

Qualification Pack



Production Machine Operator-Sterile Formulations

Electives: Preparation

QP Code: LFS/Q1203 Instantiated QP Code: LFS/Q1203-SI001

Version: 3.0

NSQF Level: 4.5

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



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LFS/Q1203-SI001: Production Machine Operator-Sterile Formulations

Brief Job Description

The production machine operator Sterile Formulation program enables the learner to be able to meet the job responsibilities of production machine operator in an aseptic plant manufacturing for sterile formulations to operate the machines following Good Manufacturing Practices for the manufacturing / packaging of sterile formulations. The program shall be able to develop learner to verify the output to ensure that in batch manufacturing/ continuous manufacturing the quality parameters are met for dosage form sterile manufacturing and he/ she would be able to perform basic in-process quality checks to ensure safe and quality manufacturing with GMP compliance. The Program shall also enable engineering skills in the learners to maintain the semi-automated and automated plant equipment and troubleshoot and resolve primary level simple engineering problems to ensure minimal breakdown of the production line and maintain sterility of the machine as per set standards.

Personal Attributes

The individual should have good communication skills in the regional language and be able to comprehend the instructions and process documents in the English language. The person 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/N1224: Discuss about Life Sciences Industry and basic of sterile Manufacturing](#)
2. [LFS/N0112: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area](#)
3. [LFS/N0265: Maintain compliance with current Good Manufacturing Practices \(cGMP\) and other regulations](#)
4. [LFS/N0113: Ensure a hygienic and clean work area to avoid contamination](#)
5. [LFS/N0268: Perform Reporting and documentation with Data Integrity](#)
6. [LFS/N0104: Coordinate and communicate with Supervisor/ production chemist, teams and auditors](#)
7. [DGT/VSQ/N0102: Employability Skills \(60 Hours\)](#)

Electives(mandatory to select at least one):

Elective : Preparation

This elective is for operators involved in preparation area of sterile formulation



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1. [LFS/N1212: Prepare machines and perform pre-preparation checks and operation activities at preparation area of sterile dosage manufacturing](#)

Qualification Pack (QP) Parameters

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Pharma Manufacturing
Country	India
NSQF Level	4.5
Credits	15
Aligned to NCO/ISCO/ISIC Code	NCO 2015/ 8131.72
Minimum Educational Qualification & Experience	<p>Completed 1st year of UG (UG Certificate) OR D.Pharma OR Completed 2nd year of the 3-year diploma after 10 (engineering) OR 12th Class with 2 Years of experience OR 10th grade pass with 1 year NTC plus NAC (2 year NTC/NAC (Engineering trade)) with 2 Years of experience OR Certificate-NSQF (level 3- Assistant- Manufacturing and Packaging (Pharma, Biologics and Medical device)) with 4.5 years of experience OR Certificate-NSQF (Level 4 Production Machine Operator- Non Sterile Formulation or Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug) with 1.5 years of experience</p>
Minimum Level of Education for Training in School	10th Class
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA



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Next Review Date	17/12/2027
NSQC Approval Date	17/12/2024
Version	3.0
Reference code on NQR	QG-4.5-LS-03404-2024-V2-LSSSDC
NQR Version	2.0

Remarks:

Not applicable



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LFS/N1224: Discuss about Life Sciences Industry and basic of sterile Manufacturing

Description

This NOS is about Introduction to Life Sciences Industry and sterile Manufacturing

Scope

The scope covers the following :

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

Elements and Performance Criteria

Life Sciences industry and sterile Manufacturing

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

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

Basics of sterile manufacturing Operations

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

- PC5.** explain preventive measures to minimize contamination risks in sterile environments.
- PC6.** comply with key regulatory requirements for sterile manufacturing facilities (e.g., cGMP, GLP, GDP).
- PC7.** recall the impact of standard quantity effect on product quality and efficacy.
- PC8.** Analyze the role of each component in ensuring efficient and compliant manufacturing operations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

