

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.

SOP list

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.

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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.

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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 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 out going 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, 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.

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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 in-house trials, reporting and interpretation of trials and conclusion of the trial program.

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Microbiology (Sterility) Laboratory Procedures

In this episode you will find procedures and practical work instructions on sterility testing concepts, principles and microbiology laboratory management guidelines for your pharmaceuticals business.

In this area you will find Standard Operating Procedures on Entry Procedure to Sterile Filling Areas, Validation of Aseptic Gowning Procedures, Microbiological Data Recording Procedure, Destruction of Biological Waste in the Microbiology Laboratory, Depyrogenation of Glassware In Micro. Lab. Oven, Media Preparation in Microbiology Laboratory, Aseptic Media Filling and Micro. Integrity Leak (Soup) Testing Procedure, Aseptic Media Filling and Soup Test Guideline, Environmental and Plant Hygiene Monitoring Procedure, Microbial Limit Testing Procedure by Using Laminar Flow Cabinets etc 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.

SOP List

MICLAB 005: Entry Procedure to Sterile Filling Areas

This SOP outlines the gowning procedure that must be followed by each and every person who enters a Sterile Area. The procedure is designed to reduce the risk of contaminating product with bacteria and/or particles

MICLAB 010 Validation of Aseptic Gowning Procedures

Aseptic gowning is the ability to complete the gowning procedure without compromising the sterility of the garment. This SOP outlines the sterile gowning validation procedure as required for the final sign off for the initial sterile training and the revalidation of currently trained Operators, Fitters, Electricians and Cleaners and all organization staff who are authorized to enter Sterile areas.

MICLAB 015 Microbiological Data Recording Procedure

To describe procedures for the recording of Microbiological data using the in-house hard copy and computerized recording system. All documents containing test results are legal documents and therefore it is imperative that all the information required is recorded accurately. Any changes/corrections to be made must be signed with that person's initials and dated.

MICLAB 020 Destruction of Biological Waste in the Microbiology Laboratory

To describe procedures for destroying all Laboratory Biological Waste to comply with Quarantine Regulations

MICLAB 025 Depyrogenation of Glassware In Micro. Lab. Oven

To outline the procedure for the depyrogenation of glassware using the Microbiology Laboratory Qualtex Oven.

MICLAB 030 Media Preparation in Microbiology Laboratory

To describe the procedures for the preparation of microbiological media for use in the Microbiology Laboratory.

MICLAB 035 Aseptic Media Filling and Micro. Integrity Leak (Soup) Testing Procedure

One of the requirements of cGMP is a periodic evaluation of all aseptic processes by filling media into the appropriate containers under normal production conditions. The media fill should reflect the sterility of the entire process from the Sterilizing filter to the filled primary container and should include all subsequent manufacturing steps. This SOP outlines the procedures for both Media Fills and Microbiological Leak Tests.

For Validation purposes, a Microbiological Leak Test (Soup test) or a separate Protocol to verify the entire process from the 'Bioburden Reduction Filter' to the primary container may be required.

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MICLAB 040 Aseptic Media Filling and Soup Test Guideline

Media Fills are designed to verify the entire process, equipment and staff (see MICLAB 035). This process simulation should be performed as initial validation with three (3) consecutive satisfactory simulation tests per shift and repeated at defined 6 monthly intervals (twice per year per process per shift) and after any significant modification to the HVAC-system, equipment, process and number of shifts” for aseptically filled process.

Soup test has to be conducted at least once per year per shift for terminally sterilised lines and non-sterile process. Validation and re-validation media fills are to assure the sterility of the entire process. This process simulation test should imitate as closely as possible the routine aseptic manufacturing process and include all the critical subsequent manufacturing steps.

The Media Fill should challenge the “worst case” situation and should include all the possible interventions of a normal production run. The duration of the media run should be at least 4 hours or half a production shift to allow for all routine interventions.

An example of valid media fill is 10,000 units per shift for a high speed filling machines.

MICLAB 045 Environmental and Plant Hygiene Monitoring Procedure

Description for Microbiological testing of areas of the environment which may influence or affect product performance and/or quality - including, air, surfaces, personnel, clothing and disinfectants

Daily monitoring of sterile grade areas during production is to be conducted by trained production staff. The Microlab is to ensure that the necessary plates are delivered on a daily basis so monitoring can take place.

Once a test has been completed, the responsible operator is to initial the plate and make sure that the batch number of the batch running at the time of the test is written on the plate. Plates will be labeled with prompts to ensure this isn't forgotten. If no batch is running at the time of the test N/A should be put on the plate instead of a batch number.

If an area of concern is noted during routine daily testing, inform Micro immediately so that further steps can be taken.

