

Qualification Pack



Secondary and Tertiary Packaging Assistant- (Pharma, Biologics and Medical Devices)

QP Code: LFS/Q0217

Version: 4.0

NSQF Level: 2

Life Sciences Sector Skill Development Council || # 14, Rear 2nd Floor, Palam Marg, Vasant Vihar
New Delhi-110057 || email:goutam.b@lsssdn.in



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LFS/Q0217: Secondary and Tertiary Packaging Assistant- (Pharma, Biologics and Medical Devices)

Brief Job Description

The Secondary & Tertiary Packaging Assistant- (Pharma, Biologics and Medical device) supports the packaging team in secondary and tertiary packaging activities by performing a combination of tasks. The job role holder also supports the team in maintaining a healthy, safe and secure environment and disposal of waste packing material as per current Good Manufacturing Practices(cGMP) Guidelines.

Personal Attributes

The individual should be good in communication skills. The job holder should be able to give attention to detail and understand the criticality of work. The person is expected to be physically strong.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. [LFS/N0275: Discuss about Life Sciences Industry and basics of Packaging Operations](#)
2. [LFS/N0264: Perform the secondary and tertiary packaging of drug products in adherence to current Good Manufacturing Practices \(cGMP\) guidelines](#)
3. [LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area](#)
4. [LFS/N0103: Clean and sanitize work area and machines to avoid cross- contamination](#)
5. [LFS/N0114: Coordinate with the supervisor, teammates and cross- functional teams](#)
6. [DGT/VSQ/N0101: Employability Skills \(30 Hours\)](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Medical Devices and In Vitro Diagnostic (IVD), Biotechnology
Occupation	Manufacturing
Country	India



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NSQF Level	2
Credits	10
Aligned to NCO/ISCO/ISIC Code	NCO-2015/9321.0101
Minimum Educational Qualification & Experience	8th Class
Minimum Level of Education for Training in School	8th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	4.0
Reference code on NQR	QG-02-LS-03400-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

NA



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LFS/N0275: Discuss about Life Sciences Industry and basics of Packaging Operations

Description

This NOS is related to discuss about Life Sciences Industry and basics of Packaging Operations in manufacturing Plant

Scope

The scope covers the following :

- Life Sciences industry and Packaging Operations
- Environmental Sustainability

Elements and Performance Criteria

Life Sciences industry and Packaging operations

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

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

Environmental Sustainability

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

- PC5.** ensure energy conservation by switching off the machine and equipment post operations
- PC6.** identify ways to optimize the usage of electricity/energy in various tasks/activities/processes and also by optimizing the lab machine/ equipment performance
- PC7.** ensure no leakage of water in the packaging area
- PC8.** identify recyclable and non-recyclable, and hazardous waste generated
- PC9.** segregate waste into different categories to achieve zero pollution of land and water

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** the organizational coding system of finished materials, compounds and company manual
- KU2.** the basic principle of the packaging process for drug products
- KU3.** types of packaging in Pharma and Bio Pharma
- KU4.** different types of machines used in the packaging process and their operating procedure
- KU5.** types of tertiary packaging materials used
- KU6.** basic quality requirements for packaging materials



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- KU7.** labelling requirement as per regulatory and legal guidelines
- KU8.** cGMP guidelines for tertiary packaging and storage conditions
- KU9.** documentation method for tertiary packaging as per cGMP and GDP
- KU10.** material segregation guidelines as per cGMP
- KU11.** methods of waste disposal for packaging waste

