STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: User Requirement Specification for ERP System	**Effective Date:**
Supersedes: Nil	**Review Date:**
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USER REQUIREMENT SPECIFICATION (URS)		
ERP SYSTEM		
Name of the system	:	ERP System
Location	:	
Document No.	:	
Validation No.	:	
Document Type	:	Original
Effective Date	:	
Prepared For	:	
Prepared By	:	

STANDARD OPERATING PROCEDURE

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1.0 APPROVAL- USER REQUIREMENT SPECIFICATION:

The User Requirement Specification for installed Progen ERP System has been approved for release by the management of …….

		Activity	Name & Designation		Sign.	Date
		Prepared by				
		Department	**Name**	**Designation**	**Sign.**	**Date**
	Reviewed by	Information Technology				
		Purchase				
		Warehouse				
		Quality Control				
		Production				
		Quality Assurance				
		Engineering				
	Approved by	Quality Assurance				

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2.0 REVISION HISTORY

Version / Revision Number	Revised Date	Reason for Revision
00		

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3.0 OBJECTIVE:

The implemented ERP System is to be used for Material Management, Quality, Manufacturing, Purchase, Inventory Management and Sales related activities.

The User Requirement Specifications documented here provides the basis for carrying out Qualification Challenge Testing

4.0 SCOPE:

The scope of User Requirement Specification (URS) is applicable to ERP System installed.

This User Requirement Specification (URS) is applicable to modules described below:

1. Manufacturing Inventory Module
2. Purchase Module
3. Quality Control Module
4. Production Module
5. Sales Inventory Module
6. Setup Module
7. Centralised System Administration
8. Requisition
9. Quality Assurance

5.0 RESPONSIBILITY:

The following department will be involved in the preparation, review and approval of User Requirement Specifications.

Department	Responsibilities
Professional Consultancy Services	• To prepare User Requirement Specification with Validation, User, IT and QA Department.
User Department	• To provide information related to System functionality • To review URS document
IT Department	• To provide technical assistance during the compilation of the user requirement specifications • To provide information related to system hardware, software • To arrange the necessary technical information and other required documents. • To review URS document
Quality Assurance	• To approve the URS document • Document control and retention of executed documents

6.0 SYSTEM DETAILS:

System Name	ERP System
Location	
Software Developed By	
Application Name & Version	
Application Build No.	
Database Build No.	

7.0 OPERATIONAL REQUIREMENTS:

7.1 BUSINESS PROCESS DESCRIPTION:

ERP application including database software and ERP application software limited to following GMP modules only.

ERP Application Software:

1. Manufacturing Inventory Module
2. Purchase Module
3. Quality Control Module
4. Production Module
5. Sales Inventory Module
6. Setup Module
7. Centralized System Administration Module
8. Requisitions
9. Quality Assurance

Standard reports are generated by system in PDF/RTF format and users are taking printouts as per their requirements.

The Purchase Order, GRN and Material Return should be generated in PDF/RTF format. The same report should be maintained.

7.2 BUSINESS PROCESS SUMMARY:

Functional modules:

The heart of the system from an application viewpoint is the application module. These modules may not all be implemented or critical to regulatory requirement viewpoint, but they are all related and are listed below.

INV: Manufacturing Inventory Module - It provides the functionality to support the procurement and inventory functions occurring in day-to-day business operations such as inventory management etc.

The primary functions required within this module are:

1. Goods Receipt Note (GRN)
2. Goods Receipt from Others (GRO)
3. Purchase Return Note (PRN)
4. Material Issue to Production (MIP)
5. Material Issue to Other Departments (MID)
6. Material Issue to Other Location (MIL)
7. Material Issue to Other (MIO)
8. Shortage Stock Adjustment (SSA)
9. Excess Stock Adjustment (ESA)
10. QC Intimations for Testing of GRN
11. QC Intimation for Retesting of GRN
12. Un-Authorization Work Bench
13. Document Closing Work Bench

PUR: Purchase Module -- It provides the functionality to support the procurement and inventory functions occurring in day-to-day business operations such as Purchasing etc.

The primary functions required within this module are:

1. Vendor Item Catalog
2. Purchase Order (PO)
3. Purchase Order Amendment
4. Un-Authorization Work Bench
5. Document Closing Work Bench

QCS: Quality Control Module -- It provides the functionality to support a quality control and information system supporting quality planning, inspection, and control for manufacturing and procurement.

1. QC Register Entry for GRN’s
2. QC Analysis Update for GRN’s
3. Extend AR Validity for GRN’s
4. QC Register Entry For Production

5. QC Analysis Update For Production
6. QC Register Entry For Intimation
7. QC Analysis Update For Intimation
8. GRN's Pending for QC
9. Intimations Pending for QC
10. Production Batches Pending for QC
11. QC Specifications Due for Renewal Query
12. Item's Re-testing History Query
13. QC Test Property Trend Report
14. QC Assay Test Trend Report
15. Un-authorization Work Bench

PRD: Production Module: It provides the functionality to support a Production and information system supporting Production and control for manufacturing and procurement.

The primary functions required within this module are:

1. Production Batch Order
2. Store requisition from Production (SRP)
3. Batch production activity log
4. Material Return From Production (MRP)
5. Store requisition from Other Department (SRD)
6. Production Transfer note (PTN)
7. Open Completed Batches
8. Location wise Production Query
9. Production Batches Release Query
10. Un-authorization Work Bench
11. QC Intimation for Production Batch
12. Document Closing Work Bench

SLM: Sales Module - It provides the functionality to support the sales and distribution functions occurring in day-to-day business operations such as Invoicing etc.

The primary functions required within this module are:

1. Sales Order Regular (SOR)
2. Sales Order Regular Amendment
3. Invoice Using Sales Order Rates (ISO)
4. Sales Return Note (SRN)
5. Finished Goods Inward (FGI)
6. Finished Goods Outward (FGO)
7. Goods Receipt Note- Trading (GRT)

8. Write Back Memo (WBK)
9. Write Off Memo (WOF)
10. Sale Stock balance query
11. Un-authorization Work Bench
12. Document Closing Work Bench

CSA: Centralized System Administration Module - The primary functions required within this module are:

1. Show Current Users
2. Show Locked Users
3. Examine Session Log
4. Application Module Control
5. Application Wise User Roles
6. Application Wise Program Access Rights
7. Location Wise Users
8. Generate Password and Pin
9. Location – Application wise User Accounts
10. Special Access Privileges
11. Transaction Series Control (Post - GST)

STM: Setup Module- The primary functions required within this module are:

1. Item Types
2. Item Sub – Types
3. Item Master
4. Purchase Groups
5. Location/Item Type/Sub Type wise purchase group
6. PO Standard Terms
7. Manufacturers
8. Bought – out Item wise Approved Manufacturers
9. Analysts
10. QC Standards
11. QC Properties Groups
12. Common QC Properties
13. Item's QC Specifications
14. Production Centre
15. Production Stages
16. Production Stage Wise Activities
17. Bill of Process Definition
18. Vendor Master
19. Customer Master
20. Sales Division

21. Standard Payment Terms
22. Stores
23. HSN & SAC Codes Masters (Single Entry)
24. User Management Preferences

QAS: Quality Assurance Module- The primary functions required within this module are:

1. Item Wise Manufactures (QA Approval)
2. Item's QC Specifications (QA Approval)
3. Bill of Process (QA Approval)
4. Vendor-Item Manufacturer's (QA Approval)
5. Production Batch Release (By QA In-charge)
6. Production Batch Release (By QA Manager)

RQS: Requisition Module- The primary functions required within this module are:

1. Purchase Requisition
2. Store Requisition from Other Department
3. Un-authorization

8.0 FUNCTIONAL REQUIREMENTS FOR MANUFACTURING INVENTORY MODULE:

8.1 Goods Receipt Note (GRN)

8.1.1 Key Process Elements

1. To prepare Goods Receipt Note.
2. To inform Quality Control Departments for carry out sampling & testing of material.

8.1.2 Automated System Checks and Controls

URS ID.	Description
8.1.2.1	GRN should not allow in back date and future date
8.1.2.2	Batch Ref. number should enter manually and unique for same item
8.1.2.3	Batch no. should not allow to modify once transaction is saved
8.1.2.4	The GRN should not be made without purchase order
8.1.2.5	The system should not allow modification of QC required in GRN for Raw Material and Packing Material
8.1.2.6	GRN should not allow for cancelled or hold Purchase Order
8.1.2.7	Expiry date should be greater than manufacturing date
8.1.2.8	Supplier Invoice date should not be greater than GRN date
8.1.2.9	Disallow modification of received quantity after QC
8.1.2.10	Should not allow PO date greater than supplier Invoice date
8.1.2.11	Should not allow to print quarantine label once sampling done
8.1.2.12	GRN should not allow for the manufacturer not approved by QA

8.1.3 Key Process Elements

S.No.	Name of Report
1.	GRN Document
2.	Quarantine Label

8.2 Goods Receipt from Others (GRO)

8.2.1 Key Process Elements

1. To prepare Goods Receipt from others
2. To inform Quality Control Departments for carry out sampling & testing of material.

