

QUALIFICATIONS PACK - OCCUPATIONAL STANDARDS FOR LIFE SCIENCES INDUSTRY

What are Occupational Standards (OS)?

- OS describe what individuals need to do, know and understand in order to carry out a particular job role or function
- OS are performance standards that individuals must achieve when carrying out functions in the workplace, together with specifications of the underpinning knowledge and understanding

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Introduction

Qualifications Pack-Store Chemist/Supervisor/In Charge - Raw Materials – Life Sciences

SECTOR: LIFE SCIENCES

SUB-SECTOR: PHARMACEUTICAL AND BIO PHARMACEUTICAL

OCCUPATION: SUPPLY CHAIN

REFERENCE ID:LFS/Q0601

ALIGNED TO: NCO 2004/NIL

Store Chemist – Raw Materials, also known as Store Supervisor or In Charge, is responsible for ensuring storage of raw materials and maintaining storage premises according to set procedures and standards. He facilitates a safe and secure working environment.

Brief Job Description: Store Chemist – Raw Materials is responsible for inspecting raw materials, placing them in correct storage area, reporting and documenting, housekeeping, disposing of waste raw material, and maintaining a secure working environment.

Personal Attributes: The individual should have knowledge of different materials and chemicals along with the storing requirements. He must be able to identify defects, select appropriate storage areas, and handle inventory/stock. He should have the ability to differentiate the various batches of stock.

Qualifications Pack Code	LFS/Q0601		
Job Role	Store Chemist/Supervisor/In Charge – Raw Materials – Life Sciences		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/012/14
Sub-sector	Pharmaceutical and Biopharmaceutical	Last reviewed on	01/08/16
Occupation	Supply Chain	Next review date	01/08/19
NSQC Clearance on	20/07/2015		

Job Role	Store Chemist/Supervisor/In Charge – Raw Materials – Life Sciences
Role Description	Responsible for ensuring storage of raw materials , disposing them and maintaining cleanliness according to set procedures and standards
NSQF level	4
Minimum Educational Qualifications	Diploma/ D.Pharma/B.Sc. Preferable/ Graduation in any field
Maximum Educational Qualifications	M.Sc / Materials Management specialization
Training (Suggested but not mandatory)	On the job training, training related to adherence to SOPs and cGMP
Minimum Job Entry Age	20 Years
Experience	0-2 years
Applicable National Occupational Standards (NOS)	<p>Compulsory:</p> <ol style="list-style-type: none"> LFS/N0601: Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed LFS/N0602: Carry out reporting and documentation for appropriate storage of material/products LFS/N0103: Ensure cleanliness in the work area LFS/N0656: Carry out disposing of waste raw material

- | | |
|--|---|
| | <p>5. LFS/N0101 Maintain a healthy, safe and secure working environment in the life sciences facility environment</p> |
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	Optional: N.A.
Performance Criteria	As described in the relevant NOS units

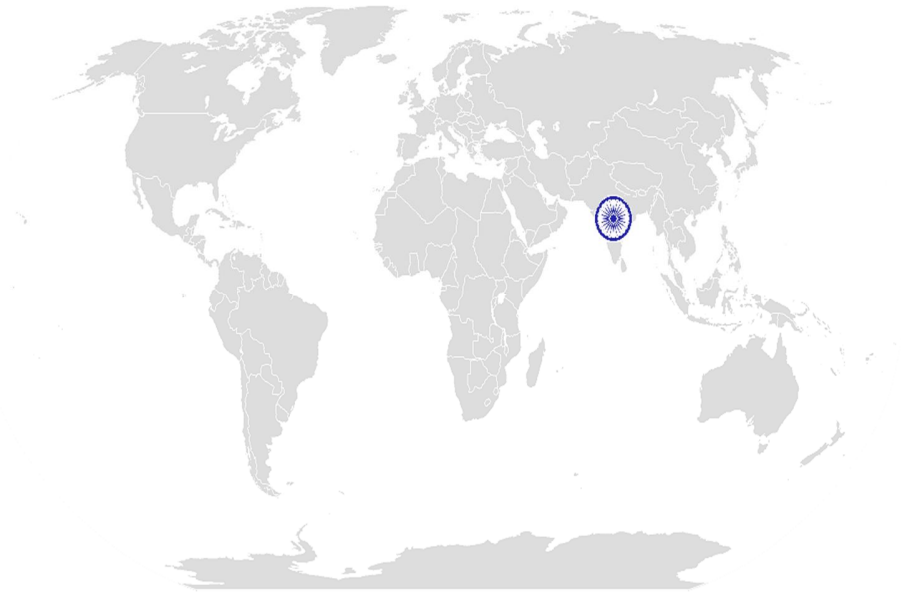
Keywords /Terms	Description
Core Skills/Generic Skills	Core Skills or Generic Skills are a group of skills that are key to learning and working in today's world. These skills are typically needed in any work environment. In the context of the NOS, these include communication related skills that are applicable to most job roles.
Description	Description gives a short summary of the unit content. This would be helpful to anyone searching on a database to verify that this is the appropriate NOS they are looking for.
Function	Function is an activity necessary for achieving the key purpose of the sector, occupation, or area of work, which can be carried out by a person or a group of persons. Functions are identified through functional analysis and form the basis of NOS.
Job role	Job role defines a unique set of functions that together form a unique employment opportunity in an organisation.
Knowledge and Understanding	Knowledge and Understanding are statements which together specify the technical, generic, professional and organisational specific knowledge that an individual needs in order to perform to the required standard.
National Occupational Standards (NOS)	NOS are Occupational Standards which apply uniquely in the Indian context.
Occupation	Occupation is a set of job roles, which perform similar/related set of functions in an industry.
Organisational Context	Organisational Context includes the way the organisation is structured and how it operates, including the extent of operative knowledge managers have of their relevant areas of responsibility.
Performance Criteria	Performance Criteria are statements that together specify the standard of performance required when carrying out a task.
Qualifications Pack(QP)	Qualifications Pack comprises the set of NOS, together with the educational, training and other criteria required to perform a job role. A Qualifications Pack is assigned a unique qualification pack code.
Qualifications Pack Code	Qualifications Pack Code is a unique reference code that identifies a qualifications pack.
Scope	Scope is the set of statements specifying the range of variables that an individual may have to deal with in carrying out the function which have a critical impact on the quality of performance required.
Sector	Sector is a conglomeration of different business operations having similar businesses and interests. It may also be defined as a distinct subset of the economy whose components share similar characteristics and interests.

