



**Operational SOPs for ALL non-GMP Production Sites –**  
**Protocols and Regulation**

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## **Quality Assurance (QA) Management Procedures**

In this section you will find procedures and practical work instructions on every aspect of Quality Assurance and Technical areas to build up a highly effective Quality Management System.

You will find Standard Operating Procedures for establishing quality assurance practices, such as preparation, maintenance, definition, classification and change Control of Quality and Master file documentation necessary for your products; recording and reporting procedure for deviations management; quality concern investigation; customer complaint handling procedure; quality audit procedures; vendor assessment, evaluation and certification procedure; rework procedures for the defective manufactured products; procedures on training for staff and other procedures.

### **Extended Table of Contents**

#### **QMS-005 How to Write Standard Operating Procedure**

This SOP describes standard SOP format that you can use immediately for your quality procedures. This SOP has instructions on how to write a formal Operating Procedure for your systems which your people can follow everyday.

#### **QMS-010 All Documents - Classification, Definition and Approval Matrix**

In this SOP you will find all type of quality and Technical/Master file documents to build up a good quality management system for your manufacturing sites, definition of documents, their classification, approval requirements and retention requirements. This procedure has schematic diagrams for your understanding of how different types of documents are prepared and stored in a typical documentation database.

#### **QMS-015 Quality Documentation Management and Change Control**

This SOP describes how to generate new quality documents or change control of existing documents, review of quality documents, role of document author, approver, document control officer and satellite file administrator. In this SOP you will also find numbering systems of different quality documents like audit files, SOPs, forms, QA agreements, project files and their effective archiving system.

#### **QMS-020 Documentation Rules for Documents**

This SOP describes the principles to be followed in documents, entry of data and information, signature requirements and correction technique of incorrectly entered data or information.

#### **QMS-025 Quality Documentation - Control, Tracking and Distribution**

In this SOP you will find mainly the role of document control officer during the initiation, creation, circulation and approval of new quality related documents. It also describes the procedure of modification and review of existing document using a documentation database. Management of existing and superseded documents is also a part of this procedure. You will see all the forms referred during the instruction are attached at the end of the procedure.

#### **QMS-030 Preparation, Maintenance and Change Control of Master Documents**

This SOP focuses particularly on the management of master file documents like specifications, control methods, raw materials, finished goods and packaging specification and test reports, formulation, stability files etc required to generate during the product registration in the market. This SOP gives instruction on their creation, change control, numbering system, approval requirements and maintenance in a simple master file database. You will see all the forms referred during the instruction are attached at the end of the procedure.

### **QMS-035 Deviation Report System**

It is a regulatory requirement to capture all sorts of deviations evolves in your systems in order to maintain the continuous improvement of your processes and systems. This SOP describes how to categorize the deviations between production, audit, quality improvements, technical deviations, customer complaints and environmental, health and safety deviations. It describes the management responsibilities of initiating deviation, capture data, analysis, investigation, determination of assignable causes, generation of management report and initiatives to be taken on corrective and preventative actions.

### **QMS-040 Product Shelf Life**

This simple SOP describes the meaning of shelf life and provides direction on how to interpret shelf lives and storage conditions for your raw materials from the Certificate of Analysis, determining expiry date for your finished products by use of raw material date of manufacturing and their shelf lives.

### **QMS-045 Vendor Selection and Evaluation**

This SOP describes the procedure to be followed during the vendor assessment and vendor evaluation for purchasing of raw materials, critical and non critical packaging components, laboratory supplies, engineering supplies and imported finished goods from the vendor. These instructions are essential for approving prospective vendor.

### **QMS-050 Vendor Certification**

This procedure aims to describe the process by which a vendor may be certified to supply materials or services. This procedure applies to vendors that supply a material or service to be used at any stage of manufacture by operations. Here you will get the roles of each department in the process to certify an approved vendor.

### **QMS-055 Product Complaint Procedure**

This procedure covers the receipt, logging, evaluation, investigation and reporting system of all complaints received from customers for the marketed products. This SOP contains step by step instruction to be followed in the customer complaint management like numbering of complaint, registration, evaluation of complaints, determination of assignable cause for the complaint deviation, implementation of corrective and preventative actions, trending of complaints and handling of counterfeit products.

