Annexure -9: Description of Functional and Operational Requirements for Quality Assurance Module

5.9.1 Item Wise Manufactures (QA Approval)

Req. No.	Description
5.9.1.1	System has provision for unauthorized user not be able to create Item wise Manufacturers (QA Approval)
5.9.1.2	System has provision for user 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

5.9.2 Item's QC Specifications (QA Approval)

Req. No.	Description
5.9.2.1	System has provision to approve QC Specification manually
5.9.2.2	System has provision to set access rights for authorized users to approve Item QC Specification
5.9.2.3	System has provision not to allow Item QC Specifications approval by QA if Item QC Specifications is not authorized by QC

5.9.3 Bill of Process (QA Approval)

Req. No.	Description
5.9.3.1	System has provision for bill of process (QA Approval) to be manually generated.
5.9.3.2	System has provision for unauthorized user not be able to create bill of process (Q.A. approval)
5.9.3.3	System has provision below fields to be made mandatory during BOP approval ➢ Master Formula No. & Dated ➢ Product Lic. No. & expiry Date

5.9.4 Vendor-Item Manufacturer's (QA Approval)

Req. No.	Description
5.9.4.1	System has provision for unauthorized user not be able to create Vendor-Item Manufacturer's QA Approval.
5.9.4.2	System has provision for user not be able to create Vendor Item Manufacturer's QA Approval unless following transactions is performed Vendor-item catalog

Annexure -9: Description of Functional and Operational Requirements for Quality Assurance Module

5.9.5 Production Batch Release (By QA In-charge)

Req. No.	Description
5.9.5.1	System has provision for unauthorized user not be able to release the Production batch
5.9.5.2	System has provision for unauthorized user not be able to modify the production batch release.
5.9.5.3	System has provision for uncompleted batch cannot be released by QA
5.9.5.4	System has provision for disallow modification of batch release by QA indicator
5.9.5.5	System has provision for Production Batch Release Date not be less than Batch date.
5.9.5.6	System has provision for not to allow production batch release for AR is not authorized
5.9.5.7	System has provision not to allow release batch in future date
5.9.5.8	System has provision to print Production Batch Release (by QA In-charge)

5.9.6 Production Batch Release (By QA Manager)

Req. No.	Description
5.9.6.1	System has provision for unauthorized user not be able to release the Production batch
5.9.6.2	System has provision for unauthorized user not be able to modify the production batch release.
5.9.6.3	System has provision for uncompleted batch cannot be released by QA
5.9.6.4	System has provision for disallow modification of batch release by QA indicator
5.9.6.5	System has provision for Production Batch Release Date not be less than Batch date.
5.9.6.6	System has provision for not to allow production batch release for AR is not authorized
5.9.6.7	System has provision not to allow release batch in future date
5.9.6.8	System has no provision not allow to remove the approval tag once batch is released.
5.9.6.9	System has provision to print Production Batch Release (by QA Manager)