

NSQF QUALIFICATION FILE

Approved in 14th NSQC, dated- 30/12/2021

Rationalized on file 20.03.2023

Qualification Code

QM-05-LS-00248-2023-V1.1-LSSSDC

CONTACT DETAILS OF THE BODY SUBMITTING THE QUALIFICATION FILE

Name and address of submitting body:

Life Sciences Sector Skill Development Council

14, Palam Marg, Rear 2nd Floor, Vasant Vihar, New Delhi, PIN 110057

Phone: +91 11 41042407/ 408, E-mail: info@lsssd.in

Name and contact details of individual dealing with the submission

Name: Mr. Anshul Saxena

Position in the organisation: Senior Director

Address if different from above:

Same as above

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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 this qualification
- 7 List of qualification /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

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SUMMARY

| | | |
|---|---|--|
| 1 | Qualification Title | Analyst/Chemist-Quality Control Electives: 1.High-Performance Liquid Chromatography (HPLC) 2.Gas Chromatography (GC) 3.Ultraviolet-visible Spectroscopy (UV) 4.Fourier Transform Infrared Spectroscopy (FT-IR) 5.Dissolution Test Apparatus |
| 2 | Qualification Code, if any | LFS/Q1301 Ver.3.0 |
| 3 | NCO code and occupation | NCO-2015/2113.0601 Pharma Quality |
| 4 | Nature and purpose of the qualification (Please specify whether qualification is short term or long term) | Short term training with or without apprenticeship And Elective Subject in B. Pharma. 8 th Sem |
| 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 | Pharma Quality |
| 9 | Job description of the occupation | Analyst/Chemist-Quality Control tests samples, reagents from all phases of the manufacturing process to ensure the product quality meets the standards. The individual is responsible for the testing of in-process/input raw materials, packaging materials, product stability of samples, in-process intermediate samples, finished products, preliminary investigation in case of out of specification results, laboratory incidents and handling/preparation of standards. The person is responsible for preparing the |

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| | | documents for reporting the test results and ensures compliance with cGMP, GLP and workplace safety while handling hazardous materials. The role holder also carries out testing of process validation samples and cleaning validation samples. |
| 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 the NSQF | 5 |
| 13 | Anticipated volume of training/learning required to complete the qualification | <p>Compulsory Notional Hours Theory= 150 Hours Practical=240 Hours Employability Skills= 90 Hours Total Compulsory Notional Hours= 480 Hours Min. Hours – 840 Max. Hours – 480+All Electives</p> <p>(Compulsory NOS Duration=480 Hours and Elective 1 Duration=360 Hours Elective 2 Duration=360 Hours Elective 3 Duration=210 Hours Elective 4 Duration=210 Hours Elective 5 Duration=360 Hours)</p> <p>with mandatory apprenticeship of 12 Months</p> <p>Note: i) Minimum one Elective is MUST to be taken ii) B. Pharma is exempted from mandatory apprenticeship"</p> |
| 14 | Indicative list of training tools required to deliver this qualification | Attached as annexure 2 |
| 15 | Entry requirements and/or recommendations and minimum age | B. Pharma 7th Sem. Or M.Sc. (Chemistry/ Analytical Chemistry / Industrial Chemistry) Or |

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| | | <p>Certificate-NSQF Level 4 (Junior Quality Analyst/Wet Lab Analyst-Life Sciences)- with minimum 3 Years of experience</p> <p>Age: 21 Years</p> |
| 16 | Progression from the qualification (Please show Professional and academic progression) | <p>Vertical progression</p> <p>1.Instrumental Analysis Specialist- Quality Control (Pharma) (Level-6)</p> <p>Lateral/Horizontal progression</p> <p>1.Chemist In-Process Quality Assurance (Level-5)</p> <p>Also, have a horizontal progression across manufacturing and R&D based sectors</p> |
| 17 | Arrangements for the Recognition of Prior Learning (RPL) | <p>The process to award the qualification via RPL mode and detailed methodology is given in point No.22</p> |
| 18 | International comparability Whether known (research evidence to be provided) | <p>While preparing the NOSs, a detailed secondary desk research was conducted. The European, South African and Australian NOSs were referred to. The relevant International NOSs for the job role are listed below for reference:</p> <p>UK NOS</p> <ul style="list-style-type: none">•COGLS314 Analysis of samples using high performance liquid•COGLS315 Analysis of samples using spectroscopy in life sciences•COGLS328 Analysis of samples using gas chromatography in life sciences•COGPI03.6 maintaining product quality•COGPI03.2 control emergencies•SFHPHARM23 check documentation and materials•SKSPI25 Mix, store and manage processing chemistry |

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| | <ul style="list-style-type: none">•COGLS2 Maintain effective and efficient working relationships•COGLS15 Improve product(s) and process quality within life•COGLS201 Follow health and safety procedures in life sciences•COGLS202 Maintain effective and efficient working relationships in life Sciences and related industries•COGLS206 Preparing reagents in life sciences and related industries•COGLS205 Maintain stocks of resources, equipment and consumables in life sciences and related industries•COGLS212 Carry out testing using manual or automated equipment•COGLS215 Carry out sampling operations in life sciences•COGLS301 Maintain health and safety in life sciences <p>Switzerland NOS</p> <ul style="list-style-type: none">•Refer page no. 190 International Standard Classification of Occupations ILO Geneva <p>Australia NOS</p> <ul style="list-style-type: none">•Communicate workplace information•Operate a separation process using chromatography•Participate in OHS processes•Perform basic tests•Participate in work teams and groups <p>South Africa NOS</p> <ul style="list-style-type: none">•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 December 2024 |

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| 20 | Formal structure of the qualification | | | |
| | Mandatory components | | | |
| | i.)domain | | | |
| | NOS/ Module Details | Total Duration Hours | Level | Credits |
| | Compulsory Bridge Module Introduction of Life Sciences industry and applicable regulations | 30:00 | Level-5 | 1.00 |
| | Compulsory Module LFS/N1306: Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) NOS Version No. 2.0 | 150:00 | Level-5 | 5.00 |
| | Compulsory Module LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by self and subordinates NOS Version No. 2.0 | 30:00 | Level-5 | 1.00 |
| | Compulsory Module LFS/N0302: Coordinate with Manager, colleagues and auditors NOS Version No. 3.0 | 60:00 | Level-5 | 2.00 |
| | Compulsory Module LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP NOS Version No. 3.0 | 60:00 | Level-5 | 2.00 |
| | Compulsory Module LFS/N1307: carry out process-related checks in the quality control process NOS Version No. 2.0 | 60:00 | Level-5 | 2.00 |
| | DGT/VSQ/N0103: Employability Skills NOS Version No. 1.0 | 90:00 | | 3.00 |
| | Total Duration (A) | 480:00 | | |
| | Total Credits (A) | | | 16.00 |
| | a) Elective Modules | | | |
| | Elective 1: High-Performance Liquid Chromatography (HPLC) | | | |

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| NOS/ Module Details | Total Duration Hours | Level | Credits |
|--|-----------------------------|--------------|----------------|
| Elective 1: High-Performance Liquid Chromatography (HPLC) LFS/N1301 - Perform QC Analysis using High-Performance Liquid Chromatography NOS Version No.2 | 360:00 | Level-5 | 12.00 |
| Sub Total Duration (Hours) (B) | 360:00 | | |
| Sub Total Credits (B) | | | 12.00 |
| Elective 2: Gas Chromatography (GC) | | | |
| NOS/ Module Details | Total Duration Hours | Level | Credits |
| Elective 2:Gas Chromatography(GC) LFS/N1302 – Perform QC Analysis using Gas Chromatography NOS Version No.2.0 | 360:00 | Level-5 | 12.00 |
| Sub Total Duration (Hours) (C) | 360:00 | | |
| Sub Total Credits (C) | | | 12.00 |
| Elective 3: Ultraviolet-visible Spectroscopy (UV) | | | |
| NOS/ Module Details | Total Duration Hours | Level | Credits |
| Elective 3:Ultraviolet-visible Spectroscopy(UV) LFS/N1303 – Perform QC Analysis using Ultraviolet-visible spectroscopy NOS Version No.2.0 | 210:00 | Level-5 | 7.00 |
| Sub Total Duration (Hours) (D) | 210:00 | | |
| Sub Total Credits (D) | | | 7.00 |
| Elective:4 Fourier Transform Infrared Spectroscopy (FT-IR) | | | |
| NOS/ Module Details | Total Duration Hours | Level | Credits |
| Elective 4:Fourier Transform Infrared Spectroscopy (FT-IR) LFS/N1304 – Perform QC Analysis using Fourier Transform Infrared Spectroscopy NOS Version No.2.0 | 210:00 | Level-5 | 7.00 |