### **QMS-060 Annual Product Review**

This procedure provides a guideline to annual product review which is required to be performed for each product produced for the commercial market to evaluate data, trends and to identify any preventative or corrective action that would lead to product quality improvements and report them to management.

### **QMS-065 Rework Procedure**

This SOP contains the step by step instruction to be followed when the rework of an in-process or completed finished good is required. This SOP covers the reworks of in-process manufactured goods where the new batch number is introduced for the reworked part and rework of manufactured finished good keeping the same batch number. This SOP also describes how to create rework protocols for each individual case.

### **QMS-070 Authorized Person**

This simple procedure describes the accreditation, accountabilities and responsibilities of an Authorized Person, responsible for release of finished goods for sale.

### **QMS-075 Product Identification and Traceability**

The purpose of this SOP is to define the method used for the identification of all contributing materials that could affect product quality and to ensure their full traceability. Here you will find instruction on all the records and documents used for the identification and traceability of incoming raw materials and outgoing finished goods.

### **QMS-080 Audits**

This SOP describes the process of planning, performing, reporting and follow-up of different audits for your systems like Internal Quality audit, Vendor audit, Environmental Health and Safety (EHS) audit, EHS workplace inspection, Housekeeping audit. This SOP also describes the process to be followed by manufacturing personnel during an audit from a Regulatory authority.

### **QMS-085 Example-Checklist for Batch Documentation**

This SOP describes the identification of all documentation relevant to a production process in the form of Batch Documentation Checklists and to ensure their collection by completion of the checklists by Authorized Persons. This procedure is based on an example of tablet packaging process described in the Manufacturing category.

### **QMS-090 Evaluation of Batch Documentation and Release for Sale**

This procedure describes the process of collection, evaluation and record of batch related document generated during the production of a batch before an authorized person can release the batch for sale. This procedure is based on an example of tablet packaging process described in the Manufacturing category.

### **QMS-115 Criteria for Sourcing of RM, Critical Packaging Components and Imported Finished Goods**

The purpose of this SOP is to describe the process for approval of an external vendor/manufacturer supplying products to your company. It covers raw materials (including bulk products from subsidiaries and contract manufacturers), critical packaging components in contact with product and imported finished goods. The SOP also references affiliated documentation detailing the scope of active materials used and the approved manufacturers of these materials.

### **QMS-120 Quality Concern Investigation Process**

This procedure contains instruction to be followed when conducting Investigations and to raise and assess Deviation Report when an Investigation or Incident Investigation occurs. This procedure is to be used in conjunction with SOP QMS-035, which covers the approval and follow up activities associated with a Deviation Report. Here you will find collection of information for an incident or a deviation, steps to be followed for a cross functional investigation, reporting and implementing of the outcomes of investigation.

## **Audit Training Manuals**

1. Audit - 01 Auditing Principles for Audit
2. Audit - 02 Understanding Worldwide Regulatory Requirements
3. Audit - 03 Auditing a Personnel & Training System
4. Audit - 04 Auditing a Deviation Management System
5. Audit - 05 Auditing a Validation System
6. Audit - 06 Auditing a Change Management System
7. Audit - 07 Auditing a Complaint System
8. Audit - 08 Auditing a Documentation System
9. Audit - 09 Auditing a Calibration, Preventative Maintenance & Housekeeping System
10. Audit - 10 Auditing Computerized Systems
11. Audit - 11 Auditing Utilities System
12. Audit - 12 Auditing Warehouse and Distribution System
13. Audit - 13 Auditing Environmental Monitoring System

14. Audit - 14 Auditing Microbiology and Sterility Testing Laboratory - N/A
15. Audit - 15 Auditing an Analytical Quality & Stability Testing Laboratory
16. Audit - 16 Auditing a Material Handling System
17. Audit - 17 Auditing an Active API Manufacturer
18. Audit - 18 Auditing Packaging Material Vendors

### **Process, Cleaning and Methodology Validation Procedures**

In this section you will find procedures and practical work instructions on different aspects of validation necessary to build up an effective validation and revalidation systems. You will find procedures on validation-concept and procedure, revalidation procedure, method validation procedure, procedure for cleaning validation, validation of laboratory instruments, equipment specification and qualification and in-house trial procedure. All procedures have reference of prepared Forms and Templates for effective record keeping and reporting purposes. Forms are attached at the end of each procedure.

