Production Technician: Medical Device-Stents

Drug Coating

QP Code: LFS/Q6202   Instantiated QP Code: LFS/Q6202-SI005

Version: 1.0

NSQF Level: 5

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LFS/Q6202-SI005: Production Technician: Medical Device-Stents

Brief Job Description

The Production Technician for stent manufacturing is responsible for performing various processes like laser cutting, descaling, annealing, electropolishing, Ultrasonic Cleaning, drug coating and primary packaging of stent following Good Manufacturing Practices for the manufacturing of stent. The jobholder verifies the output to ensure that in batch manufacturing the quality parameters are met and ensures basic in-process quality checks for quality management. He/She also generates the critical records for every activity performed in compliance with data integrity rules. He/she also analyzes and report production/maintenance/quality related issues to the senior for solving work related problems. He/she also inspects products to verify conformance to specification.

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/N6203: Perform pre-production check and preparation of various machines for manufacturing](#)

2. [LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area](#)

3. [LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility](#)

4. [LFS/N6211: Perform reporting and documentation with data integrity for medical devices and IVD](#)

5. [LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors](#)

6. [DGT/VSQ/N0103: Employability Skills (90 Hours)](#)

Electives(mandatory to select at least one):

Elective : Drug Coating

1. [LFS/N6208: Perform Drug Coating Process](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
Country	India
NSQF Level	5
Credits	14
Aligned to NCO/ISCO/ISIC Code	NCO-2015- 3139.1400
Minimum Educational Qualification & Experience	Pursuing 2nd year of 2-year diploma after 12th (approved by AICTE or State Technical Education Regulatory Body in relevant field and continuous education) OR Pursuing 2nd year of UG (in life sciences or relevant fields)
Minimum Level of Education for Training in School	Not Applicable
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	01/11/2026
NSQC Approval Date	01/11/2023
Version	1.0
Reference code on NQR	QG-5-LS-01272-2023-V1-LSSSDC
NQR Version	1

LFS/N6203: Perform pre-production check and preparation of various machines for manufacturing

Description

This NOS is about performing pre-production checks and preparing machines for manufacturing operations

Scope

The scope covers the following :

- The NOS Scope are :
- Material Check
- Pre-production Safety Check
- Preparation of various machines for manufacturing

Elements and Performance Criteria

Material Check

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

PC1. ensure stocks of required raw materials are ready and available as per minimum stock required

PC2. perform thorough inspection and verification of quality of all raw material

PC3. ensure that critical starting material, raw material are from a respective batch and analyzed by QC and approved by QA

PC4. match the Batch Code/ Item Code and 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)

PC5. measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)

PC6. reach out to the supervisor for rejection control if disparities exist during visual inspection

PC7. 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:

PC8. follow safe working instructions as per SOP and regulatory guidelines

PC9. ensure manufacturing process follows relevant safety regulations

PC10. perform comprehensive risk assessments to identify potential risks

PC11. Perform machinery and equipment basic function testing to ensure their proper working

PC12. Perform Job Safety Analysis in accordance with International/ National Standards

PC13. take secure permit/ authorization to work from appropriate authority

Preparation of various machines for manufacturing

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

PC14. prepare machinery setup and configuration for stent manufacturing

PC15. ensure all the machines and equipments are calibrated & validated

PC16. ensure that facilities, equipments and machinery are qualified by QA post cleaning validation and equipment validation

PC17. ensure proper loading of material into machine

PC18. Perform trial run and random tests to ensure accuracy

PC19. Perform routine maintenance of machinery and equipment

PC20. maintain history records and breakdown maintenance records

PC21. 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 pre-production safety check and preparation of machines for manufacturing operations

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 and defined ISO Class guidelines

KU6. equipments used for broad level checks and their operative procedures

KU7. common issues in machine operations and their solutions

KU8. procedure for changeover cleaning

KU9. machinery and equipment calibration process

KU10. process for generating electronic records

KU11. methods for randoms tests in stent manufacturing

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. understand the various coding systems as per company norms

