NSQF QUALIFICATION FILE
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CONTACT DETAILS OF THE BODY SUBMITTING THE QUALIFICATION FILE

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List of documents submitted in support of the Qualifications File

1 Qualifications Pack
2 LSSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guidelines
3 Minutes of meeting of Governing Body
   - Composition of National Committee of NOS
4 NSDC Sector Skill Gap Report for Life Sciences Sector is available at http://nsdcindia.org/sites/default/files/files/Pharmaceuticals.pdf
5 Occupational Map and Career Progression Map
6 List of companies and Industry associations participated in the development of these qualification packs
7 List of QP/NOS validating companies

Model Curriculum (attached as annexure) including the following:

- Indicative list of tools/equipment to conduct the training
- Trainers qualification
- Unit Plan with Learning Objective
- Distribution of training duration into theory/skill practical/Project and Viva component

SUMMARY

1	**Qualification Title**	Production Machine Operator-Active Pharmaceutical Ingredient (API)/ Bulk Drug Electives: 1.Non Sterile Manufacturing (90 Hours) 2.Non Sterile Packaging (90 Hours) 3. Sterile Manufacturing and Packaging (90 Hours) • Minimum 1 and Maximum 2 Electives can be taken at once
2	**Qualification Code, if any**	LFS/Q0207 Ver. 3.0
3	**NCO code and occupation**	NCO-2015/ 3133.99
4	**Nature and purpose of the qualification (Please specify whether qualification is short term or long term)**	Short term training with or without apprenticeship
5	**Body/bodies which will award the qualification**	Life Sciences Sector Skill Development Council
6	**Body which will accredit providers to offer courses leading to the qualification**	Life Sciences Sector Skill Development Council
7	**Whether accreditation/affiliation norms are already in place or not, if applicable (if yes, attach a copy)**	Yes, attached the copy as annexure 1
8	**Occupation(s) to which the qualification gives access**	Manufacturing
9	**Job description of the occupation**	The production machine operator is responsible for operating the machines following Good Manufacturing Practices for the manufacturing/packaging of bulk drugs / active pharmaceutical ingredients (API). The job holder performs basic in-process quality checks to verify that the quality parameters are met for batch manufacturing/ continuous manufacturing. He/ She also generates the critical records for

		every activity performed in compliance with data integrity rules.
10	**Licensing requirements**	Not applicable
11	**Statutory and Regulatory requirement of the relevant sector (documentary evidence to be provided)**	Nil
12	**Level of the qualification in theNSQF**	4
13	**Anticipated volume of training/learning required to complete the qualification**	Compulsory Notional Hours Theory=120 Hours Practical= 210 Hours Employability Skills= 60 Hours Total compulsory Notional Hours=390 Hours Total Notional Hours for Elective Module 1 = 90 Hours Total Notional Hours for Elective Module 2 = 90 Hours Total Notional Hours for Elective Module 3 = 90 Hours Min Notional Hours with 1 Elective: 480 Hours Max Notional Hours with 2 Electives: 570 Hours Mandatory Apprenticeship Duration=12 months (2010 hours) Mandatory apprenticeship as below: • 2 years for Class 12/ITI • 1 year for L-3 certified candidate Note-D. Pharma is exempted from mandatory apprenticeship
14	**Indicative list of training tools required to deliver this qualification**	Attached as annexure 2
15	**Entry requirements and/or recommendations and minimum age**	• 12th Class (Science Subjects Preferred) OR • 10th + I.T.I (Any trade)

		OR • Certificate- NSQF Level 3 (Assistant- Manufacturing and Packaging (Pharma, Biologics and Medical device)) with 1-2 Years of relevant experience OR • D. Pharma Age: 18 Years
16	**Progression from the qualification (Please show Professional and academic progression)**	**Vertical progression** 1. Production Supervisor/ Junior Chemist – API/Chemical Manufacturing/ Packaging 2. Production Chemist- Life Sciences (API/ Non Sterile Formulation/ Sterile Formulation/AYUSH/Sanitary Products) **Lateral/Horizontal progression** 1. Production Machine Operator - Non Sterile Formulation (Level-4) 2. Production Machine Operator - Sterile Formulations (Level-4) 3. Production Machine Operator-AYUSH Products (Level-4)
17	**Arrangements for the Recognition of Prior Learning (RPL)**	The process to award the qualification via RPL mode and detailed methodology is given in point No.22
18	**International comparability Whether known (research evidence to be provided)**	While preparing the NOSs, a detailed secondary desk research was conducted. The European, South African and Australian NOSs were referredto. The relevant International NOSs for the job role are listed below for reference: UK NOS • COGLS206 Preparing reagents in life sciences andrelated industries • COGLS205 Maintain stocks ofresources,

		equipment and consumables in life sciences and related industries • COGLS2 Maintain effectiveand efficient working relationships • COGLS215 Carry out samplingoperations in life sciences • SFHPHARM22 Assist in the preparation of documentation,materials and other items for manufacture and assembly ofmedicinal products • COGLS202 Maintain effective and efficient working relationships in life Sciences andrelated industries • COGPIO3.2 control emergencies • COGLS201 Follow health andsafety procedures in life sciences • COGLS301 Maintain healthand safety in life sciences Switzerland NOS • Refer page no. 190 Unit Group3212 Australia NOS • Handle dangerous goods/hazardous substances • Communicate workplace information • Participate in OHS processes • Participate in work teams and groups South Africa NOS Act in accordance with ethical and legal codes of pharmaceutical representation and the laws of the country
19	**Date of planned review of the qualification**	30/09/2024
20	**Formal structure of the qualification** **a) Mandatory components**	

NOS/ Module Details	Total Duration Hours	Level	Credits
Compulsory Bridge Module Introduction to life sciences industry and applicable regulations & Fundamentals of Manufacturing in Life Sciences Sector	**30:00**	Level-4	**1.00**
Compulsory Module LFS/N0213 v4.0: Perform pre- production check and prepare machines for bulk drug production	**90:00**	Level-4	**3.00**
Compulsory Module LFS/N0112 v2.0: Adherence to Environment, health and safety guidelines in a production facilityand GMP controlled areas	**30:00**	Level-4	**1.00**
Compulsory Module LFS/N0265 v2.0: Maintain compliance with Good Manufacturing Practices (GMP) and other regulations	**120:00**	Level-4	**4.00**
Compulsory Module LFS/N0113 v2.0: Ensure a hygienic and clean work area to avoid contamination	**30:00**	Level-4	**1.00**
Compulsory Module LFS/N0104 v3.0: Coordinate and communicate withSupervisor/ production chemist, teams andauditors	**30:00**	Level-4	**1.00**
DGT/VSQ/N0102: Employability Skills	**60:00**		**2.00**
Total Duration (A)	**390:00**		
Total Credits (A)			**13.00**

a) Elective Modules

Elective 1: Non Sterile Manufacturing

NOS/ Module Details	Total Duration Hours	Level	Credits
Elective 1: Non-Sterile Manufacturing LFS/N0214 v4.0: Perform non- sterile bulk drug/API manufacturing operations	**90:00**	Level-4	**3.00**
Sub Total Duration (Hours) (B)	**90:00**		
Sub Total Credits (B)			**3.00**

Elective 2: Non-Sterile Packaging

NOS/ Module Details	Total Duration Hours	Level	Credits
Elective 2: Non-Sterile Packaging	**90:00**	Level-4	**3.00**

LFS/N0266 v2.0: Perform primary packaging operations for Bulk Drug / API			
Sub Total Duration (Hours) (C)	**90:00**		
Sub Total Credits (C)			**3.00**

Elective 3: Sterile Manufacturing and Packaging

NOS/ Module Details	Total Duration Hours	Level	Credits
Elective 3: Sterile Manufacturing and Packaging LFS/N0267 v2.0: Perform sterile Bulk drug API/ manufacturing and primary packaging operations	**90:00**	Level-4	**3.00**
Sub Total Duration (Hours) (D)	**90:00**		
Sub Total Credits (D)			**3.00**

Total Maximum Duration of Notional Hours (Mandatory Component with 2 Electives)	**570:00**		
Total Maximum Credits of Qualification (A+B+C) (Mandatory Component with 2 Electives)			**19.00**