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 stakeholders by using hand-written report or computer-based record/electronic mail
- GS2.** use verbal communication skills to communicate critical information to the authorized person and to interact with teammates
- GS3.** apply problem-solving skills to find solutions for day to day workflow-related problems
- GS4.** apply analytical skills to give attention to detail for cGMP compliance
- GS5.** apply critical thinking skills to decide when to report an issue/concern to the supervisor
- GS6.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Life Sciences industry and Packaging operations</i>	20	-	5	5
PC1. identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC2. discuss key insights in the life sciences sector through various market research reports	-	-	-	-
PC3. Elaborate the role of a skilled individual in packaging Operations	-	-	-	-
PC4. Discuss the role of government policies and initiatives in promoting the growth of the life sciences industry in India.	-	-	-	-
<i>Environmental Sustainability</i>	20	30	10	10
PC5. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC6. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes and also by optimizing the lab machine/ equipment performance	-	-	-	-
PC7. ensure no leakage of water in the packaging area	-	-	-	-
PC8. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC9. segregate waste into different categories to achieve zero pollution of land and water	-	-	-	-
NOS Total	40	30	15	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0275
NOS Name	Discuss about Life Sciences Industry and basics of Packaging Operations
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	2
Credits	1.00
Version	1.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



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LFS/N0264: Perform the secondary and tertiary packaging of drug products in adherence to current Good Manufacturing Practices (cGMP) guidelines

Description

This NOS is about the job holder performing secondary and tertiary packaging of products for Pharma, Biologics and Medical device.

Scope

The scope covers the following :

- Secondary and Tertiary Packaging Activities

Elements and Performance Criteria

Secondary and Tertiary packaging support activities

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

- PC1.** adhere to the clean room behaviour protocol and personal protective equipment (PPE) usage guidelines
- PC2.** clean the tertiary packaging equipment as per the SOP
- PC3.** ensure the availability of the quality checked and approved packaging materials like sheets, pallets, stretch wrap and strapping labels for drug products as per cGMP Guidelines
- PC4.** perform the stacking, wrapping and cartoning of different drug product batches in suitable containers under supervision
- PC5.** label the containers / cartons with an appropriate marker / barcode and with proper handling and storage specifications along with batch details as per SOP
- PC6.** check for the un-labelled containers/cartons and for damaged labels on containers/ cartons of packed drug products
- PC7.** report to the supervisor/operators for remedial intervention for any damage/ deviation for drug product tertiary packaging
- PC8.** generate the records for the work performed in Batch Packaging Record for each batch as per cGMP guidelines and SOP
- PC9.** stack the shippers with packed drug products on the pallet as per SOP
- PC10.** load and transport the batches to the storage area using trolley or forklift for manual warehousing
- PC11.** load the packaged and labelled finished goods on the conveyer belt for automated warehousing
- PC12.** place all the equipment and materials in place after the completion of work as per SOP
- PC13.** Ensure the reconciliation of unused and/or damaged packaging material as per SOP
- PC14.** follow line-clearance steps as per SOP for smooth flow of work

Knowledge and Understanding (KU)



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The individual on the job needs to know and understand:

- KU1.** the organizational coding system of finished materials, compounds and company manual
- KU2.** the basic principle of the packaging process for drug products
- KU3.** types of packaging in Pharma and Bio Pharma
- KU4.** different types of machines used in the packaging process and their operating procedure
- KU5.** types of tertiary packaging materials used
- KU6.** basic quality requirements for packaging materials
- KU7.** labelling requirement as per regulatory and legal guidelines
- KU8.** cGMP guidelines for tertiary packaging and storage conditions
- KU9.** documentation method for tertiary packaging as per cGMP and GDP
- KU10.** material segregation guidelines as per cGMP
- KU11.** methods of waste disposal for packaging waste

