



Operational SOPs for ALL Production Sites -
Protocols and Regulations

August, 2009

Master Table of Contents – Complete

GMP Quality Assurance and Compliance Procedures

1. QMS-005 How to Write Standard Operating Procedure
2. QMS-010 All Documents - Classification, Definition and Approval Matrix
3. QMS-015 GMP Quality Documentation Management and Change Control
4. QMS-020 Documentation Rule for GMP Documents
5. QMS-025 GMP Quality Documentation - Control, Tracking and Distribution
6. QMS-030 Preparation, Maintenance and Change Control of Master Documents
7. QMS-035 Pharmaceutical Deviation Report System
8. QMS-040 Shelf Life of Product
9. QMS-045 Vendor Selection and Evaluation Procedure
10. QMS-050 Vendor Certification Procedure
11. QMS-055 Pharmaceutical Product Complaint Procedure
12. QMS-060 Annual Product Review
13. QMS-065 Manufacturing Rework Procedure
14. QMS-070 Responsibility of Authorized Person
15. QMS-075 Procedure for Product Identification and Traceability
16. QMS-080 GMP Audit Procedures
17. QMS-085 Example of Checklist for Batch Documentation
18. QMS-090 Evaluation of Batch Documentation and Release for Sale
19. QMS-095 GMP Training Procedure
20. QMS-100 How to Write GMP Training Materials
21. QMS-105 House Keeping Audit Procedure
22. QMS-110 Management and Control of Contract Work
23. QMS-115 Criteria for Sourcing of Raw Materials, Packaging Components & Imported Finished Goods
24. QMS-120 Quality Concern Investigation Process
25. TEMPLATE-085 Training Report Template
26. TEMPLATE-090 Form Template

27. TEMPLATE-095 SOP Template
28. TEMPLATE-100 Quality Assurance Agreement Template
29. TEMPLATE-105 Third Party Manufacture Dispatch Report Template
30. TEMPLATE-110 In-House Manual Template
31. TEMPLATE-115 Protocol Rework- Manufactured Finished Goods
32. TEMPLATE-120 Vendor Audit Report Template
33. TEMPLATE-125 Protocol Rework- In Process Manufactured Goods
34. TEMPLATE-130 Position Paper Template
35. TEMPLATE-135 Control Method Template
36. TEMPLATE-140 Formulation Template
37. TEMPLATE-145 Finished Product Specification and Test Report Template
38. TEMPLATE-150 Packaging Material Specification and Test Report
39. TEMPLATE-155 Bill of Materials Template

Quality Assurance (QA) Management Procedures

In this episode 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 for your pharmaceuticals business.

In this area 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 Process; customer complaint handling procedure; quality audit procedures; vendor assessment, evaluation and certification procedure; rework procedures for the defective manufactured products; procedures on training for your staffs and many other procedures according to your need.

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. Templates are listed separately.

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, satellite file management, 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, manuals, training files, QA agreements, project files etc and their effective archiving system.

QMS-020 Documentation Rule for GMP Documents

This SOP describes the principles to be followed in GMP 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 particularly focused 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 Shelf Life of Product

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-095 GMP Training

This SOP describes how to design and deliver GMP related trainings for your manufacturing staffs, training assessment design, recording of assessment and preparation of training reports.

QMS-100 How to Write Training Materials

This simple SOP contains instructions on how to write training materials, identification of training requirements, available resources, and preparation of training aid checklists for your manufacturing staffs.

QMS-105 House Keeping Audit Procedure

This SOP describes the requirements, checklists and reporting procedure on housekeeping audits. Individual checklist forms are attached at end of the procedure for different areas like process, laboratory, engineering stores, warehouses. This procedure also describes the handling of non-compliance found during the housekeeping audits.

QMS-110 Management and Control of Contract Work

The procedure describes the management and control of contract work provided by the contractors for packaging and finished products for your company as well as control of contract works done by your company on behalf of others.

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 for 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.