Apprenticeship Component

Mandatory Apprenticeship	**12 Months**

SECTION 1 ASSESSMENT

21	**Body/Bodies which will carry out assessment:** **Following assessment agencies will carry out assessments:** 1. Induslynk Training Services Pvt. Ltd.- Mercer- Mettl , Plot Number 85, Sector 44, Gurugram, India 2. Aspiring Minds Assessment Pvt. Ltd.- 323, Udyog Vihar, Phase 2, Gurugram, Haryana 3. CoCubes Technologies Pvt. Ltd.- 1205-1206, 12th Floor, Welldone Tech Park, Sohna Road, Gurugram 122002, Haryana 4. Glocal Thinkers Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana 5. Life Sector Skill Development Council, 14, Palam Marg, Pandav Nagar, Sector B 1, Vasant Vihar, New Delhi, Delhi 110057
22	**How will RPL assessment be managed and who will carry it out?** **Assessment process for RPL programs (Candidates with experience in the occupation or for informally trained and employed trainees):** • Every RPL batch is uploaded on Skill Development Management System (SDMS) managed by National Skill Development Corporation (NSDC). SDMS reflects the proposed date of assessment for the batch. The batch is uploaded on SDMS by RPL project implementation agency. • LSSSDC conducts Assessments via its empaneled Assessment Agencies and assigns the batch to an assessment agency pre-notified with NSQC for the job role. • Assessment agency ensures the availability of required infrastructure, tools for the assessment. • Assessments for RPL candidates are conducted in following two modes: A) Theory and Skill Practical on a fully digital platform. B) Theory part digital and practical part through actual assessor observation. The authenticity of Trainee's identity and eligibility is verified by project implementation agency by verifying the ID proof documents (any document issued by GOI, such as Aadhaar Card, Driving License, Passport, election card etc.) and experience proof (industry endorsement, experience letters) • Assessment agency collects evidences of the assessment in best possible way (videos, pictures, assessment logs etc.) • The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days from the date of assessment. • LSSSDC validates the assessment results and announces the result on SDMS within 15 days of assessment date. • Passed candidates are provided with qualification certificate. **Assessment tools:** For the Training assessment, the assessment instrument development is done by the selected assessment body with close monitoring and support of LSSSDC at every stage. **Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man

	out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee. **Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee. **Following assessment agencies will carry out assessments:** 1. Induslynk Training Services Pvt. Ltd.- Mercer- Mettl , Plot Number 85, Sector 44, Gurugram, India 2. Aspiring Minds Assessment Pvt. Ltd.- 323, Udyog Vihar, Phase 2, Gurugram, Haryana 3. CoCubes Technologies Pvt. Ltd.- 1205-1206, 12th Floor, Welldone Tech Park, Sohna Road, Gurugram 122002, Haryana 4. Glocal Thinkers Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana 5. Life Sector Skill Development Council, 14, Palam Marg, Pandav Nagar, Sector B 1,Vasant Vihar, New Delhi, Delhi 110057
23	**Describe the overall assessment strategy and specific arrangements which have been put in place to ensure that assessment is always valid, reliable and fair and show that these are in line with the requirements of the NSQF.** **Assessment Agencies:** An assessment agency is selected based on • Prior experience and understanding of Life Sciences or similar sector. • Experience in conducting assessments for similar job roles. • Manpower and Technical capabilities. • Geographical reach • Existing Network in the Life Sciences Sector • Agency's internal policies to maintain Standards, Quality & professional Integrity • Agency's policy in assessor management **Assessment development:** The assessment development is done with close monitoring and under supervision of LSSSDC at every stage. Steps for assessment development: • Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification Pack.

- For Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drugassessment a blue print of the question paper, is part of assessment tool for training.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). This SME must have over 13-15 years of experience in the industry in manufacturing occupation.
- SME is screened and approved by LSSSDC. He is the oriented by both LSSSDC and Assessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

Assessor: The Assessors are engaged to conduct the assessments. Assessor guidelines are followed as below:

Assessor Prerequisites						
Minimum Educational Qualification	**Specialization**	**Relevant Industry Experience**		**Training/Assessment Experience**		**Remarks**
		Years	**Specialization**	**Years**	**Specialization**	
12th Class	Science Subjects	6	Nutraceutical/ Pharmaceutical/ Biopharmaceutical Manufacturing /Production	2	On the job assessment / Training experience/ Vocational assessment /	
ITI Diploma	AOCP/ Fitter/ Mechanical/Chemical	6	Nutraceutical/ Pharmaceutical/ Biopharmaceutical Manufacturing /Production		On the job assessment / Training experience/ Vocational assessment / Academic assessment	
B.Sc./ B. tech/ B. Pharma.	Chemistry/ Pharmacy/ Chemical Engg./Biotech Engg.	4	Nutraceutical/ Pharmaceutical/ Biopharmaceutical Manufacturing /Production	2	On the job assessment / Training experience/ Vocational assessment / Academic assessment	

Assessor Certification	
Domain Certification	**Platform Certification**
Production Machine Operator- Active	Recommended that the Assessor is certified

Pharmaceutical Ingredient (API)/ Bulk Drug formulation mapped to the Qualification Pack: "LFS/Q0207, v1."with minimum accepted score of 80%.	for the Job Role: "Assessor", mapped to the Qualification Pack: "MEP/Q2701, v1.0" with minimum scoreof 80%.

Assessment process for fresh skill development programs (Short term without apprenticeship):

- Every fresh batch is uploaded on Skill Development Management System (SDMS) managed by National Skill Development Corporation (NSDC). SDMS reflects the Start date, end date of the training and date of assessment for the batch. The batch is uploaded on SDMS by Vocational Training Centre.
- LSSSDC conducts Assessments via its empaneled Assessment Agencies and assigns the batch to an assessment agency pre-notified with NSQC for the job role.
- Assessment agency ensures the availability of required infrastructure, tools for the assessment.
- Assessments for Fresh candidates are conducted in mode of Theory and Viva for Skill Practical. Skill Viva is conducted by an Assessor
- In case an assessor is involved in the assessment methodology, the trainees are scheduled in such a way that an assessor shall not assess more than 30 candidates in a day.
- Assessor and proctor from Assessment agency are present on the day of assessment to manage the process at assessment location.
- The assessor carry Aadhaar card and which has been pre informed to the vocational training center.
- Assessor ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Aadhar Card, Driving License, Passport, election card etc.)
- Assessor collects evidences of the assessment in best possible way (videos, pictures etc.)
- Proctor maintains the records of attendance, verified documents, and whatever other evidence of assessment as applicable.
- Assessor maintains complete confidentiality of the score, compiles the data and document and sends it to assessment agency.
- In cases where 100% digital assessment methodology is used, the above verifications and document collection and maintenance is done by the proctor.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days from the date of assessment.
- LSSSDC validates the assessment results and announces the result on SDMS within15 days of assessment date.
- Passed candidates are provided with qualification certificate.

Assessment tools: Assessment tools for a QP are decided based on composition of knowledge and skill in that QP. All assessments shall have at least two tools unless indicatedotherwise. All assessments carry time allotment required per trainee, within which the assessment should be completed.

Digital Written test for knowledge assessment:
Scope – Is used to test the knowledge component of the Qualification Pack.
Tools – Computer or tab based online or offline.
Method – objective type questions, match the columns, fill in the blanks, tick the odd man

out, choose the correct option, choose the best answer, True or false, Identify the object, toolor machinery, arrange in proper sequence, case study, scenario-based responses.
Analysis – Question paper is divided in sections. Each Section intends to assess a particularknowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea ofthe areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

Digital Written test for skill assessment

Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.
Tools – computer or tab based online or offline questions.
Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations.
Analysis – Question paper is divided in sections. Each Section intends to assess a particularskill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overallrating of the trainee.

Assessment process for Apprenticeship linked fresh skill development programs(Short term with apprenticeship):

The assessment for the Basic Training and On the Job Training will be conducted toward theend of the OJT duration.

Assessment Process:

The assessment will be in two parts as below:

Part 1: OJT Assessment

For OJT assessment the Industry nominated assessor will be assessing the candidates based on the OJT monitoring report submitted by Industry supervisor and Viva by the Industry nominated assessor

1.1 Industry nominated aassessor:

The Assessors are engaged to conduct the assessments by Industry. The selection takesplace as follows

- Industry defines the criteria for profile of an assessor.
- Assessor is a person who is currently working in the same industry on same or higher job role and has minimum 5-7 years of experience.
- Once selected, the assessor is oriented by Industry using LSSSDC guidelines on various aspects of the assessment and management of assessment, such as
- QP and its background.
- Training on Assessment methodology and how to use Assessment tools. Scoring system. (as per the attached assessment guide)
- Maintain integrity at the assessment site.
- Crisis handling and support system available for the same.
- Scope of his authorities
- Administrative responsibilities.
- Required documentation of Trainee credentials, mark sheet management.
- Confidentiality management.

1.2 Assessment Tool for OJT:

.2.1 OJT Monitoring Report:

- As in Life Sciences Sector reproducing the evidence for assessment is not feasible due to constraints like cost, confidentiality and controlled environment, every apprentice is required to record the evidences performed during the OJT and the same gets authorized by his/her supervisor.
- The evidence recording is done in a structured monitoring report, termed as OJT monitoring report.
- During the OJT, every trainee is required to fill the OJT monitoring report which is required to be signed by his/her supervisor.
- Towards the end of OJT period these reports are submitted with the HR department of company
- These duly submitted reports are then verified by an Industry nominated assessor for verification of evidence.

