OPERATION PROCEDURE FOR QUALITY CONTROL MODULE

1.0 PURPOSE:

1.1 To provide an operation procedure for Quality control module in ERP software.

2.0 SCOPE:

2.1 This procedure is applicable for QC and QA department for handling of Quality control module.

3.0 RESPONSIBILITIES:

3.1 QA personnel responsible to follow the procedure for authorization of QC analysis update for production

3.2 QC department is responsible to follow the procedure as detailed in this SOP.

3.3 QC and QA Head is responsible to provide training and ensure compliance to the SOP.

4.0 REFERENCES:

4.1 ERP Systems,
Version No.:- erp2024
Application build No.: ….., DB build No.:…..
Release Date: 27/11/2024

5.0 DEFINITIONS:

5.1 Enterprise Resource Planning:- Is a process by which a company (often a manufacturer) manages and integrates the important parts of its business. An ERP management information system integrates areas such as planning, purchasing, inventory, sales, marketing, finance and human resources.

6.0 PROCEDURE::

6.1 Sampling Entry for RM & PM

6.1.1 QC Register Entry for GRN (QCG)

6.1.1.1 Specific Purpose

This transaction is used to generate the register entry for GRN after receipt from ware house.

6.1.1.2 To raise QC Register Entry for GRN

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and click on QC Register (GRN) and Click on QC Register Entry for GRN's.

Step 3: Select location, year and series and then click on new button.

Step 4: Entry date shall be generated automatically.

Step 5: Select GRN No., Item, Batch Ref. No.,

Step 6: Click sampling date generated automatically, enter sampling time, select sampled by and enter sampling qty.

Step 7: Enter allot date and select analyst from the drop down.

Step 8: Microbiologist /QC chemist name [If applicable].

Step 9: To save the transaction, click on save button.

Step 10: Transaction number (AR. No) shall be generated automatically.
Eg : MRS/2024/QCG/XXX/00001
Where MRS is location code,
2024 is current financial year,
XXX will be replaced by corresponding transaction series

Step 11: To take print, click on print and select layout id as applicable.

Step 12: To clear from QC Register Entry for GRN's data click on Clear button.

Step 13: To exit from QC Register Entry for GRN's screen click on exit button.

6.2 QC Analysis for RM & PM

6.2.1 QC Analysis Update for GRN (QCG)

6.2.1.1 Specific Purpose

This transaction is used to generate the Analysis Update for GRN after sampling is done

6.2.1.2 To raise QC Analysis Update for GRN

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and click on QC Register (GRN) on header and Click on QC Analysis Update for GRN's.

Step 3: Select location, year and series.

Step 4: Click on find and select the transaction no or on enter the AR No.

Step 5: Click on Modify and then click on Analysis Update.

Step 6: Click Sample qty., then click on test details once loading is over.

Step 7: To delete unwanted Property name, select Property name and click on footer delete button

Step 8: **For Subjective Property details**

Define Tested as "Y" for selected property name. Click on actual obs. box and change the property details.

Click on Complies or does not comply for tested property name.

For Measurable Property details

Define Tested as "Y" for selected property name. Put value for the test completed. Then click back button.

Step 9: Define Sample's result as pass or fail based on test completed. Then click back button.

Step 10: Put tick on testing completed and define test completion date and AR date.

Step 11: Select result as per requirement.

Step 12: Define Assay and LOD as applicable.

Step 13: Tick on revalidation required (If applicable) enter the retest date.

Step 14: Define Extra Info details as applicable.

Step 15: Click save button to save the transaction.

Step 16: Modify to verify and authorize the transaction

Step 17: To take print, click on print and select layout id as applicable.

Step 18: To clear the QC Analysis Update for GRN data, click on clear button.

Step 19: To exit the QC Analysis Update for GRN screen, click on exit button.

6.3 Sampling Entry for IM and FG

6.3.1 QC Register Entry for Production (QCP)

6.3.1.1 Specific Purpose

This transaction is used to generate the register entry for Production after intimation receipt from production

6.3.1.2 To raise QC Register Entry for Production

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and click on QC Register (Prod) and Click on QC Register Entry for Production.

Step 3: Select location, year and series and then Click on new button.

Step 4: Entry date shall be generated automatically

Step 5: Select Batch of, batch no., for product and batch ref no.

Step 6: Click sampling date generated automatically, enter sampling time, select sampled by and enter sampling qty.

Step 7: Enter allot date and select analyst from the drop down.

Step 8: Microbiologist /QC chemist name [If applicable].

Step 9: Verify the Batch Details.

Step 10: Click save button.

Step 11: Transaction number (AR No) shall be generated automatically.
Eg : MRS/2024/QCP/XXX/00001
Where MRS is location code,
2024 is current financial year,
XXX will be replaced by corresponding transaction series

Step 12: To take print, click on print and select layout id as applicable.

Step 13: To clear from QC Register Entry for Production data click on Clear button.

Step 14: To exit from QC Register Entry for Production screen click on exit button.