### **SOP list**

#### **VAL-005 Validation-Concept and Procedure**

This procedure describes general validation concepts and practices, the way processes and systems must be qualified/validated and the confirmatory documentation required. Here you will find the philosophy of validation, responsibilities, validation approaches of design qualification, installation qualification, operational qualification, performance qualification, cleaning validation, method validation, computer validation, general and specific criteria of validation, validation documentation and change control, validation reporting, guidelines of validation acceptance criteria.

#### **VAL-010 Revalidation Procedure**

This procedure contains step by step instruction on initiation of revalidation categories, changes that warrant revalidation programs, basic steps of revalidation procedure, revalidation activities and specific responsibilities, revalidation protocols, revalidation timing, equipment checklist, revalidation discrepancy procedure, release of revalidated equipment, preparation of the revalidation reporting file.

#### **VAL-015 Method Validation Procedure**

This procedure provides a guideline for a validation on the characteristics that must be considered during the validation of an analytical testing procedure. The procedures set out in this SOP apply to qualitative and quantitative analytical methods which are used to test finished goods, in-process material, excipients and raw materials in support of registration documentation and cleaning validations and management responsibilities towards completing those method validation tasks.

#### **VAL-020 Procedure for Cleaning Validation**

This SOP describes the types of cleaning process and cleaning agents of process equipments and their validation, complete instruction on cleaning validation procedure, calculation of acceptance limits for rinse and swab samples, calculation of acceptance limits for swabs, analytical method validation for cleaning, cleaning validation test protocols and change control for revalidation.

#### **VAL-025 Validation of Laboratory Instruments**

This procedure describes the validation practices for laboratory instrument/equipment to be validated or calibrated and the confirmatory documentation required showing that the instrument/equipment is capable and operating effectively for its intended purpose. This procedure has practical instruction on Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) to be performed by the qualified equipment service technician in the presence of the laboratory staff with reference to the instrument/equipment manual.

### **VAL-030 Equipment Specification and Qualification**

This procedure describes in detail the procedures for the procurement of equipment, incorporating standardized demand specifications and Installation Qualification documentation, to ensure that equipment procured complies with in-house requirements and standards and conform to Good Engineering Practice, to detail the general procedure to be followed regarding the reporting of Factory and Site Acceptance Tests, to detail the manner by which the equipment Installation Qualification is documented.

### **VAL-035 In-House Trial Procedure**

The purpose of this SOP is to define common procedures to follow when organizing Trials/Evaluation Studies for the purpose of process improvement, equipment capability and validation studies. It defines the responsibilities within the trial process and documents that need to be considered when preparing the Trial documentation to ensure that the trial meets and where applicable validation requirements. This SOP defines the procedures for conducting in house stand-alone trials on systems, processes and equipment. There can be an overlap between a trial and validation in that Trial documentation may form part of a latter process validation, (i.e. concurrent and prospective validation) and qualifications (OQ, PQ).

### **Quality Control Analytical Laboratory Procedures**

1. LAB-005 Retest Dating of Raw Materials
2. LAB-010 Calibration Policies for Laboratory Instruments
3. LAB-015 Archiving Laboratory Documentation
4. LAB-020 Management of Reference Substances
5. LAB-025 Laboratory Workbook
6. LAB-030 Creation of Certificate of Analysis
7. LAB-035 Managing Analytical Reagents
8. LAB-040 Laboratory Waste Management
9. LAB-045 Retention Samples Management in Laboratory
10. LAB-050 Laboratory Supplier Approval
11. LAB-055 Laboratory Results Out of Specification Investigation
12. LAB-055 Appendix - Flowchart - Handling of OOS Results
13. LAB-060 Laboratory Testing and Documentation of Raw Materials
14. LAB-060 Appendix - Flowchart of Raw Materials through Laboratory
15. LAB-065 Laboratory Testing and Documentation of Finished Products
16. LAB-065 Appendix - Flowchart for Finished Goods
17. LAB-070 Preparation and Maintenance of Stability Protocols for s Products
18. LAB-075 Stability and Trial Testing Procedure for s Products