8.2.2 Automated System Checks and Controls:

URS Id.	Description
8.2.2.1	GRO should not allow in back date and future date
8.2.2.2	Batch Ref. number should enter manually and unique for same item
8.2.2.3	Expiry date should not be lesser than manufacturing date
8.2.2.4	Should not allow modification of QC required
8.2.2.5	Disallow authorization if QC status is on test
8.2.2.6	Should not allow to print quarantine label once sampling done

8.2.3 List of record:

S.No.	Name of Report
1.	GRO Document

8.3 Purchase Return Note (PRN):

8.3.1 Key Process Elements:

1. To return the rejected material to the supplier

8.3.2 Automated System Checks and Controls

URS ID	Description
8.3.2.1	Without Against GRN Purchase return Note should not be prepared
8.3.2.2	System should not allow return more quantity than GRN.
8.3.2.3	Purchase return reason code must be specified in purchase return note.
8.3.2.4	Disallow PRN of unauthorized GRN item
8.3.2.5	PRN should not allow in back date and future date

8.3.3 List of record

S.No.	Name of Report
1.	Purchase return note document

8.4 Material Issue to Production (MIP)

8.4.1 Key Process Elements

1. To create material issue to production

8.4.2 Automated System Checks and Controls

URS ID	Description
8.4.2.1	Store Requisition Id. must be specified.
8.4.2.2	System should issue material in first expiry first out basis
8.4.2.3	Disallow issue of expired batch in material issue to production
8.4.2.4	Disallow issue of unauthorized AR's items in material issue to production
8.4.2.5	Disallow issue of unvalued GRN's item in material issue to production
8.4.2.6	Check issue date w.r.t. to AR date in material issue to production
8.4.2.7	Does not allow issue of expired QC re-validity AR in material issue to production
8.4.2.8	MIP should not allow in back date and future date

8.4.3 List of record

S.No.	Name of Report
1.	Material Issue to Production document
2.	Dispensing label

8.5 Material Issue to Other Location (MIL)

8.5.1 Key Process Elements

1. To create Material Issue to other location

8.5.2 Automated System Checks and Controls

URS ID	Description
8.5.2.1	Does not allow issue of expired batches
8.5.2.2	Does not allow issue of unauthorized AR's item
8.5.2.3	Stop issue of unvalued GRN's item
8.5.2.4	MIL should not allow in back date and future date

8.5.3 List of record

S.No.	Name of Report
1.	Material Issue to Other location document

8.6 Material Issue to Other Department (MID)

8.6.1 Key Process Elements

1. To create Material Issue to other department

8.6.2 Automated System Checks and Controls

URS ID	Description
8.6.2.1	Store Requisition Id. must be specified in MID
8.6.2.2	Not allowing issue of expired batches
8.6.2.3	Does not allow issue unauthorized AR's item
8.6.2.4	Stop issue of unvalued GRN's item
8.6.2.5	Check issue date w.r.t GRN date
8.6.2.6	Retest validity expired material should not allow to issue
8.6.2.7	MID should not allow in back date and future date

8.6.3 List of record

S.No.	Name of Report
1.	Material Issue to other department document

8.7 Material Issue to Others (MIO)

8.7.1 Key Process Elements

1. To create Material Issue to others

8.7.2 Automated System Checks and Controls

URS ID	Description
8.7.2.1	Does not allow issue of expired batches
8.7.2.2	Does not allow issue of unauthorized AR's items
8.7.2.3	Stop issue of unvalued GRN's items
8.7.2.4	Does not allow issue of expired re-validity AR's
8.7.2.5	MIO should not allow in back date and future date

8.7.3 List of record

S.No.	Name of Report
1	Material Issue to others document

8.8 Shortage Stock Adjustment (SSA)

8.8.1 Key Process Elements

1. To create Shortage Stock adjustment.

8.8.2 Automated System Checks and Controls

URS ID	Description
8.8.2.1	Shortage Stock Adjustment Number is auto system generated and unique.
8.8.2.2	Shortage Stock adjustment should not be deleting once transaction is authorized.
8.8.2.3	System should not allow generating stock adjustment in back date.
8.8.2.4	System should not allow generating stock adjustment in future date.

8.8.3 List of record

S.No.	Name of Report
1.	Shortage Stock adjustment document

8.9 Excess Stock Adjustment (ESA)

8.9.1 Key Process Elements

1. To create Excess Stock adjustment.

8.9.2 Automated System Checks and Controls

URS ID	Description
8.9.2.1	Excess Stock Adjustment number is auto system generated and unique.
8.9.2.2	Should not allow to delete once authorized
8.9.2.3	System should not allow generating excess stock adjustment in back date.
8.9.2.4	System should not allow generating excess stock adjustment in future date.
8.9.2.5	Disallow modification of transaction date

8.9.3 List of record

S.No.	Name of Report
1.	Excess Stock adjustment document

8.10 QC Intimation for Retesting of GRN (QIN)

8.10.1 Key Process Elements

1. To send QC intimation for retest material

8.10.2 Automated System Checks and Controls

URS ID	Description
8.10.2.1	Intimation No. should be system generated and unique
8.10.2.2	Right to delete the QIN should with higher authority only
8.10.2.3	System should allow modification of Containers and No. of Slips
8.10.2.4	Should not allow intimation for expired QC specification revision date
8.10.2.5	QIN should not allow in back date and future date

8.10.3 List of record

S.No.	Name of Report
1.	QC Intimation Slip document

8.11 Un-Authorization Work Bench

8.11.1 Key Process Elements

1. To authorize the authorized transaction

8.11.2 Automated System Checks and Controls

URS ID	Description
8.11.2.1	Unauthorized user should not be able to un-authorize transaction

8.12 QC Intimation For Testing of GRN

8.12.1 Key Process Elements

1. To send QC intimation for testing of GRN

8.12.2 Automated System Checks and Controls

URS ID	Description
8.12.2.1	Intimation No. should be system generated and unique
8.12.2.2	Right to delete the QIN should with higher authority only
8.12.2.3	System should allow modification of Containers and No. of Slips
8.12.2.4	Should not allow intimation for expired QC specification revision date
8.12.2.5	QIN should not allow in back date and future date

8.12.3 Key Process Elements

S.No.	Name of Report
1.	QC Intimation Slip document

8.13 Document Closing Work Bench

8.13.1 Key Process Elements

1. To close pending transaction

8.13.2 Automated System Checks and Controls

URS ID	Description
8.13.2.1	Unauthorized user should not be able to close transaction

9.0 FUNCTIONAL REQUIREMENTS FOR PURCHASE MODULE:

9.1 Vendor Item Catalog

9.1.1 Key Process Elements

1. To maintain Vendor Item Catalog

9.1.2 Automated System Checks and Controls

URS ID	Description
9.1.2.1	Unauthorized user should not be able to delete the vendor item catalog.
9.1.2.2	Once vendor item catalog transacted should not be able to delete.
9.1.2.3	The user should not be able to tag Manufacturer's name in Vendor Item Catalog unless following transaction is performed. • Bought –out Item Wise Approved Manufacturer's QA Approval

9.1.3 List of record

Sr. No.	Name of Report
1.	Vendor Item Catalog Record

9.2 Purchase Order (POS)

9.2.1 Key Process Elements

1 To create Purchase Order.

9.2.2 Automated System Checks and Controls

URS Id.	Description
9.2.2.1	Disallow creation of Purchase Order for raw material & packing material without QA Approved Manufacturer Item (For domestic purchase)
9.2.2.2	The delivery date should not be less than the Purchase Order date
9.2.2.3	The Purchase Order should not be deleted after the material is received.
9.2.2.4	Right to delete the Purchase Order data should with higher authority only.
9.2.2.5	PO should not allow for unapproved vendor.
9.2.2.6	PO should not allow in back date and future date

9.2.3 List of record

Sr. No.	Name of Report
1.	Purchase Order Print

9.3 Purchase Order Amendment

9.3.1 Key Process Elements

1. To amend Purchase Order

9.3.2 Automated System Checks and Controls

URS Id.	Description
9.3.2.1	Unauthorized PO should not be amended.
9.3.2.2	Purchase Order Amendment note must be specified in Purchase order amendment.
9.3.2.3	Purchase order amendment should not create in back date.
9.3.2.4	Purchase order amendment should not create in future date.

