Qualification Pack

Production Machine Operator-Non-Sterile Formulation

Electives: Soft Gelatin Capsule/ Packaging- Tablet & Capsules

QP Code: LFS/Q1202 Instantiated QP Code: LFS/Q1202-SI008

Version: 3.0

NSQF Level: 4

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Qualification Pack

LFS/Q1202-SI008: 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: Soft Gelatin Capsule

This elective is for operators involved in manufacturing and filling operations for soft gelatin Capsule

1. LFS/N1205: Perform Soft-gelatin Capsule Manufacturing 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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Life Sciences industry and Manufacturing Occupation	**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.	-	-	-	-
Basics of manufacturing Operations	**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

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

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 randoms 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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Material Check	**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	-	-	-	-
Pre-production Safety check	**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	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Prepare Machine for Production	**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:

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and personal hygiene protocols	**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	-	-	-	-
Follow safety and security procedures	**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	-	-	-	-

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	-	-	-	-
Follow emergency procedures	**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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
GMP compliance in production process	**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	-	-	-	-
GMP Compliance in waste management	**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	-	-	-	-
GMP compliance in equipment maintenance	**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	-	-	-	-
GMP compliance in documentation	**7**	**8**	**5**	**5**

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	-	-	-	-
Environment Sustainability	**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**

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
sanitation activities before starting the work	**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	-	-	-	-
Sanitation activities during work	**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	-	-	-	-
Sanitation activities after completion of work	**10**	**10**	**5**	**5**

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

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 plus principles

KU4. ALCOA Principles, Data integrity, and information security rules

KU5. procedure for line clearance

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 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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting and escalation of deviations	**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	-	-	-	-
Documentation	**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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Supervisor / production chemist	**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	-	-	-	-
Coordination with cross-functional teams	**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	-	-	-	-

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	-	-	-	-
Coordination with auditors	**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	-	-	-	-
Sensitivity towards all genders and people with disability	**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

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:

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.

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Introduction to Employability Skills	**1**	**1**	**-**	**-**
PC1. identify employability skills required for jobs in various industries	-	-	-	-
PC2. identify and explore learning and employability portals	-	-	-	-
Constitutional values – Citizenship	**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	-	-	-	-
Becoming a Professional in the 21st Century	**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	-	-	-	-
Basic English Skills	**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	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**

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	-	-	-	-
Communication Skills	**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	-	-	-	-
Diversity & Inclusion	**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	-	-	-	-
Financial and Legal Literacy	**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	-	-	-	-
Essential Digital Skills	**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	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Entrepreneurship	**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	-	-	-	-
Customer Service	**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	-	-	-	-
Getting ready for apprenticeship & Jobs	**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

LFS/N1205: Perform Soft-gelatin Capsule Manufacturing Operations

Description

This NOS unit is about a machine operator performing manufacturing process for soft-gelatine capsule

Scope

The scope covers the following :

- Manufacturing operations
- In-process checks
- Post-production critical activities

Elements and Performance Criteria

Manufacturing Operations

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

PC1. perform sanitization and gowning procedures as per SOP and clean room guidelines

PC2. wear personal protective equipment(PPE) before entering into the production area

PC3. mix water, pasticizer and other ingredients like colouring agent, specifying agent and sugar to prepare gelatin as per batch manufacturing record (BMR) in a reactor

PC4. operate the gelatin melting tank/ reactor to heat, molt and mix all ingredianets as per BMR

PC5. ensure liquid gelatin mixer flows to spreaderbox through a controlled gap to form a thin gelatin ribbon

PC6. prepare the homogeneous fill material from API and excipients as per the BMR

PC7. fill the hooper or product tank with fill material

PC8. operate softget encapsulation machine to perform encapusation process through either of the processes from rotary die process/ plate process/ reciprocating die/ accogel machine

PC9. dry the filled soft gelatin capsule either through tumbler dryer or in stackable trays

PC10. operate polishing machine to polish soft gelatin capsule before packing

PC11. unload the polished soft gelatin capsule in a container with lid, lined with double poly-bag

PC12. operate automatic capsule printing machine to print capsule shells as per BMR

PC13. minimize waste/ rejections during entire production operation

In-process checks

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

PC14. perform total range of in-process checks specified to be performed as per SOP

