Annexure - 5: Description of Functional and Operational Requirements for Quality Control Module

5.5.1 QC Register Entry for GRN's

Req. No.	Description
5.5.1.1	System has provision not to allow creating QC Register entry for GRN in back date and future date
5.5.1.2	System has provision for tested AR not to be deleted
5.5.1.3	System has provision for sampling date not be less than current date
5.5.1.4	System has provision for not to allow QC if Item's QC specification is due for revision
5.5.1.5	System has provision for GRN date can not be greater than AR entry date
5.5.1.6	System has provision for not to allow QC entry for unapproved item QC specifications
5.5.1.7	System has provision under test label not to allow to reprint once QC analysis done
5.5.1.8	System has provision to print Under test label

5.5.2 QC Analysis Update For GRN's

Req. No.	Description
5.5.2.1	System has provision to pass, reject, part accepted or pass with deviation
5.5.2.2	System has provision not to allow accepting, rejecting or consumed more qty. than the batch qty.
5.5.2.3	System has provision for test completion date must be equal to or greater than allotment date.
5.5.2.4	System has provision for next level authorization be available.
5.5.2.5	System has provision for sample cannot pass if any tests fails
5.5.2.6	System has provision for batch cannot pass if any sample fails
5.5.2.7	System has provision for QC validity date not be greater than expiry date
5.5.2.8	System has provision for approved label not to allow for reprint, allowed only with proper justification for the deviation
5.5.2.9	System has provision approved label should not allow to generate once test is failed.
5.5.2.10	System has provision rejected label should not allow to generate once test is passed.
5.5.2.11	System has provision to reduce sample size once test is completed
5.5.2.12	System has provision to print Approved Label, Certificate of Analysis

Annexure - 5: Description of Functional and Operational Requirements for Quality Control Module

5.5.3 Extend AR validity for GRN's

Req. No.	Description
5.5.3.1	System has provision not to allow extend unauthorized AR
5.5.3.2	System has provision not to allow extend if revalidation data is not defined
5.5.3.3	System has provision for unauthorized person not to allow extend

5.5.4 QC Register Entry For Production

Req. No.	Description
5.5.4.1	System has provision not to allow creating QC Register entry for Production in back date and future date
5.5.4.2	System has provision for sampling date not be less than current date
5.5.4.3	System has provision for tested AR not to be modified
5.5.4.4	System has provision for tested AR not to be deleted
5.5.4.5	System has provision for disallow QC if Item's QC specification is due for revision
5.5.4.6	System has provision for disallow QC entry for unapproved items QC specification

5.5.5 QC Analysis Update For Production

Req. No.	Description
5.5.5.1	System has provision to pass, reject, part accepted or pass with deviation.
5.5.5.2	System has provision not to allow accepting, rejecting or consumed more qty. than the produce qty.
5.5.5.3	System has provision for test completion date must be equal to or greater than allotment date.
5.5.5.4	System has provision for next level authorization be available.
5.5.5.5	System has provision for sample cannot pass if any tests fails
5.5.5.6	System has provision for batch cannot pass if any sample fails
5.5.5.7	System has provision for QC validity date not be greater than expiry date
5.5.5.8	System has provision for Approved label not allow for reprint, allowed only with proper justification for the deviation
5.5.5.9	System has provision for approved label not to allow to generate once test is failed.
5.5.5.10	System has provision for rejected label not to allow to generate once test is passed
5.5.5.11	System has provision to reduce sample size once test is completed
5.5.5.12	System has provision to print Approved Label, Certificate of Analysis Report

Annexure - 5: Description of Functional and Operational Requirements for Quality Control Module

5.5.6 QC Register Entry for Intimation

Req. No.	Description
5.5.6.1	System has provision not allow creating QC Register entry for Intimation in back date and future date
5.5.6.2	System has provision for sampling date not be less than current date
5.5.6.3	System has provision for tested AR cannot be modified
5.5.6.4	System has provision for tested AR cannot be deleted
5.5.6.5	System has provision for disallow QC if Item's QC specification is due for revision
5.5.6.6	System has provision for Allotment date can not be less than sampling date
5.5.6.7	System has provision for under test label not to allow to reprint once QC analysis done
5.5.6.8	System has provision to print Under test label

5.5.7 QC Analysis Update For Intimation

Req. No.	Description
5.5.7.1	System has provision to Pass, reject, Part accepted or pass with deviation
5.5.7.2	System has provision not to allow accepting, rejecting or consumed more qty. than the batch qty.
5.5.7.3	System has provision for Test completion date must be equal to or greater than allotment date.
5.5.7.4	System has provision for Next level Authorization be available.
5.5.7.5	System has provision for Sample cannot pass if any tests fails
5.5.7.6	System has provision for Batch cannot pass if any sample fails
5.5.7.7	System has provision for QC validity date not be greater than expiry date
5.5.7.8	System has provision for Approved label not allow for reprint, allowed only with proper justification for the deviation
5.5.7.9	System has provision for approved label not to allow to generate once test is failed
5.5.7.10	System has provision for rejected label not to allow to generate once test is passed.
5.5.7.11	System has provision to reduce Sample size once test is completed
5.5.7.12	System has provision to print Approved label and Certificate of Analysis Report

5.5.8 GRN's Pending For QC

Req. No.	Description
5.5.8.1	System has provision for unauthorized user not be able to view GRN
5.5.8.2	System has provision for unauthorized user not be able to view register entry

Annexure - 5: Description of Functional and Operational Requirements for Quality Control Module

Req. No.	Description
5.5.8.3	System has provision for unauthorized user not be able to view analysis update

5.5.9　Intimation Pending For QC

Req. No.	Description
5.5.9.1	System has provision for unauthorized user not be able to view intimation
5.5.9.2	System has provision for unauthorized user not be able to view register entry
5.5.9.3	System has provision for unauthorized user not be able to view analysis update

5.5.10　Production Batches Pending For QC

Req. No.	Description
5.5.10.1	System has provision for unauthorized user not be able to view batch release details
5.5.10.2	System has provision for unauthorized user not be able to release batch

5.5.11　QC Specification Due for Renewal Query

Req. No.	Description
5.5.11.1	System has provision for unauthorized user not be able to access QC specifications due for renewal query

5.5.12　Items Re-Testing history Query

Req. No.	Description
5.5.12.1	System has provision for unauthorized user not be able to access QC specifications due for renewal query

5.5.13　QC Test Property Trend Report

Req. No.	Description
5.5.13.1	System has provision for unauthorized user not to be able to access the screen to run the report
5.5.13.2	System has provision to display test value against each test along with AR Id. for particular material

Annexure - 5: Description of Functional and Operational Requirements for Quality Control Module

5.5.14 QC Assay Test Trend Report

Req. No.	Description
5.5.14.1	System has provision for unauthorized user not to be able to access the screen to run the report
5.5.14.2	System has provision to display test value against each active ingredient along with AR Id. details

5.5.15 Un-Authorization Work Bench

Req. No.	Description
5.5.15.1	System has provision to restrict unauthorized user to un-authorize transaction