.2.2 Viva:

***Scope* –** Is used to test the knowledge and understanding and skills acquired during the OJTas well as to conform the OJT monitoring report.
Some personality traits and generic skills (such as – promptness, sharpness, communicationskills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.
Tools – Direct dialogue between assessor and Trainee.

Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are includedto test relevant PCs from the QP

Analysis – Assessor draws a spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batchor different institutes can be gauged.

1.3 Execution of OJT Assessment:

- HR department then hands over the individual OJT monitoring report with Industry nominated assessor and schedules an assessment meeting for each trainee
- Industry nominated assessor assesses each trainee based on OJT monitoring report, viva on each PC and attendance with each trainee towards the end of the OJT period.
- The OJT marks are compiled for each NOS by the Industry nominated assessor and submitted with HR department of company.
- The OJT assessment results are then sent to LSSSDC by HR department of companyin a sealed envelope for compiling the assessment results.

Part 2: Basic Training Assessment
For Execution of the assessment for basic training, LSSSDC will be engaging more than oneassessment agencies/ body.

2.1 Criteria of selection of assessment body/agency:
The assessment body/agency is selected on the basis of

- Prior experience and understanding of Life Sciences or similar sector.
- Experience in conducting assessments for similar job roles.
- Manpower and Technical capabilities.
- Geographical reach
- Existing Network in the Life Sciences Sector
- Agencies internal policies to maintain standards, quality & professional Integrity
- Agencies policy in assessor management

2.2 Assessment tool for Basic Training:

For the Basic training assessment, the assessment instrument development is done by theselected assessment body with close monitoring and support of LSSSDC at every stage.

2.2.1 Digital Written test for knowledge assessment:

Scope – Is used to test the knowledge component of the QP.

Tools –computer or tab based online or offline.

Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, toolor machinery, arrange in proper sequence, case study, scenario-based responses.

Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.

2.2.2 Digital Written test for skill assessment:

Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested.

Tools – computer or tab based online or offline questions

Method – A situation is narrated or created in the question posed to the trainee and he isasked objective type questions to select the correct reaction to the situation. The selectedsituations are based on real situations.

Analysis – Question paper is divided in sections. Each Section intends to assess a particularskill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overallrating of the trainee.

2.3 Steps for assessment development:

- Selection of assessment tool(s) is done as per the assessment criteria prescribed inQualification Pack.
- For Production Machine Operator – Active Pharmaceutical Ingridient (API)/Bulk Drugassessment a blue print of the question paper, is part of assessment tool for basic training.
- Development of lay-out of Question paper is such that the entire PCs (Performance Criteria) of that QP are covered.
- Score per question maps with the weightage given to that PC, in the assessment criteria and the level of difficulty of the question.
- An expert from industry is selected who is called "Subject Matter Expert" (SME). ThisSME must have over 13-15 years of experience in the industry in same occupation.
- SME is screened and approved by LSSSDC. He is the oriented by both LSSSDC andAssessment agency on – creating question Bank, level of questions, end desired outcome of the assessment.

2.4 Execution of Basic Training Assessment:

- Post the assessment schedule confirmation of all trainees due for assessments through Apprenticeship India portal, the assessment date for basic training is decidedwith common agreement of Industry and LSSSDC and LSSSDC directs it's an assessment body/agency.
- Assessment agency ensures the availability of required infrastructure, tools for theassessment.
- The assessment is executed in two possible ways depending on the choice ofindustry:

2.4.1 Tab based assessment using physical proctoring
2.4.2 Smart phone-based assessment using e-proctoring

2.4.1 Tab-based assessment using physical proctoring

- A representative from Assessment agency are present on the day of assessment to execute the assessment at venue in case of physical proctoring.
- Assessment agency representative carries an identity card and letter from the council authorising to conduct the assessment.
- Assessment agency representative ensures authenticity of Trainee's identity by verifying the documents (any document issued by GOI, such as Ration card, AadhaarCard, Driving Licence, Passport, election card etc)
- Assessment agency representative maintains the records of attendance, verified documents and tablet instruments used in assessment.
- Assessment agency representative collects evidences of the assessment in best possible way (videos, pictures, voice recordings etc)
- Assessment agency representative transfer the assessment scores from tab to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

2.4.2 Smart phone-based assessment using e-proctoring

- All trainees due for assessments are registered on a assessment tool application using their unique mobile number and e-mail ID along with a Govt. ID issued proof.
- An assessment link is sent to the mail ID of each trainee with a defined expiry date of the link.
- Trainee at any location can click on the link using his/her smart phone or a web camera enabled computer system
- Using the unique credentials and govt ID number, trainee logs in for start of assessment and completes the assessment.
- Authenticity of Trainee's identity is done by assessment application by verifying the documents (any document issued by GOI, such as Ration card, Aadhaar Card, Driving Licence, Passport, election card etc.) and a live photo capture
- A live video of candidate during the assessment is captured to collect the evidences of the assessment
- Once the assessment is complete, the assessment application automatically assessment scores to assessment agency server, using a secure, encrypted web-based program.
- The assessment agency after processing the results and putting them in standard format hands over to LSSSDC within 7 days of assessment.

Assessment Result compilation:

- In case of offline OJT assessment -The OJT assessment results are sent to LSSSDC by HR department of company in a sealed envelope for compiling the assessment

results.
- LSSSDC cross checks and validates the data and declares the result to Industry and trainee.
- In case of online OJT assessment-Industry nominated assessor certified by LSSSDC will be uploading the results on apprenticeshipindia.org portal.
- Passed trainees are provided with certificate.

Note: At any point of time assessment strategy would be as per the current guidelinesfrom MSDE.

- LSSSDC Protocol for Accreditation of Assessment Agencies and Assessment GuidelineVer1.00 is attached as annexure 3

ASSESSMENT EVIDENCE

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
1. LFS/N0213 V4.0: Perform pre-productioncheck and prepare machines for bulk drug production	***Material check***	**5**	**5**	**2**	**3**
	PC 1. check availability of stock ofrequired materials in the production area	-	-	-	-
	PC 2. ensure that approved critical starting material, raw materials, excipients, and packaging material are from a respective batch	-	-	-	-
	PC 3. perform a visual inspection of material for signs of contamination and bloom	-	-	-	-
	Pre-production safety check	**6**	**12**	**5**	**12**
	PC 4. perform safety checks as per standard operating procedure (SOP)/ batch manufacturing record (BMR) and material	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	safety data sheet (MSDS) and chemical handling guidelines				
	PC 5. Ensure that the lift /ejection/ slide/ pneumatic valve mechanism of the reactor is properly functioning	-	-	-	-
	PC 6. ensure that the nozzle/valve mechanism of the utilities are properly functioning	-	-	-	-
	PC 7. perform job safety analysis in accordance with international/ national standards	-	-	-	-
	PC 8. secure permit/ authorization on job safety analysis(JSA) form before start of work from an appropriate authority				
	Prepare machines for bulk drug production	**10**	**15**	**10**	**15**
	PC 9. check product changeover, equipment maintenance, calibration, and validation records and ensure that facilities and equipment are qualified by QA	-	-	-	-
	PC 10. ensure availability of all the accessories and necessary machine tool kits for production process	-	-	-	-
	PC 11. set critical parameters for the machine based on machine history and BMR	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 12. perform trial run and random verification tests as per machine SOP to ensure accuracy	-	-	-	-
	PC 13. perform concurrent documentation	-	-	-	-
	Total	**21**	**32**	**17**	**30**
2. LFS/N0112 v 2.0: Adhere to Environment, health and safetyguidelines in a production facilityand GMP controlled areas	***Follow health and personal hygiene protocols***	***10***	***10***	***5***	***5***
	PC 1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines	-	-	-	-
	PC 2. wash hands before entering in the production area as per SOP	-	-	-	-
	PC 3. report any allergy, sickness or any other environment- related breach before or after entering the work premises to the designated person	-	-	-	-
	PC 4. follow gowning procedures while entering an environment controlled work area	-	-	-	-
	Follow safety and security procedures	***10***	***20***	***5***	***5***
	PC 5. comply with safety and security policies and procedures				
	PC 6. use appropriate safety gears like headgear, masks, gloves and other relevant safety accessories as mentioned in the guidelines, while carrying out work	-	-	-	-
	PC 7. use helmets, ropes,				

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	harness, and ladders while working at heights	-	-	-	-
	PC 8. use pulleys/ forklift (if available) to transport the material/ spares/ heavy assembly and tools	-	-	-	-
	PC 9. report any identified breaches in safety and security policies and procedures to the designated person				
	PC 10. segregate material and follow the 5S system at the storage area				
	PC 11. adhere to storage and handling guidelines for hazardous material	-	-	-	-
	PC 12. identify and correct any hazards that one can deal with safely, competently and within the limits of authority	-	-	-	-
	PC 13. record the details of completed safety drills and training	-	-	-	-
	Follow emergency procedures	***10***	***10***	***5***	***5***
	PC 14. 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				
	PC 15. inform the concerned person immediately about every unsafe act/ incident	-	-	-	-
	PC 16. follow emergency procedures efficiently	-	-	-	-
	Total	**30**	**40**	**15**	**15**