Pharmaceutical Audit Training Manuals

1. Audit - 01 Auditing Principles for GMP 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

Pharmaceutical Process / Cleaning / Method / Computer Validation

1. VAL-005 Validation - Concept and Procedure
2. VAL-010 Revalidation Procedure
3. VAL-015 Method Validation Procedure
4. VAL-020 Procedure for Cleaning Validation
5. VAL-025 Validation of Laboratory Instruments
6. VAL-030 Equipment Specification and Qualification
7. VAL-035 In-House Trial Procedure
8. VAL-040 Computer System Validation
9. VAL-045 Impact Assessment for Computerized Systems
10. VAL-050 Functional Testing Guide for Computerized System
11. VAL-055 Design Qualification Guidelines
12. VAL-060 Protecting Reliability of Electronic GMP Documents
13. TEMPLATE-010 Cleaning Validation-Rinsing Test Template
14. TEMPLATE-015 Cleaning Validation-Swab Test Template
15. TEMPLATE-020 Cleaning Validation-Comparative Analysis Template
16. TEMPLATE-025 Example of Installation Qualification Report
17. TEMPLATE-030 Example of Operational Qualification Report
18. TEMPLATE-035 Example of Operational Qualification Test Protocol
19. TEMPLATE-040 Example of Performance Qualification Test Protocol
20. TEMPLATE-045 Example Product Quality Risk assessment
21. TEMPLATE-050 Example Validation File Index
22. TEMPLATE-055 Example of Validation Plan
23. TEMPLATE-060 Example of Validation Report
24. TEMPLATE-065 Example EHS Audit Report
25. TEMPLATE-070 Example of User Requirement Specification
26. TEMPLATE-160 Example of Commissioning Plan
27. TEMPLATE-165 Example of Design Qualification Protocol
28. TEMPLATE-170 Example of Installation Qualification Equipment

29. TEMPLATE-175 Example of Installation Qualification HVAC
30. TEMPLATE-180 Example of Installation Qualification Operating Environment
31. TEMPLATE-185 Example of Installation Qualification Pipe Work
32. TEMPLATE-190 Example of Installation Qualification Utilities
33. TEMPLATE-195 Example of Electrical Demand Specification
34. TEMPLATE-200 Example of Instrumentation Demand Specification
35. TEMPLATE-205 Example of Mechanical Demand Specification
36. TEMPLATE-210 Example of HAZOP Report
37. TEMPLATE-215 Example of Traceability Matrix Report
38. TEMPLATE-220 Example of Validation Discrepancy Form
39. TEMPLATE-225 Example of Validation Report Combined OQ/PQ
40. TEMPLATE-230 Example of Project Definition Report
41. TEMPLATE-235 Example of Project Evaluation and Closeout Report
42. TEMPLATE-240 Example of Test Protocol Change Request Form
43. TEMPLATE-245 Example of Installation Qualification Computer

Process, Cleaning and Methodology Validation Procedures

In this episode you will find procedures and practical work instructions on different aspects of validation to build up an effective validation and revalidation system for your business. In this area 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. Templates are listed separately.

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 Technician 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 GMP 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 pharmaceuticals Products
18. LAB-075 Stability and Trial Testing Procedure for pharmaceuticals Products

Quality Control Laboratory Procedures

In this episode you will find procedures and practical work instructions on every aspect of analytical laboratory to build up a highly effective Quality Control System for your business. In this area 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 (pharmaceuticals); Stability and Trial Testing Procedure (pharmaceuticals). 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 GMP 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 (pharmaceuticals)

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 (pharmaceuticals)

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 inhouse 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 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