## **Quality Control Laboratory Procedures**

In this section you will find procedures and practical work instructions on every aspect of analytical laboratory conduct necessary to build up an effective Quality Control System. You will find practical procedures on Retest Dating of Raw Materials; Calibration Policies for Laboratory Instruments; Archiving Laboratory Documentation; Management of Reference Substances; GLP requirements of Laboratory Workbook; Creation of Certificate of Analysis; Managing Analytical Reagents; Laboratory Waste Management; Managing of Retention Samples in Laboratory; Laboratory Supplier Approval; Laboratory Results: Out-of-Specification Investigation; Raw Materials- Laboratory Testing and Documentation; Finished Goods - Laboratory Testing and Documentation; Preparation and Maintenance of Stability Protocols(s); Stability and Trial Testing Procedure(s). All procedures have reference of prepared Forms for effective record keeping and reporting purposes. Forms are attached at the end of each procedure.

## **SOP lists**

### **LAB-005 Retest Dating of Raw Materials**

The purpose of this procedure is to describe how to run the expired stock report; to describe how to define the requirements for the retesting and assignment of storage periods for active ingredients, excipients and raw materials; to instruct retesting procedure and to determine the status of a finished goods batch with a shorter shelf life.

### **LAB-010 Calibration Policies for Laboratory Instruments**

This SOP describes the calibration policies of laboratory instruments/ equipments. It describes labeling and security requirements of laboratory instruments/ equipments. This SOP also describes the investigational steps to be required in the case of failed calibration.

### **LAB-015 Archiving Laboratory Documentation**

This procedure describes retention and disposal procedures of laboratory documentation, general laboratory documentation system that includes handling of rejected raw material and finished product reports, finished goods certificate of analysis, finished goods register, raw material certificate of analysis, raw material register, trend cards, procedure for long term document retention.

### **LAB-020 Management of Reference Substances**

This SOP describes the ordering, referencing, storing, coding, use and general register maintenance of primary and impurity reference substances, primary reagent reference solutions, secondary raw material reference substance, assay testing procedure of secondary raw material reference substance, use of secondary raw material reference substance in the laboratory routine analysis, determination of expiry date and re-test date of reference substances.

### **LAB-025 Laboratory Workbook**

This SOP describes types of laboratory workbooks, general and requirements of using workbooks, analytical data entry in the workbook, formatting of laboratory workbooks for routine testing, experiments and trials, workbook retention policy, instruction on data entry for incomplete experiments and additional data.

### **LAB-030 Creation of Certificate of Analysis**

The purpose of this procedure is to define the content and format of a Certificate of Analysis (C/A) and Certificate of Manufacture (C/C) and to provide guidance for issuing a Certificate of Analysis or Certificate of Manufacture and to locate the appropriate data required for this task.

### **LAB-035 Managing Analytical Reagents**

This procedure identifies the need for all analytical reagents and solutions prepared from the reagents, to have an assigned expiry date and storage conditions recorded on the label. Here you will find the procedure for purchase and management of analytical reagents and laboratory prepared reagents.



**LAB-040 Laboratory Waste Management**

This simple procedure describes how to dispose off laboratory generated wastes of toxic, explosive, flammable, corrosive, oxidizing and biologically damaging natures.

**LAB-045 Retention Samples - Laboratory**

The purpose of this SOP is to describe the finished good and raw material sample retention procedures, products manufactured and/or received onsite and/or chemically tested by the Laboratory.

**LAB-050 Laboratory Supplier Approval**

In this simple SOP you will find the procedures for approving laboratory suppliers and criteria for the purchase of equipment, instrumentation, consumables, durables and glassware for the laboratory.

**LAB-055 Laboratory Results-Out Of Specification Investigation**

This procedure describes the actions to be taken by an analyst in the event the result of a test does not conform to raw material/components or finished products specifications for physical and chemical tests. An out of specification (OOS) result does not necessarily mean the batch under investigation fails and shall be rejected. The OOS results shall be investigated and the findings of the investigation, including re-test results shall be interpreted to evaluate the batch and reach a decision regarding release or rejection.