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
3.LFS/N0265 v2.0: Maintain compliance with Good Manufacturing Practices (GMP) and other regulations	***GMP compliance in productionprocess***	***7***	***8***	***5***	***5***
	PC 1. perform the cleaning of machine in compliance with cGMP guidelines and SOP	-	-	-	-
	PC 2. monitor environmental conditions in production area as per SOP and cGMP guidelines	-	-	-	-
	PC 3. perform and record pre-production checks, job PC 4. safety analysis	-	-	-	-
	PC 5. ensure adherence to Good Manufacturing Practices related to machine operations	-	-	-	-
	PC 6. perform the specific in-process production checks as directed in SOPs	-	-	-	-
	PC 7. comply with the appropriate cGMP rules for the batch change over procedure	-	-	-	-
	GMP Compliance in waste management	***5***	***7***	***5***	***3***
	PC 8. comply with the appropriate environmental rules and organizational SOP for the waste management and disposal	-	-	-	-
	PC 9. perform waste segregation and generate record for the same	-	-	-	-
	PC 10. perform waste disposal under supervision	-	-	-	-
	GMP compliance in machinemaintenance	***7***	***8***	***5***	***5***

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 11. perform the general routine maintenance of machine as per schedule	-	-	-	-
	PC 12. perform the calibration of machine under supervision as per SOP	-	-	-	-
	GMP compliance in documentation	***7***	***8***	***5***	***5***
	PC 13. adhere to ALCOA principles during documentation of the activities performed				
	PC 14. secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity	-	-	-	-
	PC 15. ensure Audit trail of every document generated by oneself	-	-	-	-
	PC 16. ensure that only authorized user ID is used to enter the record entries in an automated system	-	-	-	-
	PC 17. file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager	-	-	-	-
	PC 18. correct the wrong entries, using ALCOA principles	-	-	-	-
	PC 19. perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer	-	-	-	-
	Environment Sustainability	***1***	***2***	***1***	***1***

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 20. ensure energy conservation by switching off the machine and equipment post operations	-	-	-	-
	PC 21. identify ways to optimize the usage of electricity/energy in various tasks/activities/processes	-	-	-	-
	PC 22. ensure energy conservation by optimizing the machine/ equipment performance	-	-	-	-
	PC 23. apply environment-friendly methods given in SOPs for waste disposal	-	-	-	-
	PC 24. ensure no leakage of water in the plant	-	-	-	-
	PC 25. follow organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution of land, water, and air	-	-	-	-
	Total	**27**	**33**	**21**	**19**
5. LFS/N0113 v2.0: Ensure a hygienic and clean work area to avoid contamination	*sanitation activities before starting the work*	***10***	***10***	***5***	***5***
	PC 1. inspect the area and machine, taking into account various surfaces	-	-	-	-
	PC 2. check for cleaning validation tag on machines and accessories				
	PC 3. ensure to clean the				

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	area or machine part as per SOP, in case of any stain on floor or PC 4. machine				
	PC 5. perform the cleaning validation in the presence of authorized personnel or QA inspector	-	-	-	-
	PC 6. ensure that there is adequate ventilation for the work being carried out	-	-	-	-
	PC 7. handle the cleaning material/ reagent only after wearing the personal protective equipment required for the cleaning method	-	-	-	-
	PC 8. segregate and store the chemicals/ material with an appropriate label in designated places to avoid contamination	-	-	-	-
	Sanitation activities during work	***10***	***20***	***5***	***5***
	PC 9. deal with accidental spillage, if any, caused while carrying out the work and clean as per SOP	-	-	-	-
	PC 10. segregate and store the intermediate material with an appropriate label in designated places to avoid contamination	-	-	-	-
	PC 11. report any additional cleaning requirement that is PC 12. outside one's purview, to the appropriate person	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 13. segregate, store and dispose of the rejected products or generated waste as per SOP under the supervision of supervisor and EHS personnel	-	-	-	-
	Sanitation activities after completion of work	***10***	***10***	***5***	***5***
	PC 14. ensure that there is no oily substance on the floor to avoid slippage	-	-	-	-
	PC 15. ensure that no scrap material is lying around	-	-	-	-
	PC 16. perform the cleaning of the equipment after every batch production as per SOP	-	-	-	-
	PC 17. perform the cleaning validation of the equipment in the presence of designated authorized personnel and QA inspector	-	-	-	-
	PC 18. ensure that, on completion of the work, the area is left clean and dry and meets WHO and GMP requirements of sanitized premises	-	-	-	-
	PC 19. place the trolley, equipment, materials and personal protective equipment at the designated place after use, ensuring they are clean and securely stored	-	-	-	-
	PC 20. dispose of the waste garnered from the activity as per SOP	-	-	-	-
	PC 21. dispose of used and un- used solutions	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	according to manufacturer's instructions, and clean the equipment thoroughly				
	Total	**30**	**40**	**15**	**15**
5. LFS/N0104 v 3.0: Coordinate and communicate with Supervisor/production chemist, teams and auditors	***Coordination with Supervisor /production chemist***	***10***	***10***	***5***	***5***
	PC 22. work as per instructions given by reporting supervisor	-	-	-	-
	PC 23. seek guidance/advice from supervisor on production plan for meeting the timelines	-	-	-	-
	PC 24. communicate process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment to reporting supervisor/ production chemist	-	-	-	-
	PC 25. ensure timely intimation to supervisor/ production chemist about planned absence/ illness/ dizziness during work/ critical issues requiring his/her intervention	-	-	-	-
	PC 26. coordinate with supervisor on work-related and behavioral feedback	-	-	-	-
	Coordination with cross-functional teams	***10***	***10***	***5***	***5***
	PC 27. support team members and colleagues of other departments in work	-	-	-	-
	PC 28. take handover from				