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| Sub Total Duration (Hours) (E) | 210:00 | | |
| Sub Total Credits (E) | | | 7.00 |
| Elective 5: Dissolution Test Apparatus | | | |
| NOS/ Module Details | Total Duration Hours | Level | Credits |
| Elective 5:Dissolution Test Apparatus LFS/N1305 – Perform QC Analysis using Dissolution Test Apparatus NOS Version No.2.0 | 360:00 | Level-5 | 12.00 |
| Sub Total Duration (Hours) (F) | 360:00 | | |
| Sub Total Credits (F) | | | 12.00 |
| Total Maximum Duration of Notional Hours (A+B+C+D+E+F) | 1980:00 | | |
| Total Maximum Credits of Qualification (A+B+C+D+E+F) | | | 66.00 |
| Apprenticeship Component | | | |
| Mandatory Apprenticeship | 12 Months | | |

SECTION 1
ASSESSMENT

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|-----------|--|
| 21 | <p><u>Body/Bodies which will carry out assessment:</u> Following assessment agencies will carry out assessments:</p> <ol style="list-style-type: none"> 1. Induslynk Training Services Pvt. Ltd.- Mercer- Mettl, 7&8th Floor, SN 1&2, Good Earth Buiness Bay, Sector 58, Gurugram, 122101 2. SHL (India) Pvt. Ltd.- 6-Tower-B, 10, DLF Building, DLF Cyber City, Gurugram, Haryana, 122002 3. Cleveratti Skill Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana |
|-----------|--|

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| 22 | <p>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):</p> <ol style="list-style-type: none">1. 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.2. LSSSDC conducts Assessments via its empaneled Assessment Agencies and assigns the batch to an assessment agency pre-notified with NSQC for the job role.3. Assessment agency ensures the availability of required infrastructure, tools for the assessment.4. Assessments for RPL candidates are conducted in following two modes:5. Theory and Skill Practical on a fully digital platform.6. Theory part digital and practical part through actual assessor observation.7. 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)8. Assessment agency collects evidences of the assessment in best possible way (videos, pictures, assessment logs etc.)9. 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.10. LSSSDC validates the assessment results and announces the result on SDMS within 15 days of assessment date.11. Passed candidates are provided with qualification certificate. <p>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.</p> <p>Digital Written test for knowledge assessment: <u>Scope</u> – Is used to test the knowledge component of the Qualification. <u>Tools</u> – Computer or tab based online or offline. <u>Method</u> – 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. <u>Analysis</u> – 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.</p> <p>Digital Written test for skill assessment <u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested. <u>Tools</u> – computer or tab based online or offline questions. <u>Method</u> – 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.</p> |
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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:

Induslynk Training Services Pvt. Ltd.- Mercer- Mettl , Plot Number 85, Sector 44, Gurugram, India

1.Induslynk Training Services Pvt. Ltd.- Mercer- Mettl, 7&8th Floor, SN 1&2, Good Earth Business Bay, Sector 58, Gurugram, 122101

2.SHL (India) Pvt. Ltd.- 6-Tower-B, 10, DLF Building, DLF Cyber City, Gurugram, Haryana, 122002

3.Cleveratti Skill Pvt. Ltd.- 3704, DLF Phase IV, Near Galleria Market, Gurugram 122002, Haryana

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.
- For Analyst/Chemist-Quality Control assessment 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 qualification 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 Pharma Quality occupation.
- SME is screened and approved by LSSSDC. He is 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

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| Minimum Educational Qualification | Specialization | Relevant Industry Experience | | Training/Assessment Experience | | Remarks |
|-----------------------------------|---|------------------------------|---------------------------------|--------------------------------|---|---|
| | | Years | Specialization | Years | Specialization | |
| Graduate | B. Pharma/ B. Tech Chemical Engg. | 5 | Analyst/Chemist-Quality Control | 2 | On the job assessment/ Training experience/ Vocational assessment/ Academic assessment | Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus |
| Post Graduate in Sciences | M.Sc. Chemistry/ M. Pharm./ M. Tech.- Chemical Engg | 3 | Analyst/Chemist-Quality Control | 2 | On the job assessment/ Training experience/ Vocational assessment/ Academic assessment | Relevant Specialization in HPLC/ GC/ UV/ FT-IR/ Dissolution Apparatus |

Assessor Certification

| Domain Certification | Platform Certification |
|--|--|
| Analyst/Chemist-Quality Control" mapped to the Qualification Pack: "LFS/Q1301, v3.0" with minimum accepted score of 80%. | Recommended that the Assessor is certified for the Job Role: "Assessor (VET and Skills)", mapped to the Qualification Pack: "MEP/Q2701, v2.0" with minimum score of 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.

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- 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 within 15 days of assessment date.
- Passed candidates are provided with qualification certificate.

Assessment tools: Assessment tools for a qualification are decided based on composition of knowledge and skill in that qualification. All assessments shall have at least two tools unless indicated otherwise. 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.

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 qualification. 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.

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 the end 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 assessor:

The Assessors are engaged to conduct the assessments by Industry. The selection takes place 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
- qualification 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:

1.2.1 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.

1.2.2 Viva:

Scope – Is used to test the knowledge and understanding and skills acquired during the OJT as well as to conform the OJT monitoring report.

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 qualification.

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 included to test relevant PCs from the qualification

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 batch or 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 company in 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 one assessment 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 the selected 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 qualification.

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.

2.2.2 Digital Written test for skill assessment:

Scope – Is used to test primarily the Skill component of the qualification. 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.

2.3 Steps for assessment development:

- Selection of assessment tool(s) is done as per the assessment criteria prescribed in Qualification.
- For Analyst/Chemist-Quality Control assessment 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 qualification 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 same 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.

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 decided with 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 the assessment.
- The assessment is executed in two possible ways depending on the choice of industry:

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.

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- 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, Aadhaar Card, 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 guidelines from MSDE.

- LSSSDC Protocol for Accreditation of Assessment Agencies and Assessment Guideline Ver1.00 is attached as annexure 3

ASSESSMENT EVIDENCE

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Rationalized on file 20.03.2023

| Marks Allocation | | | | | |
|--|---|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| 1. LFS/N1306 v2.0 : Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) | Perform pre-analysis checks | 20 | 30 | - | 5 |
| | PC1. check the availability of resources (like Validated methods, work instructions) to undertake the work post receiving and logging of samples for testing | - | - | - | - |
| | PC2. ensure the availability of appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required | - | - | - | - |
| | PC3. ensure the status and accuracy of instruments used for measurement | - | - | - | - |
| | PC4. ensure that all the pre analysis checks are performed as per Standard Operating Procedure (SOP), GMP and GLP guidelines | - | - | - | - |
| | PC5. review the data given by junior quality analyst and ensure that it is as per the SOP approved within procedures | - | - | - | - |
| | PC6. check and report on supplies for QC orders involving devices and reagents as per schedule | - | - | - | - |
| | Laboratory investigations and analysis | 15 | 25 | - | 5 |
| | PC7. perform laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard | - | - | - | - |

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|--|---|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | expired solutions/standards as per written procedures | | | | |
| | PC8. collect inputs from cross-functional teams to integrate findings and recommendations | - | - | - | - |
| | PC9. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents | - | - | - | - |
| | PC10. recommend changes in compliance with SOP for corrective action and preventive action (CAPA) / Change Control Procedures to improve the product's quality and to avoid future deviations | | | | |
| | Total | 35 | 55 | - | 10 |
| 2 LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab | <i>Adhere to health and hygiene protocols</i> | 10 | 20 | - | - |
| | PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines | - | - | - | - |
| | PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates | - | - | - | - |
| | PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person | - | - | - | - |
| | PC4. take preventive actions on the report of any allergy, | - | - | - | - |

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|---------------------|---|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | sickness or any other environment-related breach by subordinates | | | | |
| | PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area | - | - | - | - |
| | PC6. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates | - | - | - | - |
| | Adhere to safety and security procedures | 10 | 20 | - | 5 |
| | PC7. observe compliance by self and subordinates with safety and security policies and procedures | - | - | - | - |
| | PC8. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work | - | - | - | - |
| | PC9. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates | - | - | - | - |
| | PC10. ensure proper material segregation and labelling | - | - | - | - |
| | PC11. comply with material handling, segregation, storage, and MSDS | - | - | - | - |

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|---------------------|--|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | guidelines as per 5S system | | | | |
| | PC12. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel | - | - | - | - |
| | PC13. take corrective actions for reported hazards in consultation with EHS personnel | - | - | - | - |
| | PC14. complete records of safety drills and training undertaken by self and subordinates | - | - | - | - |
| | Adhere to emergency procedures | 10 | 20 | - | 5 |
| | PC15. raise the alarm and inform the concerned designated person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion | - | - | - | - |
| | PC16. follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision | - | - | - | - |
| | PC17. follow emergency procedures efficiently | - | - | - | - |
| | PC18. ensure injured employees are provided appropriate first aid and medical aid | - | - | - | - |
| | Total | 30 | 60 | - | 10 |
| | Coordination with Manager | 10 | 20 | - | 5 |

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|--|---|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| 3. LFS/N0302 v3.0: Coordinate with Manager, colleagues and auditors | PC1. coordinate with the reporting manager to obtain work instructions | - | - | - | - |
| | PC2. communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required | - | - | - | - |
| | PC3. communicate deviations / abnormal incidents to the reporting manager | - | - | - | - |
| | PC4. communicate any potential hazards or expected process disruptions to the manager | - | - | - | - |
| | Coordination with colleagues and auditors | 15 | 25 | - | 5 |
| | PC5. support team members and colleagues of other departments in work | - | - | - | - |
| | PC6. train lab assistants and trainees | - | - | - | - |
| | PC7. find solutions to workflow related difficulties with mutual agreement | - | - | - | - |
| | PC8. coordinate with QA for audit related documentation for QC analysis | - | - | - | - |
| | PC9. maintain sense of calm/equilibrium in self as well as team members | - | - | - | - |
| | PC10. provide clear answers to the auditor's queries | - | - | - | - |
| | PC11. produce the documented records of performed activities and operations to auditors | - | - | - | - |

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|---|---|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC12. maintain data integrity while responding to auditors and regulatory inspectors | - | - | - | - |
| | <i>Sensitivity towards all genders and people with disability</i> | 10 | 10 | - | - |
| | PC13. respect all genders, religions, and caste | - | - | - | - |
| | PC14. empathize with the people with disability | - | - | - | - |
| | PC15. offer support or help to a person with disability only when asked | - | - | - | - |
| | PC16. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act | - | - | - | - |
| | PC17. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee | - | - | - | - |
| | Total | 35 | 55 | - | 10 |
| 4. LFS/N0314 v3.0 : To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP | <i>Recording and reporting</i> | 15 | 25 | - | 5 |
| | PC1. review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures | - | - | - | - |
| | PC2. fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standards | - | - | - | - |

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|---------------------|--|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC3. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP | - | - | - | - |
| | PC4. prepare analytical reports for detailed findings and recommendations as per SOPs | - | - | - | - |
| | PC5. prepare quality control reports for raw materials, packing materials, in-process sample, and finished products | - | - | - | - |
| | PC6. prepare certificate of analysis (CoA) for finished products and stability reports | - | - | - | - |
| | PC7. provide reports of validations, deviations and OOS and OOT incidents to production and quality assurance team | | | - | |
| | PC8. write and update the inspection procedures, protocols, and checklists | - | - | - | - |
| | PC9. prepare inspection reports as per the inspection activity performed | - | - | - | - |
| | Documentation compliance with GDP, GLP and GMP | 10 | 15 | - | 5 |
| | PC10. identify documentation to be completed relating to one's role | - | - | - | - |
| | PC11. ensure that the final document meets regulatory and compliance requirements as per GDP, GLP and GMP | - | - | - | - |

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|---|---|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | Data Integrity | 10 | 15 | - | - |
| | PC12. document the results of the testing and analysis accurately | - | - | - | - |
| | PC13. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles | - | - | - | - |
| | PC14. respond to requests for information in an appropriate manner whilst following organizational procedures | - | - | - | - |
| | PC15. make sure documents are available to all appropriate authorities to inspect/ audit | - | - | - | - |
| | Total | 35 | 55 | - | 10 |
| 5. LFS/N1307 v2.0 : Carry out process related checks in the quality control process | Routine inspection of instruments | 8 | 12 | - | 5 |
| | PC1.monitor and conduct regular checks of equipment and instrument conditions and document calibrations | - | - | - | - |
| | PC2.coordinate with maintenance team for preventive maintenance | - | - | - | - |
| | PC3.follow preventive maintenance schedules and maintain the logs for instrument maintenance | - | - | - | - |
| | PC4.investigate "out-of-calibration" lab instrument (if any), and ascertain the impact of calibration error on previously analyzed products | - | - | - | - |
| | Identification of Non-conformities | 10 | 15 | - | 5 |

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|---------------------|---|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC5.identify non-conformities to working standards (quality assurance standards) | - | - | - | - |
| | PC6.identify the impact on final product due to non-conformance to quality assurance standards | - | - | - | - |
| | PC7.evaluate the need for action to ensure that problems do not recur | - | - | - | - |
| | PC8.suggest corrective action to address the problem | - | - | - | - |
| | PC9.review the effectiveness of corrective action | - | - | - | - |
| | Labelling | 10 | 20 | - | 5 |
| | PC10. ensure all samples are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions | - | - | - | - |
| | PC11. ensure compliance with relevant national regulations and international agreements for labels of radiopharmaceutical products | - | - | - | - |
| | PC12. cross-check that the proper dosages and storage conditions are mentioned on labels | - | - | - | - |
| | PC13. check the appearance of a label/leaflet on package for specific product information and indications | - | - | - | - |
| | Environment Sustainability | 2 | 3 | - | 5 |
| | PC14. ensure energy conservation by switching off the machine and equipment post lab operations | - | - | - | - |

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|--|---|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC15. ensure no leakage of water in the laboratory | - | - | - | - |
| | PC16. choose and apply environment-friendly methods given in SOPs for waste disposal | - | - | - | - |
| | PC17. create awareness in the team about organizational environment sustainability guidelines and procedures to achieve energy and water conservation as well as zero pollution of land, water, and air | - | - | - | - |
| | Total | 30 | 50 | - | 20 |
| 6.DGT/VSQ/N0103 V1.0: Employability Skills (90 Hours) | <i>Introduction to Employability Skills</i> | 1 | 1 | - | - |
| | PC1. understand the significance of employability skills in meeting the current job market requirement and future of work. | - | - | - | - |
| | PC2. identify and explore learning and employability relevant portals | - | - | - | - |
| | PC3. research about the different industries, job market trends, latest skills required and the available opportunities | | | | |
| | <i>Constitutional values – Citizenship</i> | 1 | 1 | - | - |
| | PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal | - | - | - | - |

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|---------------------|---|--------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | values and ethics such as honesty, integrity, caring and respecting others, etc. | | | | |
| | PC5.follow environmentally sustainable practices | - | - | - | - |
| | <i>Becoming a Professional in the 21st Century</i> | 1 | 3 | - | - |
| | PC6.recognize the significance of 21st Century Skills for employment | - | - | - | - |
| | PC7.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 | - | - | - | - |
| | PC8.adopt a continuous learning mindset for personal and professional development | | | | |
| | <i>Basic English Skills</i> | 3 | 4 | - | - |
| | PC9.use basic English for everyday conversation in different contexts, in person and over the telephone | - | - | - | - |
| | PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English | - | - | - | - |
| | PC11. write short messages, notes, letters, e-mails etc. in English | - | - | - | - |
| | <i>Career Development & Goal Setting</i> | 1 | 2 | - | - |

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|---------------------|---|----------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC12. identify career goals based on the skills, interests, knowledge, and personal attributes | - | - | - | - |
| | PC13. prepare a career development plan with short- and long-term goals. | - | - | - | - |
| | <i>Communication Skills</i> | 2 | 2 | - | - |
| | PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings | - | - | - | - |
| | PC15. use active listening techniques for effective communication | - | - | - | - |
| | PC16. communicate in writing using appropriate style and format based on formal or informal requirements | | | | |
| | PC17. work collaboratively with others in a team | | | | |
| | <i>Diversity & Inclusion</i> | 1 | 1 | - | - |
| | PC18. communicate and behave appropriately with all genders and PwD | - | - | - | - |
| | PC19. escalate any issues related to sexual harassment at workplace according to POSH Act | - | - | - | - |
| | <i>Financial and Legal Literacy</i> | 2 | 3 | - | - |
| | PC20. identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc. | - | - | - | - |

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| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC21. carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook | - | - | - | - |
| | PC22. identify common components of salary and compute income, expenses, taxes, investments etc | - | - | - | - |
| | PC23. identify relevant rights and laws and use legal aids to fight against legal exploitation | - | - | - | - |
| | <i>Essential Digital Skills</i> | 3 | 5 | - | - |
| | PC24. operate digital devices and carry out basic internet operations securely and safely | - | - | - | - |
| | PC25. carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc. | - | - | - | - |
| | PC26. display responsible online behavior while using various social media platforms | - | - | - | - |
| | PC27. create a personal email account, send and process received messages as per requirement | | | | |
| | PC28. carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications | | | | |
| | PC29. utilize virtual collaboration tools to work effectively | | | | |
| | <i>Entrepreneurship</i> | 2 | 3 | - | - |

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|---------------------|---|----------|------------------|---------|------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC30. identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research | - | - | - | - |
| | PC31. develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion | - | - | - | - |
| | PC32. identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity | - | - | - | - |
| | <i>Customer Service</i> | 1 | 2 | - | - |
| | PC33. identify different types of customers and ways to communicate with them | - | - | - | - |
| | PC34. identify and respond to customer requests and needs in a professional manner | - | - | - | - |
| | PC35. use appropriate tools to collect customer feedback | - | - | - | - |
| | PC36. follow appropriate hygiene and grooming standards | | | | |
| | <i>Getting ready for apprenticeship & Jobs</i> | 2 | 3 | - | - |
| | PC37. create a professional Curriculum vitae (Résumé) | - | - | - | - |
| | PC38. search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively | - | - | - | - |
| | PC39. apply to identified job openings using offline | - | - | - | - |

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| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | /online methods as per requirement | | | | |
| | PC40. answer questions politely, with clarity and confidence, during recruitment and selection | - | - | - | - |
| | PC41. identify apprenticeship opportunities and register for it as per guidelines and requirements | - | - | - | - |
| | NOS Total | 20 | 30 | - | - |
| 7. LFS/N1301 v2.0: Perform QC Analysis using High-Performance Liquid Chromatography (HPLC) | HPLC Analysis | 35 | 55 | - | 10 |
| | PC1. follow the instrument cleaning procedure for the analysis before using the instrument | - | - | - | - |
| | PC2. select the developed and validated method for HPLC analysis | - | - | - | - |
| | PC3. prepare mobile phase, resolution solution, and standard solution | - | - | - | - |
| | PC4. prepare the sample considering stability and storage requirement | - | - | - | - |
| | PC5. validate system suitability to verify the chromatographic system | - | - | - | - |
| | PC6. perform sample analysis using HPLC | - | - | - | - |
| | PC7. record, analyze and document all the chromatogram | - | - | - | - |
| | PC8. ensure to perform the calculation required for analysis | - | - | - | - |
| | PC9. raise/log an incident in the Lab Management Information system for OOS, OOC, and OOT in case of | - | - | - | - |

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|---|--|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | non-conformity during sample analysis on HPLC | | | | |
| | PC10. perform calibration of HPLC | | | | |
| | PC11. ensure issuance, maintenance, and disposal of HPLC column | - | - | - | - |
| | Total | 35 | 55 | - | 10 |
| 8. LFS/N1302 v2.0: Perform QC Analysis using Gas Chromatography | Gas Chromatography Analysis | 35 | 55 | - | 10 |
| | PC1. identify and select the correct types of columns, injections and detectors used in Gas Chromatograph | - | - | - | - |
| | PC2. prepare the sample considering stability and storage requirement | - | - | - | - |
| | PC3. analyze the sample using Gas Chromatograph | - | - | - | - |
| | PC4. record, analyze and document all the chromatogram | - | - | - | - |
| | PC5. calculate and derive ideal coefficient correlation as per the respective SOP | - | - | - | - |
| | PC6. raise/log an incident in the system SAP, OOS, OOC, and OOT in case of non-conformity during sample analysis | - | - | - | - |
| | PC7. perform calibration of Gas Chromatograph | - | - | - | - |
| | PC8. ensure issuance, maintenance, and disposal of sample in Gas Chromatography column | - | - | - | - |
| | Total | 35 | 55 | - | 10 |

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|---|---|-----------|------------------|---------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| 9.LFS/N1303 v2.0: Perform QC Analysis using Ultraviolet-visible spectroscopy | <i>Ultraviolet (UV)- visible spectroscopy Analysis</i> | 35 | 55 | - | 10 |
| | PC1. prepare the samples for analysis by UVvisible spectroscopy | - | - | - | - |
| | PC2. select the correct developed and validated method for analysis | - | - | - | - |
| | PC3. set the desired wavelength with the knob in increasing order as per the developed and validated method | - | - | - | - |
| | PC4. operate the UV spectrophotometer as per SOP | - | - | - | - |
| Marks Allocation | | | | | |
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| | PC5. handle cuvette with loaded samples | 20 | 30 | - | 10 |
| | PC6. record the readings for different samples and make the entry in instrument logbook | - | - | - | - |
| | PC7. perform calibration and performance qualification of UV spectrophotometer | - | - | - | - |
| | PC8. perform maintenance of UV spectrophotometer | - | - | - | - |
| | Total | 35 | 55 | - | 10 |
| | <i>FT-IR Analysis</i> | 35 | 55 | - | 10 |

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|---|--|-----------|------------------|----------|-----------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| 10. LFS/N1304 v2.0: Perform QC Analysis using Fourier Transform Infrared Spectroscopy | PC1. follow the procedure for analysis using FT-IR Spectrophotometer | - | - | - | - |
| | PC2. ensure that instrument is properly calibrated | - | - | - | - |
| | PC3. operate the FT-IR instrument | - | - | - | - |
| | PC4. select the correct analysis procedure for solids, liquids and mineral oil dispersion | - | - | - | - |
| | PC5. perform sample analysis as per specified software | - | - | - | - |
| | PC6. prepare the samples for quality check | - | - | - | - |
| | PC7. run the samples on FT-IR spectrophotometer | - | - | - | - |
| | PC8. compare the wave function for accuracy with different ideal limits | - | - | - | - |
| | PC9. check resolution performance of the instrument | - | - | - | - |
| | PC10. record and evaluate qualitative and quantitative results | - | - | - | - |
| | Total | 35 | 55 | - | 10 |
| 11. LFS/N1305 v2.0: Perform QC Analysis | <i>Analysis using Dissolution Test (DT) Apparatus</i> | 35 | 55 | - | 10 |
| | PC1. identify and select right type of dissolution apparatus used for testing on different types of dosage forms | - | - | - | - |