- KU1.** clean room behaviour practices and gowning procedures
- KU2.** various contamination risks in sterile environments.
- KU3.** SOP for entry and exit from GMP area
- KU4.** PPE used in sterile formulation manufacturing and their work instructions
- KU5.** material, segregation, handling and storage guidelines of WHO
- KU6.** type of reactors for sterile formulation (injectable/ eye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing, their operating process and critical parameters



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- KU7.** manufacturing process of Water for Pharma Use (WPU)/ water for injection and distilled water
- KU8.** utilities in sterile formulation (Injectable/ eye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing plant
- KU9.** in- process checks for sterile formulation (Injectable/ eye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing

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 plant operations and to achieve resource optimization
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** use critical thinking skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, compliance and cost
- GS8.** apply customer-centricity while responding to auditors and QA personnel



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Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Life Sciences industry and sterile Manufacturing</i>	20	-	5	5
PC1. discuss key insights in the life sciences sector through various market research reports	-	-	-	-
PC2. identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).	-	-	-	-
PC3. Elaborate importance of a skilled individual in sterile manufacturing	-	-	-	-
PC4. Discuss the role of government policies and initiatives in promoting the growth of the life sciences industry in India.	-	-	-	-
<i>Basics of sterile manufacturing Operations</i>	20	30	10	10
PC5. explain preventive measures to minimize contamination risks in sterile environments.	-	-	-	-
PC6. comply with key regulatory requirements for sterile manufacturing facilities (e.g., cGMP, GLP, GDP).	-	-	-	-
PC7. recall the impact of standard quantity effect on product quality and efficacy.	-	-	-	-
PC8. Analyze the role of each component in ensuring efficient and compliant manufacturing operations	-	-	-	-
NOS Total	40	30	15	15



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1224
NOS Name	Discuss about Life Sciences Industry and basic of sterile Manufacturing
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4.5
Credits	2.00
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/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/N0265: Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

GMP compliance in production process

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

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

GMP Compliance in waste management

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

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

GMP compliance in equipment maintenance

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

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

GMP compliance in documentation

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

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



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

Environment Sustainability

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)

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

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



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

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Assessment Criteria

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

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



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National Occupational Standards (NOS) Parameters

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



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

sanitation activities before starting the work

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

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

Sanitation activities during work

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

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

Sanitation activities after completion of work

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

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



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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)

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

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

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Assessment Criteria

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



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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

LFS/N0268: Perform Reporting and documentation with Data Integrity

Description

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

Scope

The scope covers the following :

- Reporting and escalation of deviation
- Documentation

Elements and Performance Criteria

Reporting and escalation of deviations

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

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

Documentation

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

Generic Skills (GS)



Qualification Pack

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

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

Qualification Pack

Assessment Criteria

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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Coordination with Supervisor / production chemist

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

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

Coordination with cross-functional teams

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

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

Coordination with auditors

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

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



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

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

Sensitivity towards all genders and people with disability

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

PC18. respect all genders, religions, and caste

PC19. empathize with people with disability

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

PC21. Adhere to the guidelines laid in POSH Act

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

KU2. the reporting structure of the organization

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

KU4. the required regulatory and statutory compliance-related documentation

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

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

KU7. the methods of workplace communication

KU8. importance of team coordination

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

KU10. the challenges faced by PwD

KU11. the importance of displaying empathy towards PwD

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

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

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

KU15. method to receive the performance feedback

Generic Skills (GS)

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

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

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



Qualification Pack

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

Qualification Pack

Assessment Criteria

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

Qualification Pack

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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Introduction to Employability Skills