Acronyms

Sub-Sector	Sub-sector is derived from a further breakdown based on the characteristics and interests of its components.
Sub-functions	Sub-functions are sub-activities essential to fulfil the achieving the objectives of the function.
Technical Knowledge	Technical Knowledge is the specific knowledge needed to accomplish specific designated responsibilities.
Unit Code	Unit Code is a unique identifier for an NOS unit, which can be denoted with an 'N'.
Unit Title	Unit Title gives a clear overall statement about what the incumbent should be able to do.
Keywords /Terms	Description
NOS	National Occupational Standard(s)
NSQF	National Skill Qualifications Framework
NCO-2004	National Classification of Occupations-2004
OS	Occupational Standard(s)
QP	Qualifications Pack
GMP	Good Manufacturing Practices
cGMP	Current Good Manufacturing Practices
ISO	International Organization for Standardization
OHSAS	Occupational Health & Safety Assessment Systems
JIT	Just In Time

LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Store Chemist – Raw Materials to ensure that procedures related to moving, handling, receiving, and placing raw material in correct storage area are being followed.

LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

National Occupational Standard	Unit Code	LFS/N0601
	Unit Title (Task)	Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed
	Description	This NOS is about a Store Chemist – Raw Materials inspecting, matching, and scrutinizing raw materials with specified standards and measurements.
	Scope	The unit covers the following: <ul style="list-style-type: none"> Inspecting the raw material Receipt of delivery Storing received material in designated area
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Inspecting the raw material	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. carry out stock inspection at specified intervals to identify defects, leakages, defected sealing and impurities as per the SOP and cGMP PC2. carry out stock checks to ensure that raw material is available in sufficient quantity at all times as per the plan provided by planning department PC3. carry out checks of storage areas at regular intervals to ensure they meet organizational guidelines and remain fit for purpose PC4. identify causes of defects to maintain raw material quality PC5. monitor rectified materials to ensure the problems have been solved PC6. interpret the results correctly PC7. take up results of the findings with appropriate authority to incorporate process modifications to avoid defects
	Receipt of delivery	<ul style="list-style-type: none"> PC8. check and confirm deliveries against the delivery note and original order to identify any discrepancies PC9. sign for the received order when satisfied that all items are received and fit for purpose PC10. match material colour with master sample and accordingly accept or reject delivery (wherever required) PC11. ensure that the materials are not altered in any way during inspection PC12. dispense raw material and prepare batch dispensing records and make entries in log books for the raw material as per cGMP, under the guidance of store/warehouse manager
	Storing received material in designated area	<ul style="list-style-type: none"> PC13. identify the correct storage areas/locations and special storage requirements for received goods PC14. place received stock into the correct storage areas/locations taking account of security requirements, access control, procedures, special storage requirements and the requirements for stock rotation as per cGMP PC15. notify the appropriate person of the availability of stock where the goods are for a special or outstanding order and check for expired/ obsolete stock

LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

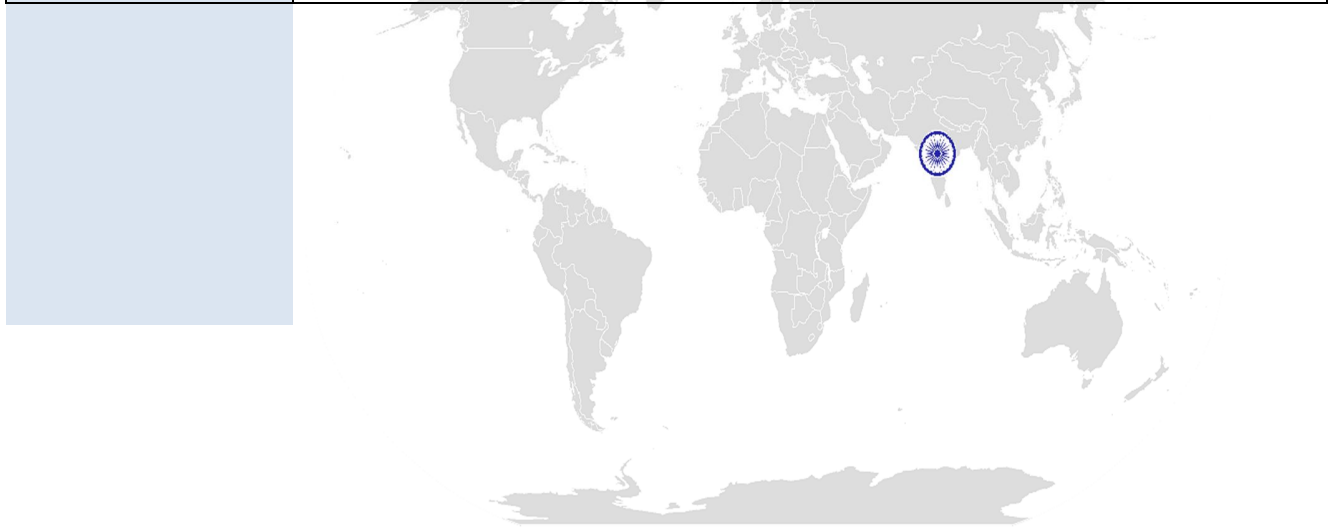
	<p>PC16. follow organizational procedures for safe storage and control of hazardous substances related to maintenance, also ensure maintenance and calibration of Material handling equipment as per SOP</p> <p>PC17. take appropriate action to resolve problems with storage areas and the surrounding environment for damaged/expired goods and update bin cards along with environment monitoring records and coordinate with Facility Management Team to ensure product specific temperature requirements are maintained at all times</p> <p>PC18. collate month wise rejection reports for incoming, in-process & outbound materials, generate required reports to be sent to vendors and initiate action for improvements accordingly</p>
<p>Knowledge and Understanding (K)</p>	
<p>A. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. different quality management systems (ISO-9000, ISO-14001, OHSAS-18000) and good laboratory (GLP) and good manufacturing practices (GMP)</p> <p>KA2. organizational coding system of finished materials, compounds and company manual</p> <p>KA3. implications of not adhering to quality control procedures</p> <p>KA4. quality and damage checks to be done and importance of the same</p> <p>KA5. quality control procedures followed by the company and importance of the same</p>
<p>B. Technical Knowledge</p>	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. good manufacturing practices and relevant legal requirements for safe and secure storage of raw materials</p> <p>KB2. procedures that apply to receiving raw material including only receiving stock identified on the original order, expiry dates and batch numbers</p> <p>KB3. methods of identifying and maintaining safe storage areas/locations and secure storage environments</p> <p>KB4. storage requirements for different types of products and why they are important</p> <p>KB5. various storage practices</p> <p>KB6. concept of Just in Time (JIT)</p> <p>KB7. the role and purpose of an effective stock taking program and how this affects daily operations</p> <p>KB8. different techniques/inspection methods used to identify defects</p> <p>KB9. standard method of drawing samples and preparing them for testing</p> <p>KB10. methods of using testing equipment, related test methods and purpose of tests</p> <p>KB11. factors that adversely affect integrity of the sample</p> <p>KB12. importance of maintaining master sample</p> <p>KB13. statistical analysis of test data</p>
<p>Skills (S)</p>	

LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

A. Core Skills/ Generic Skills	Writing skills
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper records as per given format SA3. use computer applications/software
	Reading and Understanding skills
	The user/individual on the job needs to know and understand how to: SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards, etc. SA5. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, material labels and safety information as provided SA6. use and interpret the various coding systems as per company norms
B. Professional Skills	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA7. communicate with upstream and downstream teams SA8. disclose information only to those who have the right and need to know it SA9. communicate confidential and sensitive information discretely to authorized person as per the SOP
	Decision Making
	The user/individual on the job needs to know and understand how to: SB1. evaluate multiple options on defined, objective parameters to take decision on storage requirement and preference SB2. appropriately use the escalation matrix for complex decisions and issue-management SB3. apply commercial awareness as a decision parameter
B. Professional Skills	Plan & Organize
	The user/individual on the job needs to know and understand how to: SB4. plan and organize assigned work in order to address production needs SB5. effectively interact with the various stakeholders within and outside the company to complete defined tasks SB6. effectively delegate and lead
	Analytical Thinking
The user/individual on the job needs to know and understand how to: SB7. pay attention to detail for identifying non-compliances/non-conforming stock or storage area	

LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

	SB8. analyse obtained information and past data for root-cause analysis on defects/non-conformities/non-compliance causes
	Critical Thinking
	The user/individual on the job needs to know and understand how to:
	SB9. apply balanced judgement to different situations
	Problem Solving
	NA
	Customer Centricity
NA	



LFS/N0601 : Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed

NOS Version Control

NOS Code	LFS/N0601		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceuticals and Biopharmaceuticals	Last reviewed on	01/08/16
Occupation	Supply Chain	Next review date	01/08/19

LFS/N0602 : Carry out reporting and documentation for appropriate storage of material/products

National Occupational Standards



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Store Chemist – Raw Materials to carry out reporting and documentation for appropriate storage of material/products.

LFS/N0602 : Carry out reporting and documentation for appropriate storage of material/products

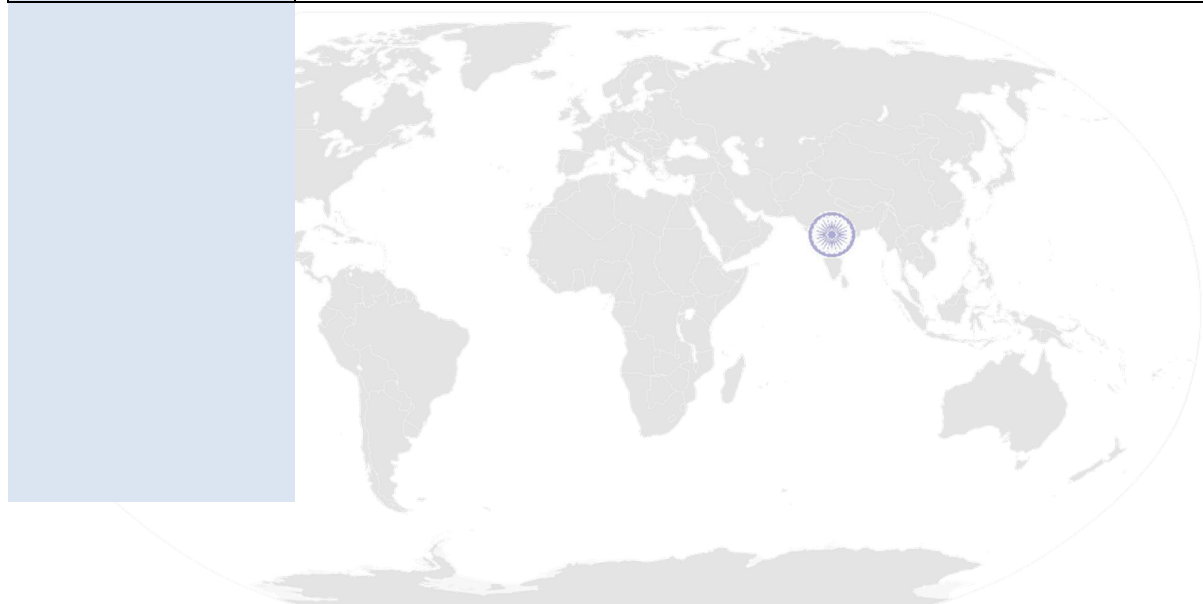
National Occupational Standard	Unit Code	LFS/N0602
	Unit Title (Task)	Carry out reporting and documentation for appropriate storage of material/products
	Description	This NOS unit is about a Store Chemist – Raw Materials reporting defects, test results, and documenting all relevant records for received stock, stock rotation, stock checks, and damaged goods.
	Scope	<p>This unit covers the following:</p> <ul style="list-style-type: none"> • Reporting quality issues and test results • Recording and documentation
	Performance Criteria (PC) w.r.t the Scope	
	Element	Performance Criteria
	Reporting quality issues and test results	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner</p> <p>PC2. report to the appropriate authority as laid down by the company</p> <p>PC3. follow reporting procedures as prescribed by the company and cGMP</p>
	Recording and documentation	<p>PC4. maintain documents regarding stock received and stock rotation</p> <p>PC5. maintain documents regarding damaged goods and disposal methods</p> <p>PC6. maintain documents regarding storage techniques</p> <p>PC7. identify documentation to be completed relating to one’s role as per cGMP</p> <p>PC8. record details accurately in an appropriate format</p> <p>PC9. accurately document the results of the inspections and testing</p> <p>PC10. maintain all controlled document files and test records in a timely and accurate manner</p> <p>PC11. ensure that the final document meets regulatory and compliance requirements</p> <p>PC12. make sure documents are available to all appropriate authorities to inspect</p> <p>PC13. evaluate problems and make initial recommendations for possible corrective action to supervise</p> <p>PC14. perform review of records and other documentation for compliance to established procedures and good documentation practices</p> <p>PC15. write and update the inspection procedures, protocols and checklists</p> <p>PC16. prepare inspection reports as per the inspection activity performed</p>
	Knowledge and Understanding (K)	
	A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	<p>The user/individual on the job needs to know and understand:</p> <p>KA1. risk and impact of not following defined procedures/work instructions</p> <p>KA2. escalation matrix for reporting identified issues</p>