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 stakeholders by using hand-written report or computer-based record/electronic mail
- GS2.** use verbal communication skills to communicate critical information to the authorized person and to interact with teammates
- GS3.** apply problem-solving skills to find solutions for day to day workflow-related problems
- GS4.** apply analytical skills to give attention to detail for cGMP compliance
- GS5.** apply critical thinking skills to decide when to report an issue/concern to the supervisor
- GS6.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Secondary and Tertiary packaging support activities</i>	30	47	10	13
PC1. adhere to the clean room behaviour protocol and personal protective equipment (PPE) usage guidelines	-	-	-	-
PC2. clean the tertiary packaging equipment as per the SOP	-	-	-	-
PC3. ensure the availability of the quality checked and approved packaging materials like sheets, pallets, stretch wrap and strapping labels for drug products as per cGMP Guidelines	-	-	-	-
PC4. perform the stacking, wrapping and cartoning of different drug product batches in suitable containers under supervision	-	-	-	-
PC5. label the containers / cartons with an appropriate marker / barcode and with proper handling and storage specifications along with batch details as per SOP	-	-	-	-
PC6. check for the un-labelled containers/cartons and for damaged labels on containers/ cartons of packed drug products	-	-	-	-
PC7. report to the supervisor/operators for remedial intervention for any damage/ deviation for drug product tertiary packaging	-	-	-	-
PC8. generate the records for the work performed in Batch Packaging Record for each batch as per cGMP guidelines and SOP	-	-	-	-
PC9. stack the shippers with packed drug products on the pallet as per SOP	-	-	-	-
PC10. load and transport the batches to the storage area using trolley or forklift for manual warehousing	-	-	-	-
PC11. load the packaged and labelled finished goods on the conveyer belt for automated warehousing	-	-	-	-



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. place all the equipment and materials in place after the completion of work as per SOP	-	-	-	-
PC13. Ensure the reconciliation of unused and/or damaged packaging material as per SOP	-	-	-	-
PC14. follow line-clearance steps as per SOP for smooth flow of work	-	-	-	-
NOS Total	30	47	10	13



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0264
NOS Name	Perform the secondary and tertiary packaging of drug products in adherence to current Good Manufacturing Practices (cGMP) guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Manufacturing
NSQF Level	2
Credits	5.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



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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:



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- 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



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- 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

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Assessment Criteria

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



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



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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



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LFS/N0103: Clean and sanitize work area and machines to avoid cross-contamination

Description

This job function is about the job holder maintaining the hygienic and clean work area to avoid cross-contamination

Scope

The scope covers the following :

- Sanitation activities before starting the work
- Segregation and sanitation activities during work
- Segregation and sanitation activities post completion of work

Elements and Performance Criteria

Sanitation activities before the start of work

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

- PC1.** ensure that there is adequate ventilation for the work being carried out
- PC2.** inspect the area and machines to identify cleaning requirements
- PC3.** handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method
- PC4.** clean the area or machine part under supervision as per SOP, in case of any stain on floor or machine
- PC5.** report any additional cleaning requirement, beyond his/her responsibility or skill, to the appropriate person
- PC6.** ensure to get the clearance from the authorized personnel post cleaning validation

Segregation and sanitation activities during work

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

- PC7.** deal with accidental spillage, if any, caused while carrying out the work and perform the cleaning as per SOP
- PC8.** segregate and store the finished goods/ material with an appropriate label in designated places to avoid cross-contamination
- PC9.** return the trolley, equipment, materials and personal protective equipment that was used to the right places making sure they are clean, safe and securely stored
- PC10.** segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision

Segregation and sanitation activities post completion of work

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

- PC11.** ensure that there is no slippery substance on the floor to avoid slippage
- PC12.** ensure that no scrap/ waste material is lying around



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- PC13.** ensure that, on completion of each batch packaging, the area is left clean and dry and meets WHO and cGMP requirements
- PC14.** ensure to get clearance from authorized personnel
- PC15.** dispose off the waste garnered from the activity as per SOP

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.** simple methods of cleaning of surfaces/ stains and soils
- 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 hygiene, cleaning and sanitation activity
- KU7.** concept of cleaning validation and its importance
- 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.** record and communicate details of work done to appropriate people using hand-written report or computer-based record/electronic mail
- GS2.** communicate with cross-functional teams and supervisor effectively
- GS3.** apply critical thinking skills while performing the area inspection
- GS4.** apply customer centricity at work
- GS5.** apply problem-solving and decision making while dealing with any deviation