GMP Manufacturing & Quality Assurance Manuals

1. Manual - 001 Evaluation of Contaminant Options for Packing of Solid Dosage Forms
2. Manual - 002 Retention and Disposal of GMP Documents and Retention Samples
3. Manual - 003 Certificate of Materials Supplied to Receiving Manufacturing Site
4. Manual - 004 Quality Assurance Agreements
5. Manual - 005 Procedure for Quality Assurance Management of Contractors
6. Manual - 006 Guidelines for Regulatory Inspections
7. Manual - 007 Quality and Compliance Auditing
8. Manual - 008 Facility Based R&D Quality Assurance Audit
9. Manual - 009 Auditor Training
10. Manual - 010 GMP Compliance Improvements Plans
11. Manual - 011 Archiving, Disposal and Record Management
12. Manual - 012 Internal Quality Assurance Agreements
13. Manual - 013 Audit of a Distribution Site
14. Manual - 014 Supplier Auditing
15. Manual - 015 Management of Master GMP Document
16. Manual - 016 Artwork Creation & Control of Printed Packaging Components
17. Manual - 017 Release of API Bulk Formulated Products & Part Finished Packs
18. Manual - 018 Computerized Systems Risk Management
19. Manual - 019 Batch Confirmation Certification & Release by a Qualified Person within the EU
20. Manual - 020 Cross Contamination Risk Evaluation Process for Commercial Compounds
21. Manual - 021 Certificate of Analysis & Certificate of Manufacture
22. Manual - 022 Pharmaceutical Product Reviews
23. Manual - 023 Warehousing and Distribution of Commercial Products
24. Manual - 024 Utility Standards
25. Manual - 025 Conducting Investigations
26. Manual - 026 Management and Documentation of Training
27. Manual - 027 Definition and Documentation of Raw Data
28. Manual - 028 Risk Management in the Quality Assurance and Compliance Area

29. Manual - 029 Manufacturing Deviation Management
30. Manual - 30 Study Based GLP Quality Assurance Audit for Critical Phases
31. Manual - 31 Guideline for Development and Contents of Specifications
32. Manual - 32 R&D QA Audits for Suppliers and Vendors
33. Manual - 33 Manufacture Packing and Shipping of Materials Ahead of Full QA Clearance
34. Manual - 34 Determination of Storage Periods for APIs Excipients Intermediates and Raw Materials
35. Manual - 35 The Preparation of Process Validation Master Plan
36. Manual - 36 Process Validation of Bulk Drug (API and Intermediate)
37. Manual - 37 Process Validation for Formulated Products
38. Manual - 38 Cleaning and Cleaning Validation of API Plant and Equipment
39. Manual - 39 Sterilization Process Validation
40. Manual - 40 Cleaning and Cleaning Validation For Formulated Products
41. Manual - 41 Analytical Laboratory Procedure Validation
42. Manual - 42 Water Quality Standard
43. Manual - 43 Sterility Testing Procedure
44. Manual - 44 Endotoxin Testing Procedure
45. Manual - 45 Guideline for Stability Testing for R&D
46. Manual - 46 Storage and Expiry Dating of Analytical Reagents in Laboratory
47. Manual - 47 Preparation & Maintenance of Stability Protocols and Stability Master Plans
48. Manual - 48 Commercial Stability Testing of API (Pure Bulk Drug)
49. Manual - 49 Commercial Stability Studies at Contractors
50. Manual - 50 R&D Laboratory Quality Assurance Record Retention Procedure
51. Manual - 51 Microbiological Testing for Non Sterile Drug Product
52. Manual - 52 Reference & Retention Samples
53. Manual - 53 Laboratory Equipment Qualification
54. Manual - 54 Manufacture and Microbiological Testing of Sterile API & Drug Product Within R&D
55. Manual - 55 Commercial Stability Testing For Formulated Products

56. Manual - 56 Environmental Monitoring
57. Manual - 57 Trending of Stability Data
58. Manual - 58 Laboratory Out of Specification Results Investigation
59. Manual - 59 Manufacturing Documentation
60. Manual - 60 Maintenance and Calibration of GMP Critical Items in Manufacturing Operations and R&D
61. Manual - 61 Retreatment and Blending of API & Formulated Product
62. Manual - 62 In-Process Testing, Checks and Sampling
63. Manual - 63 Management of Returned Goods
64. Manual - 64 Receipt Handling and Storage of Starting & Packaging Materials
65. Manual - 65 Control of Packaging Operation
66. Manual - 66 Requirements of Facilities For Sterile and Non-sterile Drug Manufacturing
67. Manual - 67 Labeling and Packaging of Investigational Medicinal Products and APIs in R&D
68. Manual - 68 Principles and Responsibilities for The Management of Change in Manufacturing
69. Manual - 69 The Validation of Facilities and Systems
70. Manual - 70 Information Technology Infrastructure Qualification

