Qualification Pack

Chemist - Production (Pharma, Cosmetics & Biologics)

Electives: API / Excipient Manufacturing

QP Code: LFS/Q1201 Instantiated QP Code: LFS/Q1201-SI001

Version: 4.0

NSQF Level: 5

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LFS/Q1201-SI001: Chemist - Production (Pharma, Cosmetics & Biologics)

Brief Job Description

Chemist - Production (Pharma, Cosmetics & Biologics) is responsible for monitoring the production processes and maintaining the compliance with regulatory standards. The job role holder carryout the reporting and documentation for regulatory compliance and responsible for maintaining the strict compliance to EHS and cGMP guidelines.

Personal Attributes

The individual should have good time management and analytical skills. The job holder must possess good communication and problem-solving skills. The person should be detail and result oriented.

Applicable National Occupational Standards (NOS)

Compulsory NOS:

1. LFS/N0274: Discuss about Life Sciences Industry and Basics of manufacturing Operations
2. LFS/N1219: Monitor the production process in compliance with cGMP and other regulatory guidelines
3. LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas
4. LFS/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors
5. LFS/N1220: Perform reporting and documentation for regulatory compliance
6. DGT/VSQ/N0102: Employability Skills (60 Hours)

Electives*(mandatory to select at least one):*

Elective : API / Excipient Manufacturing

This elective is for production chemist involved in the management of API manufacturing process.

1. LFS/N1221: Manage API / excipient manufacturing process in compliance with cGMP and other regulatory guidelines

Qualification Pack (QP) Parameters

Qualification Pack

Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Biotechnology
Occupation	Pharma Manufacturing
Country	India
NSQF Level	5
Credits	20
Aligned to NCO/ISCO/ISIC Code	NCO-2015/2262.0101
Minimum Educational Qualification & Experience	Completed 3 year diploma after 10th (Mechanical/ Mechatronics/ Electronics/ Chemical Engineering) with 1.5 years of experience in production of relevant product OR Completed 2nd year of UG (UG Diploma) (with Chemistry Subject)) OR Completed 2nd year of UG (UG Diploma) (B.E./ B.Tech. in Chemical Engineering / Biotechnology) OR Completed 2nd year of UG (UG Diploma) (B. Pharma) OR Certificate-NSQF (Level 4 Qualification for Production Machine Operator- Non Sterile Formulation) with 3 Years of experience in production of relevant product OR Certificate-NSQF (Level 4 Qualification for Production Equipment Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug) with 3 Years of experience in production of relevant product OR Certificate-NSQF (Level 4.5 Qualification for Production Equipment Operator- Sterile Formulation) with 1.5 years of experience in production of relevant product
Minimum Level of Education for Training in School	
Pre-Requisite License or Training	NA
Minimum Job Entry Age	18 Years
Last Reviewed On	NA
Next Review Date	08/04/2028
NSQC Approval Date	08/04/2025

Qualification Pack

Version	4.0
Reference code on NQR	QG-05-LS-00255-2025-V2-LSSSDC
NQR Version	2.0

Qualification Pack

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Life Sciences industry and Manufacturing Occupation

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

PC1. discuss key insights in the life sciences sector through various market research reports

PC2. Identify the major segments within the life sciences industry (pharmaceuticals, biotechnology, medical devices, etc.).

PC3. Elaborate importance of a skilled individual in manufacturing Occupation

PC4. explain the role of government policies and initiatives in promoting the growth of the life sciences industry in India.

Basics of manufacturing Operations

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

PC5. Comply with key regulatory requirements for manufacturing facilities (e.g., cGMP, cGLP, cGDP).

PC6. Ensure ethical considerations in life sciences manufacturing, including data integrity and patient safety.

PC7. Analyze the impact of standard quantity effect on product quality and efficacy.

PC8. Analyze the role of each component in ensuring efficient and compliant manufacturing operations

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. Understand the Indian Life Sciences industry's key features and challenges.

KU2. major segments like pharmaceuticals, biotechnology, and medical devices.

KU3. critical role of skilled individuals in ensuring quality and safety in manufacturing.

KU4. various guidelines like current Good Manufacturing Practices, current Good Storage Practices, Good Documentation Practices

KU5. basics of ALCOA Principles, data integrity and information security rules

KU6. methods to conserve water and energy

KU7. methods to minimize the pollution

KU8. how government policies and initiatives drive industry growth.