LFS/N0602 : Carry out reporting and documentation for appropriate storage of material/products

	<p>KA3. types of documentation used in the organization, importance of maintaining the same and different methods of recording information, including implications of non-maintenance of the same</p> <p>KA4. impact of various documentations practices on cost, quality, productivity, delivery and safety</p>
B. Technical Knowledge	<p>The user/individual on the job needs to know and understand:</p> <p>KB1. how to carry out good stock management</p> <p>KB2. importance of complete and accurate documentation</p>
Skills (S)	
A. Core Skills/ Generic Skills	Writing skills
	<p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. record and communicate details of work to appropriate people using written/typed report or computer based record/electronic mail</p> <p>SA2. maintain proper records as per given format</p> <p>SA3. use computer applications, including data management systems</p>
	Reading skills
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA4. read and understand manuals, SOPs, health and safety instructions, memos, reports, job cards etc.</p> <p>SA5. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, material labels and safety information as provided</p> <p>SA6. use and interpret the various coding systems as per company norms</p>
	Oral Communication (Listening and Speaking skills)
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SA7. communicate with upstream and downstream teams</p> <p>SA8. disclose information only to those who have the right and need to know it</p> <p>SA9. communicate confidential and sensitive information discretely to authorized person as per the SOP</p>
B. Professional Skills	Analytical thinking
	<p>The user/individual on the job needs to know and understand how to:</p> <p>SB1. suggest improvements(if any) in process/formats for reports/documentation based on experience and observation</p> <p>SB2. use available data and computer software to create required reports and documents</p> <p>SB3. pay attention to detail when capturing information and reviewing reports/documents</p>
	Decision Making
	<p>The user/individual on the job needs to know and understand how to:</p>

LFS/N0602 : Carry out reporting and documentation for appropriate storage of material/products

	SB4. appropriately use the escalation matrix for complex decisions, including highlighting non-compliances
	Plan and Organise
	The user/individual on the job needs to know and understand how to:
	SB5. effectively plan and allocate ownership for documentation/information within the team
	SB6. take responsibility for completing one's own work assignment
	SB7. plan and prioritize reporting/documentation based on criticality and urgency
	Critical Thinking
	NA
	Problem Solving
	NA
Customer Centricity	
NA	



LFS/N0602 : Carry out reporting and documentation for appropriate storage of material/products

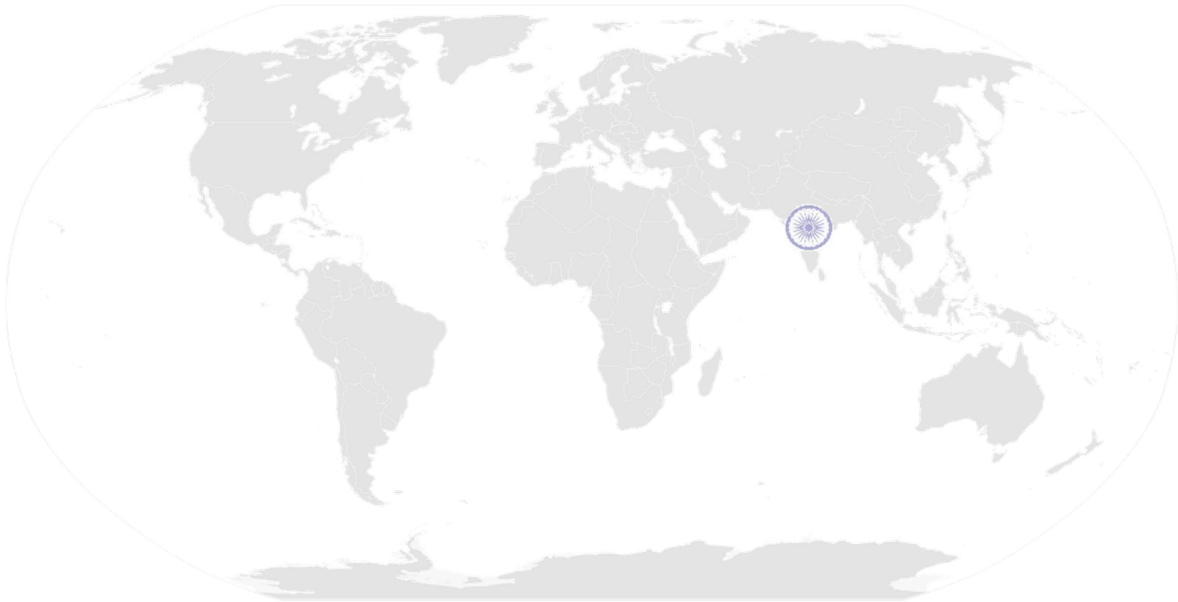
NOS Version Control

NOS Code	LFS/N0602		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceuticals and Biopharmaceuticals	Last reviewed on	01/08/16
Occupation	Supply Chain	Next review date	01/08/19



LFS/N0103 : Ensure cleanliness in the work area

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Store Chemist – Raw Materials to ensure cleanliness in the work area by carrying out housekeeping of their respective area