9.3.3 List of record

Sr. No.	Name Of Report
1.	Purchase Order Amendment document

9.4 Un-Authorization Work Bench

9.4.1 Key Process Elements

1. To authorize the authorized transaction

9.4.2 Automated System Checks and Controls

URS Id.	Description
9.4.2.1	Unauthorized user should not be able to un-authorize transaction

9.5 Document Closing Work bench

9.5.1 Key Process Elements

1. To close transaction

9.5.2 Automated System Checks and Controls

URS Id.	Description
9.5.2.1	Unauthorized user should not be able to close transaction

10.0 FUNCTIONAL REQUIREMENTS FOR QUALITY CONTROL MODULE

10.1 QC Register Entry For GRN

10.1.1 Key Process Elements

1. To create QC Register entry for GRN for sampling of material

10.1.2 Automated System Checks and Controls

URS Id.	Description
10.1.2.1	Tested AR cannot be deleted
10.1.2.2	Sampling date should not be less than current date
10.1.2.3	Does not allow QC if Item's QC specification is due for revision

URS Id.	Description
10.1.2.4	GRN date can not be greater than AR entry date
10.1.2.5	Should not allow QC entry for item's QC specification not approved by QA
10.1.2.6	Under test label should not allow to reprint once QC analysis done
10.1.2.7	QC register entry should not allow in back date and future date

10.1.3 List of record

Sr. No.	Name of Report
1.	Under test label

10.2 QC Analysis Update For GRN

10.2.1 Key Process Elements

1. To create QC Analysis update for GRNs.

10.2.2 Automated System Checks and Controls

URS Id.	Description
10.2.2.1	There should be a Provision to Pass, reject, Part accepted or pass with deviation
10.2.2.2	System should not allow accepting, rejecting or consumed more qty. than the batch qty.
10.2.2.3	Test completion date must be equal to or greater than allotment date.
10.2.2.4	Next level Authorization should be available.
10.2.2.5	Sample cannot pass if any tests fails
10.2.2.6	Batch cannot pass if any sample fails
10.2.2.7	QC validity date should not be greater than expiry date
10.2.2.8	Approved label should not allow for reprint, allowed only with proper justification for the deviation
10.2.2.9	Approved label should not allow to generate once test is failed.
10.2.2.10	Rejected label should not allow to generate once test is passed.
10.2.2.11	Sample size should reduce once test is completed

10.2.3 List of record

Sr. No.	Name of Report
1.	Approved Label
2.	Certificate of Analysis Report

10.3 Extend AR Validity For GRN

10.3.1 Key Process Elements

1. To extend validity for revalidation date

10.3.2 Automated System Checks and Controls

URS Id.	Description
10.3.2.1	Should not allow to extend for unauthorized AR
10.3.2.2	Should not allow to extend if revalidation data is not defined
10.3.2.3	Unauthorized person should not allow to extend

10.4 QC Register Entry For Production

10.4.1 Key Process Elements

1. To create QC Register entry for Production for sampling of product

10.4.2 Automated System Checks and Controls

URS Id.	Description
10.4.2.1	Sampling date should not be less than current date
10.4.2.2	Tested AR cannot be modified
10.4.2.3	Tested AR cannot be deleted
10.4.2.4	Does not allow QC if Item's QC specification is due for revision
10.4.2.5	Should not allow QC entry for item's QC specification not approved by QA
10.4.2.6	QC register entry should not allow in back date and future date

10.5 QC Analysis Update For Production

10.5.1 Key Process Elements

1. To create QC Analysis update for Production

10.5.2 Automated System Checks and Controls

URS Id.	Description
10.5.2.1	There should be a Provision to Pass, reject, Part accepted or pass with deviation.
10.5.2.2	System should not allow accepting, rejecting or consumed more qty than the produce qty.
10.5.2.3	Test completion date must be equal to or greater than allotment date.
10.5.2.4	Next level Authorization should be available.
10.5.2.5	Sample cannot pass if any tests fails
10.5.2.6	Batch cannot pass if any sample fails

URS Id.	Description
10.5.2.7	QC validity date should not be greater than expiry date
10.5.2.8	Approved label should not allow for reprint, allowed only with proper justification for the deviation
10.5.2.9	Approved label should not allow to generate once test is failed.
10.5.2.10	Rejected label should not allow to generate once test is passed.
10.5.2.11	Sample size should reduce once test is completed

10.5.3 List of record

Sr. No.	Name of Report
1	Approved Label
2	Certificate of Analysis Report

10.6 QC Register Entry For Intimation

10.6.1 Key Process Elements

1. To create QC Register entry for Intimation for retested material

10.6.2 Automated System Checks and Controls

URS Id.	Description
10.6.2.1	Sampling date should not be less than current date
10.6.2.2	Tested AR cannot be modified
10.6.2.3	Tested AR cannot be deleted
10.6.2.4	Does not allow QC if Item's QC specification is due for revision
10.6.2.5	Allotment date can not be less than sampling date
10.6.2.6	QC register entry should not allow in back date and future date
10.6.2.7	Under test label should not allow to reprint once QC analysis done

10.6.3 List of record

Sr. No.	Name of Report
1	Under test label

10.7 QC Analysis Update For Intimation

10.7.1 Key Process Elements

1. To create QC Analysis update for Intimation

10.7.2 Automated System Checks and Controls

URS Id.	Description
10.7.2.1	There should be a Provision to Pass, reject, Part accepted or pass with deviation
10.7.2.2	System should not allow accepting, rejecting or consumed more qty. than the batch qty.
10.7.2.3	Test completion date must be equal to or greater than allotment date.
10.7.2.4	Next level Authorization should be available.
10.7.2.5	Sample cannot pass if any tests fails
10.7.2.6	Batch cannot pass if any sample fails
10.7.2.7	QC validity date should not be greater than expiry date
10.7.2.8	Approved label should not allow for reprint, allowed only with proper justification for the deviation
10.7.2.9	Approved label should not allow to generate once test is failed
10.7.2.10	Rejected label should not allow to generate once test is passed.
10.7.2.11	Sample size should reduce once test is completed

10.7.3 List of record

Sr. No.	Name of Report
1	Approved Label
2	Certificate of Analysis Report

10.8 GRN's Pending For QC

10.8.1 Key Process Elements

1. To list GRN's pending for QC

10.8.2 Automated System Checks and Controls

URS Id.	Description
10.8.2.1	Un-authorized User should not be able to view GRN
10.8.2.2	Un-authorized User should not be able to view register entry
10.8.2.3	Un-authorized User should not be able to view analysis update

10.9 Intimation Pending For QC

10.9.1 Key Process Elements

1. To list intimation pending for QC

10.9.2 Automated System Checks and Controls

URS Id.	Description
10.9.2.1	Un-authorized User should not be able to view Intimation
10.9.2.2	Un-authorized User should not be able to view register entry
10.9.2.3	Un-authorized User should not be able to view analysis update

10.10 Production Batches Pending For QC

10.10.1 Key Process Elements

1. To list production batches pending for QC

10.10.2 Automated System Checks and Controls

URS Id.	Description
10.10.2.1	Unauthorized User should not be able to view batch release details
10.10.2.2	Unauthorized User should not be able to release the batch

10.11 QC Specification due for renewal query

10.11.1 Key Process Elements

1. To QC specification due for renewal

10.11.2 Automated System Checks and Controls

URS Id.	Description
10.11.2.1	Unauthorized User should not be able to access QC specifications due for renewal query

10.12 Item’s re-testing history query

10.12.1 Key Process Elements

1. To list item’s re-testing details

10.12.2 Automated System Checks and Controls

URS Id.	Description
10.12.2.1	Unauthorized User should not be able to access Item’s re-testing history query

10.13 QC Test property Trend Report

10.13.1 Key Process Elements

1. To create QC test property trend report

10.13.2 Automated System Checks and Controls

URS Id.	Description
10.13.2.1	Unauthorized user should not be able to access to run the report
10.13.2.2	Report should display test value against each test along with AR Id. for particular material

10.14 QC Assay Test Trend Report

10.14.1 Key Process Elements

1. To create QC Assay Test Trend Report

10.14.2 Automated System Checks and Controls

URS Id.	Description
10.14.2.1	Unauthorized user should not be able to access to run the report
10.14.2.2	Report should display test value against each active ingredient along with AR Id. details

10.15 Un-Authorization Work Bench

10.15.1 Key Process Elements

1. To authorize the authorized transaction

10.15.2 Automated System Checks and Controls

URS Id.	Description
10.15.2.1	Unauthorized user should not be able to un-authorize transaction

11.0 FUNCTIONAL REQUIREMENTS FOR PRODUCTION MODULE

11.1 Production Batch Order

11.1.1 Key Process Elements

1. To create production batch order

11.1.2 Automated System Checks and Controls

URS Id.	Description
11.1.2.1	Batch no. cannot be modified once generated
11.1.2.2	Expiry month/year must be specified in production batch order
11.1.2.3	Production batch order can't be created for any bill of process not approved by QA
11.1.2.4	Once Batch is completed and released it cannot modify
11.1.2.5	Should not allow modification of Manufacturing month/yyyy
11.1.2.6	Should not allow modification of Expiry month/yyyy

11.1.3 List of record

Sr. No.	Name of Report
1.	Production batch order record

11.2 Store Requisition from Production (SRP)

11.2.1 Key Process Elements

1. To create store requisition from production

11.2.2 Automated System Checks and Controls

URS Id.	Description
11.2.2.1	Should not allow store requisitions from production if no stock
11.2.2.2	Should not allow back dated SRP
11.2.2.3	Should not allow future date SRP
11.2.2.4	Should not allow modification of transaction date

11.2.3 List of record

Sr. No.	Name of Report
1.	Store Requisition from Production document

11.3 Batch Production Activity Log

If in bill of process definition RM/PM input required is ticked for the Stage then in batch production activity log have to select the RM/ PM Input issued for the batch.
If in bill of process definition in process input required is ticked for the Stage then in batch production activity log have to select the in process input required issued for the batch.
If in bill of process definition output Expected is ticked for the Stage then in batch production activity log have to select the Output input required issued for the batch.