Generic Skills (GS)

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

GS1. use written communication skills to record information accurately in compliance with ALCOA principles as per SOP and GMP guidelines

GS2. use reading and comprehension skills to read the various coding systems, instructions, guidelines, procedures, rules, and signages

GS3. use listening skills to interpret the instructions, escalation matrix, procedures to be followed and to seek clarifications

GS4. use verbal communication skills to interact with teammates, supervisor, production chemist, and cross-functional teams

GS5. use team-building skills while dealing with teammates

GS6. apply problem-solving skills to find solutions for deviations found during process-related checks, non-conformities in standards and labeling

GS7. apply critical thinking skills to analyze and identify when to report an issue/concern to the supervisor and when to deal with a process error individually, depending on the type of concern

GS8. apply customer centricity to remain compliant with data integrity rules, GMP/GLP guidelines and to evaluate impact of wrongdoings

GS9. apply decision-making skills to make balanced judgments within the authority while dealing with daily work-life situations

Assessment Criteria

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

Qualification Pack

National Occupational Standards (NOS) Parameters

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

Qualification Pack

LFS/N1219: Monitor the production process in compliance with cGMP and other regulatory guidelines

Description

This NOS is about a Chemist - Production (Pharma, Cosmetics & Biologics) monitoring the production process while ensuring its compliance with cGMP and other regulatory guidelines

Scope

The scope covers the following :

- Pre-production process
- Production process
- Post-production process
- Environment sustainability

Elements and Performance Criteria

Pre-production process

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

PC1. ensure to wear PPE before entering in the production area and follow cleanroom behavior

PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective BMR

PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and cGMP guidelines

PC4. identify out of order, non- calibrated, non- validated equipment and ensure they are segregated for maintenance

PC5. ensure the availability of sufficient stock of raw materials and chemicals for production process as per the production schedule

Production Process

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

PC6. maintain cGMP standards at shop floor and conditions suitable for production of quality products as per requirement

PC7. prepare standard operating procedures, equipment master list, and equipment qualification plan for production process

PC8. ensure the raw material is processed strictly as per BMR and SOP

PC9. check the production process is carried out as per the respective production schedules

PC10. monitor all the critical operations of the production process

PC11. check on production yields and reconciliation at various stages of production process

PC12. PC12. Implement and monitor automation systems and control technologies to optimize production efficiency, reduce manual errors, and ensure consistent product quality as per cGMP standards.

PC13. monitor the production output of each shift operation for recording in the Batch Process Report (BPR) as per the approved guidelines

PC14. ensure that all the in-process checks are carried out and quality of the product is ensured at each stage as per the Standard Operating Procedures (SOP)

PC15. observe production incidents for any deviations from the standard production process

PC16. coordinate with QA for any change by originating change control request

PC17. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system

Post-production process

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

PC18. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules

PC19. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow

PC20. perform verification for the labels on finished good containers in compliance to labelling guidelines

Environment Sustainability

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

PC21. ensure energy conservation by switching off the machine and equipment post operations

PC22. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes

PC23. ensure energy conservation by optimizing the machine/ equipment performance

PC24. identify recyclable and non-recyclable, and hazardous waste generated

PC25. segregate waste into different categories to achieve minimum pollution of land and water

PC26. check for water leakage in plant/ work area and take corrective actions

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the selection of safety gears and PPE to be used and their operating procedures

KU2. the cleanroom behaviour and guidelines to be followed

KU3. the standard environmental conditions of the production area

KU4. the different types of pre-analysis checks performed

KU5. the different types of production process

KU6. the production equipment and their operating procedures

KU7. the chemicals and reagents used in production process, their properties and storage conditions

KU8. the ideal working conditions of equipment

KU9. the change control procedures

KU10. the standard operating procedures of the entire production unit

KU11. the guidelines related to manufacturing operations and environmental sustainability

KU12. the WHO guidelines and ICH-cGMP rules for waste disposal and waste management

KU13. the standard labelling guidelines

KU14. the line clearance SOP

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health, and safety instructions

GS2. use written communication skills to draft reports or electronic mails to communicate the details of work done to appropriate people

GS3. use problem-solving skills in dealing with any deviation from SOPs and day-today problems