6.4 QC Analysis for IM and FG

6.4.1 QC Analysis Update for Production

6.4.1.1 Specific Purpose

This transaction is used to generate the Analysis Update for Production after sampling is done

6.4.1.2 To raise QC Analysis Update for Production

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and click on QC Register (Prod) and Click on QC Analysis Update for Production.

Step 3: Select location, year and series.

Step 4: Click on find and Select the transaction No or on enter the AR No.

Step 5: Click on Modify and then click on Analysis Update.

Step 6: Click Sample qty., then click on test details once loading is over

Step 7: **For Subjective Property details**
Define Tested as "Y" for selected property name. Click on actual obs. box and change the property details.

Click on Complies or does not comply for tested property name.

For Measurable Property details

Define Tested as "Y" for selected property name. Put value for the test completed. Then click back button.

Step 8: Define Sample's result as pass or fail based on test completed. Then click back button.

Step 9: Put tick on testing completed and define test completion date and AR date.

Step 10: Select result as per requirement

Step 11: Define Assay [If applicable]

Step 12: Click save button, to save the transaction

Step 13: Modify to verify and authorize the transaction

Step 14: To take print, click on print and select layout id as applicable.

Step 15: To clear the QC Analysis Update for Production data, click on clear button.

Step 16: To exit the QC Analysis Update for Production screen, click on exit button.

6.5 Sampling Entry for RM and PM (Retest)

6.5.1 QC Register Entry for Intimation (QCI)

6.5.1.1 Specific Purpose

This transaction is used to generate the register entry for Intimation after intimation receipt from warehouse and Production for retest

6.5.1.2 To raise QC Register Entry for Intimation (QCI)

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and Click on QC Register Entry for Intimation under QC Intimations

Step 3: Select location, year and series and then Click on new button.

Step 4: Entry date shall be generated automatically.

Step 5: Select Intimation Id. generated by Store.

Step 6: Click sampling date generated automatically, enter sampling time, select sampled by and enter sampling qty.

Step 7: Enter allot date and select analyst from the drop down.

Step 8: Microbiologist /QC chemist name [If applicable].

Step 9: Click save button, to save the transaction.

Step 10: Transaction number (AR No) shall be generated automatically.
Eg : …./2024/QCI/XXX/00001
Where …. is location code,
2024 is current financial year,
XXX will be replaced by corresponding transaction series

Step 11: To take print, click on print and select layout id as applicable.

Step 12: To clear from QC Register Entry for Intimation data, click on Clear button.

Step 13: To exit from QC Register Entry for Intimation screen, click on exit button.

6.6 QC Analysis for RM and PM (Retest):

6.6.1 QC Analysis Update for Intimation (QCI)

6.6.1.1 Specific Purpose

This transaction is used to generate the Analysis Update for Intimation after sampling is done

6.6.1.2 To raise QC Analysis Update For Intimation

Step 1: Open Quality control module.

Step 2: Click on QC Transactions and Click on QC Analysis Update for Intimation under QC Intimations

Step 3: Select location, year and series.

Step 4: Click on find and Select the AR No or enter the AR. No.

Step 5: Click on Modify and then click on Analysis Update.

Step 6: Click Sample qty., then click on test details once loading is over.

Step 7: To delete unwanted Property name, select Property name and click on footer delete button

Step 8: **For Subjective Property details**
Define Tested as “Y” for selected property name. Click on actual obs. box and change the property details.

Click on Complies or does not comply for tested property name.

For Measurable Property details:

Define Tested as "Y" for selected property name. Put value for the test completed. Then click back button.

Step 9: Define Sample's result as pass or fail based on test completed. Then click back button.

Step 10: Tick on testing completed and define test completion date and AR. date.

Step 11: Select result as per requirement

Step 12: Define Assay and LOD as applicable

Step 13: Tick on revalidation required (If applicable) enter the date

Step 14: Click save button, to save the transaction

Step 15: Modify to verify and authorize the transaction

Step 16: To take print, click on print and select layout id as applicable

Step 17: To clear the QC Analysis Update for Intimation data, click on clear button

Step 18: To exit the QC Analysis Update for Intimation screen, click on exit button

6.7 Extending AR Validity:

6.7.1 Extend AR Validity for GRN's

6.7.1.1 Specific Purpose

This transaction is used to extend retest validity after normal testing is done

6.7.1.2 To extend AR Validity for GRN's

Step 1: Login to Quality control module.

Step 2: Click on QC Transactions and click on QC Register (GRN) and Click on Extend A.R Validity for G.R.N's.

Step 3: Select Location, year and series and then click on find button.

Step 4: Click on Find to get defined AR no. and select the one you want to choose.

Step 5: Click on Modify and change the Validity in Extend Validity upto field.

Step 6: To save the changes done, click on Save button.

6.8 Track Pending Batches for QC

6.8.1 GRN's pending for QC

6.8.1.1 Specific Purpose

This transaction is used to find GRN's pending for QC

6.8.1.2 To raise GRN's pending for QC

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on QC Reports in sub header and Click on GRN's pending for QC.