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	previous shift operator and give handover to next shift operator as per SOP	-	-	-	-
	PC 29. guide manufacturing and packaging assistants during production process	-	-	-	-
	PC 30. coordinate with warehouse team for material dispensing and issuance	-	-	-	-
	PC 31. coordinate with maintenance team for preventive and corrective maintenance, break down and calibration errors	-	-	-	-
	PC 32. coordinate with quality control team for sample collection and batch release	-	-	-	-
	PC 33. coordinate with QA for machine/ equipment validation at a routine interval as per SOP	-	-	-	-
	PC 34. provide inputs to the concerned stakeholders in periodic fence line review to detect non-compliance	-	-	-	-
	PC 35. coordinate with EHS team for any safety incident, accident and emergency	-	-	-	-
	Coordination with auditors	***10***	***10***	***5***	***5***
	PC 36. provide clear answers to the auditor's queries	-	-	-	-
	PC 37. provide the required documents of performed activities and operations to	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	auditors on time				
	PC 38. maintain data integrity while responding to auditors and regulatory inspectors	-	-	-	-
	Sensitivity towards all gendersand people with disability	***2***	***3***	***2***	***2***
	PC 39. respect all genders, religions, and caste	-	-	-	-
	PC 40. empathize with people with disability	-	-	-	-
	PC 41. offer support or help to a person with disability only when asked	-	-	-	-
	PC 42. adhere to the guidelines laid in POSH Act	-	-	-	-
	PC 43. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee	-	-	-	-
	Total	**32**	**33**	**17**	**18**
6. DGT/VSQ/N0102 V1.0: Employability Skills (60 Hours)	*Introduction to Employability Skills*	**1**	**1**	**-**	**-**
	PC 1. Identify employability skills required for jobs in various industries	-	-	-	-
	PC 2. identify and explore learning and employability portals	-	-	-	-
	Constitutional values – Citizenship	**1**	**1**	**-**	**-**
	PC 3. 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.	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 4. follow environmentally sustainable practices	-	-	-	-
	Becoming a Professional in the 21st Century	**2**	**4**	**-**	**-**
	PC 5. recognize the significance of 21st Century Skills for employment	-	-	-	-
	PC 6. practice the 21st Century Skills such as Self-Awareness, Behavior 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**	**-**	**-**
	PC 7. use basic English for everyday conversation in different contexts, in person and over the telephone	-	-	-	-
	PC 8. read and understand routine information, notes, instructions, mails, letters etc. written in English	-	-	-	-
	PC 9. write short messages, notes, letters, e-mails etc. in English	-	-	-	-
	Career Development & Goal Setting	**1**	**2**	**-**	**-**
	PC 10. understand the difference between job and career	-	-	-	-
	PC 11. prepare a career development plan with short- and long-term goals, based on	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	aptitude				
	Communication Skills	**2**	**2**	**-**	**-**
	PC 12. follow verbal and non-verbal communication etiquette and active listening techniques in various settings	-	-	-	-
	PC 13. work collaboratively with others in a team	-	-	-	-
	Diversity & Inclusion	**1**	**2**	**-**	**-**
	PC 14. communicate and behave appropriately with all genders and PwD	-	-	-	-
	PC 15. escalate any issues related to sexual harassment at workplace according to POSH Act	-	-	-	-
	Financial and Legal Literacy	**2**	**3**	**-**	**-**
	PC 16. select financial institutions, products and services as per requirement	-	-	-	-
	PC 17. carry out offline and online financial transactions, safely and securely	-	-	-	-
	PC 18. identify common components of salary and compute income, expenses, taxes, investments etc	-	-	-	-
	PC 19. identify relevant rights and laws and use legal aids to fight against legal exploitation	-	-	-	-
	Essential Digital Skills	**3**	**4**	**-**	**-**
	PC 20. operate digital devices and carry out basic internet operations securely and safely	-	-	-	-
	PC 21. use e- mail and social media platforms and virtual collaboration tools to work effectively	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 22. use basic features of word processor, spreadsheets, and presentations	-	-	-	-
	Entrepreneurship	**2**	**3**	**-**	**-**
	PC 23. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research	-	-	-	-
	PC 24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion	-	-	-	-
	PC 25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity	-	-	-	-
	Customer Service	**1**	**2**	**-**	**-**
	PC 26. identify different types of customers	-	-	-	-
	PC 27. identify and respond to customer requests and needs in a professional manner.	-	-	-	-
	PC 28. follow appropriate hygiene and grooming standards	-	-	-	-
	Getting ready for apprenticeship & Jobs	**2**	**3**	**-**	**-**
	PC 29. create a professional Curriculum vitae (Résumé)	-	-	-	-
	PC 30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 31. apply to identified job openings using offline /online methods as per requirement	-	-	-	-
	PC 32. answer questions politely, with clarity and confidence, during recruitment and selection	-	-	-	-
	PC 33. identify apprenticeship opportunities and register for it as per guidelines and requirements	-	-	-	-
	NOS Total	**20**	**30**	**-**	**-**
7. LFS/N0214 V4.0: Perform non-sterile bulkdrug / API manufacturing operations	***Perform manufacturing operations***	**8**	**12**	**8**	**12**
	PC 1. perform sanitization and gowning procedures as per cleanroom guidelines	-	-	-	-
	PC 2. wear personal protective equipment(PPE) before entering into the production area	-	-	-	-
	PC 3. ensure side equipment is in closed condition while charging/ loading material	-	-	-	-
	PC 4. charge the reactors with raw materials(RM) in the correct pattern as per the batch manufacturing record (BMR)to minimize material overflow/ wastage/ excess flash/spill	-	-	-	-
	PC 5. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	injections (WFI)/distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)				
	PC 6. maintain critical process parameters of reactor and utility systems as per BMR	-	-	-	-
	PC 7. monitor reactor and utility systems during every procedure to ensure optimum performance	-	-	-	-
	In-process checks	**2**	**3**	**2**	**3**
	PC 8. perform a total range of in- process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications	-	-	-	-
	PC 9. use appropriate measuring instruments, equipment, tools, accessories, etc. as required for carrying out in- process checks	-	-	-	-
	Reporting and escalation of deviations	**2**	**3**	**2**	**3**
	PC 10. identify non-conformities to quality assurance standards and product specifications	-	-	-	-
	PC 11. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist	-	-	-	-
	PC 12. report and escalate the				

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	deviations as per the escalation matrix and SOP	-	-	-	-
	PC 13. implement the corrective and preventive actions as guided by the production chemist and quality assurance team	-	-	-	-
	Documentation	**4**	**6**	**4**	**6**
	PC 14. perform concurrent documentation as per SOP	-	-	-	-
	PC 15. ensure adherence to data integrity	-	-	-	-
	PC 16. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book, etc	-	-	-	-
	Post-production critical activities	**4**	**6**	**4**	**6**
	PC 17. carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs	-	-	-	-
	PC 18. label finished goods containers of non- sterile API in compliance to regulatory guidelines	-	-	-	-
	PC 19. segregate batchwise packaged and sealed non- sterile containers on pallets for storage and transportation in the warehouse	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 20. provide support for line clearance before the next batch of non-sterile API is produced and packaged	-	-	-	-
	PC 21. handover the work/ equipment to colleague in the next shift in adherence of the shift schedule	-	-	-	-
	Total	**20**	**30**	**20**	**30**
7. LFS/N0266 V2.0: Perform primary packaging operations for non- sterile Bulk Drug / API	***Perform Primary Packaging***	***8***	***12***	***8***	***12***
	PC 1. perform sanitization and gowning procedures as per clean room guidelines	-	-	-	-
	PC 2. wear personal protective equipment (PPE) before entering into the production area	-	-	-	-
	PC 3. ensure availability of QA approved bulk drug containers and closures	-	-	-	-
	PC 4. charge the finished goods in the filling line with care to minimize material overflow/ wastage/ excess flash/ spill	-	-	-	-
	PC 5. operate filling and packaging line in the correct pattern as per the SOP				
	PC 6. maintain critical process parameters of packaging line and automatic 2D printing and labelling machines as per the SOP	-	-	-	-
	PC 7. monitor filling, packaging, printing and labeling machines	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	during every procedure to ensure optimum performance				
	PC 8. minimize waste/ rejections during entire packaging operation	-	-	-	-
	In-process checks	***2***	***3***	***2***	***3***
	PC 9. perform total range of in- process checks specified for bulk drug/ API packaging	-	-	-	-
	PC 10. use appropriate measuring instruments, equipment, tools for carrying out in- process checks	-	-	-	-
	PC 11. confirm that packaged containers meet the specifications for packaging, storage conditions and labelling	-	-	-	-
	Reporting and escalation of deviations	***2***	***3***	***2***	***3***
	PC 12. identify non-conformities to quality assurance standards for packaging specifications	-	-	-	-
	PC 13. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist	-	-	-	-
	PC 14. report and escalate the deviations as per escalation matrix	-	-	-	-
	PC 15. implement the corrective and preventive actions as guided by the production chemist and quality assurance team	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	Documentation	***4***	***6***	***4***	***6***
	PC 16. identify documentation to be completed as per SOP and GMP rules	-	-	-	-
	PC 17. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and cGMP guidelines	-	-	-	-
	PC 18. perform concurrent documentation	-	-	-	-
	PC 19. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like breakdown time, daily manufacturing record, yield report, etc.	-	-	-	-
	PC 20. update the equipment log books , status boards and ensure they are in line with the process	-	-	-	-
	Post-packaging activities	***4***	***6***	***4***	***6***
	PC 21. segregate batch wise packaged and sealed non- sterile API containers on pallets for storage and transportation in warehouse	-	-	-	-
	PC 22. segregate packaging waste and perform disposal under supervision	-	-	-	-
	PC 23. provide support for line clearance before the next batch of non-sterile API is	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	processed for packaging				
	PC 24. handover the work/ equipment to colleague in next shift in adherence to the shift schedule	-	-	-	-
	Total	**20**	**30**	**20**	**30**
	Maintain aseptic conditions	***2***	***3***	***2***	***3***
8. LFS/N0267 V2.0: Perform Sterile Bulk Drug / API manufacturingand primary packaging operations	PC 1. wear personal protective equipment (PPE) before entering into the production area as per SOP	-	-	-	-
	PC 2. perform sanitization and sterilization as per clean room guidelines	-	-	-	-
	PC 3. inspect in-line equipment/ balance as per the SOP	-	-	-	-
	PC 4. start the equipment safely and ensure cleaning-in-place (CIP) and sterilization-in-place (SIP) are done	-	-	-	-
	PC 5. perform cleaning validation under supervision	-	-	-	-
	PC 6. maintain aseptic conditions and clean room parameters in the classified area to avoid cross contamination	-	-	-	-
	Perform aseptic manufacturingand primary packaging	***8***	***12***	***8***	***12***
	PC 7. identify approved labeled raw materials(RM) and handle appropriately to avoid contamination	-	-	-	-
	PC 8. charge the reactors with RM in the correct pattern as per the batch manufacturing	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	record (BMR) to minimize material overflow/ wastage /excess flash/spill				
	PC 9. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for injections (WFI)/distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)	-	-	-	-
	PC 10. maintain critical process parameters of reactor and utility systems as per BMR	-	-	-	-
	PC 11. perform a total range of in- process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications	-	-	-	-
	PC 12. perform sterilization process of final product	-	-	-	-
	PC 13. perform filling and containerization process using QA approved sterilized containers and closures	-	-	-	-
	Reporting and escalation of deviations	***2***	***3***	***2***	***3***
	PC 14. identify non-conformities to quality assurance standards and product specifications	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 15. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist/ biologist	-	-	-	-
	PC 16. report and escalate the deviations as per the escalation matrix and SOP	-	-	-	-
	PC 17. implement the corrective and preventive actions as guided by the production chemist/ biologist and quality assurance team	-	-	-	-
	Documentation	***4***	***6***	***4***	***6***
	PC 18. perform concurrent documentation as per BMR and SOP	-	-	-	-
	PC 19. ensure adherence to data integrity	-	-	-	-
	PC 20. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment logbook etc.	-	-	-	-
	Post-production critical activities	***4***	***6***	***4***	***6***
	PC 21. carry out status labelling and segregation of material/ intermediate/ finished goods of sterile API as per SOPs	-	-	-	-