PC15. use appropriate measuring instruments, equipment, tools, accessories etc. as required for carrying out in-process checks

PC16. 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:

PC17. weigh the containers of polished soft gelatin capsules and record in BMR

PC18. carry out status labeling and segregation of material/ intermediate / finished goods as per SOPs

PC19. segregate waste and perform disposal under supervision

PC20. provide support for line clearance before the next batch is produced

PC21. 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 soft gelatin capsule manufacturing and their work instructions

KU4. material, segregation, handling and storage guidelines of WHO

KU5. types of machines for each step in soft gelatin capsule manufacturing process, their operating process and critical parameters

KU6. manufacturing process of Distilled Water(DW) and Water for Pharma Use (WPU)

KU7. utilities in Non sterile formulation manufacturing plant

KU8. in process checks for every stage in soft gelatin capsule manufacturing process

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 read 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 when to deal with a process error individually, depending on the type of concern

GS6. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

GS7. apply customer-centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate the impact of wrongdoings

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Manufacturing Operations	**20**	**25**	**5**	**10**
PC1. perform sanitization and gowning procedures as per SOP and clean room guidelines	-	-	-	-
PC2. wear personal protective equipment(PPE) before entering into the production area	-	-	-	-
PC3. mix water, pasticizer and other ingredients like colouring agent, specifying agent and sugar to prepare gelatin as per batch manufacturing record (BMR) in a reactor	-	-	-	-
PC4. operate the gelatin melting tank/ reactor to heat, molt and mix all ingredianets as per BMR	-	-	-	-
PC5. ensure liquid gelatin mixer flows to spreaderbox through a controlled gap to form a thin gelatin ribbon	-	-	-	-
PC6. prepare the homogeneous fill material from API and excipients as per the BMR	-	-	-	-
PC7. fill the hooper or product tank with fill material	-	-	-	-
PC8. operate softget encapsulation machine to perform encapusation process through either of the processes from rotary die process/ plate process/ reciprocating die/ accogel machine	-	-	-	-
PC9. dry the filled soft gelatin capsule either through tumbler dryer or in stackable trays	-	-	-	-
PC10. operate polishing machine to polish soft gelatin capsule before packing	-	-	-	-
PC11. unload the polished soft gelatin capsule in a container with lid, lined with double poly-bag	-	-	-	-
PC12. operate automatic capsule printing machine to print capsule shells as per BMR	-	-	-	-
PC13. minimize waste/ rejections during entire production operation	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
In-process checks	**4**	**8**	**4**	**4**
PC14. perform total range of in-process checks specified to be performed as per SOP	-	-	-	-
PC15. use appropriate measuring instruments, equipment, tools, accessories etc. as required for carrying out in-process checks	-	-	-	-
PC16. confirm that the intermediate/final product meet the specifications	-	-	-	-
Post-production critical activities	**4**	**8**	**4**	**4**
PC17. weigh the containers of polished soft gelatin capsules and record in BMR	-	-	-	-
PC18. carry out status labeling and segregation of material/ intermediate / finished goods as per SOPs	-	-	-	-
PC19. segregate waste and perform disposal under supervision	-	-	-	-
PC20. provide support for line clearance before the next batch is produced	-	-	-	-
PC21. 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/N1205
NOS Name	Perform Soft-gelatin Capsule Manufacturing 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

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

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

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Primary Packaging	**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	-	-	-	-
In-process checks	**4**	**8**	**4**	**4**
PC13. perform a total range of in-process checks specified for strip/ blister packaging	-	-	-	-

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	-	-	-	-
Secondary packaging	**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	-	-	-	-
Post-packaging critical activities	**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	-	-	-	-

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

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

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)

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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Filling and primary packaging	**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	-	-	-	-

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	-	-	-	-
In-process checks	**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	-	-	-	-
Secondary packaging	**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	-	-	-	-
Post packaging critical activities	**4**	**8**	**4**	**4**
PC25. segregate batchwise packaged and sealed shippers on pallets for storage and transportation in the warehouse	-	-	-	-

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**

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 via 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

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

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 Soft Gelatin Capsule

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1205.Perform Soft-gelatin Capsule Manufacturing 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**