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| Marks Allocation | | | | | |
|----------------------------------|--|---------------|-------------------------|----------------|-------------|
| Assessment outcomes | Assessment Criteria for outcomes | Theory | Skills Practical | Project | Viva |
| using Dissolution Test Apparatus | PC2. prepare dissolution medium | - | - | - | - |
| | PC3. follow the sample withdrawal procedure | - | - | - | - |
| | PC4. perform sample analysis using DT apparatus | - | - | - | - |
| | PC5. record, analyze and document all the results | - | - | - | - |
| | PC6. ensure that calculation shall be performed as per the respective SOP | - | - | - | - |
| | PC7. raise/log an incident in the system HAP, OOS, OOC, and OOT in case of non-conformity during sample analysis | - | - | - | - |
| | PC8. carryout maintenance of Dissolution Test apparatus | - | - | - | - |
| | Total | 35 | 55 | - | 10 |

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24. Assessment evidences

Title of Component: 1. LFS/N1306 v2.0: Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP)

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Perform pre-analysis checks | PC1. check the availability of resources (like Validated methods, work instructions) to undertake the work post receiving and logging of samples for testing |
| | PC2. ensure the availability of appropriate measuring instruments, equipment, tools, accessories, MSDS and relevant personal protective equipment (PPE) as required |
| | PC3. ensure the status and accuracy of instruments used for measurement |
| | PC4. ensure that all the pre-analysis checks are performed as per Standard Operating Procedure (SOP), GMP and GLP guidelines |
| | PC5. review the data given by junior quality analyst and ensure that it is as per the SOP approved within procedures |
| | PC6. check and report on supplies for QC orders involving devices and reagents as per schedule |
| Laboratory investigations and analysis | PC7. perform laboratory investigations and check the validity/ stability of volumetric solutions/pH buffers, standards as part of daily routine and discard expired solutions/standards as per written procedures |
| | PC8. collect inputs from cross-functional teams to integrate findings and recommendations |
| | PC9. analyse the root cause for out-of-specification (OOS) and out-of-trend (OOT) products, deviations and incidents |
| | PC10. recommend changes in compliance with SOP for corrective action and preventive action (CAPA) / Change Control Procedures to improve the product's quality and to avoid future deviations |
| Means of assessment 1 | Digital Written test for knowledge assessment: <u>Scope</u> – Is used to test the knowledge component of the Qualification. <u>Tools</u> – Computer or tab based online or offline. <u>Method</u> – 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, |

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| | <p>arrange in proper sequence, case study, scenario-based responses.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>Some personality traits and generic skills (such as – promptness, sharpness, communication skills, depth</p> |

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| | <p>of knowledge, comprehension, presentation, patience etc) can also be tested required for the qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor.</p> <p>Comparative quality of trainees with in a batch or different institutes can be gauged</p> |
| Pass/Fail | <p>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%.</p> |

Title of Component: 2. LFS/N0110 v2.0: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Adhere to health and hygiene protocols | PC1. comply with health and personal hygiene-related protocols as per WHO standards and ICH GMP guidelines |
| | PC2. sanitize your hands before entering in laboratory and production area and ensure the adherence of same by subordinates |
| | PC3. report any allergy, sickness or any other environment-related breach before or after entering the work premises to the designated person |
| | PC4. take preventive actions on the report of any allergy, sickness or any other environment-related breach by subordinates |
| | PC5. wear lab coat all the time while working in a laboratory and ensure adherence of the same by every person visiting/ working in the lab area |

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| | PC6. follow gowning procedures while entering an environment controlled work area and ensure the adherence of the same by subordinates |
| Adhere to safety and security procedures | PC7. observe compliance by self and subordinates with safety and security policies and procedures |
| | PC8. ensure the use of appropriate safety gears like headgear, masks, gloves and other accessories as mentioned in the guidelines, by self and subordinates while carrying out work |
| | PC9. take preventive and corrective actions on the report of any identified breaches in safety and security policies and procedures by subordinates |
| | PC10. ensure proper material segregation and labelling |
| | PC11. comply with material handling, segregation, storage, and MSDS guidelines as per 5S system |
| | PC12. supervise the disposal of waste/unused and expired reagents/ chemicals / biological waste using environmentally sustainable methods in the presence of EHS personnel |
| | PC13. take corrective actions for reported hazards in consultation with EHS personnel |
| | PC14. complete records of safety drills and training undertaken by self and subordinates |
| Adhere to emergency procedures | PC15. raise the alarm and inform the concerned designated person immediately for action in the cases of spill, fall, injury, toxic inhale, fire or explosion |
| | PC16. follow emergency protocol for any alarms and ensure the safety of subordinates in the area under supervision |
| | PC17. follow emergency procedures efficiently |
| | PC18. ensure injured employees are provided appropriate first aid and medical aid |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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</p> |

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| | of improvement or expertise of the trainee. While a consolidated mark gives the overall rating of the trainee. |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions.</p> |

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| | Different questions are included to test relevant PCs from the qualification 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: 3. LFS/N0302 v3.0: Coordinate with Manager, colleagues and auditors

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|---|
| Coordination with manager | PC1. coordinate with the reporting manager to obtain work instructions |
| | PC2. communicate to reporting supervisor about process-flow improvements, production defects received from the previous process, repairs and maintenance of equipment as required |
| | PC3. communicate deviations / abnormal incidents to the reporting manager |
| | PC4. communicate any potential hazards or expected process disruptions to the manager |
| Coordination with colleagues and auditors | PC5. support team members and colleagues of other departments in work |
| | PC6. train lab assistants and trainees |
| | PC7. find solutions to workflow related difficulties with mutual agreement |
| | PC8. coordinate with QA for audit related documentation for QC analysis |
| | PC9. maintain sense of calm/equilibrium in self as well as team members |
| | PC10. provide clear answers to the auditor's queries |
| | PC11. produce the documented records of performed activities and operations to auditors |
| | PC12. maintain data integrity while responding to auditors and regulatory inspectors |
| Sensitivity towards genders and cultures | all |
| | PC13. respect all genders, religions, and caste PC14. empathize with the people with disability |

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| | <p>PC15. offer support or help to a person with disability only when asked</p> <p>PC16. ensure to adhere with the guidelines laid in Sexual Harassment of Women at Workplace (Prevention, Prohibition and Redressal) Act</p> <p>PC17. report any violation of prevention of sexual harassment (POSH) rules immediately to the POSH committee</p> |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – The trainee is deployed in Industry for on the job trainee or is being asked to work on a specific</p> |

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| | <p>project (utilizing skills as per qualification). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor.</p> <p>Comparative quality of trainees with in a batch or different institutes can be gauged</p> |
| Pass/Fail | <p>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%.</p> |

Title of Component: 4. LFS/N0314 v3.0: Carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Recording and reporting | PC1. review and update the test methods and procedures as per the schedule or when a regulatory requirement arises according to the written procedures |

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| | PC2. fill logbooks, worksheet (an analytical record), reference standard entries, calibration records, parameters of column, reagent, volumetric solution and working standard |
| | PC3. report defects/problem/incidents/quality issues/test results as applicable in a timely manner to the appropriate authority as per SOP |
| | PC4. prepare analytical reports for detailed findings and recommendations as per SOPs |
| | PC5. prepare quality control reports for raw materials, packing materials, in-process sample, and finished products |
| | PC6. prepare certificate of analysis (CoA) for finished products and stability reports |
| | PC7. provide reports of validations, deviations and OOS and OOT incidents to production and quality assurance team |
| | PC8. write and update the inspection procedures, protocols, and checklists |
| | PC9. prepare inspection reports as per the inspection activity performed |
| | PC10. identify documentation to be completed relating to one's role |
| Documentation compliance with GDP, GLP and GMP | PC11. ensure that the final document meets regulatory and compliance requirements as per GDP, GLP and GMP |
| Data Integrity | PC12. document the results of the testing and analysis accurately |
| | PC13. maintain all original and controlled document files and quality records in a timely and accurate manner following ALCOA PLUS principles |
| | PC14. respond to requests for information in an appropriate manner whilst following organizational procedure |
| | PC15. make sure documents are available to all appropriate authorities to inspect/ audit |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> |