11.3.1 Key Process Elements

1. To create Batch Production Activity Log.

11.3.2 Automated System Checks and Controls

URS Id.	Description
11.3.2.1	Does not allow Batch Production Activity Log if RM/PM Input is not specified
11.3.2.2	The produced qty. should not be allowed to modify or delete once QC is done for the respective batches
11.3.2.3	Should not allow produced qty. more than standard batch qty. (if defined validation in the setup module)
11.3.2.4	Output must be specified if it is mentioned in BOP
11.3.2.5	Should not allow to delete or modify existing data if batch is completed

11.4 Production Transfer Note (PTN)

11.4.1 Key Process Elements

1. To create Production Transfer Note

11.4.2 Automated System Checks and Controls

URS Id.	Description
11.4.2.1	Should not allow modification of transaction date
11.4.2.2	Does not allow transfer of on test batch.
11.4.2.3	Check transfer qty. with respect to batch qty.
11.4.2.4	PTN should not allow in back date and future date

11.4.3 List of record

Sr. No.	Name of Report
1.	Production Transfer Note Record

11.5 Material Return from Production (MRP)

11.5.1 Key Process Elements

1. To return excess material from production/packing

11.5.2 Automated System Checks and Controls

URS Id.	Description
11.5.2.1	Issue note required in material return from production
11.5.2.2	Does not allow modification of transaction date
11.5.2.3	Material cannot be returned more than material remaining qty. after batch consumption
11.5.2.4	MRP should not allow in back date and future date

11.5.3 List of record

Sr. No.	Name of Report
1.	Material Return from Production print

11.6 Store Requisition from Other Department (SRD)

11.6.1 Key Process Elements

1. To create Store Requisition from Other Department

11.6.2 Automated System Checks and Controls

URS Id.	Description
11.6.2.1	Should not allow requisition if no stock
11.6.2.2	Does not allow back dated SRD
11.6.2.3	Does not allow future date SRD

11.6.3 List of record

Sr. No.	Name of Report
1.	Store requisition from other department Record

11.7 Open Completed Batches

11.7.1 Key Process Elements

1. To open completed batch

11.7.2 Automated System Checks and Controls

URS Id.	Description
11.7.2.1	Unauthorized user should not be able to open completed batch
11.7.2.2	There should be remark field to define reason for opening the completed batch and this reason field should be mandatory field

11.8 Location Wise Production Query

11.8.1 Key Process Elements

1. To check production batch status

11.8.2 Automated System Checks and Controls

URS Id.	Description
11.8.2.1	Unauthorized user should not be able to access location wise production query

11.9 Production batches release query

11.9.1 Key Process Elements

1. To check production batches pending for release

11.9.2 Automated System Checks and Controls

URS Id.	Description
11.9.2.1	Unauthorized User should not be able to access production batches release query
11.9.2.2	Unauthorized user should not allow to release the batch

11.10 Un - Authorization Work Bench

11.10.1 Key Process Elements

1. To un-authorize transaction

11.10.2 Automated System Checks and Controls

URS Id.	Description
11.10.2.1	Unauthorized user should not be able to un-authorize transaction

11.11 QC Intimation for Production Batch

11.11.1 Key Process Elements

1. To send QC intimation for production batch

11.11.2 Automated System Checks and Controls

URS Id.	Description
11.11.2.1	Intimation No. should be system generated and unique
11.11.2.2	Intimation should not be able to create in back date
11.11.2.3	Intimation should not be able to create in future date
11.11.2.4	Should not allow modification of transaction date
11.11.2.5	Unauthorized user should not able to create QC intimation for production batch.
11.11.2.6	Right to delete the QC intimation for production batch should with higher authority only

11.11.3 List of record

Sr. No.	Name of Report
1.	QC Intimation Slip document

11.12 Document Closing Work Bench

11.12.1 Key Process Elements

1. To close transaction

11.12.2 Automated System Checks and Controls

URS Id.	Description
11.12.2.1	Unauthorized user should not be able to close transaction

12.0 FUNCTIONAL REQUIREMENTS FOR SALES MODULE:

12.1 Sales Order Regular (SOR)

12.2.1 Key Process Elements

1. To create sales order

12.2.2 Automated System Checks and Controls

URS Id.	Description
12.2.2.1	Sales Order no. should be system generated and unique
12.2.2.2	Unauthorized user should not able to create Sales order
12.2.2.3	Right to delete the Sales order should with higher authority only.
12.2.2.4	Sales order once transacted should not be deleted.
12.2.2.5	Should not allow modification of transaction date
12.2.2.6	Should not be created in back date
12.2.2.7	Should not be created in future date
12.2.2.8	Unauthorized User should not be able to close the Sales order.
12.2.2.9	The Sales order should not utilize for future transaction once it is closed.
12.2.2.10	Customer order no. must be specified

12.2.3 List of record

Sr. No.	Name of Report
1.	Sales order document

12.2 Sales Order Regular Amendment

12.2.1 Key Process Elements

1. To amend sales order

12.2.2 Automated System Checks and Controls

URS Id.	Description
12.2.2.1	Once sales order amendment transacted system should not allow deleting sales
12.2.2.2	Unauthorized SOR should not be amended.
12.2.2.3	Sale Order Amendment note must be specified in Sale order amendment.
12.2.2.4	Sale order amendment should not create in back date.
12.2.2.5	Sales order amendment should not create in future date.
12.2.2.6	Unauthorized user should not be able to modify sale order amendment.

12.2.3 List of record

Sr. No.	Name of Report
1.	Sales order amendment Print

12.3 Finished Goods Inward (FGI)

12.3.1 Key Process Elements

1. To create finished goods inward

12.3.2 Automated System Checks and Controls

URS Id.	Description
12.3.2.1	Finished inward no. should be system generated and unique
12.3.2.2	Unauthorized user should not able to create FGI
12.3.2.3	Right to delete the FGI should with higher authority only
12.3.2.4	FGI once transacted should not be deleted.
12.3.2.5	Should not allow modification of transaction date
12.3.2.6	Should not be created in back date
12.3.2.7	Should not be created in future date
12.3.2.8	Unauthorized user should not be able to close the FGI

12.3.3 List of record

Sr. No.	Name of Report
1.	Finished goods inward document

12.4 Invoice Using Sales Order Rates (ISO)

12.4.1 Key Process Elements

1. To create commercial invoice

12.4.2 Automated System Checks and Controls

URS Id.	Description
12.4.2.1	ISO No. should be system generated
12.4.2.2	ISO should not be able to create in back date
12.4.2.3	ISO should not be able to create in future date

URS Id.	Description
12.4.2.4	Should not allow modification of transaction date
12.4.2.5	Unauthorized user should not able to create ISO
12.4.2.6	Right to delete the ISO should with higher authority only.
12.4.2.7	Unauthorized sales order should not allow for invoicing
12.4.2.8	Sales order number must be specified
12.4.2.9	Batch number must be specified
12.4.2.10	Batch not released by QA should not allow for invoicing
12.4.2.11	Does not allow more qty. than order qty.
12.4.2.12	Does not allow sale of expired goods
12.4.2.13	Should not allow without GSTIN No. and HSN code
12.4.2.14	Does not allow invoice of on test batches
12.4.2.15	System should select batch in first expiry first out order

12.4.3 List of record

Sr. No.	Name of Report
1.	Invoice document

12.5 Finish Goods Outward (FGO)

12.5.1 Key Process Elements

1. To transfer FG to other location

12.5.2 Automated System Checks and Controls

URS Id.	Description
12.5.2.1	Finished outward no. should be system generated and unique
12.5.2.2	Unauthorized user should not able to create FGO
12.5.2.3	Right to delete the FGO should with higher authority only
12.5.2.4	FGO once authorized should not be deleted.
12.5.2.5	Should not allow modification of transaction date
12.5.2.6	Should not be created in back date
12.5.2.7	Should not be created in future date

12.5.3 List of record

Sr. No.	Name of Report
1.	Finish Goods Outward document

12.6 Sales Return Note (SRN)

12.6.1 Key Process Elements

1. To create sales return entry from customer

12.6.2 Automated System Checks and Controls

URS Id.	Description
12.6.2.1	SRN No. should be system generated
12.6.2.2	SRN should not be able to create back dated
12.6.2.3	SRN should not be able to create future date
12.6.2.4	Should not allow modification of transaction date
12.6.2.5	Does not allow return of more qty. than billed qty.
12.6.2.6	Unauthorized user should not able to create SRN
12.6.2.7	Should not allow to delete the SRN once it is authorized
12.6.2.8	Return reason must be specified
12.6.2.9	Should not allow without GSTIN No and HSN code

12.6.3 List of record

Sr. No.	Name of Report
1	Sales Return Note document

12.7 Write Back Memo (WBK)

12.7.1 Key Process Elements

1. To create Write Back Memo (WBK)

12.7.2 Automated System Checks and Controls

URS Id.	Description
12.7.2.1	WBK No. should be system generated and unique
12.7.2.2	WBK should not be able to create back date
12.7.2.3	WBK should not be able to create future date.