All Quality Forms

1. Form-005 Non Component Run Sheet
2. Form-010 Sample Request Form
3. Form-015 Warehouse Information Form
4. Form-020 Bin Sheet
5. Form-025 Return to Bulk Store
6. Form-030 Issue for Production
7. Form-035 Example-Bulk Tablet Sampling Form
8. Form-040 Physical Inventory Count Form
9. Form-045 Warehouse Bin Sheet Reconciliation Form
10. Form-050 Warehouse Periodic Inventory Count Sheet
11. Form-055 Material Transfer Order Form
12. Form-060 Material Transfer Order-Interim Production Form
13. Form-065 Material Transfer Order-Reject Form
14. Form-070 Material Transfer Order-Return form
15. Form-075 Goods Receipt Slip
16. Form-080 In-House Identification Label
17. Form-085 Released Stickers
18. Form-090 Sampled Stickers
19. Form-095 Rejected Stickers
20. Form-100 Sampled Partial Stickers
21. Form-105 Sampling Label
22. Form-110 Pallet Racking Damage Log form
23. Form-115 Warehouse Racking Checklist
24. Form-120 Printed Material Sample Sheet
25. Form-125 Example-Batch Reconciliation Sheet for Tablet Packing
26. Form-135 Pest Sightings Reports
27. Form-140 Visitor Entry Into The Factory
28. Form-145 IBC Cleaning Tag

29. Form-150 Example-Logbook for Tablet Batch Documents
30. Form-155 Weight Checker Weight Record
31. Form-160 Example- Line Clearance, Opening and Cleaning form for Tablet Packing
32. Form-165 Pallet ID Form
33. Form-170 Shipper Label Format
34. Form-175 Vacuum Leak Test - Hourly Form
35. Form-180 Vacuum Leak Test - New Foil and PVC Roll Form
36. Form-185 Balance Calibration Logbook
37. Form-190 Dispensary Label Form
38. Form-195 In-Process Check - Shipper Form
39. Form-200 In-Process Check-Blister and Carton form
40. Form-205 Employee Log Form
41. Form-210 Goods Booking Slip
42. Form-215 Partial Shipper Stickers
43. Form-220 Material Purchasing Information Record
44. Form-225 Purchase Order Form
45. Form-235 Monthly Production Schedule Form
46. Form-240 Finished Goods Batch With Impending Expiry
47. Form-245 Laboratory Master File of Instruments
48. Form-250 Finished Goods Register
49. Form-255 Raw Material Register
50. Form-260 Finished Goods Trend Card
51. Form-265 Raw Material Trend Card
52. Form-270 Laboratory and QA Document Log Sheet and Box Labels
53. Form-275 Workbook Checklist
54. Form-280 Reagent Storage Location Form
55. Form-285 Prepared Reagent Label Form
56. Form-290 Chemical Waste Disposal
57. Form-295 Raw Material Retention Sample Register Log