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| | <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> |

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| | <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This reduces effect of subjectivity of the assessor.</p> <p>Comparative quality of trainees with in a batch or different institutes can be gauged</p> |
| Pass/Fail | <p>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%.</p> |

Title of Component: 5. LFS/N1307 v2.0: To carry out process-related checks in the quality control process

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Routine inspection of instruments | PC1. monitor and conduct regular checks of equipment and instrument conditions and document calibrations |
| | PC2. coordinate with maintenance team for preventive maintenance |
| | PC3. follow preventive maintenance schedules and maintain the logs for instrument maintenance |
| | PC4. investigate “out-of-calibration” lab instrument (if any), and ascertain the impact of calibration error on previously analyzed products |
| Identification of Non-conformities | PC5. identify non-conformities to working standards (quality assurance standards) |
| | PC6. identify the impact on final product due to non-conformance to quality assurance standards |
| | PC7. evaluate the need for action to ensure that problems do not recur |
| | PC8. suggest corrective action to address the problem |
| | PC9. review the effectiveness of corrective action |

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| Labelling | PC10. ensure all samples are clearly identified by labels and remain permanently attached to the sample containers under all storage conditions |
| | PC11. ensure compliance with relevant national regulations and international agreements for labels of radiopharmaceutical products |
| | PC12. cross-check that the proper dosages and storage conditions on labels |
| | PC13. check the appearance of a label/leaflet on package for specific product information and indications |
| Environment Sustainability | PC14. ensure energy conservation by switching off the machine and equipment post lab operations |
| | PC15. ensure no leakage of water in the laboratory |
| | PC16. choose and apply environment-friendly methods given in SOPs for waste disposal |
| | PC17. create awareness in the team about 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 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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</p> |

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| | <p>to the situation. The selected situations are based on real situations.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – 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</p> |
| Pass/Fail | <p>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</p> |

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knowledge assessment, Digital Written test for skill assessment and Viva shall also be 70%.

Title of Component: 6 DGT/VSQ/N0103 V1.0: Employability Skills (90 Hours)

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Introduction to Employability Skills | PC1. understand the significance of employability skills in meeting the current job market requirement and future of work. |
| | PC2. identify and explore learning and employability relevant portals |
| | PC3. research about the different industries, job market trends, latest skills required and the available opportunities |
| Constitutional values – Citizenship | PC4. recognize the significance of constitutional values, including civic rights and duties, citizenship, responsibility towards society etc. and personal values and ethics such as honesty, integrity, caring and respecting others, etc. |
| | PC5. follow environmentally sustainable practices |
| Becoming a Professional in the 21st Century | PC6. recognize the significance of 21st Century Skills for employment |
| | PC7. 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 |
| | PC8. adopt a continuous learning mindset for personal and professional development |
| Basic English Skills | PC9. use basic English for everyday conversation in different contexts, in person and over the telephone |
| | PC10. read and understand routine information, notes, instructions, mails, letters etc. written in English |
| | PC11. write short messages, notes, letters, e-mails etc. in English |
| Career Development & Goal Setting | PC12. identify career goals based on the skills, interests, knowledge, and personal attributes |
| | PC13. prepare a career development plan with short- and long-term goals |
| Communication Skills | PC14. follow verbal and non-verbal communication etiquette while communicating in professional and public settings |

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| | PC15.use active listening techniques for effective communication |
| | PC16.communicate in writing using appropriate style and format based on formal or informal requirements |
| | PC17.work collaboratively with others in a team |
| Diversity & Inclusion | PC18.communicate and behave appropriately with all genders and PwD |
| | PC19.escalate any issues related to sexual harassment at workplace according to POSH Act |
| Financial and Legal Literacy | PC20.identify and select reliable institutions for various financial products and services such as bank account, debit and credit cards, loans, insurance etc. |
| | PC21.carry out offline and online financial transactions, safely and securely, using various methods and check the entries in the passbook |
| | PC22.identify common components of salary and compute income, expenses, taxes, investments etc |
| | PC23.identify relevant rights and laws and use legal aids to fight against legal exploitation |
| Essential Digital Skills | PC24.operate digital devices and carry out basic internet operations securely and safely |
| | PC25.carry out basic internet operations by connecting to the internet safely and securely, using the mobile data or other available networks through Bluetooth, Wi-Fi, etc. |
| | PC26.display responsible online behavior while using various social media platforms |
| | PC27.create a personal email account, send and process received messages as per requirement |
| | PC28.carry out basic procedures in documents, spreadsheets and presentations using respective and appropriate applications |
| | PC29.utilize virtual collaboration tools to work effectively |
| Entrepreneurship | PC30.identify different types of Entrepreneurship and Enterprises and assess opportunities for potential business through research |
| | PC31.develop a business plan and a work model, considering the 4Ps of Marketing Product, Price, Place and Promotion |
| | PC32.identify sources of funding, anticipate, and mitigate any financial/ legal hurdles for the potential business opportunity |
| Customer Service | PC33.identify different types of customers and ways to communicate with them |

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| Getting ready for apprenticeship & Jobs | PC34.identify and respond to customer requests and needs in a professional manner |
| | PC35.use appropriate tools to collect customer feedback |
| | PC36.follow appropriate hygiene and grooming standards |
| | PC37.create a professional Curriculum vitae (Résumé) |
| | PC38.search for suitable jobs using reliable offline and online sources such as Employment exchange, recruitment agencies, newspapers etc. and job portals, respectively |
| | PC39.apply to identified job openings using offline /online methods as per requirement |
| Means of assessment 1 | PC40.answer questions politely, with clarity and confidence, during recruitment and selection |
| | PC41.identify apprenticeship opportunities and register for it as per guidelines and requirements |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular skill field</p> |

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| | 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 <u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios <u>Tools</u> – Project report. <u>Method</u> – 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). 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 <u>Analysis</u> –Project Assessments are analysed on knowledge and skill component. |
| Means of assessment 4 | Viva <u>Scope</u> – 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 qualification. <u>Tools</u> – Direct dialogue between assessor and Trainee. <u>Method</u> – 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 qualification <u>Analysis</u> – 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%. | |

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Title of Component: 7 LFS/N1301 v2.0: Perform QC Analysis using High-Performance Liquid Chromatography(HPLC)

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| HPLC analysis | <p>PC1. follow the instrument cleaning procedure for the analysis before using the instrument</p> <p>PC2. select the developed and validated method for HPLC analysis</p> <p>PC3. prepare mobile phase, resolution solution, and standards solution</p> <p>PC4. prepare the sample considering stability and storage requirement</p> <p>PC5. validate system suitability to verify the chromatographic system</p> <p>PC6. perform sample analysis using HPLC</p> <p>PC7. record, analyze and document all the chromatogram</p> <p>PC8. ensure to perform the calculation required for analysis</p> <p>PC9. raise/log an incident in the Lab Management Information system for OOS, OOC, and OOT in case of non-conformity during sample analysis on HPLC</p> <p>PC10. perform calibration of HPLC</p> <p>PC11. ensure issuance, maintenance, and disposal of HPLC column</p> |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | Digital Written test for skill assessment |

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| | <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – Assessor is provided with spectrum of ready answers to be expected from trainee. This</p> |

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| 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/N1302 v2.0: Perform QC Analysis using Gas Chromatography