GS3. communicate with cross functional team and supervisor

GS4. disclose information only to those who have the right and need to know it

GS5. suggest improvements(if any) in process based on experience

GS6. make decisions related to corrective maintenance and troubleshooting

GS7. analyse the readings of various operational variables and make informed decisions as per SOP

GS8. 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**	**2**
PC1. ensure stocks of required raw materials are ready and available as per minimum stock required	-	-	-	-
PC2. perform thorough inspection and verification of quality of all raw material	-	-	-	-
PC3. ensure that critical starting material, raw material are from a respective batch and analyzed by QC and approved by QA	-	-	-	-
PC4. match the Batch Code/ Item Code and 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)	-	-	-	-
PC5. measure/weigh the starting material/ raw material/compound as per the desired specifications (shape, size and weight)	-	-	-	-
PC6. reach out to the supervisor for rejection control if disparities exist during visual inspection	-	-	-	-
PC7. return the unused material to warehouse with the appropriate label	-	-	-	-
Pre-production Safety check	**10**	**15**	**5**	**3**
PC8. follow safe working instructions as per SOP and regulatory guidelines	-	-	-	-
PC9. ensure manufacturing process follows relevant safety regulations	-	-	-	-
PC10. perform comprehensive risk assessments to identify potential risks	-	-	-	-
PC11. Perform machinery and equipment basic function testing to ensure their proper working	-	-	-	-
PC12. Perform Job Safety Analysis in accordance with International/ National Standards	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. take secure permit/ authorization to work from appropriate authority	-	-	-	-
Preparation of various machines for manufacturing	**10**	**15**	**5**	**5**
PC14. prepare machinery setup and configuration for stent manufacturing	-	-	-	-
PC15. ensure all the machines and equipments are calibrated & validated	-	-	-	-
PC16. ensure that facilities, equipments and machinery are qualified by QA post cleaning validation and equipment validation	-	-	-	-
PC17. ensure proper loading of material into machine	-	-	-	-
PC18. Perform trial run and random tests to ensure accuracy	-	-	-	-
PC19. Perform routine maintenance of machinery and equipment	-	-	-	-
PC20. maintain history records and breakdown maintenance records	-	-	-	-
PC21. maintain electronic documentation for the trial runs and random test along with justifications for any wrong entries as applicable	-	-	-	-
NOS Total	**30**	**45**	**15**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6203
NOS Name	Perform pre-production check and preparation of various machines for manufacturing
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
NSQF Level	5
Credits	2.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0130: Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

Description

This NOS is about ensuring adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area

Scope

The scope covers the following :

- The NOS scope are:
- Follow health and hygiene protocols
- Follow safety and security procedures
- Follow emergency procedures

Elements and Performance Criteria

Follow health and 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 regulatory guidelines/defined ISO class guidelines

PC2. ensure cleanroom facilities adhere to strict cleanliness guidelines

PC3. wash hands before entering in the production area as per SOP

PC4. report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person

PC5. ensure wearing cleanroom specialized garments while entering an environment-controlled work area

PC6. ensure proper disposal of used accessories

Follow safety and security procedures

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

PC7. comply with safety and security policies and procedures

PC8. use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process

PC9. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools

PC10. report any identified breaches in safety and security policies and procedures to the designated person

PC11. segregate material and follow the 5S system at the storage area

PC12. adhere to storage and handling guidelines for hazardous material and volatile chemicals

PC13. identify and correct any hazards that one can deal with safely, competently and within the limits of authority

PC14. ensure proper disposal of biohazardous material and chemical waste

Follow emergency procedures

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

PC15. raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected

PC16. inform the concerned person immediately about every unsafe act/ incident

PC17. follow emergency protocols 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 defined ISO class

KU6. limits of individual responsibility for dealing with hazards

KU7. chemical substances, their characteristics, and required precaution and safety measures