URS Id.	Description
12.7.2.4	Should not allow to modify transaction date
12.7.2.5	Unauthorized user should not able to create WBK
12.7.2.6	WBK should not be deleted once authorized.
12.7.2.7	Right to delete WBK is only with higher authority.
12.7.2.8	User should mention the reason for write back

12.7.3 List of record

Sr. No.	Name of Report
1	Write back memo document

12.8 Write Off Memo (WOF)

12.8.1 Key Process Elements

1. To create write off entry

12.8.2 Automated System Checks and Controls

URS Id.	Description
12.8.2.1	WOF. No. should be system generated.
12.8.2.2	WOF should not be able to create back date
12.8.2.3	WOF should not be able to create future date.
12.8.2.4	Should not allow to modify transaction date
12.8.2.5	Unauthorized user should not able to create WOF
12.8.2.6	WOF should not be deleted once authorized.
12.8.2.7	Right to delete WOF is only with higher authority.
12.8.2.8	User should User should mention the reason for write off.

12.8.3 List of record

Sr. No.	Name of Report
1	Write off memo document

12.9 Sales Stock Balance Query

12.9.1 Key Process Elements

1. To check finish goods stock

12.9.2 Automated System Checks and Controls

URS Id.	Description
12.9.2.1	System should able to filter stock for batch wise, product wise and sales division wise

12.10 Un-authorization Work Bench

12.10.1 Key Process Elements

1. To un-authorize transaction

12.10.2 Automated System Checks and Controls

URS Id.	Description
12.10.2.1	Unauthorized user should not be able to unauthorized transaction

12.11 Goods Receipt Note- Trading (GRT)

12.11.1 Key Process Elements

1. To receive trading material

12.11.2 Automated System Checks and Controls

URS Id.	Description
12.11.2.1	Goods Receipt No. should be system generated
12.11.2.2	Batch Ref. number should enter manually and unique.
12.11.2.3	Should not allow without GSTIN No. and HSN/SAC code
12.11.2.4	Batch no. should not allow to modify once transaction is saved
12.11.2.5	GRT should not create in back dated.
12.11.2.6	GRT should not create in future dated.
12.11.2.7	Modification of transaction date should not be allowed once GRT saved.
12.11.2.8	Unauthorized user should not be able to create Goods Receipt Note-trading
12.11.2.9	The GRT should not be made without purchase order.
12.11.2.10	The GRT should not be made for the closed vendor.
12.11.2.11	GRT should not allow for cancelled or hold Purchase Order
12.11.2.12	Expiry date should be greater than manufacturing date
12.11.2.13	Right to delete GRT only with higher authority.
12.11.2.14	Disallow GRT authorization without valuation
12.11.2.15	Supplier Invoice date should be before date than GRT date

URS Id.	Description
12.11.2.16	Should not allow PO date greater than supplier Invoice date

12.11.3 List of record

Sr. No.	Name of Report
1.	Goods receipt note- trading document

12.12 Document Closing Work Bench

12.12.1 Key Process Elements

1. To close transaction

12.12.2 Automated System Checks and Controls

URS Id.	Description
12.12.2.1	Unauthorized user should not be able to close transaction

13.0 FUNCTIONAL REQUIREMENTS FOR SETUP MODULE

13.1 Item Type

13.1.1 Key Process Elements

1. To create Item Types.
2. To use data in Item master

13.1.2 Automated System Checks and Controls

URS Id.	Description
13.1.2.1	Unauthorized user should not be able to modify Item Types.
13.1.2.2	Unauthorized user should not be able to Create Item Types.
13.1.2.3	The Item type code should not be utilized for future transaction for closed Item type
13.1.2.4	Unauthorized user should not be able to close the Item type.

13.1.3 List of record

Sr. No.	Name of Report
1.	Item type print

13.2 Item Sub Type

13.2.1 Key Process Elements

1. To create Item sub types.
2. To use data in Item master

13.2.2 Automated System Checks and Controls

URS Id.	Description
13.2.2.1	The Item type code should not be duplicated.
13.2.2.2	The Item sub type code should not be duplicated.
13.2.2.3	Un Authorized User should not be able to create Item Sub Types.
13.2.2.4	Right to close the Item Sub Types should with higher authority only.
13.2.2.5	The Item Sub Types once transacted should not be deleted.
13.2.2.6	The Item Sub Types should not utilize for future transaction once it is closed.

13.2.3 List of record

Sr. No.	Name of Report
1.	Item Sub type print

13.3 Item Master

13.3.1 Key Process Elements

1. To create raw material, packing material, intermediate material, finished goods, consumable, capital goods and spare parts item codes.
2. To maintain Basic data: Item Name, Unit of measure, Item Type and Item sub type

13.3.2 Automated System Checks and Controls

URS Id.	Description
13.3.2.1	Item Codes should be auto generated and unique.
13.3.2.2	Unauthorized User should not be able to create Item code.
13.3.2.3	Type, Sub Type and Unit of Measure should not be entered manually.
13.3.2.4	Right to close the Item code should be with higher authority only.
13.3.2.5	The Item code once transacted should not be deleted.
13.3.2.6	The Unit of measure should not be changed after Item code is transacted.
13.3.2.7	The Item code should not be utilized for future transaction for closed Item.
13.3.2.8	Should have the provision to update HSN/Sac code

13.3.3 List of record

Sr. No.	Name of Report
1.	Item Master print

13.4 Purchase Group

13.4.1 Key Process Elements

1. To create purchase group

13.4.2 Automated System Checks and Controls

URS Id.	Description
13.4.2.1	The purchases group should be manually generated.
13.4.2.2	Unauthorized user should not be able to create purchase group.
13.4.2.3	Once transacted purchase group transacted should not be able to delete
13.4.2.4	Purchase Group code & Purchase Group Name should not be duplicated
13.4.2.5	Un Authorized User should not be able to closed Purchase Group.

13.4.3 List of record

Sr. No.	Name of Report
1.	Purchase group print

13.5 Location/Item Type/Sub Type Wise Purchase Group

13.5.1 Key Process Elements

1. To create Location/Item Type/Sub Type Wise Purchase Group

13.5.2 Automated System Checks and Controls

URS Id.	Description
13.5.2.1	The location/ item type/ sub type wise purchase group should be manually generated.
13.5.2.2	Unauthorized user should not be able to define the location/ item type/ sub type wise purchase group.
13.5.2.3	Unauthorized user should not be able to modify the location/ item type/ sub type wise purchase group.
13.5.2.4	Once transacted user should not be able to delete the location/ item type/ sub type wise purchase group.
13.5.2.5	Unauthorized user should not be able to closed location/ item type/ sub type wise purchase group.
13.5.2.6	Item Sub type Code should not be duplicated.

13.5.3 List of record

Sr. No.	Name of Report
1.	Location/Item Type/ Sub-Type wise Purchase Groups record

13.6 PO Standard Terms

13.6.1 Key Process Elements

1. To create PO standard terms

13.6.2 Automated System Checks and Controls

URS Id.	Description
13.6.2.1	Un Authorized User should not be able to create PO standard terms.
13.6.2.2	The PO term code should be manually generated and unique
13.6.2.3	PO Standard terms should not be deleted once it is transacted
13.6.2.4	Closed PO Standard term should not allow in transaction

13.6.3 List of record

Sr. No.	Name of Report
1.	PO Standard terms record

13.7 Manufacturer Master

13.7.1 Key Process Elements

1. To create manufacturer master

13.7.2 Automated System Checks and Controls

URS Id.	Description
13.7.2.1	The Manufacture should manually generated
13.7.2.2	The Manufacture should not be duplicated.
13.7.2.3	Unauthorized user should not be able to create Manufacture.
13.7.2.4	Unauthorized user should not able to delete the Manufacture.
13.7.2.5	The Manufacture once transacted should not be deleted.
13.7.2.6	Unauthorized user should not able to close the Manufacture.
13.7.2.7	The Manufacture should not be utilized for future transaction once it is closed.

13.7.3 List of record

Sr. No.	Name of Report
1.	Manufacturer master record

13.8 Bought – out Item Wise Approved Manufacturers

13.8.1 Key Process Elements

1. To create bought out item wise approved manufacturer

13.8.2 Automated System Checks and Controls

URS Id.	Description
13.8.2.1	Unauthorized user should not be able to create Bought – Out Item wise Approved Manufacturers.
13.8.2.2	Un Authorized User should not be able to delete Bought – Out Item wise Approved Manufacturers.
13.8.2.3	The Bought – Out Item wise Approved Manufacturers once transacted should not be deleted.
13.8.2.4	Manufacturer name should not be duplicated.

13.8.3 List of record

Sr. No.	Name of Report
1.	Bought – Out Item wise Approved Manufacturers record

13.9 Analyst

13.9.1 Key Process Elements

1. To create analyst

13.9.2 Automated System Checks and Controls

URS Id.	Description
13.9.2.1	Analysts should be manually generated.
13.9.2.2	Analysts should not be duplicated.
13.9.2.3	Unauthorized user should not be able to create analysts.
13.9.2.4	Unauthorized user should not be able to modify analysts.
13.9.2.5	Unauthorized user should not be able to delete analysts.
13.9.2.6	Analysts once transacted should not be modified or deleted.