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| Gas Chromatography Analysis | PC1. identify and select the correct types of columns, injections and detectors used in Gas Chromatograph |
| | PC2. prepare the sample considering stability and storage requirement |
| | PC3. analyze the sample using Gas Chromatograph |
| | PC4. record, analyze and document all the chromatogram |
| | PC5. calculate and derive ideal coefficient correlation as per the respective SOP |
| | PC6. raise/log an incident in the system SAP, OOS, OOC, and OOT in case of non-conformity during sample analysis |
| | PC7. perform calibration of Gas Chromatograph |
| | PC8. ensure issuance, maintenance, and disposal of sample in Gas Chromatography column |
| Means of assessment 1 | Digital Written test for knowledge assessment: <u>Scope</u> – Is used to test the knowledge component of the Qualification. <u>Tools</u> – Computer or tab based online or offline. <u>Method</u> – 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. <u>Analysis</u> – 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 |

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| | consolidated mark gives the overall rating of the trainee. |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical questions, and decision-making based questions.</p> |

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| | Different questions are included to test relevant PCs from the qualification 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/N1303 v2.0: Perform QC Analysis using Ultraviolet-visible spectroscopy

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|---|
| Ultraviolet (UV)- visible spectroscopy Analysis | PC1. prepare the samples for analysis by UV- visible spectroscopy |
| | PC2. select the correct developed and validated method for analysis |
| | PC3. set the desired wavelength with the knob in increasing order as per the developed and validated method |
| | PC4. operate the UV spectrophotometer as per SOP |
| | PC5. handle cuvette with loaded samples |
| | PC6. record the readings for different samples and make the entry in instrument logbook |
| | PC7. perform calibration and performance qualification of UV spectrophotometer |
| | PC8. perform maintenance of UV spectrophotometer |
| Means of assessment 1 | Digital Written test for knowledge assessment: <u>Scope</u> – Is used to test the knowledge component of the Qualification. <u>Tools</u> – Computer or tab based online or offline. <u>Method</u> – 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. <u>Analysis</u> – Question paper is divided in sections. Each Section intends to assess a particular knowledge field of the trainee. Thus, section wise |

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| | 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 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – Direct questions open and close ended questions, situation-based questions, analytical</p> |

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| | questions, and decision-making based questions. Different questions are included to test relevant PCs from the qualification 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: 10. LFS/N1304 v2.0 : Perform QC Analysis using Fourier Transform Infrared Spectroscopy

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|---|--|
| FT-IR Analysis | PC1. follow the procedure for analysis using FT-IR Spectrophotometer |
| | PC2. ensure that instrument is properly calibrated |
| | PC3. operate the FT-IR instrument |
| | PC4. select the correct analysis procedure for solids, liquids and mineral oil dispersion |
| | PC5. perform sample analysis as per specified software |
| | PC6. prepare the samples for quality check |
| | PC7. run the samples on FT-IR spectrophotometer |
| | PC8. compare the wave function for accuracy with different ideal limits |
| | PC9. check resolution performance of the instrument |
| | PC10. record and evaluate qualitative and quantitative results |
| Means of assessment 1 | Digital Written test for knowledge assessment: <u>Scope</u> – Is used to test the knowledge component of the Qualification. <u>Tools</u> – Computer or tab based online or offline. <u>Method</u> – 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. |

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| | <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | <p>Viva</p> <p><u>Scope</u> – Is used to test the knowledge and understanding and breadth of awareness about the subject.</p> <p>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 qualification.</p> |

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| | <p><u>Tools</u> – Direct dialogue between assessor and Trainee.</p> <p><u>Method</u> – 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 qualification</p> <p><u>Analysis</u> – 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</p> |
| Pass/Fail | <p>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%.</p> |

Title of Component: 11. LFS/N1305 v2.0: Perform QC Analysis using Dissolution Test Apparatus

| Outcomes to be assessed/NOSs to be assessed | Assessment criteria for the outcome |
|--|---|
| Analysis using Dissolution Test (DT) Apparatus | PC1. identify and select right type of dissolution apparatus used for testing on different types of dosage forms |
| | PC2. prepare dissolution medium |
| | PC3. follow the sample withdrawal procedure |
| | PC4. perform sample analysis using DT apparatus |
| | PC5. record, analyze and document all the results |
| | PC6. ensure that calculation shall be performed as per the respective SOP |
| | PC7. raise/log an incident in the system HAP, OOS, OOC, and OOT in case of non-conformity during sample analysis |
| | PC8. carryout maintenance of Dissolution Test apparatus |
| Means of assessment 1 | <p>Digital Written test for knowledge assessment:</p> <p><u>Scope</u> – Is used to test the knowledge component of the Qualification.</p> <p><u>Tools</u> – Computer or tab based online or offline.</p> |

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| | <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 2 | <p>Digital Written test for skill assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in handling and managing the situation is tested.</p> <p><u>Tools</u> – computer or tab based online or offline questions.</p> <p><u>Method</u> – 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.</p> <p><u>Analysis</u> – 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.</p> |
| Means of assessment 3 | <p>Project Assessment</p> <p><u>Scope</u> – Is used to test primarily the Skill component of the qualification. Trainee's expertise in utilization of knowledge and skills in real life job scenarios</p> <p><u>Tools</u> – Project report.</p> <p><u>Method</u> – 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). 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</p> <p><u>Analysis</u> –Project Assessments are analysed on knowledge and skill component.</p> |
| Means of assessment 4 | Viva |

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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 qualification.

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 included to test relevant PCs from the qualification

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%.

SECTION 2

25. EVIDENCE OF LEVEL

| Title/Name of the qualification/Component: Analyst/Chemist-Quality Control Level: 5 | | | |
|---|---|--|------------|
| NSQF Domain | Key requirements of the job role | How the job role relates to the NSQF level descriptors | NSQF level |
| Process | <p>Few of the job elements, expected to be performed by Analyst/Chemist-Quality Control are:</p> <ul style="list-style-type: none"> • Perform pre-analysis checks • Laboratory investigations and analysis • Routine Inspection of Instruments • Identification of Non-conformities • Labelling • Recording and Reporting • Documentation compliance with GDP, GLP and GMP • Data Integrity • HPLC/GC/UV/FT-IR/Dissolution Test Apparatus Analysis | <p>Analyst/Chemist-Quality Control performs quality checks in various samples as per the SOPs followed in the Life Sciences Sector. The job holder is responsible to pre-analysis checks, laboratory investigations and analysis, routine Inspection of Instruments, identification of non-conformities, and labelling throughout the job functions. He/she is also responsible to perform continuous reporting and documentation at every step. The Analyst/Chemist-Quality Control is well skilled in handling instruments like HPLC/GC/UV/FT-IR/Dissolution Test Apparatus to perform sample analysis. All the above performance outcomes are routine and common in all the work assigned to Analyst/Chemist-Quality Control, hence they are categorized as familiar and predictable processes where the Analyst/Chemist-Quality Control has a situation of clear choice.</p> | 5 |

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| Professional Knowledge | <p>Few of the job elements, expected to be performed by Analyst/Chemist-Quality Control are:</p> <ul style="list-style-type: none"> • Perform pre-analysis checks • Laboratory investigations and analysis • Routine Inspection of Instruments • Identification of Non-conformities • Labelling • Coordinate with Manager, colleagues and auditors | <p>Analyst/Chemist-Quality Control needs to have the factual knowledge of facts, principles, processes and general concepts related to Good Laboratory Practices (GLP), how to routinely perform pre-analysis checks laboratory investigations and analysis, routine Inspection of Instruments, identification of non-conformities and labelling by recalling the work safety guidelines. The job holder should also be efficient to coordinate with with Manager, colleagues and auditors to meet the communication needs to fulfill work requirements of Analyst/Chemist-Quality Control</p> | 5 |
| Professional Skills | <p>Few of the job elements, expected to be performed by Analyst/Chemist-Quality Control are:</p> <ul style="list-style-type: none"> • Perform pre-analysis checks • Laboratory investigations and analysis • Routine Inspection of Instruments • Identification of Non-conformities • Labelling • Recording and Reporting • Documentation compliance with GDP, GLP and GMP • Data Integrity • HPLC/GC/UV/FT-IR/Dissolution Test Apparatus Analysis | <p>To perform the tasks of Analyst/Chemist-Quality Control the job holder utilizes professional skills like good communication and interpersonal skills, good analytical, reasoning skills, attention to details, critical thinking, and excellent organizational skills.</p> <p>For routine job activities and tasks the Analyst/Chemist-Quality Control uses the planning and organizing skills.</p> <p>The job holder demonstrates analytical and critical thinking skills while performing analysis on instruments like</p> | 5 |