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

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

Constitutional values – Citizenship

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

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

Becoming a Professional in the 21st Century

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

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

Basic English Skills

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



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

Career Development & Goal Setting

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

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

Communication Skills

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

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

Diversity & Inclusion

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

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

Financial and Legal Literacy

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

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

Essential Digital Skills

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

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

Entrepreneurship

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

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

Customer Service

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

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



Qualification Pack

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

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

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

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

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

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

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

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

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

KU11. how to compute income and expenditure

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

KU13. different legal rights and laws

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

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

KU16. how to identify business opportunities

KU17. types and needs of customers

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

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

Generic Skills (GS)

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

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

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



Qualification Pack

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

Qualification Pack

Assessment Criteria

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

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

Qualification Pack

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



Qualification Pack

National Occupational Standards (NOS) Parameters

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



Qualification Pack

LFS/N1212: Prepare machines and perform pre-preparation checks and operation activities at preparation area of sterile dosage manufacturing

Description

This NOS is about a machine operator performing preparatory operations for pre-preparation checks and operation activities at preparation area of sterile dosage manufacturing

Scope

The scope covers the following :

- Material Check
- pre production Safety Checks
- prepare machines for production

Elements and Performance Criteria

Material check

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

- PC1.** ensure gowning materials and equipment are available according to SOPs and perform gowning procedures with accuracy
- PC2.** recall personal qualification standards, sterility assurance practices, microbial kill time , Mean Kinetic Temperature (MKT), and Raw Material Certificate Of Analysis (RMCOA) guidelines to uphold aseptic conditions.
- PC3.** discuss about various qualification (Autoclave qualification, tunnel qualification, visual inspector qualification, Tanks qualifications, aseptic area qualification) as per SOP
- PC4.** operate the Warehouse Management System efficiently to manage inventory and material flows.
- PC5.** ensure that the correct raw materials, tools, consumables are available with valid documented QA approval for use in the manufacturing area
- PC6.** ensure all necessary reconciliation calculations are as per SOP and BMR
- PC7.** match the batch code/item code , Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the production planning team
- PC8.** perform visual inspection of material for signs of contamination and bloom
- PC9.** maintain classified area as per SOP to avoid cross contamination
- PC10.** segregate material in warehouse and hold area as per aseptic manufacturing operations guidelines and SOP
- PC11.** perform labelling for the containers of raw material , in process/ intermediate product and finished goods

Pre-production safety check

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

- PC12.** follow safe working instructions and sterilization process as per SOP/ batch record and MSDS chemical handling guidelines



Qualification Pack

- PC13.** use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury
- PC14.** ensure that the lift/ejection/slide/pneumatic valve mechanism/ movable parts of the machine is properly functioning
- PC15.** ensure that the nozzle/valve mechanism of the utilities are properly functioning
- PC16.** use antistatic shoes and dissipate static charge from hands on Static-charge discharge-board outside manufacturing area
- PC17.** ensure that signs indicating hot surfaces are put up wherever necessary
- PC18.** perform job safety analysis in accordance with international/ national standards
- PC19.** secure permit/ authorization to work from quality assurance/ production chemist

Prepare machine for production

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

- PC20.** follow procedure as per SOP for product changeover cleaning and sterilization
- PC21.** ensure CIP and SIP are carried out before manufacturing operations
- PC22.** principle of machines used for preparation of aseptic formulation manufacturing (Autoclave, Tunnel, DPBs (Dynamic Pass Box), LAFS (Laminar Air Flow system) , Vessels, Pressure vessels, Brevettie, UAFs (Ultra Air filtration), Vial/ PFS /Ophthalmic filling machine, Track and trace, checkweighers, Labelling machine).
- PC23.** check for any pending preventive maintenance & breakdown work and resolve primary level simple engineering problems
- PC24.** ensure that all instruments/ machines are calibrated, validated and sterilized
- PC25.** ensure that facilities & equipment are qualified by QA post sterilization, cleaning validation and equipment validation for Operation Qualification (OQ) and Performance Qualification (PQ)
- PC26.** ensure all the accessories like cleaning sample aids, tool kit, clean and sterilized utensils available in the production area
- PC27.** perform product status labeling on equipment as per SOP
- PC28.** ensure environmental monitoring in production area in compliance with WHO & ICH-GMP guidelines
- PC29.** set critical parameters (cycle time, temperature, pressure, ampere load, spray rate, etc.) for the machine as per SOP using control panel
- PC30.** ensure all the accessories and equipment change parts are sterilized before start the operation
- PC31.** perform trial run and random tests as per check list to ensure accuracy
- PC32.** maintain (electronic/manual) documentation for the trial runs and random test along with justifications for any wrong entries as applicable
- PC33.** ensure SOPs are accurately followed when equipment is dismantled, cleaned, decontaminated, stored or disposed of correctly at the end of a manufacturing or packaging process