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Sanitation activities before the start of work</i>	10	10	5	5
PC1. ensure that there is adequate ventilation for the work being carried out	-	-	-	-
PC2. inspect the area and machines to identify cleaning requirements	-	-	-	-
PC3. handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
PC4. clean the area or machine part under supervision as per SOP, in case of any stain on floor or machine	-	-	-	-
PC5. report any additional cleaning requirement, beyond his/her responsibility or skill, to the appropriate person	-	-	-	-
PC6. ensure to get the clearance from the authorized personnel post cleaning validation	-	-	-	-
<i>Segregation and sanitation activities during work</i>	15	10	5	5
PC7. deal with accidental spillage, if any, caused while carrying out the work and perform the cleaning as per SOP	-	-	-	-
PC8. segregate and store the finished goods/ material with an appropriate label in designated places to avoid cross-contamination	-	-	-	-
PC9. return the trolley, equipment, materials and personal protective equipment that was used to the right places making sure they are clean, safe and securely stored	-	-	-	-
PC10. segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision	-	-	-	-
<i>Segregation and sanitation activities post completion of work</i>	15	10	5	5



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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC11. ensure that there is no slippery substance on the floor to avoid slippage	-	-	-	-
PC12. ensure that no scrap/ waste material is lying around	-	-	-	-
PC13. ensure that, on completion of each batch packaging, the area is left clean and dry and meets WHO and cGMP requirements	-	-	-	-
PC14. ensure to get clearance from authorized personnel	-	-	-	-
PC15. dispose off the waste garnered from the activity as per SOP	-	-	-	-
NOS Total	40	30	15	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0103
NOS Name	Clean and sanitize work area and machines to avoid cross-contamination
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Generic
NSQF Level	2
Credits	1.00
Version	4.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



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LFS/N0114: Coordinate with the supervisor, teammates and cross-functional teams

Description

This NOS is about job-role holder coordinating with supervisor, teammates and other cross-functional teams to perform various activities

Scope

The scope covers the following :

- Coordination with the supervisor,
- Coordination with teammates,
- Coordination with cross-functional teams and other stakeholders,
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with the supervisor

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

- PC1.** coordinate with the supervisor to obtain work instructions
- PC2.** report in-time to the supervisor about any anticipated reasons for delay in the targeted work
- PC3.** report problems related to facility, equipment and material availability to the supervisor
- PC4.** submit complete daily work progress report to the supervisor

Coordination with teammates

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

- PC5.** takeover/ handover the shift, to/from colleagues as per defined guidelines
- PC6.** communicate and discuss workflow related difficulties with the team to find solutions with mutual agreement

Coordination with cross-functional teams and other stakeholders

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

- PC7.** coordinate with QA team to get instructions for any cGMP compliant process
- PC8.** coordinate with the store supervisor for the stocks of materials required
- PC9.** coordinate with Environment, Health and Safety team for safety incidents and in case of accidental hazard in the work area
- PC10.** provide the requisite information, documents, clarifications during actual audits

Sensitivity towards all genders and people with disability

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

- PC11.** respect all genders, religions, caste and cultures
- PC12.** empathize with the people with disability
- PC13.** offer support or help to a person with disability only when asked



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- PC14.** ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- PC15.** 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 methods of routine workplace communication
- KU3.** the method of responding to audit queries for own work
- KU4.** the shift handover/ takeover procedure in life sciences manufacturing units
- KU5.** the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act
- KU6.** the methods of team coordination
- KU7.** the types of possible disabilities among people with disability (PwD)
- KU8.** the challenges faced by PwD
- KU9.** the importance of displaying empathy towards PwD
- KU10.** the importance of awareness of gender sensitization and Prevention Of Sexual Harassment (POSH) act
- KU11.** the importance of respect for all religion, caste, and culture

Generic Skills (GS)