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date, output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

Alternative Steps:

Step 1: Open Quality Control module

Step 2: Click on **Queries** and then Click on **GRN's pending For QC**

Step 3: Select appropriate location, store & Show records and then click on refresh button

Step 4: Click on View GRN to Check GRN details

Step 5: Click on Register Entry to redirect to the QC Register Entry for GRN

Step 6: Click on Analysis Update to redirect to the QC Analysis Update for GRN

6.8.2 Intimation pending for QC:

6.8.2.1 Specific Purpose

This transaction is used to find Intimation pending for QC

6.8.2.2 To raise Intimation pending for QC

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on QC Reports in sub header and Click on Intimation pending for QC.

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date, output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

Alternative Steps:

Step 1: Open Quality Control module

Step 2: Click on **Queries** and then Click on **Intimations Pending For QC**

Step 3: Select appropriate location, QC group & Show records and then click on refresh button

Step 4: Click on View Intimation to Check QC Intimation for re-testing of GRN

Step 5: Click on Register Entry to redirect to the QC Register Entry For Intimation

Step 6: Click on Analysis Update to redirect to the QC Analysis Update For Intimation

6.8.3 Production batches pending for QC:

6.8.3.1 Specific Purpose

This transaction is used to find Production batches pending for QC

6.8.3.2 To raise I Production batches pending for QC

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on QC Reports in sub header and Click on Production batches pending for QC.

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date, output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

Alternative Steps:

Step 1: Open Quality Control module

Step 2: Click on **Queries** and then Click on **Production Batches Pending for QC**

Step 3: Select appropriate location, production centre & Show records and then click on refresh button

Step 4: Click on View Prod. Batch to Check Production Batch Order

Step 5: Click on Register Entry to redirect to the QC Register Entry for Production

Step 6: Click on Analysis Update to redirect to the QC Analysis Update for Production

6.9 Check QC Specification Due Date:

6.9.1 QC Specifications due for renewal query

6.9.1.1 Specific Purpose

This process is used to find out due date for revision date of Item's QC specification

6.9.1.2 To raise QC Specifications due for renewal query

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on Misc Reports in sub header and Click on QC Specifications due for renewal query (Q301/RA/SA).

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date,

output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

Alternative Steps:

Step 1: Login to Quality control module.

Step 2: Click on **Queries** and then Click on **QC Specifications due for Renewal Query**

Step 3: Select required upto date and then click on refresh button

Step 4: Click on View/Edit Item's QC specifications to redirect to the Item's QC Specification

6.10 Item's Re-Testing History

6.10.1 Item's re-testing history query

6.10.1.1 Specific Purpose

This process is used to find out due date for revision date of Item's QC specification

6.10.1.2 To raise Item's re-testing history query

Step 1: Login to Quality control module.

Step 2: Go to queries and click on Item's re-testing history query.

Step 3: Select Location, Item, GRN id, Batch ref no and click on refresh.

Step 4: Select a query and press the View AR button in the middle of footer to get details.

Step 5: Press exit button to exit the screen.

6.11 Analysis of trend report

6.11.1 QC Test property trend report

6.11.1.1 Specific Purpose:

This report is used to analyze trend report of all tests performed for a specific material

6.11.1.2 To run QC Test property trend report

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on Misc Reports in sub header and Click on QC Test property trend report.

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date, output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

6.11.2 QC assay test trend report:

6.11.2.1 Specific Purpose:

This report is used to analyze trend report of all assay test performed for active material

6.11.2.2 To run QC assay test trend report

Step 1: Login to Quality control module.

Step 2: Click on Reports and click on Misc Reports in sub header and Click on QC assay Test trend report.

Step 3: Select Template code, Report code along with other details like Selecting keys, process period date, output types etc.

Step 4: Click on Create and view file button in the right side of the screen to generate and view the report.

Step 5: Click on exit button to exit the screen.

6.12 Un-Authorization of authorized transaction

6.12.1 Un-authorization Work Bench

6.12.1.1 Specific purpose:

This process is being used to un-authorize any authorized transaction

6.12.1.2 How to unauthorized transaction:

Step 1: Login to inventory module.

Step 2: Click on Authorization and Auditing, and then Click on Un-authorization Work Bench.

Step 3: Select location, year, type and series. Click on Refresh button.

Step 4: Now click on below given buttons to check functionalities.

View/Edit Transaction -> Gives provision to view and edit transaction as per selection in type and series.

Mark as unauthorized -> Gives provision to unauthorized the transaction as per selection in type and series.

Unauthorized all -> Gives provision to unauthorized all the transactions as per selection in type and series.

Step 5: To exit from the screen, click on Exit button.

7.0 ATTACHMENT:

7.1 NA

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8.0 ABBREVIATIONS:

Abbreviation	Full Form
SOP(s)	Standard Operating Procedure(s)
No.	Number
QA	Quality Assurance
qty.	Quantity
NA	Not applicable
QCG	QC Analysis Update for GRN
QCP	QC Analysis Update for Production
QCI	QC Analysis Update for Intimation
GRN	Goods Receipt Note
RM	Raw Material
PM	Packaging Material
IM	Intermediate Material
FG	Finished Goods
LOD	Loss on drying

9.0 CHANGE HISTORY:

Change control no.	Version	Reason for Changes
NA	00	NEW