Marks Allocation					
Assessment outcomes	**Assessment Criteria for outcomes**	**Theory**	**Skills Practical**	**Project**	**Viva**
	PC 22. label finished goods containers of sterile API in compliance with regulatory guidelines	-	-	-	-
	PC 23. segregate batchwise packaged and sealed sterile API containers on pallets for storage and transportation in warehouse	-	-	-	-
	PC 24. segregate waste and perform disposal under supervision	-	-	-	-
	PC 25. provide support for line clearance before the next batch of sterile API is produced and packaged	-	-	-	-
	PC 26. handover the work/ equipment to colleague in next shift in adherence of the shift schedule	-	-	-	-
	Total	**20**	**30**	**20**	**30**

24. Assessment evidences

Title of Component: 1. LFS/N0213 v4.0: Perform pre-production check and prepare machines forbulk drug production

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Material check	PC1. check availability of stock of required materials in the production area
	PC2. ensure that approved critical starting material, raw materials, excipients, and packaging material are from a respective batch
	PC3. perform a visual inspection of material for signs of contamination and bloom
Pre-production safety check	PC4. perform safety checks as per standard operating procedure (SOP)/ batch manufacturing record (BMR) and material safety data sheet (MSDS) and chemical handling guidelines
	PC5. ensure that the lift/ejection/slide/pneumatic valve mechanism of the reactor is properly functioning
	PC6. ensure that the nozzle/valve mechanism of the utilities are properly functioning
	PC7.perform job safety analysis in accordance with international/ national standards
	PC8. secure permit/ authorization on job safety analysis(JSA) form before start of work from an appropriate authority
Prepare machines for bulk drug production	PC9. check product changeover, equipment maintenance, calibration, and validation records and ensure that facilities and equipment are qualified by QA
	PC10.ensure availability of all the accessories and necessary machine tool kits for production process
	PC11. set critical parameters for the machine based on machine history and BMR
	PC12.perform trial run and random verification tests as per machine SOP to ensure accuracy
	PC13. perform concurrent documentation
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular

	knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areasof improvement or expertise of the trainee. While a consolidated mark gives the overall rating of thetrainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offlinequestions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reactionto the situation. The selected situations are based onreal situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marksgives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical

	questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum ofready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

2. LFS/N0112 v2.0: Adhere to Environment, health and safety guidelines ina production facility and GMP controlled areas

Outcomes to be assessed/NOSs to be assessed	**Assessment criteria for the outcome**
Follow health and personal hygiene protocols	PC1. comply with health and personal hygiene-related protocols as per WHO standards 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	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	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
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component ofthe Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario- based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marksgives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on

	the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum ofready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

Title of Component: 3. LFS/N0265 v2.0: Perform the support operations for production in adherence to Good Manufacturing Practices (GMP) guidelines

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
GMP compliance in production process	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 machine 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	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
GMP compliance in machine maintenance	PC10. perform the general routine maintenance of machine as per schedule
	PC11. perform the calibration of machine under supervision as per SOP
GMP compliance in documentation	PC12. adhere to ALCOA principles during documentation of the activities performed
	PC13. secure authorization and approval in writing from competent authorities in quality assurance and production team before start of any production activity
	PC14. ensure Audit trail of every document generated by oneself
	PC15. ensure that only authorized user ID is used to enter the record entries in an automated system
	PC16. file deviation in case of non adherence of Good Documentation Practices and SOPs and notify supervisor / manager
	PC17. correct the wrong entries, using ALCOA principles
	PC18. perform electronic record generation only after checking validation and calibration tag on the equipment panel/ computer
Environment sustainability	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 of land, water, and air
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component ofthe Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery,arrange in proper sequence, case study, scenario- based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areasof improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offlinequestions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reactionto the situation. The selected situations are based onreal situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions,

	situation-based questions, analytical questions, and decision-making based questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCsfrom the QP Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

Title of Component: 4. LFS/N0113 v2.0: Ensure a hygienic and clean work area to avoid contamination

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
sanitation activities before starting the work	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	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	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 GMP 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
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas

	of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCsfrom the QP

	Analysis – Assessor is provided with spectrum ofready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

Title of Component: 5. LFS/N0104 v3.0: Coordinate and communicate with Supervisor/ production chemist, teams and auditors

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Coordination with Supervisor / production chemist	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	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 noncompliance
	PC14. coordinate with EHS team for any safety incident, accident and emergency
Coordination with auditors	PC15. provide clear answers to the auditor's queries
	PC16. provide the required documents of performed activities and operations to auditors on time
	PC17. maintain data integrity while responding to auditors and regulatory inspectors
Sensitivity towards all genders and people with disability	PC18. respect all genders, religions, and caste
	PC19. empathise with the people with disability
	PC20. offer support or help to a person with disability only when asked
	PC21. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace(Prevention, Prohibition and Redressal) Act
	PC22. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each

	Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marksgives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about the subject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%	

Title of Component: 6. DGT/VSQ/N0102 v1.0: Employability Skills (60 Hours)

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome	
Introduction to Employability Skills	PC 1.	Identify employability skills required for jobs in various industries
	PC 2.	identify and explore learning and employability portals
Constitutional values – Citizenship	PC 3.	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.
	PC 4.	follow environmentally sustainable practices

Becoming a Professional in the 21st Century	PC 5.	recognize the significance of 21st Century Skills for employment
	PC 6.	practice the 21st Century Skills such as Self-Awareness, Behavior 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	PC 7.	use basic English for everyday conversation in different contexts, in person and over the telephone
	PC 8.	read and understand routine information, notes, instructions, mails, letters etc. written in English
	PC 9.	write short messages, notes, letters, e-mails etc. in English
Career Development & Goal Setting	PC 10.	understand the difference between job and career
	PC 11.	prepare a career development plan with short- and long-term goals, based on aptitude
Communication Skills	PC 12.	follow verbal and non-verbal communication etiquette and active listening techniques in various settings
	PC 13.	work collaboratively with others in a team
Diversity & Inclusion	PC 14.	communicate and behave appropriately with all genders and PwD
	PC 15.	escalate any issues related to sexual harassment at workplace according to POSH Act
Financial and Legal Literacy	PC 16.	select financial institutions, products and services as per requirement
	PC 17.	carry out offline and online financial transactions, safely and securely
	PC 18.	identify common components of salary and compute income, expenses, taxes, investments etc
	PC 19.	identify relevant rights and laws and use legal aids to fight against legal exploitation
Essential Digital Skills	PC 20.	operate digital devices and carry out basic internet operations securely and safely
	PC 21.	use e- mail and social media platforms and virtual collaboration tools to work effectively
	PC 22.	use basic features of word processor, spreadsheets, and presentations
Entrepreneurship	PC 23.	identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research

	PC 24. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion
	PC 25. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity
Customer Service	PC 26. identify different types of customers
	PC 27. identify and respond to customer requests and needs in a professional manner.
	PC 28. follow appropriate hygiene and grooming standards
Getting ready for apprenticeship & Jobs	PC 29. create a professional Curriculum vitae (Résumé
	PC 30. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively
	PC 31. apply to identified job openings using offline /online methods as per requirement
	PC 32. answer questions politely, with clarity and confidence, during recruitment and selection
	PC 33. identify apprenticeship opportunities and register for it as per guidelines and requirements
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on

	real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marksgives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about the subject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%	

Title of Component: 7. LFS/N0214 v4.0: Perform non-sterile bulk drug / API manufacturing operations

Outcomes to be assessed/NOSs to be assessed	**Assessment criteria for the outcome**
Perform manufacturing operations	PC1. perform sanitization and gowning procedures as per cleanroom guidelines
	PC2. wear personal protective equipment(PPE) before entering into the production area
	PC3. ensure side equipment is in closed condition while charging/ loading material
	PC4. charge the reactors with raw materials(RM) in the correct pattern as per the batch manufacturing record (BMR) to minimize material overflow/wastage/excess flash/spill
	PC5. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for injections