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

- GS1.** use written communication skills to record and report accurate, legible and complete information as per SOP and cGMP guidelines
- GS2.** use reading and comprehension skills to understand the various coding systems, instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed
- GS3.** use listening skills to understand the instructions and procedures to be followed
- GS4.** use verbal communication skills to interact with teammates, supervisor and cross-functional teams
- GS5.** use team-building skills while interacting with teammates and while managing the difficult/stressful or emotional situations at work
- GS6.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS7.** apply planning and organizing skills to plan and organize tools and material required to fulfil work requirements
- GS8.** apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations with clear choices and written instructions

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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Coordination with the supervisor</i>	10	10	-	5
PC1. coordinate with the supervisor to obtain work instructions	-	-	-	-
PC2. report in-time to the supervisor about any anticipated reasons for delay in the targeted work	-	-	-	-
PC3. report problems related to facility, equipment and material availability to the supervisor	-	-	-	-
PC4. submit complete daily work progress report to the supervisor	-	-	-	-
<i>Coordination with teammates</i>	10	10	2	3
PC5. takeover/ handover the shift, to/from colleagues as per defined guidelines	-	-	-	-
PC6. communicate and discuss workflow related difficulties with the team to find solutions with mutual agreement	-	-	-	-
<i>Coordination with cross-functional teams and other stakeholders</i>	10	10	2	3
PC7. coordinate with QA team to get instructions for any cGMP compliant process	-	-	-	-
PC8. coordinate with the store supervisor for the stocks of materials required	-	-	-	-
PC9. coordinate with Environment, Health and Safety team for safety incidents and in case of accidental hazard in the work area	-	-	-	-
PC10. provide the requisite information, documents, clarifications during actual audits	-	-	-	-
<i>Sensitivity towards all genders and people with disability</i>	10	5	5	5
PC11. respect all genders, religions, caste and cultures	-	-	-	-



Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. empathize with the people with disability	-	-	-	-
PC13. offer support or help to a person with disability only when asked	-	-	-	-
PC14. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC15. report any violation of Prevention of Sexual Harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	40	35	9	16



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0114
NOS Name	Coordinate with the supervisor, teammates and cross- functional teams
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Generic
NSQF Level	2
Credits	1.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024



Qualification Pack

DGT/VSQ/N0101: Employability Skills (30 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
- 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. understand the significance of employability skills in meeting the job requirements

Constitutional values – Citizenship

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

PC2. identify constitutional values, civic rights, duties, personal values and ethics and environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC3. explain 21st Century Skills such as Self-Awareness, Behavior Skills, Positive attitude, self-motivation, problem-solving, creative thinking, time management, social and cultural awareness, emotional awareness, continuous learning mindset etc.

Basic English Skills

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

PC4. speak with others using some basic English phrases or sentences

Communication Skills

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

PC5. follow good manners while communicating with others

PC6. work with others in a team



Qualification Pack

Diversity & Inclusion

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

PC7. communicate and behave appropriately with all genders and PwD

PC8. report any issues related to sexual harassment

Financial and Legal Literacy

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

PC9. use various financial products and services safely and securely

PC10. calculate income, expenses, savings etc.

PC11. approach the concerned authorities for any exploitation as per legal rights and laws

Essential Digital Skills

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

PC12. operate digital devices and use its features and applications securely and safely

PC13. use internet and social media platforms securely and safely

Entrepreneurship

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

PC14. identify and assess opportunities for potential business

PC15. identify sources for arranging money and associated financial and legal challenges

Customer Service

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

PC16. identify different types of customers

PC17. identify customer needs and address them appropriately

PC18. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC19. create a basic biodata

PC20. search for suitable jobs and apply

PC21. identify and register apprenticeship opportunities as per requirement

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. need for employability skills

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 basic spoken English language

KU6. Do and dont of effective communication

KU7. inclusivity and its importance

KU8. different types of disabilities and appropriate communication and behaviour towards PwD