KU8. cleanroom specialized garment

KU9. the organization's emergency procedures for different emergency situations and the importance of following these procedures

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. Indian Medical device Rules 2017 and ISO 13485 guidelines for personal hygiene

KU14. types of safety gears and procedure to use them

KU15. importance of material segregation and 5S system

KU16. • importance of material segregation and 5S system
• 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 defined ISO class 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, defined ISO class 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

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and hygiene protocols	**15**	**15**	**5**	**5**
PC1. comply with health and personal hygiene-related protocols as per regulatory guidelines/defined ISO class guidelines	-	-	-	-
PC2. ensure cleanroom facilities adhere to strict cleanliness guidelines	-	-	-	-
PC3. wash hands before entering in the production area as per SOP	-	-	-	-
PC4. report any allergy, sickness, or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC5. ensure wearing cleanroom specialized garments while entering an environment-controlled work area	-	-	-	-
PC6. ensure proper disposal of used accessories	-	-	-	-
Follow safety and security procedures	**15**	**15**	**3**	**3**
PC7. comply with safety and security policies and procedures	-	-	-	-
PC8. use appropriate safety gears like gowns, shoecover, headgear, masks, gloves and other relevant safety accessories as per regulatory guidelines throughout the process	-	-	-	-
PC9. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
PC10. report any identified breaches in safety and security policies and procedures to the designated person	-	-	-	-
PC11. segregate material and follow the 5S system at the storage area	-	-	-	-
PC12. adhere to storage and handling guidelines for hazardous material and volatile chemicals	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. identify and correct any hazards that one can deal with safely, competently and within the limits of authority	-	-	-	-
PC14. ensure proper disposal of biohazardous material and chemical waste	-	-	-	-
Follow emergency procedures	**10**	**10**	**2**	**2**
PC15. raise the alarm and report any hazards which is not competent to deal with, to the relevant person in line with organizational procedures and warn other people who may get affected	-	-	-	-
PC16. inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
PC17. follow emergency protocols efficiently	-	-	-	-
NOS Total	**40**	**40**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0130
NOS Name	Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0131: Ensure a hygienic and clean work area to avoid contamination in manufacturing facility

Description

This NOS is about ensuring a hygienic and clean work area to avoid contamination

Scope

The scope covers the following :

- The NOS scope are:
- Sanitation activities before the start of work
- Sanitation activities during work
- Sanitation activities after 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 sanitation of cleanroom area as per SOP

PC2. check for validation tag on machines and equipments

PC3. ensure proper cleaning of machinery and equipments

PC4. ensure cleaning validation in the presence of authorized personnel or QA inspector

PC5. ensure adequate ventilation during work being carried out

PC6. ensure regular sterilization of machinery and equipment

PC7. handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method

PC8. segregate and store the 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:

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 proper disposal of hazardous material and chemical waste

PC13. ensure removal of scrap material from work area

PC14. ensure 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 clean and dry area after completion of work as per ISO requirement of sanitized premises

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. methodology to check machinery and equipment on completion of cleaning

KU4. procedures for reporting any unidentified soiling or any deviation for cleaning validation

KU5. role of different materials, machinery and equipment in cleaning and sanitation of manufacturing area

KU6. defined ISO class guidelines for cleaning/ sanitation activity and maintaining hygiene

KU7. cleaning validation process

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 the start of work	**15**	**15**	**5**	**5**
PC1. ensure sanitation of cleanroom area as per SOP	-	-	-	-
PC2. check for validation tag on machines and equipments	-	-	-	-
PC3. ensure proper cleaning of machinery and equipments	-	-	-	-
PC4. ensure cleaning validation in the presence of authorized personnel or QA inspector	-	-	-	-
PC5. ensure adequate ventilation during work being carried out	-	-	-	-
PC6. ensure regular sterilization of machinery and equipment	-	-	-	-
PC7. handle the cleaning material/reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
PC8. segregate and store the material with an appropriate label in designated places to avoid contamination	-	-	-	-
Sanitation activities during work	**15**	**15**	**3**	**3**
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**	**2**	**2**