	(WFI)/distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)
	PC6. maintain critical process parameters of reactor and utility systems as per BMR
	PC7. monitor reactor and utility systems during every procedure to ensure optimum performance
In-process checks	PC8. perform a total range of in-process checks specified in BMR to ensure that the intermediate/final product coming out from the process manufacturing meets the specifications
	PC9. use appropriate measuring instruments, equipment, tools, accessories, etc. as required for carrying out in-process checks
Reporting and escalation of deviations	PC10. identify non-conformities to quality assurance standards and product specifications
	PC11. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist
	PC12. report and escalate the deviations as per the escalation matrix and SOP
	PC13. implement the corrective and preventive actions as guided by the production chemist and quality assurance team
Documentation	PC14. perform concurrent documentation as per SOP
	PC15. ensure adherence to data integrity
	PC16. maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book, etc
Post-production critical activities	PC17. carry out status labelling and segregation of material/ intermediate / finished goods as per SOPs
	PC18. label finished goods containers of non- sterile API in compliance to regulatory guidelines
	PC19. segregate batchwise packaged and sealed non-sterile containers on pallets for storage and transportation in the warehouse
	PC20. provide support for line clearance before the next batch of non-sterile API is produced and packaged
	PC21. handover the work/ equipment to colleague in the next shift in adherence of the shift schedule
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out,

	choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marksgives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about the subject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patience etc) can also be tested required for the QP.Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also	

be 70%

Title of Component:
8. LFS/N0266 v2.0: Perform primary packaging operations for non- sterile Bulk Drug / API

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Perform Primary Packaging	PC1. perform sanitization and gowning procedures as per clean room guidelines
	PC2. wear personal protective equipment (PPE)before entering into the production area
	PC3. ensure availability of QA approved bulk drug containers and closures
	PC4. charge the finished goods in the filling line with care to minimize material overflow/ wastage/ excess flash/ spill
	PC5. operate filling and packaging line in the correct pattern as per the SOP
	PC6. maintain critical process parameters of packaging line and automatic 2D printing and labelling machines as per the SOP
	PC7. monitor filling, packaging, printing and labeling machines during every procedure to ensure optimum performance
	PC8. minimize waste/ rejections during entire packaging operation
In-process checks	PC9. perform total range of in-process checks specified for bulk drug/ API packaging
	PC10. use appropriate measuring instruments, equipment, tools for carrying out in-process checks
	PC11. confirm that packaged containers meet the specifications for packaging, storage conditions and labelling
Reporting and escalation of deviations	PC12. identify non-conformities to quality assurance standards for packaging specifications
	PC13. identify potential causes of non- conformities to quality assurance standards with the help of supervisor/ production chemist
	PC14. report and escalate the deviations as per escalation matrix
	PC15. implement the corrective and preventive actions as guided by the production chemist and quality assurance team
Documentation	PC16. identify documentation to be completed as per SOP and GMP rules

	PC17. record the required information of all significant activities, incidents and deviations as per recording formats in compliance with SOP and cGMP guidelines
	PC18. perform concurrent documentation
	PC19. maintain both electronic and manual records in the log books and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, etc.
	PC20. update the equipment log books , status boards and ensure they are in line with the process
Post-packaging activities	PC21. segregate batch wise packaged and sealed non-sterile API containers on pallets for storage and transportation in warehouse
	PC22. segregate packaging waste and performdisposal under supervision
	PC23. provide support for line clearance before the next batch of non-sterile API is processed for packaging
	PC24. handover the work/ equipment to colleague in next shift in adherence to the shift schedule
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill componentof the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offlinequestions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reactionto the situation. The selected situations are based onreal situations. Analysis – Question paper is divided in sections.

	Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill componentof the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific project (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCs from the QP Analysis – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

Title of Component: 9. LFS/N0267 v2.0: Perform Sterile Bulk Drug / API manufacturing andprimary

packaging operations

Outcomes to be assessed/NOSs to be assessed	Assessment criteria for the outcome
Maintain aseptic conditions	PC1. perform sanitization, sterilization, and gowning procedures as per clean room guidelines
	PC2. wear personal protective equipment (PPE) before entering into the production area
	PC3. inspect in-line equipment/ balance as per the SOP
	PC4 start the equipment safely and ensure cleaning-in-place (CIP) and sterilization-in-place (SIP) are done
	PC5.perform cleaning validation under supervision
	PC6. maintain aseptic conditions and clean room parameters in the classified area to avoid cross contamination
Perform aseptic manufacturing and primary packaging	PC7. identify approved labeled raw materials(RM) and handle appropriately to avoid contamination
	PC8. charge the reactors with RM in the correct pattern as per the batch manufacturing record (BMR) to minimize material overflow/wastage/excess flash/spill
	PC9. operate reactor and utilities (Steam/water for pharmaceutical use (WPU)/water for injections (WFI) /distilled water (DW)/ Gases) as per BMR and standard operating procedure (SOP)
	PC10. maintain critical process parameters of reactor and utility systems as per BMR
	PC11. perform a total range of in-process checks specified in BMR to confirm that the intermediate/final product meets the specifications
	PC12. perform sterilization process of final product
	PC13. perform filling and containerization process using QA approved sterilized containers and closures
Reporting and escalation of deviations	PC14. identify non-conformities to quality assurance standards and product specifications
	PC15. identify potential causes of non-conformities to quality assurance standards with the help of supervisor/ production chemist/ biologist
	PC16.report and escalate the deviations as per the escalation matrix and SOP
	PC17.implement the corrective and preventive actions as guided by the production chemist/biologist and quality assurance team
Documentation	PC18.perform concurrent documentation as per BMR and SOP
	PC19.ensure adherence to data integrity

	PC20.maintain both electronic and manual records in the logbooks and other documentation required as per GMP and GDP like – breakdown time, daily manufacturing record, yield report, equipment log book etc
Post-production critical activities	PC21.carry out status labelling and segregation of material/ intermediate/ finished goods as per SOPs
	PC22.label finished goods containers in compliance to regulatory guidelines
	PC23.segggregate batchwise packaged and sealed containers on pallets for storage and transportation in warehouse
	PC24.segggregate waste and perform disposal under supervision
	PC25.provide support for line clearance before the next batch is produced and packaged
	PC26.handover the work/ equipment to colleague in next shift in adherence of the shift schedule
Means of assessment 1	**Digital Written test for knowledge assessment:** Scope – Is used to test the knowledge component of the Qualification Pack. Tools – Computer or tab based online or offline. Method – objective type questions, match the columns, fill in the blanks, tick the odd man out, choose the correct option, choose the best answer, True or false, Identify the object, tool or machinery, arrange in proper sequence, case study, scenario-based responses. Analysis – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 2	**Digital Written test for skill assessment** Scope – Is used to test primarily the Skill component of the QP. Trainee's expertise in handling and managing the situation is tested. Tools – computer or tab based online or offline questions. Method – A situation is narrated or created in the question posed to the trainee and he is asked objective type questions to select the correct reaction to the situation. The selected situations are based on real situations. Analysis – Question paper is divided in sections. Each Section intends to assess a particular skill field of the trainee. Thus, section wise calculation of marks gives the clear idea of the areas of improvement or

	expertise of the trainee. While a consolidated mark gives the overall rating of the trainee.
Means of assessment 3	**Project Assessment** Scope – Is used to test primarily the Skill componentof the QP. Trainee's expertise in utilization of knowledge and skills in real life job scenarios Tools – Project report. Method – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specificproject (utilizing skills as per qualification pack). A project report duly endorsed by his/her project supervisor is prepared by the trainee and submitted for evaluation. The Assessor asks Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-makingbased questions based on the project report Analysis –Project Assessments are analysed on knowledge and skill component.
Means of assessment 4	**Viva** Scope – Is used to test the knowledge and understanding and breadth of awareness about thesubject. Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth of knowledge, comprehension, presentation, patienceetc) can also be tested required for the QP. Tools – Direct dialogue between assessor andTrainee. Method – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions. Different questions are included to test relevant PCsfrom the QP Analysis – Assessor is provided with spectrum ofready answers to be expected from trainee. This reduces effect of subjectivity of the assessor. Comparative quality of trainees with in a batch or different institutes can be gauged
Pass/Fail The aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment, Project and Viva is 70%. In case of RPL where Project will not be there ,the aggregate pass marks for Digital Written test for knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.	