GS4. use critical thinking skills in analyzing any situation which needs an immediate escalation or emergency alarm

GS5. apply problem-solving skills to find solutions for workflow-related difficulties using concepts of basic sciences (chemistry), mathematics, statistics

GS6. use planning and organizing skills in every activity planned and performed in production operations and to achieve resource optimization

GS7. apply analytical skill to observe and identify OOS/ OOT/ deviations in the production process

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Pre-production process	**10**	**15**	**3**	**2**
PC1. ensure to wear PPE before entering in the production area and follow cleanroom behavior	-	-	-	-
PC2. ensure that environmental conditions of the production area are maintained within the limits specified in the respective BMR	-	-	-	-
PC3. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP) and cGMP guidelines	-	-	-	-
PC4. identify out of order, non- calibrated, non-validated equipment and ensure they are segregated for maintenance	-	-	-	-
PC5. ensure the availability of sufficient stock of raw materials and chemicals for production process as per the production schedule	-	-	-	-
Production Process	**10**	**15**	**3**	**2**
PC6. maintain cGMP standards at shop floor and conditions suitable for production of quality products as per requirement	-	-	-	-
PC7. prepare standard operating procedures, equipment master list, and equipment qualification plan for production process	-	-	-	-
PC8. ensure the raw material is processed strictly as per BMR and SOP	-	-	-	-
PC9. check the production process is carried out as per the respective production schedules	-	-	-	-
PC10. monitor all the critical operations of the production process	-	-	-	-
PC11. check on production yields and reconciliation at various stages of production process	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. PC12. Implement and monitor automation systems and control technologies to optimize production efficiency, reduce manual errors, and ensure consistent product quality as per cGMP standards.	-	-	-	-
PC13. monitor the production output of each shift operation for recording in the Batch Process Report (BPR) as per the approved guidelines	-	-	-	-
PC14. ensure that all the in-process checks are carried out and quality of the product is ensured at each stage as per the Standard Operating Procedures (SOP)	-	-	-	-
PC15. observe production incidents for any deviations from the standard production process	-	-	-	-
PC16. coordinate with QA for any change by originating change control request	-	-	-	-
PC17. verify various online documentation entries at each production step in a manufacturing process information system and lab management information system	-	-	-	-
Post-production process	**5**	**10**	**3**	**2**
PC18. observe to ensure waste disposal in compliance with WHO guidelines and ICH-cGMP rules	-	-	-	-
PC19. monitor the line clearance activities performed by junior staff on the shop floors for smooth work- flow	-	-	-	-
PC20. perform verification for the labels on finished good containers in compliance to labelling guidelines	-	-	-	-
Environment Sustainability	**5**	**10**	**3**	**2**
PC21. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
PC22. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC23. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
PC24. identify recyclable and non-recyclable, and hazardous waste generated	-	-	-	-
PC25. segregate waste into different categories to achieve minimum pollution of land and water	-	-	-	-
PC26. check for water leakage in plant/ work area and take corrective actions	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1219
NOS Name	Monitor the production process in compliance with cGMP and other regulatory guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	3.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N0111: Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas

Description

This job function is about the job role holder ensuring adherence to the health, hygiene, safety and environment guidelines while working in the production facility and GMP controlled areas by self and subordinates

Scope

The scope covers the following :

- Follow health and hygiene protocols
- Adherence to safety and security procedures
- Adherence to 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 WHO standards, revised GMP and ICH GMP guidelines

PC2. wash hands before entering in the production area with soap/alcohol based sanitisers

PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person

PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates

PC5. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by others

Adherence to safety and security procedures

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

PC6. comply with safety and security policies and procedures

PC7. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work

PC8. take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates

PC9. ensure that discipline for material segregation and 5S system is followed at the storage area

PC10. comply with material handling, segregation, and storage guidelines for hazardous material

PC11. take corrective actions for reported hazards in consultation with EHS personnel

PC12. complete the records of safety drills and trainings undertaken by self and subordinates

Adherence to emergency procedures

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

PC13. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected

PC14. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion

PC15. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision

PC16. follow emergency procedures efficiently

PC17. ensure injured employees are provided appropriate first aid and medical aid

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. company's procedures for the environment, health, and safety

KU2. implications that any non-compliance with health, safety and security may have on individuals and the organization