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. ensure proper disposal of hazardous material and chemical waste	-	-	-	-
PC13. ensure removal of scrap material from work area	-	-	-	-
PC14. ensure 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 clean and dry area after completion of work as per ISO requirement of sanitized premises	-	-	-	-
NOS Total	**40**	**40**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0131
NOS Name	Ensure a hygienic and clean work area to avoid contamination in manufacturing facility
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N6211: Perform reporting and documentation with data integrity for medical devices and IVD

Description

This NOS is about performing reporting and documentation with data integrity for medical devices and IVD

Scope

The scope covers the following :

- The NOS scope are :
- Reporting and escalation of deviations
- 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 to quality assurance standards and product specifications

PC2. identify potential causes of non-conformities to quality assurance standards with the help of supervisor

PC3. implement the corrective and preventive actions as guided by the engineer and quality assurance team

Documentation

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

PC4. identify documentation to be completed as per SOP and ISO class rules

PC5. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and defined ISO class guidelines

PC6. maintain both electronic and manual records in the log books and other documentation required as per defined ISO class

PC7. update the Equipment log books , status boards & ensure in line with the process

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 manual and electronic records

KU3. ALCOA Principles, Data integrity, and information security rules

KU4. 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	**20**	**20**	**5**	**5**
PC1. identify non-conformities to quality assurance standards and product specifications	-	-	-	-
PC2. identify potential causes of non-conformities to quality assurance standards with the help of supervisor	-	-	-	-
PC3. implement the corrective and preventive actions as guided by the engineer and quality assurance team	-	-	-	-
Documentation	**20**	**20**	**5**	**5**
PC4. identify documentation to be completed as per SOP and ISO class rules	-	-	-	-
PC5. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and defined ISO class guidelines	-	-	-	-
PC6. maintain both electronic and manual records in the log books and other documentation required as per defined ISO class	-	-	-	-
PC7. update the Equipment log books , status boards & ensure in line with the process	-	-	-	-
NOS Total	**40**	**40**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6211
NOS Name	Perform reporting and documentation with data integrity for medical devices and IVD
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
NSQF Level	5
Credits	1
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

LFS/N0133: Coordinate and communicate with supervisor/ engineer, teams and auditors

Description

This NOS unit is about coordinating and communicating with supervisor/ engineer, teams and auditors

Scope

The scope covers the following :

- Coordination with supervisor/engineer
- Team coordination
- Respond to audit queries
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with supervisor/engineer

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

PC1. follow work instructions received from the reporting supervisor

PC2. adhere to the production plan to meet timelines

PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor

PC4. ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention

PC5. engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction

Team coordination

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 manufacturing process

PC9. coordinate with warehouse team for material dispensing and issuance

PC10. find solutions for workflow related difficulties with mutual agreement

PC11. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors

PC12. coordinate with quality control team for sample collection, batch release and in-process checks

PC13. coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP

PC14. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance

PC15. coordinate with EHS team for any safety incident, accident and emergency

Respond to audit queries

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

PC16. ensure interact with auditor in a preferable language

PC17. provide an honest and clear answer to the raised queries

PC18. maintain data integrity while responding to auditors or while producing the documented records for activities performed