13.9.3 List of record

Sr. No.	Name of Report
1.	Analysis Record

13.10 QC Standards

13.10.1 Key Process Elements

1. To create QC standards

13.10.2 Automated System Checks and Controls

URS Id.	Description
13.10.2.1	Unauthorized user should not be able to create QC Standard.
13.10.2.2	Unauthorized user should not be able to modify QC Standard.
13.10.2.3	Unauthorized user should not be able to delete the QC standard.
13.10.2.4	QC standard code should not be duplicated.
13.10.2.5	Once Transacted should not delete.

13.10.3 List of record

Sr. No.	Name of Report
1.	QC Standard record

13.11 Common QC Properties

13.11.1 Key Process Elements

1. To create common QC properties

13.11.2 Automated System Checks and Controls

URS Id.	Description
13.11.2.1	Common QC properties test data sheet should be added manually and unique.
13.11.2.2	Unauthorized user should not be able to create Common QC properties
13.11.2.3	Unauthorized user should not be able to modify Common QC properties
13.11.2.4	Unauthorized user should not be able to delete the Common QC properties

13.11.3 List of record

Sr. No.	Name of Report
1.	Common QC properties record

13.12 QC Properties Groups

13.12.1 Key Process Elements

1. To create QC properties groups

13.12.2 Automated System Checks and Controls

URS Id.	Description
13.12.2.1	QC properties group should be manually generated
13.12.2.2	QC properties group should not be duplicated
13.12.2.3	Unauthorized user should not be able to create QC properties group
13.12.2.4	Unauthorized user should not be able to modify QC properties group
13.12.2.5	Unauthorized user should not be able to delete the QC properties group.

13.12.3 List of record

Sr. No.	Name of Report
1.	QC properties group record

13.13 Item's QC Specifications

13.13.1 Key Process Elements

1. To create item's QC specifications

13.13.2 Automated System Checks and Controls

URS Id.	Description
13.13.2.1	Item QC Specification should be manually generated.
13.13.2.2	Unauthorized user should not be able to create Item QC Specification.
13.13.2.3	Unauthorized user should not be able to modify Item QC Specification.
13.13.2.4	Unauthorized user should not be able to delete the Item QC Specification.
13.13.2.5	Item QC Specifications once transacted should not delete.
13.13.2.6	Should not allow to modify once QA approval done

13.13.3 List of record

Sr. No.	Name of Report
1.	Item's QC specifications record

13.14 Production Stages

13.14.1 Key Process Elements

1. To create Production Stages

13.14.2 Automated System Checks and Controls

URS Id.	Description
13.14.2.1	The production stage should be manually generated.
13.14.2.2	Unauthorized user should not be able to create production stage.
13.14.2.3	Unauthorized user should not be able to delete production stage.
13.14.2.4	Once production stage transacted should not be able to delete.
13.14.2.5	Unauthorized user should not be able to close the production stage.

13.14.3 List of record

Sr. No.	Name of Report
1.	Production Stages record

13.15 Production Stage Wise Activity

13.15.1 Key Process Elements

1. To create production stage wise activity

13.15.2 Automated System Checks and Controls

URS Id.	Description
13.15.2.1	The production stage wise activity should be manually generated.
13.15.2.2	Unauthorized user should not be able to create production stage wise activity.
13.15.2.3	Unauthorized user should not be able to delete production stage wise activity.
13.15.2.4	Once production stage wise activity transacted should not be able to delete.
13.15.2.5	Unauthorized user should not be able to close the production stage wise activity.

13.15.3 List of record

Sr. No.	Name of Report
1.	Production stage wise activities record

13.16 Bill of Process Definitions

13.16.1 Key Process Elements

1. To create Bill of Process Definitions

13.16.2 Automated System Checks and Controls

URS Id.	Description
13.16.2.1	The BOP product code should be manually generated and unique
13.16.2.2	Stage code should not be duplicated
13.16.2.3	Input items should not be duplicated
13.16.2.4	Bill of process can't be deleted or modified once QA approved
13.16.2.5	Unauthorized user should not be able to create bill of process
13.16.2.6	Unauthorized user should not be able to delete bill of process
13.16.2.7	Once bill of process transacted should not be able to delete
13.16.2.8	Unauthorized user should not be able to close the bill of process

13.16.3 List of record

Sr. No.	Name of Report
1.	Bill of process definition record

13.17 Vendor Master

13.17.1 Key Process Elements

1. To create vendor master

13.17.2 Automated System Checks and Controls

URS Id.	Description
13.17.2.1	Vendor number should be auto generated.
13.17.2.2	Unauthorized user should not be able to create vendor master
13.17.2.3	The vendor master should not be generated in back date.
13.17.2.4	The vendor master should not be generated in future date.
13.17.2.5	Once vendor master transacted should not be able to delete.
13.17.2.6	Unauthorized user should not be able to close vendor master
13.17.2.7	Unauthorized user should not be able to delete Vendor Master
13.17.2.8	GSTIN No. should not be mandatory in vendor master

13.17.3 List of record

Sr. No.	Name of Report
1.	Vendor master print

13.18 Production Centre

13.18.1 Key Process Elements

1. To create production centre

13.18.2 Automated System Checks and Controls

URS Id.	Description
13.18.2.1	Unauthorized user should not be able to create production centre
13.18.2.2	The production centre should be manually generated.
13.18.2.3	Unauthorized user should not be able to delete production centre
13.18.2.4	Once production centre transacted should not be able to delete.
13.18.2.5	Unauthorized user should not be able to close the production centre

13.18.3 List of record

Sr. No.	Name of Report
1.	Production Centre print

13.19 Standard Payment Terms

13.19.1 Key Process Elements

1. To create Standard Payment Terms

13.19.2 Automated System Checks and Controls

URS Id.	Description
13.19.2.1	Unauthorized user should not be able to create standard payment terms
13.19.2.2	Payment terms code should be unique and there should be provision to define term details
13.19.2.3	Unauthorized user should not be able to close standard payment terms

13.19.3 List of record

Sr. No.	Name of Report
1.	Standard Payment terms print

13.20 Customer Master

13.20.1 Key Process Elements

1. To create Customer

13.20.2 Automated System Checks and Controls

URS Id.	Description
13.20.2.1	Unauthorized user should not able to create Customer Master
13.20.2.2	Customer No. generated should be unique
13.20.2.3	Right to delete the Customer should with higher authority only.
13.20.2.4	The Customer once transacted should not be deleted.
13.20.2.5	Unauthorized user should not be able to close the Customer.
13.20.2.6	The Customer should not utilize for future transaction once it is closed.

13.20.3 List of record

Sr. No.	Name of Report
1.	Customer print

13.21 Stores

13.21.1 Key Process Elements

1. To create Stores

13.21.2 Automated System Checks and Controls

URS Id.	Description
13.21.2.1	Unauthorized user should not be able to create stores
13.21.2.2	The code and store name should be manually generated and unique
13.21.2.3	Unauthorized user should not be able to delete stores
13.21.2.4	Unauthorized user should not be able to close the stores

13.21.3 List of record

Sr. No.	Name of Report
1.	Stores print

13.22 HSN & SAC Code Master (Single entry)

13.22.1 Key Process Elements

1. To create HSN & SAC Codes

13.22.2 Automated System Checks and Controls

URS Id.	Description
13.22.2.1	Unauthorized user should not be able to create HSN & SAC Codes
13.22.2.2	HSN/SAC Code and description should be unique
13.22.2.3	Unauthorized user should not be able to close and delete code
13.22.2.4	Should have provision to define reverse charge as applicable

13.22.3 List of record

Sr. No.	Name of Report
1.	HSN & SAC Codes print

13.23 Sales Division

13.23.1 Key Process Elements

1. To create Sales Division

13.23.2 Automated System Checks and Controls

URS Id.	Description
13.23.2.1	Unauthorized user should not be able to create Sales division
13.23.2.2	Code and sales division name should be unique
13.23.2.3	Unauthorized user should not be able to close and delete code
13.23.2.4	Should have provision to define overdue check

13.23.3 List of record

Sr. No.	Name of Report
1.	Sales Division print

13.24 User Management Preferences

13.24.1 Key Process Elements

1. To control user's account

13.24.2 Automated System Checks and Controls

URS Id.	Description
13.24.2.1	Block user after 5 consecutive failed login attempts
13.24.2.2	Expire password after 60 days
13.24.2.3	Close user session if inactive for 30 minutes
13.24.2.4	Show user as idle if inactive for 5 minutes

14.0 FUNCTIONAL REQUIREMENTS FOR CENTRALIZED SYSTEM ADMINISTRATION MODULE:

14.1 Show Current Users

14.1.1 Key Process Elements

1. To check current users

14.1.2 Automated System Checks and Controls

URS Id.	Description
14.1.2.1	Unauthorized user should not be able to access show current users
14.1.2.2	There should be provision to clear timed-out and idle users
14.1.2.3	There should be provision to check user details and clear user's pending transaction

14.2 Show Locked Users

14.2.1 Key Process Elements

1. To check locked users

14.2.2 Automated System Checks and Controls

URS Id.	Description
14.2.2.1	Unauthorized user should not be able to access show locked users
14.2.2.2	System should display locked users and unlock option
14.2.2.3	There should be provision to check failed login attempts