LFS/N0103 : Ensure cleanliness in the work area

National Occupational Standard	Unit Code	LFS/N0103
	Unit Title (Task)	Ensure cleanliness in the work area
	Description	This OS unit is about the Store Chemist – Raw Materials to carry out housekeeping activities for respective area
	Scope	This unit/task covers the following: <ul style="list-style-type: none"> • Pre housekeeping activities • Operations • Post housekeeping activities
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Pre housekeeping activities	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. inspect the area while taking into account various surfaces PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain PC3. ensure that the cleaning equipment is in proper working condition PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces PC6. inform the affected people about the cleaning activity PC7. display the appropriate signage for the work being conducted PC8. ensure that there is adequate ventilation for the work being carried out PC9. wear the personal protective equipment required for the cleaning method and materials being used
	Operations	<ul style="list-style-type: none"> PC10. use the correct cleaning method for the work area, type of soiling and surface PC11. deal with accidental damage, if any, caused while carrying out the work PC12. report to the appropriate person any difficulties in carrying out work PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill
	Post housekeeping activities	<ul style="list-style-type: none"> PC14. ensure that there is no oily substance on the floor to avoid slippage PC15. ensure that no scrap material is lying around PC16. maintain and store housekeeping equipment and supplies PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored

LFS/N0103 : Ensure cleanliness in the work area

	PC20. dispose the waste garnered from the activity in an appropriate manner PC21. dispose of used and un-used solutions according to manufacturer’s instructions, and clean the equipment thoroughly PC22. maintain schedules and records for housekeeping duty PC23. replenish any necessary supplies or consumables
Knowledge and Understanding (K)	
A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: KA1. levels of hygiene required by storage area and importance of maintaining the same KA2. methodology for storage area inspection with methods and materials required for cleaning variety of surfaces and equipment KA3. the method to check the treated surface and equipment on completion of cleaning KA4. procedures for reporting any unidentified soiling KA5. escalation procedures for soils or stains that could not be removed
B. Technical Knowledge	The user/individual on the job needs to know and understand: KB1. role of different materials, chemicals and equipment
Skills (S)	
A. Core Skills/ Generic Skills	Writing Skills
	The user/ individual on the job needs to know and understand how to: SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail
	Reading and Understanding Skills
	The user/individual on the job needs to know and understand how to: SA2. understand the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to: SA3. communicate with upstream and downstream teams SA4. disclose information only to those who have the right and need to know it.
B. Professional Skills	Critical Thinking
	The user/individual on the job needs to know and understand how to: SB1. suggest improvements(if any) in process based on experience

LFS/N0103 : Ensure cleanliness in the work area

	Decision Making
	SB2. make decisions to maintain cleanliness in the area of work
	Analytical Thinking
	NA
	Plan and Organize
	NA
	Problem Solving
	NA
	Customer Centricity
NA	



LFS/N0103 : Ensure cleanliness in the work area

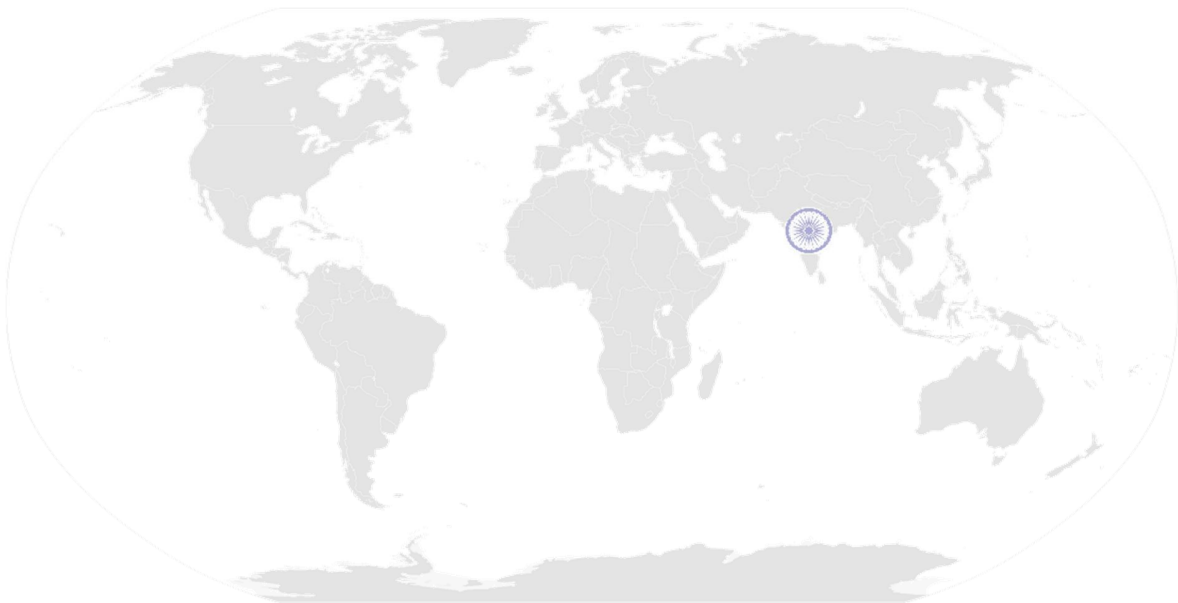
NOS Version Control

NOS Code	LFS/N0103		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	22/12/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



LFS/N0656 : Carry out disposing of waste raw material

National Occupational Standard



Overview

This Occupational Standard describes the knowledge, understanding and skills required for a Store Chemist – Raw Materials to carry out disposing of waste/ non-conforming raw material.

LFS/N0656 : Carry out disposing of waste raw material

National Occupational Standard	Unit Code	LFS/N0656
	Unit Title (Task)	Carry out disposing of waste raw material
	Description	This NOS is about a Store Chemist – Raw Materials carrying out quality checks and disposing defective or waste raw material according to good manufacturing practices.
	Scope	The unit covers the following: <ul style="list-style-type: none"> Inspecting the raw material Disposing non-conforming raw material
	Performance Criteria (PC) w.r.t. the Scope	
	Element	Performance Criteria
	Inspecting the raw material	To be competent, the user/individual on the job must be able to: <ul style="list-style-type: none"> PC1. ensure that total range of checks are regularly and consistently performed PC2. identify non-conformities to quality assurance standards PC3. identify potential causes of non-conformities to quality assurance standards PC4. identify impact on final product due to non-conformance to company standards PC5. evaluate the need for action to ensure that problems do not recur
	Disposing non-conforming raw material	<ul style="list-style-type: none"> PC6. dispose the non-conforming raw material PC7. follow the standards and procedures as mentioned in GMP while disposing defective materials PC8. identify and analyse any problems that may arise while disposing the materials PC9. suggest corrective action to address problems PC10. review effectiveness of corrective action
	Knowledge and Understanding (K)	
	A. Organisational Context (Knowledge of the Company/ Organisation and its processes)	The user/individual on the job needs to know and understand: <ul style="list-style-type: none"> KA1. method of reporting incidents where standard operating procedures are not followed KA2. correct methods of disposal of waste according to good manufacturing practices KA3. importance of complete and accurate documentation KA4. importance of quality control procedures KA5. proper procedure for selecting the finished goods and performing quality checks without affecting the goods KA6. characteristics of the finished goods KA7. use of monitoring and measuring devices KA8. implications of inaccurate measuring and testing instruments and equipment KA9. implications of defective goods on production of final products
B. Technical Knowledge	KB1. relevant legislative responsibilities and workplace systems for recording information on dispensed pharmaceutical materials and purpose of related workplace coding and labelling systems	