Sensitivity towards all genders and people with disability

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

PC19. respect all genders, religions, and caste

PC20. empathize with the people with disability

PC21. offer support or help to a person with disability only when asked

PC22. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act

PC23. 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/engineer	**10**	**10**	**4**	**4**
PC1. follow work instructions received from the reporting supervisor	-	-	-	-
PC2. adhere to the production plan to meet timelines	-	-	-	-
PC3. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor	-	-	-	-
PC4. ensure timely intimation to supervisor/ production engineer about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
PC5. engage with supervisor on work-related and behavioral feedback and demonstrate continual learning and self-direction	-	-	-	-
Team coordination	**10**	**10**	**2**	**2**
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 manufacturing process	-	-	-	-
PC9. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
PC10. find solutions for workflow related difficulties with mutual agreement	-	-	-	-
PC11. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with quality control team for sample collection, batch release and in-process checks	-	-	-	-
PC13. coordinate with quality assurance team for machine/ equipment validation at a routine interval as per SOP	-	-	-	-
PC14. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
PC15. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
Respond to audit queries	**10**	**10**	**2**	**2**
PC16. ensure interact with auditor in a preferable language	-	-	-	-
PC17. provide an honest and clear answer to the raised queries	-	-	-	-
PC18. maintain data integrity while responding to auditors or while producing the documented records for activities performed	-	-	-	-
Sensitivity towards all genders and people with disability	**10**	**10**	**2**	**2**
PC19. respect all genders, religions, and caste	-	-	-	-
PC20. empathize with the people with disability	-	-	-	-
PC21. offer support or help to a person with disability only when asked	-	-	-	-
PC22. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act	-	-	-	-
PC23. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**40**	**40**	**10**	**10**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0133
NOS Name	Coordinate and communicate with supervisor/ engineer, teams and auditors
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Generic
NSQF Level	4.5
Credits	1
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

DGT/VSQ/N0103: Employability Skills (90 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. understand the significance of employability skills in meeting the current job market requirement and future of work

PC2. identify and explore learning and employability relevant portals

PC3. research about the different industries, job market trends, latest skills required and the available opportunities

Constitutional values – Citizenship

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

PC4. 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.

PC5. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC6. recognize the significance of 21st Century Skills for employment

PC7. 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

PC8. adopt a continuous learning mindset for personal and professional development

Basic English Skills

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

PC9. use basic English for everyday conversation in different contexts, in person and over the telephone

PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC11. 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:

PC12. identify career goals based on the skills, interests, knowledge, and personal attributes

PC13. prepare a career development plan with short- and long-term goals

Communication Skills

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

PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings

PC15. use active listening techniques for effective communication

PC16. communicate in writing using appropriate style and format based on formal or informal requirements

PC17. work collaboratively with others in a team

Diversity & Inclusion

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

PC18. communicate and behave appropriately with all genders and PwD

PC19. 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:

PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.

PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook

PC22. identify common components of salary and compute income, expenses, taxes, investments etc

PC23. 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:

PC24. operate digital devices and use their features and applications securely and safely

PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.

PC26. display responsible online behaviour while using various social media platforms

PC27. create a personal email account, send and process received messages as per requirement

PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications

PC29. utilize virtual collaboration tools to work effectively

Entrepreneurship

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

PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC32. 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:

PC33. identify different types of customers and ways to communicate with them

PC34. identify and respond to customer requests and needs in a professional manner

PC35. use appropriate tools to collect customer feedback

PC36. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC37. create a professional Curriculum vitae (Résumé)

PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively

PC39. apply to identified job openings using offline /online methods as per requirement

PC40. answer questions politely, with clarity and confidence, during recruitment and selection

PC41. 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. components of salary and 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

KU16. use applications such as word processors, spreadsheets etc.

KU17. how to identify business opportunities

KU18. types and needs of customers

KU19. how to apply for a job and prepare for an interview

KU20. 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 in English and other languages

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

GS3. behave politely and appropriately with all to maintain effective work relationship