KU9. different types of financial products and services



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- KU10.** how to compute income and expenses
- KU11.** importance of maintaining safety and security in financial transactions
- KU12.** different legal rights and laws
- KU13.** how to operate digital devices and applications safely and securely
- KU14.** ways to identify business opportunities
- KU15.** types of customers and their needs
- KU16.** how to apply for a job and prepare for an interview
- KU17.** apprenticeship scheme and the process of registering on apprenticeship portal

Generic Skills (GS)

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

- GS1.** communicate effectively using appropriate language
- GS2.** behave politely and appropriately with all
- GS3.** perform basic calculations
- GS4.** solve problems effectively
- GS5.** be careful and attentive at work
- GS6.** use time effectively
- GS7.** maintain hygiene and sanitisation to avoid infection

Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Introduction to Employability Skills</i>	1	1	-	-
PC1. understand the significance of employability skills in meeting the job requirements	-	-	-	-
<i>Constitutional values – Citizenship</i>	1	1	-	-
PC2. identify constitutional values, civic rights, duties, personal values and ethics and environmentally sustainable practices	-	-	-	-
<i>Becoming a Professional in the 21st Century</i>	1	3	-	-
PC3. explain 21st Century Skills such as Self-Awareness, Behavior Skills, Positive attitude, self-motivation, problem-solving, creative thinking, time management, social and cultural awareness, emotional awareness, continuous learning mindset etc.	-	-	-	-
<i>Basic English Skills</i>	2	3	-	-
PC4. speak with others using some basic English phrases or sentences	-	-	-	-
<i>Communication Skills</i>	1	1	-	-
PC5. follow good manners while communicating with others	-	-	-	-
PC6. work with others in a team	-	-	-	-
<i>Diversity & Inclusion</i>	1	1	-	-
PC7. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC8. report any issues related to sexual harassment	-	-	-	-
<i>Financial and Legal Literacy</i>	3	4	-	-
PC9. use various financial products and services safely and securely	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. calculate income, expenses, savings etc.	-	-	-	-
PC11. approach the concerned authorities for any exploitation as per legal rights and laws	-	-	-	-
<i>Essential Digital Skills</i>	4	6	-	-
PC12. operate digital devices and use its features and applications securely and safely	-	-	-	-
PC13. use internet and social media platforms securely and safely	-	-	-	-
<i>Entrepreneurship</i>	3	5	-	-
PC14. identify and assess opportunities for potential business	-	-	-	-
PC15. identify sources for arranging money and associated financial and legal challenges	-	-	-	-
<i>Customer Service</i>	2	2	-	-
PC16. identify different types of customers	-	-	-	-
PC17. identify customer needs and address them appropriately	-	-	-	-
PC18. follow appropriate hygiene and grooming standards	-	-	-	-
<i>Getting ready for apprenticeship & Jobs</i>	1	3	-	-
PC19. create a basic biodata	-	-	-	-
PC20. search for suitable jobs and apply	-	-	-	-
PC21. identify and register apprenticeship opportunities as per requirement	-	-	-	-
NOS Total	20	30	-	-



Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0101
NOS Name	Employability Skills (30 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	2
Credits	1
Version	1.0
Last Reviewed Date	15/03/2024
Next Review Date	14/03/2027
NSQC Clearance Date	15/03/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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



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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 : 50

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0275.Discuss about Life Sciences Industry and basics of Packaging Operations	40	30	15	15	100	10
LFS/N0264.Perform the secondary and tertiary packaging of drug products in adherence to current Good Manufacturing Practices (cGMP) guidelines	30	47	10	13	100	30
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	20
LFS/N0103.Clean and sanitize work area and machines to avoid cross- contamination	40	30	15	15	100	20
LFS/N0114.Coordinate with the supervisor, teammates and cross- functional teams	40	35	9	16	100	10
DGT/VSQ/N0101.Employability Skills (30 Hours)	20	30	-	-	50	10
Total	200	212	64	74	550	100