KU3. workplace hazards in the manufacturing facility in the life sciences sector, how and when to report hazards

KU4. limits of individual responsibility for dealing with hazards

KU5. chemical substances, their characteristics, and required precaution and safety measures

KU6. gowning procedure

KU7. the organization's emergency procedures for different emergencies and the importance of following these

KU8. evacuation procedures for employees, contract staff and visitors

KU9. how to summon medical assistance and the emergency services, where necessary

KU10. health, safety and accident reporting procedures and the importance of reporting in GMP

KU11. different types of breaches in the environment, health, safety and security and how and when to report these

KU12. WHO guidelines for personal hygiene

KU13. type of safety gears and procedure to use them

KU14. the importance of material segregation and 5S system

KU15. 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 understand the various coding systems and to read instructions, guidelines, procedures, rules, and signages to understand the procedure to be followed

GS2. use listening skills to follow the instructions and procedures during emergency alarms

GS3. use written communication skills to accurately record every information required to be reported as per SOP and GMP guidelines in the prescribed language

GS4. apply planning and organizing skills to plan and organize tools and material required for work to fulfil environment, health, safety and security requirements

GS5. use critical thinking skills to take relevant actions on the accidents and breach in compliance with EHS protocols

GS6. apply decision-making skills to make balanced judgments within the authority 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 or hazard

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Follow health and hygiene protocols	**10**	**15**	**-**	**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 with soap/alcohol based sanitisers	-	-	-	-
PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person	-	-	-	-
PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach reported by subordinates	-	-	-	-
PC5. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by others	-	-	-	-
Adherence to safety and security procedures	**10**	**25**	**-**	**5**
PC6. comply with safety and security policies and procedures	-	-	-	-
PC7. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work	-	-	-	-
PC8. take preventive and corrective actions based on the report of any identified breaches in safety and security policies and procedures by subordinates	-	-	-	-
PC9. ensure that discipline for material segregation and 5S system is followed at the storage area	-	-	-	-
PC10. comply with material handling, segregation, and storage guidelines for hazardous material	-	-	-	-
PC11. take corrective actions for reported hazards in consultation with EHS personnel	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. complete the records of safety drills and trainings undertaken by self and subordinates	-	-	-	-
Adherence to emergency procedures	**10**	**15**	**-**	**5**
PC13. report any hazards that he/she is not competent to deal with the relevant EHS personnel and warn other people who may be affected	-	-	-	-
PC14. raise the alarm and inform the concerned person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion	-	-	-	-
PC15. follow emergency protocols for any alarms and ensure the safety of subordinates in the area under supervision	-	-	-	-
PC16. follow emergency procedures efficiently	-	-	-	-
PC17. ensure injured employees are provided appropriate first aid and medical aid	-	-	-	-
NOS Total	**30**	**55**	**-**	**15**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0111
NOS Name	Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical, Contract Research
Occupation	Generic
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N0117: Coordinate with Manager, team-members, cross-functional teams and auditors

Description

This NOS unit is about a person coordinating with cross-functional teams, Supervisor, team members and responding to auditors

Scope

The scope covers the following :

- Coordination with Manager
- Coordination within team and cross-functional teams
- Respond to audit queries
- Sensitivity towards all genders and people with disability

Elements and Performance Criteria

Coordination with Manager

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

PC1. coordinate with the reporting manager to obtain work instructions and develop the production plan

PC2. communicate to reporting manager about process-flow improvements and production defects received from previous process

PC3. inform concern authority for any potential hazards or expected process disruptions

PC4. provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager

PC5. report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline

Coordination within the team and cross-functional teams

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

PC6. work as a team with colleagues and share work as per their own workload

PC7. train junior chemists on procedures and provide assistance to them when needed

PC8. communicate and discuss workflow related difficulties to find solutions with mutual agreement

PC9. coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipment's

PC10. coordinate with Engineering department at the time of equipment qualification activities

PC11. coordinate with Stores manager to receive chemicals and materials in time

PC12. coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods

PC13. coordinate with QA team for line clearance, change control approvals , calibration and validation activities

Respond to audit queries

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

PC14. provide clear answers to the auditor's queries

PC15. produce the documented records of performed activities and operations to auditors

PC16. 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:

PC17. respect all genders, religions, and caste

PC18. empathize with people with disability

PC19. offer support or help to a person with disability only when asked

PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

PC21. 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 reporting structure of the organization

KU2. types of audits in the life sciences sector for the manufacturing plant

KU3. the required regulatory and statutory compliance related documentation

KU4. the guidelines for data integrity, ethics, and compliance in the life sciences industry

KU5. the guidelines laid on Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act

KU6. the methods of workplace communication

KU7. the methods of team coordination

KU8. the types of possible disabilities among people with disability (PWD)

KU9. the importance of awareness for gender sensitization and prevention of sexual harassment (POSH) act

KU10. the importance of respect for all the religions, caste, and cultures

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/typed report or computer-based record/electronic mail

GS3. use written communication skills to maintain proper and concise records as per given format

GS4. use verbal communication skills to communicate confidential and sensitive information discretely to the authorized person while interacting with teammates

GS5. use team-building skills during the interaction with teammates while managing the difficult/stressful or emotional situations at work

GS6. apply problem-solving skills to find solutions for workflow-related difficulties

GS7. 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

GS8. apply customer-centricity while responding to auditors, customer representatives and QA personnel

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Coordination with Manager	**10**	**15**	**3**	**2**
PC1. coordinate with the reporting manager to obtain work instructions and develop the production plan	-	-	-	-
PC2. communicate to reporting manager about process-flow improvements and production defects received from previous process	-	-	-	-
PC3. inform concern authority for any potential hazards or expected process disruptions	-	-	-	-
PC4. provide maintenance, engineering related or process related change control request and its impact reports proactively to the manager	-	-	-	-
PC5. report periodically the status of planned batch/ continuous manufacturing schedule to manager within the timeline	-	-	-	-
Coordination within the team and cross-functional teams	**10**	**15**	**3**	**2**
PC6. work as a team with colleagues and share work as per their own workload	-	-	-	-
PC7. train junior chemists on procedures and provide assistance to them when needed	-	-	-	-
PC8. communicate and discuss workflow related difficulties to find solutions with mutual agreement	-	-	-	-
PC9. coordinate with maintenance team for any breakdowns and preventive and corrective maintenance of production equipment's	-	-	-	-
PC10. coordinate with Engineering department at the time of equipment qualification activities	-	-	-	-
PC11. coordinate with Stores manager to receive chemicals and materials in time	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. coordinate with quality control team for raw material availability / release of raw materials and, semi-finished and finished goods	-	-	-	-
PC13. coordinate with QA team for line clearance, change control approvals , calibration and validation activities	-	-	-	-
Respond to audit queries	**5**	**10**	**3**	**2**
PC14. provide clear answers to the auditor's queries	-	-	-	-
PC15. produce the documented records of performed activities and operations to auditors	-	-	-	-
PC16. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
Sensitivity towards all genders and people with disability	**5**	**10**	**3**	**2**
PC17. respect all genders, religions, and caste	-	-	-	-
PC18. empathize with people with disability	-	-	-	-
PC19. offer support or help to a person with disability only when asked	-	-	-	-
PC20. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act	-	-	-	-
PC21. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
NOS Total	**30**	**50**	**12**	**8**

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N0117
NOS Name	Coordinate with Manager, team-members, cross-functional teams and auditors
Sector	Life Sciences
Sub-Sector	Pharmaceutical, Bio Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

LFS/N1220: Perform reporting and documentation for regulatory compliance

Description

This NOS is about a Chemist Production (Pharma, Cosmetics & Biologics) carrying out reporting and documentation and ensuring that the final documents meet regulatory and compliance requirements.

Scope

The scope covers the following :

- Reporting
- Recording and documentation
- Data Integrity

Elements and Performance Criteria

Reporting

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

PC1. follow reporting and escalation matrix as prescribed by the company

PC2. report defects/problem/incidents/quality issues/as applicable in a timely manner to the appropriate authority as laid down by the company

PC3. provide reports of deviations and OOS and OOT incidents to quality assurance team

PC4. escalate any change control request to quality assurance and regulatory team for approval

Recording and documentation

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

PC5. identify documentation to be completed for assigned activity

PC6. review and approve the logbook entries made by operators for all the production batches

PC7. complete all documentation within stipulated time according to regulatory guidelines and SOP

PC8. prepare deviation reports with detailed findings and recommendations as per SOPs