GS4. how to work in a virtual mode, using various technological platforms

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. understand the significance of employability skills in meeting the current job market requirement and future of work	-	-	-	-
PC2. identify and explore learning and employability relevant portals	-	-	-	-
PC3. research about the different industries, job market trends, latest skills required and the available opportunities	-	-	-	-
Constitutional values – Citizenship	**1**	**1**	**-**	**-**
PC4. 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.	-	-	-	-
PC5. follow environmentally sustainable practices	-	-	-	-
Becoming a Professional in the 21st Century	**1**	**3**	**-**	**-**
PC6. recognize the significance of 21st Century Skills for employment	-	-	-	-
PC7. 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	-	-	-	-
PC8. adopt a continuous learning mindset for personal and professional development	-	-	-	-
Basic English Skills	**3**	**4**	**-**	**-**
PC9. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
PC11. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
Career Development & Goal Setting	**1**	**2**	**-**	**-**
PC12. identify career goals based on the skills, interests, knowledge, and personal attributes	-	-	-	-
PC13. prepare a career development plan with short- and long-term goals	-	-	-	-
Communication Skills	**2**	**2**	**-**	**-**
PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings	-	-	-	-
PC15. use active listening techniques for effective communication	-	-	-	-
PC16. communicate in writing using appropriate style and format based on formal or informal requirements	-	-	-	-
PC17. work collaboratively with others in a team	-	-	-	-
Diversity & Inclusion	**1**	**1**	**-**	**-**
PC18. communicate and behave appropriately with all genders and PwD	-	-	-	-
PC19. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
Financial and Legal Literacy	**2**	**3**	**-**	**-**
PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc.	-	-	-	-
PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC22. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
Essential Digital Skills	**3**	**5**	**-**	**-**
PC24. operate digital devices and use their features and applications securely and safely	-	-	-	-
PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc.	-	-	-	-
PC26. display responsible online behaviour while using various social media platforms	-	-	-	-
PC27. create a personal email account, send and process received messages as per requirement	-	-	-	-
PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications	-	-	-	-
PC29. utilize virtual collaboration tools to work effectively	-	-	-	-
Entrepreneurship	**2**	**3**	**-**	**-**
PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
Customer Service	**1**	**2**	**-**	**-**
PC33. identify different types of customers and ways to communicate with them	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC34. identify and respond to customer requests and needs in a professional manner	-	-	-	-
PC35. use appropriate tools to collect customer feedback	-	-	-	-
PC36. follow appropriate hygiene and grooming standards	-	-	-	-
Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
PC37. create a professional Curriculum vitae (Résumé)	-	-	-	-
PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-
PC39. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
PC40. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
NOS Total	**20**	**30**	**-**	**-**

National Occupational Standards (NOS) Parameters

NOS Code	DGT/VSQ/N0103
NOS Name	Employability Skills (90 Hours)
Sector	Cross Sectoral
Sub-Sector	Professional Skills
Occupation	Employability
NSQF Level	5
Credits	3
Version	1.0
Last Reviewed Date	30/05/2024
Next Review Date	30/05/2027
NSQC Clearance Date	30/05/2024

LFS/N6208: Perform Drug Coating Process

Description

The NOS is about performing drug coating process

Scope

The scope covers the following :

- The NOS Scope is :
- Preparation of Drug Coating Operations
- Drug Coating Operations

Elements and Performance Criteria

Preparation of Drug Coating Operations

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

PC1. ensure availability of high quality raw material as per defined ISO Class

PC2. perform preparation of drug coating solution under reverse laminar air in dispensing booth of class 100 (ISO class 5) surrounded by class 10000 (ISO class 8)

PC3. ensure drug coating solution is prepared as per SOP

PC4. ensure cleanroom are periodically validated and periodic environmental monitoring is performed as per SOP

PC5. ensure drug coating solution is tested as per quality plan

Drug Coating Operations

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

PC6. ensure coating process is performed with a validated process in a controlled environment of class 10000

PC7. ensure pre cleaned stent identification number and its measured weight are recorded accurately

PC8. perform pouring of prepared solution into spray gun and start coating process

PC9. ensure vacuum drying process is performed in same controlled environment of class 10000

PC10. ensure cleanroom are periodically validated

PC11. ensure drug coating process is validated as per records

PC12. ensure sending the drug coated stent to next stage after quality inspection as per quality plan