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:



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- KU1.** preparation of normality and molarity calculations
- KU2.** clean room behaviour practices and gowning procedures
- KU3.** SOP for entry and exit from GMP area
- KU4.** basics of Stock management and FIFO/FEFO
- KU5.** PPE used in sterile formulation (Injectable/ Eye Drops/ Ointment/ cosmetics/ sanitizer/ Irrigating Solutions) manufacturing and their work instructions
- KU6.** material, segregation, handling and storage guidelines of WHO
- KU7.** type of reactors for sterile formulation (injectable/ eye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing, their operating process and critical parameters
- KU8.** manufacturing process of Water for Pharma Use (WPU)/ water for injection and distilled water
- KU9.** utilities in sterile formulation (Injectable/ iye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing plant
- KU10.** in- process checks for sterile formulation (Injectable/ eye drops/ ointment/ cosmetics/ sanitizer/ irrigating solutions) manufacturing

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 manufacturing operations and to achieve resource optimization
- GS5.** apply problem-solving skills to find solutions for workflow-related difficulties
- GS6.** apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and to deal with a colleague individually, depending on the type of concern
- GS7.** use critical thinking skills in analyzing impact of deviations, wastage and rejects to the environment and efficiency, complianc and cost
- GS8.** apply customer-centricity while responding to auditors and QA personnel



Qualification Pack

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Material check</i>	10	15	5	5
PC1. ensure gowning materials and equipment are available according to SOPs and perform gowning procedures with accuracy	-	-	-	-
PC2. recall personal qualification standards, sterility assurance practices, microbial kill time , Mean Kinetic Temperature (MKT), and Raw Material Certificate Of Analysis (RMCOA) guidelines to uphold aseptic conditions.	-	-	-	-
PC3. discuss about various qualification (Autoclave qualification, tunnel qualification, visual inspector qualification, Tanks qualifications, aseptic area qualification) as per SOP	-	-	-	-
PC4. operate the Warehouse Management System efficiently to manage inventory and material flows.	-	-	-	-
PC5. ensure that the correct raw materials, tools, consumables are available with valid documented QA approval for use in the manufacturing area	-	-	-	-
PC6. ensure all necessary reconciliation calculations are as per SOP and BMR	-	-	-	-
PC7. match the batch code/item code , Authorized Return (AR) No of each compound/material with the batch code on the job schedule given by the production planning team	-	-	-	-
PC8. perform visual inspection of material for signs of contamination and bloom	-	-	-	-
PC9. maintain classified area as per SOP to avoid cross contamination	-	-	-	-
PC10. segregate material in warehouse and hold area as per aseptic manufacturing operations guidelines and SOP	-	-	-	-
PC11. perform labelling for the containers of raw material , in process/ intermediate product and finished goods	-	-	-	-