Once a week a Microlab technician will perform environmental monitoring and a housekeeping audit of the area.

If, in monitoring any of the following areas, any of the following events occur, the Microlab staff member responsible for conducting Environmental Monitoring in that area is to launch an Environmental Monitoring Investigation by IMMEDIATELY repeating the test.

MICLAB 050 Microbial Limit Testing Procedure by Using Laminar Flow Cabinets.

To describe the procedures to be followed in conducting Microbial Limit Tests in the Laminar flow Cabinets in the Microbiology Lab.

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MICLAB 055 Microbiological Monitoring of Plant Water Systems

In this SOP you will find Sampling Procedure for Bioburden and Endotoxin Samples, Bioburden Test Method and Results, Endotoxin Testing of WFI (Distilled Water), Bioburden and Bacterial Endotoxin Alert and Action Levels, Diagrammatic Representations of a typical purified Water Systems, Bioburden Waste Tank Water Sampling, Clean Steam Sampling & Testing, OOL/OOS Result Actions etc

[MICLAB 060 Micro Laboratory Procedure for Sterility Testing](#)

This sop is to describe the procedure for sterility testing of aqueous, injectable and terminally sterilized non-injectable products. To explain the correct interpretation of sterility results and to outline Stasis requirements for used sterility canisters.

[MICLAB 065 Determination of Heat Resistance of Spore Forming Organisms](#)

This SOP describes the method for calculating the Heat Resistance Factor, (D-value), of spore-forming organisms. D-Value is defined as the time required for a population of a pure culture of microorganisms to be decreased by 90% when exposed to a fixed temperature, e.g. 121°C ($\pm 1^\circ\text{C}$).

[MICLAB 070 Identification of Microorganisms to Genus and Species Level](#)

To describe the procedures for the preliminary identification of bacteria isolated from Plant Water, Environmental, Personnel, Product and Raw Material sources.

Bacteria that will require identification (ID) to **at least** genus level include organisms isolated from the manufacturing environment, personnel, in-process and finished products, plant water and other miscellaneous sources. SOP's detailing the microbiological testing procedures for each of these samples will indicate the required level of ID of recovered organisms. The following sections detail the procedures for the preliminary ID of micro-organisms. Further ID to species level is to be conducted for conformation.

[MICLAB 075 Micro Evaluation on Bioburden, Non sterile and Raw Materials](#)

This SOP describes the procedures for Microbiological Evaluation of Bioburdens, non-sterile Products & raw materials.

Bioburdens includes: Batches prior to membrane filtration, i.e. solutions; Batches prior to sterilization i.e. filled containers; Face masks; IPA.

This procedure includes Equipment preparation for Non-sterile testing, Bulk Solution Bioburden (BSB) Sampling; Filled Container Bioburdens (FCB); Raw Material Bioburdens (RMB); Surgical Face Masks; Isopropyl Alcohol (70% IPA); Speciation Procedures for Organisms found in Non-Sterile Products and Raw Materials; Out-of-Specification Procedures for Non-Sterile Products and Raw Materials; Retest and Repeat Procedures for Non-Sterile Products and Raw Materials.

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[MICLAB 080 Bacterial Endo Toxin Testing \(LAL\) - Gel Clot Method](#)

To describe the procedure for conducting a Bacterial Endotoxin Test by the LAL Gel-Clot method. The gel-clot method for bacterial endotoxin testing described in this SOP is based on the fact that Limulus Amoebocyte Lysate (LAL) will form a firm gel in the presence of bacterial endotoxin.

MICLAB 085 Bacterial Endo Toxin Testing kCA Method

The purpose of this SOP is to outline the theory of Bacterial Endotoxin testing using Kinetic Chromogenic Analysis (KCA). And to outline the procedure for routine product testing, operator / reagent verification and product validation by KCA using the BioWhittaker KQCL (brand) reader. This Procedure also describes the routine maintenance procedures for the BioWhittaker KQCL (brand) reader.

MICLAB 090 Stock Suspension of Micro Organism

The objective of this SOP is:

- To describe the method for preparing and maintaining stock suspensions of vegetative microorganisms and spores used within the Microbiology Laboratory.
- To explain the procedure for growth promotion and media verification requirements for all media used within the Laboratory.
- To outline requirements for Stasis testing on sterility canisters after sterility testing has been completed.

MICLAB 095 Sterile Sampling Procedure for Microbiology Laboratory

To detail the procedure for taking Microbiological samples for Sterility testing, Bacterial Endotoxin testing, Bioassay testing, Microbial Limit test and Micro status testing throughout Production. This procedure includes sterilization charts, Settle plates (Fallout plates) and Personnel monitoring.