LFS/N0656 : Carry out disposing of waste raw material

	KB2. control points in the disposing process KB3. principles of good inspection practices and visual standards applied in the workplace KB4. different techniques/inspection methods used to identify defects KB5. methods of using testing equipment, related test methods and purpose of tests KB6. role of different materials, chemicals and equipment KB7. factors that adversely affect integrity of the sample KB8. importance of quality checks along with quality and production targets KB9. units of measurement KB10. disposal of non-conforming and rejected samples KB11. purpose and basic principles of the dispensing process, including the characteristics of finished goods and related handling requirements
Skills (S)	
A. Core Skills/ Generic Skills	Writing skills
	The user/ individual on the job needs to know and understand how to:
	SA1. record and communicate details of work done to appropriate people using written/typed report or computer based record/electronic mail SA2. maintain proper records as per given format SA3. use computer applications/software
	Reading and Understanding skills
	The user/individual on the job needs to know and understand how to:
	SA4. read and understand manuals, sops, health and safety instructions, memos, reports, job cards, etc. SA5. read and interpret images, graphs, diagrams for typical product specifications, job sheets, procedures, material labels and safety information as provided SA6. use and interpret the various coding systems as per company norms
	Oral Communication (Listening and Speaking skills)
	The user/individual on the job needs to know and understand how to:
	SA7. communicate with upstream and downstream teams SA8. work in a team and other behavioural skills required to support the small group activities (e.g. quality circle, cross functional team, suggestion scheme) SA9. disclose information only to those who have the right and need to know it. SA10. communicate confidential and sensitive information discretely to authorized person as per the SOP
B. Professional Skills	Decision Making
	The user/individual on the job needs to know and understand how to:

LFS/N0656 : Carry out disposing of waste raw material

	SB1. evaluate multiple options on defined, objective parameters to address any issues arising in disposal
	SB2. appropriately use the escalation matrix for complex decisions
	SB3. interact with the production team and quality team for taking decisions
	SB4. apply commercial awareness as a decision parameter
	Analytical Thinking
	The user/individual on the job needs to know and understand how to:
	SB5. apply basic sciences (chemistry), mathematics, statistics along with past trends data for undertaking root-cause analysis
	SB6. pay attention to detail when identifying non-conforming or defective material
	Plan & Organize
	The user/individual on the job needs to know and understand how to:
SB7. plan and organize disposal activities to align with production schedule	
Critical Thinking	
NA	
Problem Solving	
NA	
Customer Centricity	
NA	

LFS/N0656 : Carry out disposing of waste raw material

NOS Version Control

NOS Code	LFS/N0656		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	15/12/14
Industry Sub-sector	Pharmaceuticals and Biopharmaceuticals	Last reviewed on	01/08/16
Occupation	Supply Chain	Next review date	01/08/19



LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

National Occupational Standards



Overview

This Occupational Standard is about the knowledge, understanding and skills required by a Store Chemist- Raw Materials to ensure healthy, safe and secure working environment in the life sciences facility

LFS/N0101 : Maintain a healthy, safe and secure working environment in the life sciences facility

National Occupational Standard	Unit Code	LFS /N0101
	Unit Title (Task)	Maintain a healthy, safe and secure working environment in the life sciences facility
	Description	This NOS unit is about a Store Chemist – Raw Materials monitoring the working environment and making sure that it meets the requirements for health, safety and security in the pharmaceutical/contract research/biopharmaceutical facility/manufacturing/testing/analysis/research laboratory.
	Scope	<p>This unit / task covers the following:</p> <p>Ensuring healthy, safe and secure working environment:</p> <ul style="list-style-type: none"> self monitor and adhere to safety principles and standards ensure behavioural safety by workmen to cGMP and applicable safety standards on the shop floor/ laboratory report any identified breaches in health, safety, and security policies and procedures to the designated person <p>Managing emergency procedures:</p> <ul style="list-style-type: none"> illness accidents fires other reasons to evacuate the premises breaches of security
Performance Criteria (PC) wrt the Scope		
Element	Performance Criteria	
Ensuring healthy, safe and secure working environment	<p>To be competent, the user/individual on the job must be able to:</p> <p>PC1. observe and comply with the company's current health, safety and security policies and procedures</p> <p>PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines</p> <p>PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person</p> <p>PC4. responsible for maintaining discipline at the shop-floor/ production area</p> <p>PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority</p> <p>PC6. adhere and comply to storage and handling guidelines for hazardous material</p> <p>PC7. identify and recommend opportunities for improving health, safety, and security to the designated person</p> <p>PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately</p>	
Managing emergency procedures	<p>PC9. report any hazards that the individual is not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected</p> <p>PC10. follow the company's emergency procedures promptly, calmly, and efficiently</p>	

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Knowledge and Understanding (K)	
<p>B. Organisational Context (Knowledge of the Company/ Organisation and its processes)</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KA1. legislative requirements and company's procedures for health, safety and security and individual's role and responsibilities in relation to this</p> <p>KA2. what is meant by a hazard, including the different types of health and safety hazards that can be found in the workplace</p> <p>KA3. how and when to report hazards</p> <p>KA4. limits of individual responsibility for dealing with hazards</p> <p>KA5. the organization's emergency procedures for different emergency situations and the importance of following these</p> <p>KA6. the importance of maintaining high standards of health, safety and security</p> <p>KA7. implications that any non-compliance with health, safety and security may have on individuals and the organization</p> <p>KA8. health hazards and its implications if any in the production process</p>
<p>B Technical Knowledge</p>	<p>The user/ individual on the job needs to know and understand:</p> <p>KB1. different types of breaches in health, safety and security and how and when to report these</p> <p>KB2. evacuation procedures for workers and visitors</p> <p>KB3. how to summon medical assistance and the emergency services, where necessary</p> <p>KB4. how to use the health, safety and accident reporting procedures and the importance of these</p> <p>KB5. different types of occupational health hazards</p> <p>KB6. knowledge of chemical substances, their characteristics and required precaution and safety measures</p>
Skills (S)	
<p>A. Core Skills/ Generic Skills</p>	<p>Writing skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA1. complete accurate, well written work with attention to detail</p>
	<p>Reading skills</p> <p>The user/ individual on the job needs to know and understand how to:</p> <p>SA2. read instructions, guidelines, procedures, rules and service level agreements</p>
	<p>Oral Communication (Listening and Speaking skills)</p> <p>The user/ individual on the job needs to know and understand how to:</p>