PC9. ensure that the final document meets regulatory and compliance requirements as per cGDP and cGMP

Data integrity

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

PC10. maintain all original and controlled document files and manufacturing records in a timely and accurate manner following ALCOA PLUS principles

PC11. respond to requests for information in an appropriate manner whilst following organizational procedures

PC12. make sure documents are available to all appropriate authorities to inspect/ audit

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the types of documentation in an organization and the importance of maintaining the same and different methods of recording information
KU2. the different methods of recording information
KU3. the reporting and recording formats
KU4. the importance of reporting incidents where standard operating procedures are not followed
KU5. the importance of complete and accurate documentation
KU6. the escalation matrix for reporting identified issues, hazards and breakage
KU7. the ALCOA PLUS Principles
KU8. the basic operating procedure for using a computer system and MS Office or any alternate software of MS Office
KU9. critical documentation steps for cGMP compliance in a regulated facility

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 in the English language
GS2. use reading and comprehension skills to understand the various coding systems and to read instructions, guidelines, procedures, rules, and signage to understand the procedure to be followed
GS3. use listening skills to understand the instructions and procedures to be followed
GS4. use verbal communication skills to interact with supervisor, teammates, cross-functional teams for coordination and to communicate confidential and sensitive information discretely to the authorized person
GS5. apply problem-solving skills to find solutions for workflow-related difficulties
GS6. apply customer-centricity while interacting with different stakeholders

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
Reporting	**10**	**15**	**5**	**5**
PC1. follow reporting and escalation matrix as prescribed by the company	-	-	-	-
PC2. report defects/problem/incidents/quality issues/as applicable in a timely manner to the appropriate authority as laid down by the company	-	-	-	-
PC3. provide reports of deviations and OOS and OOT incidents to quality assurance team	-	-	-	-
PC4. escalate any change control request to quality assurance and regulatory team for approval	-	-	-	-
Recording and documentation	**10**	**15**	**5**	**5**
PC5. identify documentation to be completed for assigned activity	-	-	-	-
PC6. review and approve the logbook entries made by operators for all the production batches	-	-	-	-
PC7. complete all documentation within stipulated time according to regulatory guidelines and SOP	-	-	-	-
PC8. prepare deviation reports with detailed findings and recommendations as per SOPs	-	-	-	-
PC9. ensure that the final document meets regulatory and compliance requirements as per cGDP and cGMP	-	-	-	-
Data integrity	**10**	**15**	**3**	**2**
PC10. maintain all original and controlled document files and manufacturing records in a timely and accurate manner following ALCOA PLUS principles	-	-	-	-
PC11. respond to requests for information in an appropriate manner whilst following organizational procedures	-	-	-	-
PC12. make sure documents are available to all appropriate authorities to inspect/ audit	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
NOS Total	30	45	13	12

Qualification Pack

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1220
NOS Name	Perform reporting and documentation for regulatory compliance
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	1.00
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

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

Description

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

Scope

The scope covers the following :

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

Elements and Performance Criteria

Introduction to Employability Skills

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

PC1. identify employability skills required for jobs in various industries

PC2. identify and explore learning and employability portals

Constitutional values – Citizenship

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

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

PC4. follow environmentally sustainable practices

Becoming a Professional in the 21st Century

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

PC5. recognize the significance of 21st Century Skills for employment

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

Basic English Skills

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

PC7. use basic English for everyday conversation in different contexts, in person and over the telephone

PC8. read and understand routine information, notes, instructions, mails, letters etc. written in English

PC9. write short messages, notes, letters, e-mails etc. in English

Career Development & Goal Setting

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

PC10. understand the difference between job and career

PC11. prepare a career development plan with short- and long-term goals, based on aptitude

Communication Skills

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

PC12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings

PC13. work collaboratively with others in a team

Diversity & Inclusion

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

PC14. communicate and behave appropriately with all genders and PwD

PC15. escalate any issues related to sexual harassment at workplace according to POSH Act

Financial and Legal Literacy

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

PC16. select financial institutions, products and services as per requirement

PC17. carry out offline and online financial transactions, safely and securely

PC18. identify common components of salary and compute income, expenses, taxes, investments etc

PC19. identify relevant rights and laws and use legal aids to fight against legal exploitation

Essential Digital Skills

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

PC20. operate digital devices and carry out basic internet operations securely and safely

PC21. use e- mail and social media platforms and virtual collaboration tools to work effectively

PC22. use basic features of word processor, spreadsheets, and presentations

Entrepreneurship

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

PC23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

PC24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion

PC25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity

Customer Service

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

PC26. identify different types of customers

PC27. identify and respond to customer requests and needs in a professional manner.