58. Form-300 Finished Goods Retention Sample Register Log
59. Form-305 Laboratory Investigation and Report form
60. Form-310 Raw Material Out of Specification Investigation form
61. Form-315 Stability or Trial Card
62. Form-320 Template of Certificate of Analysis
63. Form-325 Secondary RM Reference Substance (SRMRS) Summery Sheet
64. Form-330 Primary and Impurity Substance Summery Sheet
65. Form-335 Expired Raw Material Form
66. Form-340 Trial Checklist
67. Form-345 Primary Reagent Ref. Substance (PRRS) Summery Sheet
68. Form-350 SRMRS Label
69. Form-355 In-Process SRMRS Label
70. Form-360 PRRS Label
71. Form-365 Master Document Change Control Form
72. Form-370 Validation Discrepancy Form
73. Form-375 Validation Project Log Form
74. Form-380 IBC Identification Label
75. Form-385 Vendor Audit Questionnaire
76. Form-390 New Supplier Assessment Form
77. Form-395 SOP Ready for Signing
78. Form-400 Employee Signature Register
79. Form-405 Complaint Investigation Report
80. Form-410 Document Location in Satellite File
81. Form-415 Library Log Form
82. Form-420 Request for New Chemical Approval
83. Form-425 Housekeeping Audit Check Sheet for Laboratory
84. Form-430 Housekeeping Audit Check Sheet for Production Services
85. Form-435 Housekeeping Audit Check Sheet for Electrical & Mechanical Workshop
86. Form-440 Housekeeping Audit Check Sheet for Warehouse

87. Form-445 EHS Workplace Instruction Checklist
88. Form-450 Deviation Report Form
89. Form-455 Incident or Investigation Report Form
90. Form-460 Register of Contracts
91. Form-465 Complaints Details Form
92. Form-470 New Chemical Approval Certificate
93. Form-475 Housekeeping Audit Check sheet for Dispensary
94. Form-480 New Chemical Rejection Advice
95. Form-485 Housekeeping Audit Check Sheet for Tablet Production
96. Form-490 Laboratory Testing Form For Customer Complaint Enquiry
97. Form-495 Form Ready for Signing
98. Form-500 Training Participant Log
99. Form-505 Document Creation or Change Request
100. Form-510 Product To Be Reworked
101. Form-515 Goods Return for Rework Form
102. Form-520 Material Transfer Order Form
103. Form-525 Hazardous Chemical Assessment Checklist
104. Form-530 Reading Compliance Form
105. Form-535 GMP Agreement Log
106. Form-540 Pallet Booking Information
107. Form-545 Raw Material Sampling Log
108. Form-550 Finished Goods Shipping Form
109. Form-555 Example-Batch Documentation Checklist for Tablet Packing
110. Form-560 Test and Retention Sample Log Book
111. Form-565 QA Inspection Sheet
112. Form-570 Process Data Collection Form
113. Form-575 Incident Investigation Form
114. Form-580 Incident Communication Form
115. Form-585 Contents of First Aid Emergency Kits

116. Form-590 verification of Assay Result Sheet
117. Form-595 Bacterial Endotoxin Test Data
118. Form-600 Maximum Valid Dilution and Endotoxin Limit Calculations
119. Form-605 BET Gel Clot Validation - Final inhibition and Enhancement Test
120. Form-610 BET Gel Clot Validation - Preliminary inhibition and Enhancement test
121. Form-615 TOC Analyzer Calibration Worksheet
122. Form-620 Validation For Bacterial Endotoxin Using Kinetic Chromogenic Analysis (KCA)
123. Form-625 Sterile Area Sample Identification Checklist
124. Form-630 Non Steaming Machine Record For Micro Lab
125. Form-635 Daily Personnel Monitoring Logs for Sterile Areas
126. Form-640 Sample Identification Checklist For Terminally Sterilized Products
127. Form-645 Sterile Chart Log For Microbiology Laboratory
128. Form-650 Checklist for Procedure for Entry into Sterile
129. Form-655 Validation Record For Sterile Gowning Procedure
130. Form-660 Daily Store Room Temperatures
131. Form-665 Microbiological Integrity (Soup) Test
132. Form-670 Aseptic Media Fill Information Sheet
133. Form-675 Plant Water - Isolate Identification Record
134. Form-680 Sterility Test Failure Investigation Form
135. Form-685 Lal Gel-Clot Test Session Results
136. Form-690 Microbiology Out of Specification (OOS) Investigation and Report Form
137. Form-695 EHS Risk Profile
138. Form-700 Labeling of Settle (Fallout) Plates