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	SA3. listen effectively and orally communicate information accurately
B. Professional Skills	Decision making
	The user/ individual on the job needs to know and understand how to:
	SB1. make decisions on suitable courses of action
	Plan and Organise
	The user/ individual on the job needs to know and understand how to:
	SB2. plan and organize work to meet health, safety and security requirements
	Problem solving
	The user/ individual on the job needs to know and understand how to:
	SB3. apply problem solving approaches in different situations
	Analytical thinking
	The user/ individual on the job needs to know and understand how to:
	SB4. analyse data and activities
	Critical thinking
The user/ individual on the job needs to know and understand how to:	
SB5. apply balanced judgments to different situations	
Customer Centricity	
NA	

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NOS Version Control

NOS Code	LFS/N0101		
Credits(NSQF)	TBD	Version number	1.0
Industry	Life Sciences	Drafted on	26/06/14
Industry Sub-sector	Pharmaceuticals and Bio Pharmaceuticals	Last reviewed on	01/08/16
Occupation	Manufacturing, Quality, Supply Chain, R&D	Next review date	01/08/19



Annexure

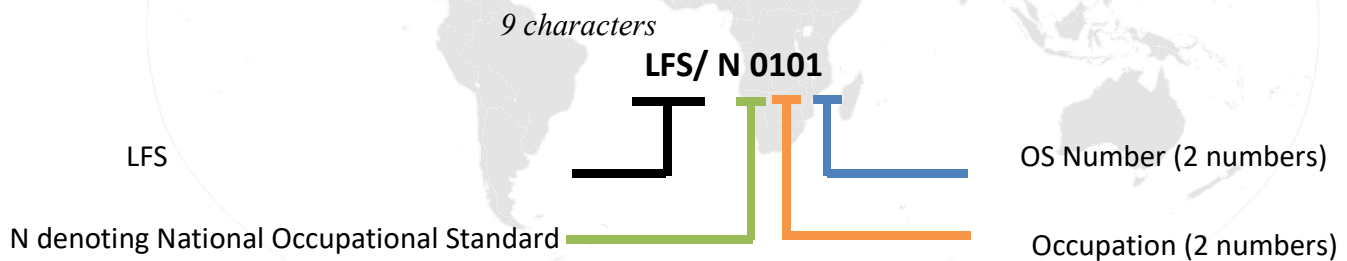
Nomenclature for QP and NOS

Qualification Pack



Occupational Standard

An example of NOS with 'N'



Qualifications Pack - Store Chemist/Supervisor/In Charge– Raw Materials – Life Sciences

The following acronyms/codes have been used in the nomenclature above:

Sub-Sector	Range of Occupation Numbers
Pharmaceutical and Biopharmaceutical and Contract Research	01-10
Pharmaceutical	11-20
Biopharmaceutical	21-30
Contract Research	31-40

Sequence	Description	Example
Three letters	Industry name	LFS
Slash	/	/
Next letter	Whether QP or NOS	Q/N
Next two numbers	Occupation code	01
Next two numbers	OS number	01

Qualifications Pack - Store Chemist/Supervisor/In Charge – Raw Materials – Life Sciences

CRITERIA FOR ASSESSMENT OF TRAINEES

Job Role Store Chemist/Supervisor/In charge – Raw Materials – Life Sciences

Qualification Pack LFS/Q0601

Sector Skill Council Life Sciences Sector Skill Development Council

Guidelines for Assessment:

1. Criteria for assessment for each Qualification Pack will be created by the Sector Skill Council. Each Performance Criteria (PC) will be assigned marks proportional to its importance in NOS. SSC will also lay down proportion of marks for Theory and Skills Practical for each PC.
2. The assessment for the theory part will be based on knowledge bank of questions created by the SSC.
3. Individual assessment agencies will create *unique question papers for theory part for each candidate at each examination/training center* (as per assessment criteria below)
4. Individual assessment agencies will create *unique evaluations for skill practical for every student at each examination/training center* based on this criteria
5. To pass the Qualification Pack, every trainee should score a minimum of 70% in every NOS
6. In case of successfully passing only certain number of NOS's, the trainee is eligible to take subsequent assessment on the balance NOS's to pass the Qualification Pack.

Assessment Outcome	Assessment Criteria of Outcomes	Total Marks (500)	Out Of	Marks Allocation	
				Theory	Skills Practical
LFS/N0601 (Ensure that procedures related to moving, handling and receiving raw material and placing raw material in correct storage area are being followed)	PC1. carry out stock inspection at specified intervals to identify defects, leakages, defected sealing and impurities as per the SOP and cGMP	100	6	3	3
	PC2. carry out stock checks to ensure that raw material is available in sufficient quantity at all times as per the plan provided by planning department		6	3	3
	PC3. carry out checks of storage areas at regular intervals to ensure they meet organizational guidelines and remain fit for purpose		6	3	3
	PC4. identify causes of defects to maintain raw material quality		6	3	3
	PC5. monitor rectified materials to ensure the problems have been solved		6	4	2
	PC6. interpret the results correctly		6	3	3
	PC7. take up results of the findings with appropriate authority to		6	3	3

