- Tablet & Capsules

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1209.Perform blister/ strip packaging of Tablet and Capsules	28	40	16	16	100	7.69
LFS/N1210.Perform dosage container packaging of Tablet and Capsules	24	40	16	20	100	15.38
Total	52	80	32	36	200	23.07