Qualification Pack

Acronyms

NOS	National Occupational Standard(s)
NSQF	National Skills Qualifications Framework
QP	Qualifications Pack
TVET	Technical and Vocational Education and Training
SOP	Standard Operating Procedure
cGMP	Current Good Manufacturing Practices
QA	Quality Assurance
GMP	Good Manufacturing Practice
POSH	Prevention of Sexual Harassment
PWD	People With Disability
ICH	International Council for Harmonisation
WHO	World Health Organisation
GMP	Good Manufacturing Practice
SOP	Standard Operating Procedure
EHS	Environment, Health and Safety
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practice
WHO	World Health Organization
QA	Quality Assurance
GMP	Good Manufacturing Practice
POSH	Prevention of Sexual Harassment
PWD	People With Disability
SOP	Standard Operating Procedure
PPE	Personal Protective Equipment
SOP	Standard Operating Procedure

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GMP	Good Manufacturing Practice
GDP	Good Distribution Practices
ICH	International Council for Harmonisation
WHO	World Health Organisation
GMP	Good Manufacturing Practice
SOP	Standard Operating Procedure
EHS	Environment, Health and Safety
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practice
WHO	World Health Organization
QA	Quality Assurance
GMP	Good Manufacturing Practice
POSH	Prevention of Sexual Harassment
PWD	People With Disability
SOP	Standard Operating Procedure
AA	Assessment Agency
AB	Awarding Body
ISCO	International Standard Classification of Occupations
NCO	National Classification of Occupations
NCrF	National Credit Framework
NOS	National Occupational Standard(s)
NQR	National Qualification Register
NSQF	National Skills Qualification Framework
OJT	On the Job Training
AA	Assessment Agency
AB	Awarding Body



Qualification Pack

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Glossary

Sector	Sector is a conglomeration of different business operations having similar business and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.
Sub-sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Occupation	Occupation is a set of job roles, which perform similar/ related set of functions in an industry.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Occupational Standards (OS)	OS specify the standards of performance an individual must achieve when carrying out a function in the workplace, together with the Knowledge and Understanding (KU) they need to meet that standard consistently. Occupational Standards are applicable both in the Indian and global contexts.
Performance Criteria (PC)	Performance Criteria (PC) are statements that together specify the standard of performance required when carrying out a task.
National Occupational Standards (NOS)	NOS are occupational standards which apply uniquely in the Indian context.
Qualifications Pack (QP)	QP comprises the set of OS, together with the educational, training and other criteria required to perform a job role. A QP is assigned a unique qualifications pack code.
Unit Code	Unit code is a unique identifier for an Occupational Standard, which is denoted by an 'N'
Unit Title	Unit title gives a clear overall statement about what the incumbent should be able to do.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate OS they are looking for.
Scope	Scope is a set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on quality of performance required.

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Knowledge and Understanding (KU)	Knowledge and Understanding (KU) are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
Organisational Context	Organisational context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Technical Knowledge	Technical knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Core Skills/ Generic Skills (GS)	Core skills or Generic Skills (GS) are a group of skills that are the key to learning and working in today's world. These skills are typically needed in any work environment in today's world. These skills are typically needed in any work environment. In the context of the OS, these include communication related skills that are applicable to most job roles.
Electives	Electives are NOS/set of NOS that are identified by the sector as contributive to specialization in a job role. There may be multiple electives within a QP for each specialized job role. Trainees must select at least one elective for the successful completion of a QP with Electives.
Options	Options are NOS/set of NOS that are identified by the sector as additional skills. There may be multiple options within a QP. It is not mandatory to select any of the options to complete a QP with Options.
National Occupational Standard	NOS defines the measurable performance outcomes required from an individual engaged in a particular task. They list down what an individual performing that task should know and also do.
Qualification	A formal outcome of an assessment and validation process is obtained when a the competent body determines that an individual has achieved learning outcomes to given standards
Qualification File	A Qualification File is a template designed to capture necessary information about a Qualification from the perspective of NSQF compliance. The Qualification File will be normally submitted by the awarding body for the qualification.
Sector	A grouping of professional activities on the basis of their main economic function, product, service, or technology.
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