14.3 Examine Session Log

14.3.1 Key Process Elements

1. To check users Session Log

14.3.2 Automated System Checks and Controls

URS Id.	Description
14.3.2.1	Unauthorized user should not be able to access examine session log
14.3.2.2	Should have the provision to display user's session details

14.4 Application Module Control

14.4.1 Key Process Elements

1. To block/unblock Application Module

14.4.2 Automated System Checks and Controls

URS Id.	Description
14.4.2.1	Unauthorized user should not be able to access application module control
14.4.2.2	Should have the provision to block module
14.4.2.3	Should have the provision to unblock module
14.4.2.4	Should have the provision to broadcast

14.5 Application Wise User Roles

14.5.1 Key Process Elements

1. To define application wise user roles

14.5.2 Automated System Checks and Controls

URS Id.	Description
14.5.2.1	Unauthorized user should not be able to create application wise user roles
14.5.2.2	Unauthorized user should not be able to delete application wise user roles

14.6 Application Wise Program Access Rights

14.6.1 Key Process Elements

1. To define application wise program access rights

14.6.2 Automated System Checks and Controls

URS Id.	Description
14.6.2.1	Unauthorized user should not be able to create application wise program access rights
14.6.2.2	There should be provision to view and edit rights

14.7 Location Wise Users

14.7.1 Key Process Elements

1. To create location wise users

14.7.2 Automated System Checks and Controls

URS Id.	Description
14.7.2.1	Unauthorized user should not be able to create location wise users
14.7.2.2	User code and user's full name should be unique
14.7.2.3	Unauthorized user should not be able to close user's account
14.7.2.4	Closed user should not allow to login

14.8 Generate Password and Pin

14.8.1 Key Process Elements

1. To generate password and pin

14.8.2 Automated System Checks and Controls

URS Id.	Description
14.8.2.1	Unauthorized user should not be able to generate password and pin
14.8.2.2	System should have provision to change password on expiry
14.8.2.3	System should not allow to assign new password below 7 alphanumeric characters
14.8.2.4	System should have password complexity feature like ➢ At least one upper case character ➢ At least one lower case character ➢ At least one numeric character ➢ At least one special character

14.9 Location – Application Wise User Accounts

14.9.1 Key Process Elements

1. To create location application wise user accounts

14.9.2 Automated System Checks and Controls

URS Id.	Description
14.9.2.1	Unauthorized user should not be able to create location application wise user accounts
14.9.2.2	User code should be unique
14.9.2.3	Should not allow to transact over sanctioning limit

14.10 Special Access Privileges

14.10.1 Key Process Elements

1. To define special access privileges

14.10.2 Automated System Checks and Controls

URS Id.	Description
14.10.2.1	Unauthorized user should not be able to create special access privileges

14.11 Transaction Series Control (Post-GST)

14.11.1 Key Process Elements

1. To assign transaction wise access rights
2. To define transaction wise process control

14.11.2 Automated System Checks and Controls

URS Id.	Description
14.11.2.1	Unauthorized user should not be able to create transaction series control(Post-GST)
14.11.2.2	Code should be unique
14.11.2.3	Unauthorized user should not be able to delete transaction series control(Post-GST)
14.11.2.4	Closed series should not allow to transact

15.0 FUNCTIONAL REQUIREMENTS FOR REQUISITION MODULE:

15.1 Purchase Requisition

15.1.1 Key Process Elements

1. To create purchase requisition

15.1.2 Automated System Checks and Controls

URS Id.	Description
15.1.2.1	PRQ number should be auto system generated.
15.1.2.2	Unauthorized user should not be able to create Purchase requisition.
15.1.2.3	The Purchase requisition should not be generated in back date.
15.1.2.4	The Purchase requisition should not be generated in future date.
15.1.2.5	Modification of transaction date should not be allowed once purchase requisition saved.
15.1.2.6	Requisition qty. must be specified
15.1.2.7	Manufacturer name must be specified in Purchase Requisition for Raw Material and Packing Material.
15.1.2.8	Should not allow to raise requisition for manufacturer not approved by QA for RM and PM
15.1.2.9	Required by date must be specified in Purchase Requisition
15.1.2.10	Unauthorized user should not be able to delete Purchase requisition.
15.1.2.11	Once Purchase requisition transacted should not be able to delete.
15.1.2.12	Unauthorized user should not be able to close Purchase requisition

15.1.3 List of records

Sr. No.	Name of Report
1.	Purchase requisition document

15.2 Store Requisition From Other Department

15.2.1 Key Process Elements

1. To create store requisition from other department

15.2.2 Automated System Checks and Controls

URS Id.	Description
15.2.2.1	The Store requisition from other department should system generated
15.2.2.2	The Store requisition from other department should not be duplicated
15.2.2.3	Unauthorized user should not be able to create Store requisition from other department
15.2.2.4	Unauthorized user should not able to delete Store requisition from other department

URS Id.	Description
15.2.2.5	Does not allow requisition if no stock
15.2.2.6	Does not allow back dated SRD
15.2.2.7	Does not allow future date SRD
15.2.2.8	Does not allow modification of transaction date

15.2.3 List of records

Sr. No.	Name of Report
1.	Store requisition from other department document

15.3 Un-Authorization Work Bench

15.3.1 Key Process Elements

1. To create purchase requisition

15.3.2 Automated System Checks and Controls

URS Id.	Description
15.3.2.1	Unauthorized user should not be able to unauthorized transaction

16.0 FUNCTIONAL REQUIREMENTS FOR QUALITY ASSURANCE MODULE

16.1 Item Wise Manufacturer (QA Approval)

16.1.1 Key Process Elements

1. To approve item wise manufacturer by QA

16.1.2 Automated System Checks and Controls

URS Id.	Description
16.1.2.1	Unauthorized user should not be able to create Item wise Manufacturers (QA Approval)
16.1.2.2	The user should not be able to tag Manufacturer's name in Item wise Manufacturers (QA Approval) unless following transaction is performed. • Bought –out Item Wise Approved Manufacturer's QA Approval

16.2 Item's QC Specification (QA Approval)

16.2.1 Key Process Elements

1. To approve item's QC specification by QA

16.2.2 Automated System Checks and Controls

URS Id.	Description
16.2.2.1	Item QC Specification QA approval should be manually generated.
16.2.2.2	Unauthorized user should not be able to create Item QC Specification QA approval
16.2.2.3	Does not allow Item QC Specifications approval by QA if Item QC Specifications is not authorized by QC

16.3 Bill of Process (QA Approval)

16.3.1 Key Process Elements

1. To approve bill of process by QA

16.3.2 Automated System Checks and Controls

URS Id.	Description
16.3.2.1	The bill of process (QA Approval) should be manually generated.
16.3.2.2	Unauthorized user should not be able to create bill of process (QA approval).
16.3.2.3	In BOP, below fields to be made mandatory during approval ➢ Master Formula No. & Dated ➢ Product Lic. No. & expiry Date

16.4 Vendor-Item Manufacturer (QA Approval)

16.4.1 Key Process Elements

1. To approve vendor-item manufacturer by QA

16.4.2 Automated System Checks and Controls

URS Id.	Description
16.4.2.1	Unauthorized user should not be able to create Vendor-Item Manufacturer's QA Approval.
16.4.2.2	The user should not be able to create Vendor Item Manufacturer's QA Approval unless following transactions is performed. ➢ Vendor Item Catalog

16.5 Production Batch Release (By QA In-Charge)

16.5.1 Key Process Elements

1. To release production batch

16.5.2 Automated System Checks and Controls

URS Id.	Description
16.5.2.1	Unauthorized user should not be able to release the Production batch
16.5.2.2	Unauthorized user should not be able to modify the Production batch release
16.5.2.3	Uncompleted batch cannot be released by QA
16.5.2.4	Disallow modification of batch release by QA indicator
16.5.2.5	Production Batch Release Date should not be less than Batch date.
16.5.2.6	Should not allow production batch release for AR is not authorized
16.5.2.7	Should not allow to release batch in future date

16.5.3 List of record

Sr. No.	Name of Report
1.	Production Batch Release document

16.6 Production Batch Release (By QA Manager)

16.6.1 Key Process Elements

1. To release production batch

16.6.2 Automated System Checks and Controls

URS Id.	Description
16.6.2.1	Unauthorized user should not be able to release the Production batch
16.6.2.2	Unauthorized user should not be able to modify the Production batch release.
16.6.2.3	Uncompleted batch cannot be released by QA
16.6.2.4	Disallow modification of batch release by QA indicator
16.6.2.5	Production Batch Release Date should not be less than Batch date.
16.6.2.6	Should not allow production batch release for AR is not authorized
16.6.2.7	Should not allow to release batch in future date
16.6.2.8	System should not allow to remove the approval tag once batch is released.