**LAB-060 Raw Materials-Laboratory Testing and Documentation**

This SOP describes the procedure for sampling, location, pre-testing, testing and documentation of all raw materials and components subject to test, out of specification results, microbiological tests and release procedure for passed raw materials and components.

**LAB-065 Finished Goods-Laboratory Testing and Documentation**

This SOP describes the procedure for sampling, location, pre-testing, testing and documentation of all finished products subject to test, reagents and standards to be used for analysis, management of out of specification results, microbiological tests and release procedure for passed finished goods.

**LAB-070 Preparation and Maintenance of Stability Protocols(s)**

This procedure describes the preparation and management of Stability Protocols for marketed products. This procedure is applicable to all protocols for stability studies on commercial products. The responsibility of the commercial Site Stability Manager for creating and maintaining protocols that are required for studies that came as a result of validation or process deviation.

**LAB-075 Stability and Trial Testing Procedure(s)**

To describe the steps necessary to ensure the effective control of stability and trial testing programs of new and existing products. This procedure is focused on setting up of stability programs, testing, reporting, general sampling procedure for stability programs, data generation and analysis, annual maintenance of stability, new product stability procedure, procedure for in-house trials, reporting and interpretation of trials and conclusion of the trial program.

**Warehouse Management Procedures**

1. PUR-005 Material Purchasing Information Record and Source List
2. PUR-010 Generation of Purchase Order For Inventory and Consumables
3. WAR-005 Procedure for Receipt of Incoming Goods
4. WAR-010 Incoming Raw Materials and Components-Handling by QC Sampler
5. WAR-015 Warehouse Processing Issues, Returns and Rejects

6. WAR-020 Dispatch of Goods From Warehouse
7. WAR-025 Warehouse Inventory Management Procedure
8. WAR-030 Design of Warehouse Locations and Storage Area
9. WAR-040 Finished Goods Transfer to Quarantine and Distribution Warehouse
10. WAR-045 Sampling Procedure of Raw Materials
11. WAR-050 Sampling of Components and Printed Materials
12. WAR-055 Work in Progress Area
13. WAR-060 Safety Procedure of Warehouse Racking
14. WAR-065 Forklift Operation in Warehouse
15. WAR-075 Example of Tablet Dispensary Procedure
16. WAR-080 Example of Tablet Sampling Procedure as Raw Material

#### **Environmental Health and Safety (EHS) Procedures**

1. EHS-005 Hazardous Chemical Substance Management
2. EHS-010 Environmental, Health and Safety Risk Management
3. EHS-010 Figure 1 Assess the risk (Risk Matrix)
4. EHS-015 Waste Removal Process
5. EHS-020 Identifying EHS Issues
6. EHS-025 EHS Incident Management Procedure
7. EHS-030 First Aid Procedure

## All Quality Forms

1. Form-010 Sample Request Form
2. Form-015 Warehouse Information Form
3. Form-020 Bin Sheet
4. Form-025 Return to Bulk Store
5. Form-030 Issue for Production
6. Form-035 Example-Bulk Tablet Sampling Form
7. Form-040 Physical Inventory Count Form
8. Form-045 Warehouse Bin Sheet Reconciliation Form
9. Form-050 Warehouse Periodic Inventory Count Sheet
10. Form-055 Material Transfer Order Form
11. Form-060 Material Transfer Order-Interim Production Form
12. Form-065 Material Transfer Order-Reject Form
13. Form-070 Material Transfer Order-Return form
14. Form-075 Goods Receipt Slip
15. Form-080 In-House Identification Label
16. Form-085 Released Stickers
17. Form-090 Sampled Stickers
18. Form-095 Rejected Stickers
19. Form-100 Sampled Partial Stickers
20. Form-105 Sampling Label
21. Form-110 Pallet Racking Damage Log form
22. Form-115 Warehouse Racking Checklist
23. Form-120 Printed Material Sample Sheet
24. Form-125 Example-Batch Reconciliation Sheet for Tablet Packing
25. Form-135 Pest Sightings Reports
26. Form-140 Visitor Entry Into The Factory
27. Form-145 IBC Cleaning Tag
28. Form-155 Weight Checker Weight Record