SECTION 2

25. EVIDENCE OF LEVEL

Tittle/Name of the qualification/Component:			Level:
NSQF Domain	**Key requirements of the job role**	**How the job role relates to the NSQF level descriptors**	**NSQF level**
Process	Few of the job elements, expected to be performed Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drug are: • Machine preparation for bulk drug production • Perform pre-production checks • Ensure health and safety at shop floor as per SoPs, EHS and regulatory guidelines • Reporting and documentation • Non-sterile manufacturing and packaging operations	Production Machine Operator API/ Bulk Drug works in life sciences manufacturing plant as per the SOPs followed in the Life Sciences Sector. He/she is responsible for machine preparation and maintaining compliance with regulatory guidelines. He/she is also responsible to perform API/Bulk drug manufacturing and packaging operations. To carry out all the above performance outcomes the job holder performs limited range of activities which are part of routine job, hence they are categorized as familiar and predictable processes.	4

Professional Knowledge	Few of the job elements, expected to be performed Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drug are: • Reporting and documentation • Non-sterile manufacturing and packaging operations • Machine preparation for bulk drug production • Coordinate with Supervisor/ production chemist, teams and auditors	Production Machine Operator API/ Bulk Drug needs to have the factual knowledge of API plant and machinery, how to use them to manufacture API/ bulk drug by recalling the SOPs, work safety guidelines and maintain documentation for cGMP compliance. The job holder should also be efficient to coordinate with Supervisor & quality team and respond to audit queries by using basic English language sentences, expressions and text to meet the communication needs to fulfil work requirements of Production Machine Operator API/ Bulk Drug.	**4**
Professional Skills	Few of the job elements, expected to be performed Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drug are: • Machine preparation for bulk drug production • Perform pre-production checks • Ensure health and safety at shop floor as per SoPs, EHS and regulatory guidelines • Reporting and documentation • Non-sterile manufacturing and packaging operations	To perform the tasks of Production Machine Operator API/ Bulk Drug the job holder utilizes good critical thinking skills and should demonstrate the ability to understand and take instant decisions. The Production Machine Operator API/ Bulk Drug uses analytical skills to measure and estimate chemical and reagent quantities . For timely maintenance of manufacturing records and segregation & storage of raw material, finished goods and waste, the individual uses the planning and organizing skills. The scope of utilization of all above	**4**

		professional skills remains limited to routine and repetitive and for a narrow range of applications **.**	
Core Skills	Few of the job elements, expected to be performed Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drug are: • Machine preparation for bulk drug production • Perform pre-production checks • Ensure health and safety at shop floor as per SoPs, EHS and regulatory guidelines • Reporting and documentation Non-sterile manufacturing and packagingoperations	To perform the tasks, Production Machine Operator API/ Bulk Drug uses Communication, written and oral with minimum required clarity in written or oral mode. For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles. For coordination related tasks and ensuring compliance to organizational SOPs and regulatory requirements, he/she is expected to have a basic understanding of the social-political and natural environment at the place of work/ organization he/she is workingfor.	**4**
Responsibility	Few of the job elements, expected to be performed by Production Machine Operator – Active Pharmaceutical Ingredient (API)/Bulk Drug are: • Machine preparation for bulk drug production • Perform pre-production checks • Ensure health and safety at shop floor as per SoPs, EHS and regulatory guidelines • Reporting and documentation • Non-sterile manufacturing and packaging operations	Production Machine Operator API/ Bulk Drug has responsibility for his/her work and learn under close supervision of production team and researchers (in case of employment in a Kilo Lab/ Pilot plant). And in case of a scenario/situation of no clear choice, he is expected to take guidance from the supervisor.	**4**

	• Coordinate with Supervisor/ production chemist,teams and auditors		

SECTION 3

EVIDENCE OF NEED

26	**What evidence is there that the qualification is needed? What is the industry relevance of this qualification and what is the basis of this?**	
	Need of the qualification	LSSSDC has prepared a skill gap report forecasting the need for this job role both on a short-term and long-term basis. Additionally, all the industries that have validated the qualification have expressed the need for this qualification considering the futuristic need.
	Industry Relevance	Experts from following companies have consented for relevance of this qualification with Indutry need.

S.No	Name of Organization
1	Anglo French Drugs and Industries Ltd.
2	Anthem Biosciences P Ltd
3	Belco Pharma
4	Blue Cross Laboratories Pvt Ltd.
5	Dr. Reddy's Limited
6	Drugfarm Laboratries
7	Emcure Pharmaceuticals Ltd
8	FDC Limited
9	Group Pharmaceuticals Ltd
10	Intas Pharmaceuticals Ltd.
11	Kumar Organic Products Limited
12	Macleods Pharmaceuticals Ltd.
13	Micro Labs Limited
14	Modgal Pharmaceuticals Pvt. Ltd.
15	Neuland Laboratories Limited
16	Prerana Bio-Innovations Research Pvt. Ltd.
17	Pure & Cure Healthcare Pvt.Ltd
18	Smruti Organics Limited
19	Strides Pharma Science Ltd
20	Sun Pharmaceutical Industries Ltd.
21	Unimarck Healthcare Ltd.

	Usage of	LSSSDC would submit periodic details (directly/Via NSDC) of the employment generated (wherever applicable) and realize under training in the Qualifications post-approval of NSQC and implementation of the qualification
	Estimated uptake	LSSSDC has prepared a skill gap report forecasting the year wise estimated uptake. The forecasted uptake is given as annexure-4.
27	**Recommendation from the concerned Line Ministry of the Government/Regulatory Body. To be supported by documentary evidences**	
	We have requested a recommendation from the Ministry of Health and Family Welfare as well as Department of Biotechnology for the job role of Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug (copy of request letter is enclosed in Annexure 5). The response from both the Ministries is awaited and will be submitted sooner we receive it.	

28	**What steps were taken to ensure that the qualification(s) does (do) not duplicate already existing or planned qualifications in the NSQF? Give justification for presenting a duplicate qualification** Before submission of the qualification to NSQC we have checked the availability of with other councils on the portal of NSDCand we found no other qualification matching with the submitted job role. We have revalidated the first version of NSQC approved Qualification of Production Machine Operator from Life Sciences Sector Skill Development Council. Hence no duplication is found of the submitted job role. As we moved for Rationalization exercise of Production Machine Operator-Life Sciences (LFS/Q0207 Ver 1.0), the feedback was very different in comparison of other QPs. Unlike other QPs where Industry experts shared feedback to merge the QPs or make them multi skilled, for Production Machine Operator-Life Sciences, the feedback was to split it into multiple QPs based on the Business Verticals to impact in-depth skilling required for Manufacturing a Specific kind of regulated and licensed Product. Hence the deliberation was done with experts and NOS committee Members which resulted into a Ver 1 QP giving the way to 5 QPs as below, which further will have the electives and options: • Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug • Production Machine Operator-Non-Sterile Formulation • Production Machine Operator-Sterile Formulations • Production Machine Operator-AYUSH Products • Production Machine Operator-Sanitary Products We have revised the first version of NSQC approved Qualification of Production Machine Operator- Life Sciences based on the feedback from Life Sciences Sector employers giving it a way to 3 electives and added 5 NOSs and removed 2 NOSs.

	Hence following NOS have been newly drafted for the revised Qualification Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug and new mandatory employability skills NOS has been added as per the guidelines from NCVET: 1. LFS/N0112 v2.0: Adherence to Environment, health and safety guidelines in a production facility and GMP controlled area 2. LFS/N0113 v2.0: Ensure a hygienic and clean work area to avoid contamination 3. LFS/N0265 v2.0: Maintain compliance with Good Manufacturing Practices (GMP) and other regulations Following NOS have been revised based on the inputs for the revised Qualification of Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug 4. LFS/N0104 v3.0: Coordinate and communicate with Supervisor/ production chemist, teams and auditors 5. LFS/N0213 v4.0: Perform pre-production checks and prepare machines for bulk drug production This qualification have 3 electives as stated under where in 1 NOS have been revised for elective one and 2 newly drafted for elective 2 and 3 for the revised Qualification of Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug: Elective 1: Non Sterile Manufacturing 1. LFS/N0214 v4.0: Perform non-sterile bulk drug / API manufacturing operations Elective 2: Non Sterile Packaging 1. LFS/N0266 v2.0: Perform primary packaging operations for Bulk Drug / API Elective 3: Sterile Manufacturing and Packaging 1.LFS/N0267 v2.0: Perform Sterile Bulk Drug / API manufacturing and primary packaging operations
	What arrangements are in place to monitor and review the qualification(s)? What data will be used and at what point will the qualification(s) be revised or updated? Specify the review process here Workshops with Industry Associations of Employers are part of a continuous awareness drive and will be utilized as a channel to get continual feedback from Industry. LSSSDC will be engaged with Training Providers and Authorised educational institutions, who are imparting training as per QP guidelines, to gather feedback in implementation Monitoring of candidate Assessment Result will be carried out Employer feedback will be sought post placement of trainee's batch A formal review is scheduled in a three-year time frame

SECTION 4
EVIDENCE OF PROGRESSION

30	**What steps have been taken in the design of this or other qualifications to ensure that there is a clear path to other qualifications in this sector?** ***Show the career map here to reflect the clear progression*** Mobility options to other qualifications are enabled through the alignment of educational qualifications and prior work experience stated as a requirement in the respective qualifications. For Example: After 3-4 years of Industry work experience as Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug post-qualifying the certification of Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk Drug, a candidate has an option to qualify for Production Supervisor/ Junior Chemist – API/Chemical Manufacturing/ Packaging or Production Chemist- Life Sciences (API/ Non Sterile Formulation/ Sterile Formulation/AYUSH/Sanitary Products) as an upward progression. Also Production Machine Operator- Active Pharmaceutical Ingredient (API)/ Bulk has option to move for horizontal progression as 1. Production Machine Operator - Non Sterile Formulation (Level-4) or 2. Production Machine Operator - Sterile Formulations (Level-4) or 3. Production Machine Operator- AYUSH Products (Level-4)