PC28. follow appropriate hygiene and grooming standards

Getting ready for apprenticeship & Jobs

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

PC29. create a professional Curriculum vitae (Résumé)

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

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

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

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

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

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

KU2. various constitutional and personal values

KU3. different environmentally sustainable practices and their importance

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

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

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

KU7. about effective communication

KU8. POSH Act

KU9. Gender sensitivity and inclusivity

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

KU11. how to compute income and expenditure

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

KU13. different legal rights and laws

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

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

KU16. how to identify business opportunities

KU17. types and needs of customers

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

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

Generic Skills (GS)

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

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

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

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

Assessment Criteria

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

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

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

Qualification Pack

National Occupational Standards (NOS) Parameters

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

LFS/N1221: Manage API / excipient manufacturing process in compliance with cGMP and other regulatory guidelines

Description

This NOS is about a Chemist Production (Pharma, Cosmetics & Biologics) monitoring and managing the API manufacturing process and ensuring compliance with cGMP and other regulatory guidelines

Scope

The scope covers the following :

- API/excipient Manufacturing process
- cGMP compliant documentation

Elements and Performance Criteria

API/ excipient Manufacturing process

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

PC1. ensure the API/excipient manufacturing process area is clean and is as per cleanroom guidelines

PC2. ensure the ICH Q7 GMP guidelines are followed for API/excipient manufacturing process

PC3. ensure raw material used for API/excipient manufacturing process is QC approved

PC4. check for labels on all the equipments, chemicals, reagents and raw materials

PC5. ensure implementation of all the controls for equipment as per written procedure to assure the quality of intermediate or API/ excipient

PC6. ensure all the API/excipient manufacturing process are carried out as per SOP

PC7. ensure final manufactured product is QC and QA approved and meets all quality standards

PC8. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products in case of deviations in production process

PC9. maintain batch production records for each intermediate and API/ excipient product

cGMP compliant documentation

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

PC10. perform documentation of the activities as per ALCOA principles

PC11. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines

PC12. identify corrective and preventive action (CAPA) for every incident and deviations in compliance with cGMP and other regulatory guidelines

PC13. review and approve the change control request in case of deviations in consultation with QA and regulatory team

PC14. review and approve the logbook entries and trial run records

PC15. maintain online documentation related to production activities like BMRs, BPRs, log books , daily records and production SOP’s as per cGMP and cGDP guidelines

Knowledge and Understanding (KU)

The individual on the job needs to know and understand:

KU1. the basic process of API manufacturing
KU2. the PPE used in API manufacturing and their work instructions
KU3. the cleanroom behaviour and guidelines for API manufacturing process
KU4. the ICH Q7 GMP guidelines for API production
KU5. the API production equipment and their operating procedures
KU6. the chemicals and reagents used in API production process, their properties and storage conditions
KU7. the procedures for reporting non-conformance, deviations, OOS/OOT
KU8. procedures for documentation, reporting and escalation
KU9. the concepts of data integrity and ALCOA PLUS
KU10. how to maintain online documentation

Generic Skills (GS)

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

GS1. use reading and comprehension skills to read and understand manuals, SOPs, health and safety instructions
GS2. use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle
GS3. use problem-solving skills to deal with any deviation from SOPs and day-today problems
GS4. use critical thinking skills in analyze any situation that requires immediate escalation or emergency alarm
GS5. apply problem-solving skills to find solutions for workflow-related difficulties
GS6. use planning and organizing skills in every activity planned and performed in production operations to achieve resource optimization
GS7. apply analytical skill to observe and identify OOS/ OOT/ deviations in the production process
GS8. apply decision making skills to make balanced judgments within the authority while dealing with daily work-life situations
GS9. use written communication skills to maintain proper and concise records as per given format and compliant with ALCOA principle