PC13. ensure any rejected drug coated stents are modified if feasible else segregate and dispose them as per SOP

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 manufacturing area

KU3. PPE used in descaling and annealing process and their work instructions

KU4. material segregation, handling and storage guidelines

KU5. type of machinery and equipment for drug coating process of stent and critical parameters

KU6. care and maintenance of equipment and machinery

KU7. removing and replacing components or parts of machinery and equipment

KU8. specialized techniques used in drug coating process

KU9. utilities used in drug coating process

KU10. basic in-process checks for drug coating process

KU11. procedure of preparation of drug coating

KU12. procedure of drug coating

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 in communicating the details of work done to appropriate people and during interaction with regulatory inspectors and other teammates

GS4. use planning and organizing skills in every activity planned and performed in stent operations and to achieve resource optimization

GS5. apply problem-solving skills to find solutions for workflow-related difficulties

GS6. apply critical skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern

GS7. use critical skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, complianc and cost

GS8. demonstrate decision making while making necessary adjustments in parameters to achieve quality specifications

GS9. apply customer-centricity while responding to auditors and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Preparation of Drug Coating Operations	**15**	**25**	**5**	**5**
PC1. ensure availability of high quality raw material as per defined ISO Class	-	-	-	-
PC2. perform preparation of drug coating solution under reverse laminar air in dispensing booth of class 100 (ISO class 5) surrounded by class 10000 (ISO class 8)	-	-	-	-
PC3. ensure drug coating solution is prepared as per SOP	-	-	-	-
PC4. ensure cleanroom are periodically validated and periodic environmental monitoring is performed as per SOP	-	-	-	-
PC5. ensure drug coating solution is tested as per quality plan	-	-	-	-
Drug Coating Operations	**15**	**25**	**5**	**5**
PC6. ensure coating process is performed with a validated process in a controlled environment of class 10000	-	-	-	-
PC7. ensure pre cleaned stent identification number and its measured weight are recorded accurately	-	-	-	-
PC8. perform pouring of prepared solution into spray gun and start coating process	-	-	-	-
PC9. ensure vacuum drying process is performed in same controlled environment of class 10000	-	-	-	-
PC10. ensure cleanroom are periodically validated	-	-	-	-
PC11. ensure drug coating process is validated as per records	-	-	-	-
PC12. ensure sending the drug coated stent to next stage after quality inspection as per quality plan	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC13. ensure any rejected drug coated stents are modified if feasible else segregate and dispose them as per SOP	-	-	-	-
NOS Total	**30**	**50**	**10**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N6208
NOS Name	Perform Drug Coating Process
Sector	Life Sciences
Sub-Sector	Medical Devices and In Vitro Diagnostic (IVD)
Occupation	Manufacturing - Medical Devices and IVD
NSQF Level	5
Credits	4.0
Version	1.0
Last Reviewed Date	01/11/2023
Next Review Date	01/11/2026
NSQC Clearance Date	01/11/2023

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/N6203.Perform pre-production check and preparation of various machines for manufacturing	30	45	15	10	100	20
LFS/N0130.Ensure adherence to environment, health and safety guidelines in manufacturing facility and controlled cleanroom area	40	40	10	10	100	10
LFS/N0131.Ensure a hygienic and clean work area to avoid contamination in manufacturing facility	40	40	10	10	100	10
LFS/N6211.Perform reporting and documentation with data integrity for medical devices and IVD	40	40	10	10	100	10
LFS/N0133.Coordinate and communicate with supervisor/ engineer, teams and auditors	40	40	10	10	100	10

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0103.Employability Skills (90 Hours)	20	30	-	-	50	10
Total	**210**	**235**	**55**	**50**	**550**	**70**

Elective: 1 Drug Coating

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N6208.Perform Drug Coating Process	30	50	10	10	100	30
Total	**30**	**50**	**10**	**10**	**100**	**30**