16.6.3 List of record

Sr. No.	Name of Report
1.	Production Batch Release Document

17.0 GENERAL TECHNICAL REQUIREMENTS:

17.1 Security and Access Control Requirements

URS Id.	Description
17.1.1	Proper alarms must be raised if the user has entered wrong user name or password, and the user must not be able to access the module if erroneous log-in information is entered.
17.1.2	Track of log information regarding user activity must be made available
17.1.3	System must be designed in such a way that the system administrator must be the only one who can change but cannot access user's passwords(In case password is lost)
17.1.4	All users who are authorized to access the system shall be provided with a username and password
17.1.5	At least three levels of password should be available

17.2 User Interface And Capacity

URS Id.	Description
17.2.1	System should be designed in such a way that one module can be accessed by multiple users, however the same user may not access the same module by logging into two different workstations
17.2.2	ERP should display correct time and date
17.2.3	System must support access right and user right for transaction where the administration must have complete control over the system
17.2.4	The ERP has provision to support more than 34 concurrent user accounts based on license procured

17.3 Data Backup / Restore Requirements

URS Id.	Description
17.3.1	There should be provision for data backup procedure. The restored data should retrieve all the original data.

17.4 Regulatory Requirements

URS Id.	Description
17.4.1	Individual unique users should be created and function wise rights are assigned
17.4.2	After a configurable period of time, system will automatically ask user to enter new password. In this procedure system will ask for existing password & new password and this new password should not be same as existing password
17.4.3	User's password should comply with minimum 7 length requirement.
17.4.4	System should have password complexity feature like ➢ At least one upper case character ➢ At least one lower case character ➢ At least one numeric character

URS Id.	Description
	➢ At least one special character
17.4.5	The authorized user can change the system data & time
17.4.6	Audit Trails must independently record the time (hour:minute) and date of operator entries and actions that create, modify, or delete electronic records. Time and Date must be taken from a network server and not from the users desktop.
17.4.7	Database should be password protected

17.5 Training Requirements

URS Id.	Description
17.5.1	The user must be trained for operation of Progen ERP before usage

17.6 Documentation Requirements

URS Id.	Description
17.6.1	For Lifecycle management of ERP System should develop various Standard Operating Procedures as mentioned below. 1. Access Control 2. System Administrator 3. Password Policy 4. Data Backup and Restore Management 5. Disaster Management and Recovery 6. User creation and deletion 7. Process wise Operational SOPs for ERP The ERP and data backup are managed by IT - IT is ensuring the requirements are addressed.

17.7 Minimum Hardware and Software Requirements for Server

URS Id.	Description
Hardware Requirements	
17.7.1	Processor Intel (R) Xeon (R) CPU E3 – 2630 V4 @ 2.0 GHz (Application Server)
17.7.2	8 GB RAM (Application Server)
17.7.3	500 GB Hard Disk (Application Server)
Software Requirements	
17.7.4	The system at the server side should run on Windows server (2008 or above). The system at the client side has provision to run on Windows 7 or above.

18.0 AUDIT TRAIL MANAGEMENT:

Use of secure, computer-generated, time-stamped audit trails to independently record the date and time of operator entries and actions that create, modify, delete, verify, authorize, un-authorize or printed electronic records. Record changes should not obscure previously recorded information. Such audit trail documentation should be retained for a period at least as long as that required for the subject electronic records and should be available for agency review and copying.

Independently/Network Server

- Audit Trails must independently record the time (hour:minute) and date of operator entries and actions that create, modify, or delete electronic records.
- Time and Date must be taken from a network server and not from the users desktop.

The audit trail should be:

- Secure, i.e., protected from accidental or intentional modification or deletion.
- Computer generated, i.e., not written on paper and not prompted by the user, and saved in chronological order.
- Independent i.e. cannot be turned off by users.
- Operational at all times.
- Backed up and restored with the corresponding records.
- Archived and retrieved with the corresponding records.

➢ Audit trail Configuration in Revision History Format for following Module:

- Name (User)
- Date and time of the action
- Revision No.
- Action Taken – Create/Modify/Delete/Verify/Authorize/Unauthorize/Print

Manufacturing Inventory Module

1. Goods Receipt Note (GRN)
2. Goods Receipt from Others (GRO)
3. Purchase Return Note (PRN)
4. Material Issue to Production (MIP)
5. Material Issue to Other Departments (MID)
6. Material Issue to Other Location (MIL)
7. Material Issue to Other (MIO)
8. Shortage Stock Adjustment (SSA)
9. Excess Stock Adjustment (ESA)
10. QC Intimation for Testing of GRN

11. QC Intimation for Retesting of GRN

Purchase Module

1. Vendor Item Catalog
2. Purchase Order (PO)
3. Purchase Order Amendment

Quality Control Module

1. QC Register entry for GRN's
2. QC Analysis update for GRN's
3. Extend AR Validity for GRN's
4. QC Register Entry For Production
5. QC Analysis Update For Production
6. QC Register Entry For Intimation
7. QC Analysis Update For Intimation
8. QC Test Property Trend Report
9. QC Assay Test Trend Report

Production Module

1. Production Batch Order
2. Store requisition from Production (SRP)
3. Batch production activity log
4. Material Return From Production (MRP)
5. Store requisition from Other Department (SRD)
6. Production Transfer note (PTN)
7. Open Completed Batches
8. QC Intimation for Production Batch

Sales Module

1. Sales Order Regular (SOR)
2. Sales Order Regular Amendment
3. Invoice Using Sales Order Rates (ISO)
4. Sales Return Note (SRN)
5. Finished Goods Inward (FGI)
6. Finished Goods Outward (FGO)
7. Goods Receipt Note- Trading (GRT)
8. Write Back Memo (WBK)
9. Write Off Memo (WOF)

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Setup Module

1. Item Types
2. Item Sub – Types
3. Item Master
4. Purchase Groups
5. Location/Item Type/Sub Type wise purchase group
6. PO Standard Terms
7. Manufacturers
8. Bought – out Item wise Approved Manufacturers
9. QC Standards
10. Analysts
11. Common QC Properties
12. Item QC Specifications
13. QC Properties Groups
14. Bill of process Definition
15. Production Stages
16. Production Stage Wise Activities
17. Production Centre
18. Vendor Master
19. Customer Master
20. Standard Payment Terms
21. Stores
22. HSN & SAC Codes Masters (Single Entry)
23. Sales Division

Centralized System Administration

1. Application Wise User Roles
2. Location Wise Users
3. Location – Application wise User Accounts
4. Special Access Privileges
5. Transaction Series Control (Post - GST)

Requisition Module

1. Purchase Requisition
2. Store Requisition from Other Department

Quality Assurance Module

1. Production Batch Release (By QA In-charge)

2. Production Batch Release (By QA - Manager)
3. Item Wise Manufacturer (QA Approval)
4. Item QC Specifications (QA Approval)
5. Bill of Process (QA Approval)
6. Vendor-Item Manufacturer's (QA Approval)

19.0 SYSTEM CONSTRAINTS:

- The system at the server side should run on Linux (Red Hat 4.1 or above). The system at the client side should run on Windows 7 or above
- The System must be compatible with the existing LAN infrastructure.
- **SUPPORT AND MAINTENANCE:**

  The system hardware and software support is managed by IT department. For any upgrade in installed ERP system same should be managed by …….

22.0 ABBREVIATIONS

ABBREVIATION	FULL FORM
CSV	Computerized System Validation
URS	User Requirement specification
ERP	Enterprise Resource Planning
FIFO	First in first out
FEFO	First expiry first out
RM	Raw Material
PM	Packing Material
FG	Finished Goods
IM	Intermediate Material
GMP	Good Manufacturing Practices
A/C	Account
Qty.	Quantity
QA	Quality Assurance
IT	Information Technology
INV	Manufacturing Inventory
PUR	Purchase
PRD	Production
QCS	Quality Control

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ABBREVIATION	FULL FORM
SLM	Sales
DMS	Document Management System
MNT	Maintenance
STM	Setup
CSA	Centralized System Administration
SOP	Standard Operating Procedure
LL	Loan License
LOD	Loss on dry
GxP	Good "X" Practice where X = M, C, D, E M = Manufacturing C = Clinical D = Documentation E = Engineering
PRQ	Purchase Requisition
PO	Purchase Order
GRN	Goods Receipt Note
GRO	Goods Receipt From Others
GRL	Goods Receipt From Other Location
PRN	Purchase Return
MIL	Material Issue To Other Location
MIO	Material Issue To Others
MIP	Material Issue To Production
MID	Material Issue To Other Department
SSA	Shortage Stock Adjustment
ESA	Excess Stock Adjustment
MRD	Material Return From Other Department
QIN	• QC Intimation for Testing of Production Batch • QC Intimation for Retesting of GRN • QC Intimation for Testing of GRN
PO	Purchase Order
QCG	• QC Register Entry for GRN • QC Analysis Update for GRN
QCP	• QC Register Entry For Production • QC Analysis Update For Production
QCI	• QC Register Entry For Intimation • QC Analysis Update For Intimation

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ABBREVIATION	FULL FORM
BOP	Bill of Process
SRP	Store Requisition From Production
SRD	Store Requisition From Other Department
MRP	Material Return From Production
IMT	Intermediate Material Transfer Note
PTN	Production Transfer Note
SOR	Sales Order Regular
ISO	Invoice Using Sales Order Rates
IPM	Invoice Using Price Master Rate
FGI	Finished Goods Inward
SRN	Sales Return Note
GRT	Goods Receipt Note- Trading
WBK	Write Back Memo
WOF	Write Off Memo
PCS	Professional Consultancy Services
URS	User Requirement Specification