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| | | <p>HPLC/GC/UV/FT-IR/Dissolution Test Apparatus analysis.</p> <p>The scope of utilization of all above professional skills remains limited to routine and repetitive and for a narrow range of applications</p> | |
| Core Skills | <p>Few of the job elements, expected to be performed by Analyst/Chemist-Quality Control are:</p> <ul style="list-style-type: none"> • Coordination with Manager • Coordination with colleagues and auditors • Sensitivity towards all genders and people with disability • Recording and Reporting • Documentation compliance with GDP, GLP and GMP • Data Integrity | <p>To perform the tasks, Analyst/Chemist-Quality Control uses organizing information, communication and problem solving skills.</p> <p>For reporting and documentation proposed, he/she applies the basics of arithmetic and algebraic principles and organizational skills.</p> <p>For coordination related tasks and ensuring compliance to organizational SOPs and regulatory requirements, the job holder is expected to have a basic understanding of the social-political and natural environment at the place of work/ organization he/she is working for.</p> | 5 |
| Responsibility | <p>Few of the job elements, expected to be performed by Analyst/Chemist-Quality Control are:</p> <ul style="list-style-type: none"> • Perform pre-analysis checks • Laboratory investigations and analysis • Routine Inspection of Instruments • Identification of Non-conformities • Labelling | <p>Analyst/Chemist-Quality Control has responsibility for his/her work and learning and supports to Junior Quality Analyst/ Wet Lab Analyst, Lab Technician and cross functional Teams. And in case of a scenario/situation of no clear choice,</p> | 5 |

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| | <ul style="list-style-type: none">• Coordination with Manager• Coordination with colleagues and auditors• Sensitivity towards all genders and people with disability• Recording and Reporting• Documentation compliance with GDP, GLP and GMP• Data Integrity• HPLC/GC/UV/FT-IR/Dissolution Test Apparatus Analysis | he is expected to take guidance from the Head of Quality Department. | |
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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 Industry need.

| S.No | Name of Organization |
|------|--|
| 1 | Anglo French Drugs and Industries Ltd. |
| 2 | Arbro Pharmaceuticals Private Limited |
| 3 | Belco Pharma |
| 4 | Ciron Drugs & Pharmaceuticals Limited |
| 5 | Drugfarm Laboratories |
| 6 | Dr. Reddy's Limited |
| 7 | Emcure Pharmaceuticals Ltd |
| 8 | FDC Limited |
| 9 | Jubilant Chemsys Limited |
| 10 | Kumar Organic Products Limited |
| 11 | Lupin Limited |
| 12 | Macleods Pharmaceuticals Ltd. |
| 13 | Micro Labs Limited |
| 14 | Modgal Pharmaceuticals Pvt. Ltd. |
| 15 | Nakoda Chemicals Limited |
| 16 | Neuland Laboratories Limited |
| 17 | Prerana Bio-Innovations Research Pvt. Ltd. |
| 18 | Pure & Cure Healthcare Pvt.Ltd |
| 19 | Smruti Organics Limited |
| 20 | Serum Institute of India Pvt. Ltd. |
| 21 | Sri Krishna Pharmaceuticals Limited |
| 22 | Umed Pharma labs P Ltd. |
| 23 | Unimarck Healthcare Ltd. |
| 24 | Unichem Laboratories Ltd. |

Usage of qualification

LSSSDC would submit periodic details (directly/Via NSDC) of the employment generated (wherever applicable) and realize under training in the

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| | Qualifications post-approval of NSQC and implementation of the qualification. |
| | <p>Estimated uptake LSSSDC has prepared a skill gap report forecasting the year wise estimated uptake. The forecasted uptake is given as annexure-4.</p> |
| 27 | <p>Recommendation from the concerned Line Ministry of the Government/Regulatory Body. To be supported by documentary evidences</p> |
| | <p>We have requested a recommendation from the Ministry of Health and Department of Biotechnology for the job role of Analyst/Chemist-Quality Control. (copy of request letter is enclosed in Annexure 5).</p> <p>We have received a recommendation from Department of Biotechnology for the job role of Analyst/Chemist-Quality Control - Life Sciences .</p> <p>The response from the Ministry of Health and Family Welfare is awaited and will be submitted sooner we receive it.</p> |
| 28 | <p>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</p> <p>Before submission of the qualification to NSQC we have checked the availability of Analyst/Chemist-Quality Control with other councils on the portal of NSDC and we found no other qualification matching with the submitted job role. We have revalidated the first version of NSQC approved Qualification of Quality Control Chemist from Life Sciences Sector Skill Development Council. Hence no duplication is found of the submitted job role.</p> <p>While performing the functional analysis approved by industry we identified skill gap in some competencies and NOSs which have been rewritten and revalidated from industries. The validation mails and inputs received from industries are attached in (annexure 6) as one of the evidence. Based on the functional analysis of job role we have found that there are some functions of Analyst/Chemist-Quality Control in life sciences sector that are not covered in the version 2 of Analyst/Chemist-Quality Control, so we added 5 elective NOSs to fulfil the skill gap. Hence following NOS have been newly drafted for the qualification of Analyst/Chemist-Quality Control:</p> <p>Compulsory NOS:</p> <ol style="list-style-type: none"> 1. LFS/N1306: Perform laboratory investigations and analysis in compliance with Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) 2. LFS/N0110: Ensure adherence to Environment, health and safety guidelines in GMP/GLP controlled areas and Lab by self and subordinates 3. LFS/N0302: Coordinate with Manager, colleagues and auditors 4. LFS/N0314: To carry out reporting and documentation for Quality Control analysis in compliance with GDP, GLP and GMP 5. LFS/N1307: carry out process-related checks in the quality control process 6. DGT/VSQ/N0103 : Employability Skills (90 Hours) |

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| | <p>Elective 1: High-Performance Liquid Chromatography (HPLC) 7. LFS/N1301: Perform QC Analysis using High-Performance Liquid Chromatography</p> <p>Elective 2: Gas Chromatography (GC) 8. LFS/N1302: Perform QC Analysis using Gas Chromatography</p> <p>Elective 3: Ultraviolet-visible Spectroscopy (UV) 9. LFS/N1303: Perform QC Analysis using Ultraviolet-visible spectroscopy</p> <p>Elective 4: Fourier Transform Infrared Spectroscopy (FT-IR) 10. LFS/N1304: Perform QC Analysis using Fourier Transform Infrared Spectroscopy</p> <p>Elective 5: Dissolution Test Apparatus 11. LFS/N1305: Perform QC Analysis using Dissolution Test Apparatus</p> |
| 29 | <p>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</p> <p>On one meetings 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.</p> <p>LSSSDC will be engaged with Training Providers and Authorised educational institutions, who are imparting training as per qualification guidelines, to gather feedback in implementation</p> <p>Monitoring of candidate Assessment Result will be carried out</p> <p>Employer feedback will be sought post placement of trainee's batch</p> <p>A formal review is scheduled in a three-year time frame</p> |

SECTION 4

EVIDENCE OF PROGRESSION

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| 30 | <p>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? <i>Show the career map here to reflect the clear progression</i></p> <p>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:</p> <p>After 3-4 years of Industry work experience as Analyst/Chemist-Quality Control post-qualifying the certification of Analyst/Chemist-Quality Control, a candidate has an option to qualify QC Reviewer/Section In- Charge (Level-6) and Instrumental Analysis Specialist- Quality Control (Pharma) (Level-6) (Under Industry Validation) as an upward progression.</p> <p>Lateral/Horizontal progression 1.Chemist In-Process Quality Assurance(Level-5)</p> <p>Also, have a horizontal progression across manufacturing and R&D based sectors</p> |
|----|---|