29. Form-160 Example- Line Clearance, Opening and Cleaning form for Tablet Packing
30. Form-165 Pallet ID Form
31. Form-170 Shipper Label Format
32. Form-175 Vacuum Leak Test - Hourly Form
33. Form-180 Vacuum Leak Test - New Foil and PVC Roll Form
34. Form-185 Balance Calibration Logbook
35. Form-205 Employee Log Form
36. Form-210 Goods Booking Slip
37. Form-215 Partial Shipper Stickers
38. Form-220 Material Purchasing Information Record
39. Form-225 Purchase Order Form
40. Form-235 Monthly Production Schedule Form
41. Form-240 Finished Goods Batch With Impending Expiry
42. Form-245 Laboratory Master File of Instruments
43. Form-250 Finished Goods Register
44. Form-255 Raw Material Register
45. Form-260 Finished Goods Trend Card
46. Form-265 Raw Material Trend Card
47. Form-270 Laboratory and QA Document Log Sheet and Box Labels
48. Form-275 Workbook Checklist
49. Form-280 Reagent Storage Location Form
50. Form-285 Prepared Reagent Label Form
51. Form-290 Chemical Waste Disposal
52. Form-295 Raw Material Retention Sample Register Log
53. Form-300 Finished Goods Retention Sample Register Log
54. Form-305 Laboratory Investigation and Report form
55. Form-310 Raw Material Out of Specification Investigation form
56. Form-320 Template of Certificate of Analysis
57. Form-330 Primary and Impurity Substance Summery Sheet

58. Form-335 Expired Raw Material Form
59. Form-340 Trial Checklist
60. Form-345 Primary Reagent Ref. Substance (PRRS) Summery Sheet
61. Form-365 Master Document Change Control Form
62. Form-370 Validation Discrepancy Form
63. Form-375 Validation Project Log Form
64. Form-380 IBC Identification Label
65. Form-385 Vendor Audit Questionnaire
66. Form-390 New Supplier Assessment Form
67. Form-395 SOP Ready for Signing
68. Form-400 Employee Signature Register
69. Form-405 Complaint Investigation Report
70. Form-410 Document Location in Satellite File
71. Form-415 Library Log Form
72. Form-420 Request for New Chemical Approval
73. Form-425 Housekeeping Audit Check Sheet for Laboratory
74. Form-430 Housekeeping Audit Check Sheet for Production Services
75. Form-435 Housekeeping Audit Check Sheet for Electrical & Mechanical Workshop
76. Form-440 Housekeeping Audit Check Sheet for Warehouse
77. Form-445 EHS Workplace Instruction Checklist
78. Form-450 Deviation Report Form
79. Form-455 Incident or Investigation Report Form
80. Form-460 Register of Contracts
81. Form-465 Complaints Details Form
82. Form-470 New Chemical Approval Certificate
83. Form-475 Housekeeping Audit Check sheet for Dispensary
84. Form-480 New Chemical Rejection Advice
85. Form-485 Housekeeping Audit Check Sheet for Tablet Production
86. Form-490 Laboratory Testing Form For Customer Complaint Enquiry

87. Form-495 Form Ready for Signing
88. Form-500 Training Participant Log
89. Form-505 Document Creation or Change Request
90. Form-510 Product To Be Reworked
91. Form-515 Goods Return for Rework Form
92. Form-520 Material Transfer Order Form
93. Form-525 Hazardous Chemical Assessment Checklist
94. Form-530 Reading Compliance Form
95. Form-535 Agreement Log
96. Form-540 Pallet Booking Information
97. Form-545 Raw Material Sampling Log
98. Form-550 Finished Goods Shipping Form
99. Form-555 Example-Batch Documentation Checklist for Tablet Packing
100. Form-560 Test and Retention Sample Log Book
101. Form-565 QA Inspection Sheet
102. Form-570 Process Data Collection Form
103. Form-575 Incident Investigation Form
104. Form-580 Incident Communication Form
105. Form-585 Contents of First Aid Emergency Kits