Assessment Criteria

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
API/ excipient Manufacturing process	**15**	**30**	**10**	**5**
PC1. ensure the API/excipient manufacturing process area is clean and is as per cleanroom guidelines	-	-	-	-
PC2. ensure the ICH Q7 GMP guidelines are followed for API/excipient manufacturing process	-	-	-	-
PC3. ensure raw material used for API/excipient manufacturing process is QC approved	-	-	-	-
PC4. check for labels on all the equipments, chemicals, reagents and raw materials	-	-	-	-
PC5. ensure implementation of all the controls for equipment as per written procedure to assure the quality of intermediate or API/ excipient	-	-	-	-
PC6. ensure all the API/excipient manufacturing process are carried out as per SOP	-	-	-	-
PC7. ensure final manufactured product is QC and QA approved and meets all quality standards	-	-	-	-
PC8. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products in case of deviations in production process	-	-	-	-
PC9. maintain batch production records for each intermediate and API/ excipient product	-	-	-	-
cGMP compliant documentation	**10**	**15**	**10**	**5**
PC10. perform documentation of the activities as per ALCOA principles	-	-	-	-
PC11. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and ICH-GMP guidelines	-	-	-	-

Assessment Criteria for Outcomes	Theory Marks	Practical Marks	Project Marks	Viva Marks
PC12. identify corrective and preventive action (CAPA) for every incident and deviations in compliance with cGMP and other regulatory guidelines	-	-	-	-
PC13. review and approve the change control request in case of deviations in consultation with QA and regulatory team	-	-	-	-
PC14. review and approve the logbook entries and trial run records	-	-	-	-
PC15. maintain online documentation related to production activities like BMRs, BPRs, log books , daily records and production SOP's as per cGMP and cGDP guidelines	-	-	-	-
NOS Total	**25**	**45**	**20**	**10**

National Occupational Standards (NOS) Parameters

NOS Code	LFS/N1221
NOS Name	Manage API / excipient manufacturing process in compliance with cGMP and other regulatory guidelines
Sector	Life Sciences
Sub-Sector	Pharmaceutical
Occupation	Pharma Manufacturing
NSQF Level	5
Credits	11
Version	3.0
Last Reviewed Date	08/04/2025
Next Review Date	08/04/2028
NSQC Clearance Date	08/04/2025

Assessment Guidelines and Assessment Weightage

Assessment Guidelines

1. Criteria for assessment for each Qualification Pack will be created by Life Sciences Sector Skill Development Council (LSSSDC)

2. Each Element will be assigned marks proportional to its importance in NOS. LSSSDC will also lay down the proportion of marks for Theory, Practical, Project, and Viva for each Element.

3. The assessment for the theory part will be based on the knowledge bank of questions created by the LSSSDC.

4. Assessment will be conducted for all compulsory NOS, and where applicable, on the selected elective/option NOS/set of NOS.

5. LSSSDC as assessment and awarding body will create unique evaluations for each assessment component i.e. theory, practical, project and via for every student at each examination/training center based on this criterion.

6. Wherever any assessment component is not applicable/ feasible, the balance assessment components will be used to assess the candidate and accordingly the total marks will be calculated only for the applied

assessment component.

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

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

Minimum Aggregate Passing % at QP Level : 70

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

Minimum Passing % at NOS Level: 70

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

Assessment Weightage

Compulsory NOS

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N0274.Discuss about Life Sciences Industry and Basics of manufacturing Operations	40	30	15	15	100	10
LFS/N1219.Monitor the production process in compliance with cGMP and other regulatory guidelines	30	50	12	8	100	15
LFS/N0111.Ensure adherence to Environment, health and safety guidelines in production facility and cGMP controlled areas	30	55	-	15	100	10
LFS/N0117.Coordinate with Manager, team-members, cross-functional teams and auditors	30	50	12	8	100	10
LFS/N1220.Perform reporting and documentation for regulatory compliance	30	45	13	12	100	15

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
DGT/VSQ/N0102.Employability Skills (60 Hours)	20	30	-	-	50	10
Total	**180**	**260**	**52**	**58**	**550**	**70**

Elective: 1 API / Excipient Manufacturing

National Occupational Standards	Theory Marks	Practical Marks	Project Marks	Viva Marks	Total Marks	Weightage
LFS/N1221.Manage API / excipient manufacturing process in compliance with cGMP and other regulatory guidelines	25	45	20	10	100	30
Total	**25**	**45**	**20**	**10**	**100**	**30**