Qualification Pack

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
<i>Pre-production safety check</i>	10	15	5	5
PC12. follow safe working instructions and sterilization process as per SOP/ batch record and MSDS chemical handling guidelines	-	-	-	-
PC13. use lifting equipment such as forklift/trolleys while lifting heavy materials to avoid physical injury	-	-	-	-
PC14. ensure that the lift/ejection/slide/pneumatic valve mechanism/ movable parts of the machine is properly functioning	-	-	-	-
PC15. ensure that the nozzle/valve mechanism of the utilities are properly functioning	-	-	-	-
PC16. use antistatic shoes and dissipate static charge from hands on Static-charge discharge-board outside manufacturing area	-	-	-	-
PC17. ensure that signs indicating hot surfaces are put up wherever necessary	-	-	-	-
PC18. perform job safety analysis in accordance with international/ national standards	-	-	-	-
PC19. secure permit/ authorization to work from quality assurance/ production chemist	-	-	-	-
<i>Prepare machine for production</i>	10	15	3	2
PC20. follow procedure as per SOP for product changeover cleaning and sterilization	-	-	-	-
PC21. ensure CIP and SIP are carried out before manufacturing operations	-	-	-	-
PC22. principle of machines used for preparation of aseptic formulation manufacturing (Autoclave, Tunnel, DPBs (Dynamic Pass Box), LAFS (Laminar Air Flow system) , Vessels, Pressure vessels, Brevettie, UAFs (Ultra Air filtration), Vial/ PFS /Ophthalmic filling machine, Track and trace, checkweighers, Labelling machine).	-	-	-	-
PC23. check for any pending preventive maintenance & breakdown work and resolve primary level simple engineering problems	-	-	-	-

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Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC24. ensure that all instruments/ machines are calibrated, validated and sterilized	-	-	-	-
PC25. ensure that facilities & equipment are qualified by QA post sterilization, cleaning validation and equipment validation for Operation Qualification (OQ) and Performance Qualification (PQ)	-	-	-	-
PC26. ensure all the accessories like cleaning sample aids, tool kit, clean and sterilized utensils available in the production area	-	-	-	-
PC27. perform product status labeling on equipment as per SOP	-	-	-	-
PC28. ensure environmental monitoring in production area in compliance with WHO & ICH-GMP guidelines	-	-	-	-
PC29. set critical parameters (cycle time, temperature, pressure, ampere load, spray rate, etc.) for the machine as per SOP using control panel	-	-	-	-
PC30. ensure all the accessories and equipment change parts are sterilized before start the operation	-	-	-	-
PC31. perform trial run and random tests as per check list to ensure accuracy	-	-	-	-
PC32. maintain (electronic/manual) documentation for the trial runs and random test along with justifications for any wrong entries as applicable	-	-	-	-
PC33. ensure SOPs are accurately followed when equipment is dismantled, cleaned, decontaminated, stored or disposed of correctly at the end of a manufacturing or packaging process	-	-	-	-
NOS Total	30	45	13	12



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National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1212
NOS Name	Prepare machines and perform pre-preparation checks and operation activities at preparation area of sterile dosage manufacturing
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	4.5
Credits	3.00
Version	3.0
Last Reviewed Date	17/12/2024
Next Review Date	17/12/2027
NSQC Clearance Date	17/12/2024

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

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



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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 : 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/N1224.Discuss about Life Sciences Industry and basic of sterile Manufacturing	40	30	15	15	100	10
LFS/N0112.Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area	30	40	15	15	100	10
LFS/N0265.Maintain compliance with current Good Manufacturing Practices (cGMP) and other regulations	27	33	21	19	100	15
LFS/N0113.Ensure a hygienic and clean work area to avoid contamination	30	40	15	15	100	10
LFS/N0268.Perform Reporting and documentation with Data Integrity	25	35	20	20	100	10



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National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0104.Coordinate and communicate with Supervisor/ production chemist, teams and auditors	33	33	17	17	100	10
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	5
Total	205	241	103	101	650	70

Elective: 1 Preparation

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1212.Prepare machines and perform pre-preparation checks and operation activities at preparation area of sterile dosage manufacturing	30	45	13	12	100	30
Total	30	45	13	12	100	30