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	incorporate process modifications to avoid defects			
	PC8. check and confirm deliveries against the delivery note and original order to identify any discrepancies	6	2	4
	PC9. sign for the received order when satisfied that all items are received and fit for purpose	4	2	2
	PC10. match material colour with master sample and accordingly accept or reject delivery (wherever required)	6	3	3
	PC11. ensure that the materials are not altered in any way during inspection	4	2	2
	PC 12. dispense raw material and prepare batch dispensing records and make entries in log books for the raw material as per cGMP under the guidance of store/warehouse manager	4	2	2
	PC13. identify the correct storage areas/locations and special storage requirements for received goods	6	3	3
	PC14. place received stock into the correct storage areas/locations taking account of security requirements, access control, procedures, special storage requirements and the requirements for stock rotation as per cGMP	6	3	3
	PC15. notify the appropriate person of the availability of stock where the goods are for a special or outstanding order and check for expired/ obsolete stock	5	3	2
	PC16. follow organizational procedures for safe storage and control of hazardous substances , also ensure maintenance and calibration of Material handling equipment as per SOP	6	3	3
	PC17. take appropriate action to resolve problems with storage areas and the surrounding	5	2	3

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	environment for damaged/expired goods and update bin cards along with environment monitoring records and coordinate with Facility Management Team to ensure product specific temperature requirements are maintained at all times				
	PC18. collate month wise rejection reports for incoming, in-process & outbound materials, generate required reports to be sent to vendors and initiate action for improvements accordingly		6	3	3
	Total		100	50	50
LFS/N0602 (Carry out reporting and documentation for appropriate storage of material/ products)	PC1. report defects/problem/incidents/quality issues/test results as applicable in a timely manner	100	6	3	3
	PC2. report to the appropriate authority as laid down by the company		6	3	3
	PC3. follow reporting procedures as prescribed by the company and cGMP		6	3	3
	PC4. maintain documents regarding stock received and stock rotation		7	4	3
	PC5. maintain documents regarding damaged goods and disposal methods		6	3	3
	PC6. maintain documents regarding storage techniques		7	3	4
	PC7. identify documentation to be completed relating to one's role as per cGMP		6	3	3
	PC8. record details accurately in appropriate format		6	3	3
	PC9. accurately document the results of the inspections and testing		7	4	3
	PC10. maintain all controlled document files and test records in a timely and accurate manner		6	3	3
	PC11. ensure that the final document meets regulatory and compliance requirements		6	3	3

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	PC12. make sure documents are available to all appropriate authorities to inspect		7	3	4
	PC13. evaluate problems and make initial recommendations for possible corrective action to supervise		6	3	3
	PC14. perform review of records and other documentation for compliance to established procedures and good documentation practices		6	3	3
	PC15. write and update the inspection procedures, protocols and checklists		6	3	3
	PC16. prepare inspection reports as per the inspection activity performed		6	3	3
	Total		100	50	50
LFS/N0103 (Ensure cleanliness in the work area)	PC1. inspect the area while taking into account various surfaces	100	4	2	2
	PC2. identify the material requirements for cleaning the areas inspected, by considering risk, time, efficiency and type of stain		5	2	3
	PC3. ensure that the cleaning equipment is in proper working condition		5	2	3
	PC4. select the suitable alternatives for cleaning the areas in case the appropriate equipment and materials are not available and inform the appropriate person		4	2	2
	PC5. plan the sequence for cleaning the area to avoid re-soiling clean areas and surfaces		4	1	3
	PC6. inform the affected people about the cleaning activity		4	2	2
	PC7. display the appropriate signage for the work being conducted		4	2	2
	PC8. ensure that there is adequate ventilation for the work being carried out		5	2	3
	PC9. wear the personal protective equipment required for the		4	2	2

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	cleaning method and materials being used				
	PC10. use the correct cleaning method for the area, type of soiling and surface		4	2	2
	PC11. deal with accidental damage, if any, caused while carrying out the work		4	1	3
	PC12. report to the appropriate person any difficulties in carrying out the work		4	2	2
	PC13. identify and report to the appropriate person any additional cleaning required that is outside one's responsibility or skill		4	2	2
	PC14. ensure that there is no oily substance on the floor to avoid slippage		4	2	2
	PC15. ensure that no scrap material is lying around		4	2	2
	PC16. maintain and store housekeeping equipment and supplies		4	2	2
	PC17. follow workplace procedures to deal with any accidental damage caused during the cleaning process		4	2	2
	PC18. ensure that, on completion of the work, the area is left clean and dry and meets requirements		4	2	2
	PC19. return the equipment, materials and personal protective equipment that were used to the right places making sure they are clean, safe and securely stored		5	2	3
	PC20. dispose the waste garnered from the activity in an appropriate manner		5	2	3
	PC21. disposal of used and unused solutions according to manufacturer's instructions, and clean the equipment thoroughly		5	2	3
	PC22. maintain schedules and records for housekeeping duty		5	2	3
	PC23. replenish any necessary supplies or consumables		5	2	3
	Total		100	44	56

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LFS/N0656 (Carry out disposing of waste raw material)	PC1. ensure that total range of checks are regularly and consistently performed	100	10	5	5
	PC2. identify non-conformities to quality assurance standards		10	5	5
	PC3. identify potential causes of non-conformities to quality assurance standards		10	5	5
	PC4. identify impact on final product due to non-conformance to company standards		10	5	5
	PC5. evaluate the need for action to ensure that problems do not recur		10	5	5
	PC6. dispose the non-conforming raw material		10	5	5
	PC7. follow the standards and procedures as mentioned in GMP while disposing defective materials		10	5	5
	PC8. identify and analyse any problems that may arise while disposing the materials		10	5	5
	PC9. suggest corrective action to address problem		10	5	5
	PC10. review effectiveness of corrective action		10	5	5
	Total		100	50	50
LFS/N0101 (Maintain a healthy, safe and secure working environment in the life sciences facility)	PC1. observe and comply with the company's current health, safety and security policies and procedures	100	10	5	5
	PC2. while carrying out work, use appropriate safety gears like head gear, masks, gloves and other accessories as mentioned in the guidelines		10	5	5
	PC3. report any identified breaches in health, safety, and security policies and procedures to the designated person		10	5	5
	PC4. responsible for maintaining discipline at the shop-floor/ production area		10	5	5
	PC5. identify and correct any hazards that the individual can deal with safely, competently and within the limits of their authority		10	5	5

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	PC6. adhere and comply to storage and handling guidelines for hazardous material		10	5	5
	PC7. identify and recommend opportunities for improving health, safety, and security to the designated person		10	5	5
	PC8. complete any health, safety and security activities like safety drills and prepare records legibly and accurately		10	4	6
	PC9. report any hazards that the individuals not competent to deal with to the relevant person in line with organizational procedures and warn other people who may be affected		10	4	6
	PC10. follow the company's emergency procedures promptly, calmly, and efficiently		10	5	5
		Total	100	48	52