MICLAB 105 Gel Clot Validation Method

The gel clot validation method for Bacterial Endotoxin testing described in this SOP, is to determine the level of Inhibition/Enhancement of products on the LAL test for endotoxins within the allowable Maximum Valid Dilution (MVD) for each type of product. The Gel-Clot techniques detect or quantify endotoxins based on clotting of the LAL reagent in the presence of endotoxin.

To be determined for each type of product, using the highest and lowest concentration of active. If either concentration shows inhibition or enhancement, then each remaining concentration must be tested. At least three (3) Production batches of each finished product should be tested for inhibition and enhancement.

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MICLAB 110 Microbiology Laboratory Investigation and Retest Procedure for Atypical and OOS Results

The purpose of this procedure is to provide guidance when investigating microbiology laboratory out of specification (OOS) results associated with raw material samples, in-process samples and finished product samples. This procedure describes the actions taken by Microbiology Laboratory staff in the event the result of a test does not conform to company specifications for microbiological release.

This procedure will also provide guidance for re-testing raw material samples, in-process samples and finished product samples when it has been decided through a laboratory investigation that retesting is justified. Retesting should be viewed as an investigational tool to aid in determination of the root cause of the discrepant laboratory result.

MICLAB 115 TOC Analyser - Operation and Calibration of Sievers 820 (brand) Analyser

To define the procedures to be followed and the responsibility for the operation, calibration and maintenance of the Sievers 820 TOC Analyser with Autosampler.

MICLAB 120 IPA Contamination Testing Procedure

To describe the test sometimes used to check the purity of the IPA used in the factory as a disinfectant.

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GMP | Manufacturing Procedures

In this episode you will find procedures and practical work instructions on many areas of manufacturing division. Some procedures can be commonly used in any manufacturing site. Some procedures are set up to provide a common guideline for all types of manufacturing activities by using an example of a tablet packaging plant.

In this area you will find exciting procedures on Clothing Requirements Inside the Factory Area, Cleaning Responsibilities and Methods for Employees, Factory Cleaning Procedure, Manufacturing Pest Control, Tours of Factory, Requirements of Production Logbook, Packaging Configuration for Production Line, Checking of Components Prior to Use, Tag Out Procedure, Procedures for Line Clearance, Line Opening and Line Cleaning, Reconciliation of Component and Product, Operation of Barcode Reader as an example, Intermediate Bulk Container (IBC) Operation and Cleaning, Tablet Packing Machine and Cartoner-construction, operation and cleaning as an example, Manufacturing Instruction for Tablet Packing as an example, Mop Cleaning Procedure, Scheduling Production Lines, Vacuum Leak Testing Procedure, Weighing Equipment - Checking and Calibration, Operation of Checkweigher as an example, Tablet Packing-Start up and In-process Testing as an example, Packed Tablet Sampling by Production Personnel for Testing as an example

All procedures have reference of prepared Forms and Visual Displays for effective record keeping and reporting purposes. Forms are attached at the end of each procedure.

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SOP list

MAN-005 Clothing Requirements Inside the Factory Area

This SOP covers the clothing requirements needed in all Factory areas for your manufacturing site. The different levels of cleanliness must be maintained to minimize microbial and particle contamination. This procedure contains general rules and restriction to be followed by your manufacturing employees, defining different environmentally graded areas and entry requirements for those areas.

MAN-010 Cleaning Responsibilities and Methods for Employees

This SOP describes the cleaning procedures to be followed by all employees working in the manufacturing area in order to prevent contamination of product by foreign materials from another batch, or by dirty parts, which may contain bacteria. This SOP contains instruction on responsibility of cleaning, degree of cleaning to be done, popular cleaning aids and solutions permitted to use for cleaning, rubbish removal and outline of cleaning methods for different environmentally graded areas.

MAN-015 Factory Cleaning Procedure

This SOP defines the methods, frequency and the intensity of Factory Cleaning. The purpose of cleaning is to remove debris from within the plant in a sanitary and effective manner and to avoid contamination from dust or foreign materials. This procedure describes which popular cleaning aids and solutions are to be used to clean the floors, walls, sinks and windows in the Production areas, office areas, change rooms, workshops, laboratories, stores, canteens, plus the toilet facilities. This procedure also describes the scope and responsibility of contract cleaners.

MAN-020 Manufacturing Pest Control

This SOP describes the responsibilities of all employees and pest control services, classification of pests, frequency of the pest control service and effective treatments against all types of pest.

MAN-025 Tours of Factory

This simple procedure describes the management of visitor's entry, their safety and security inside the manufacturing site.

MAN-030 Production Logbook

This procedure outlines the generation, maintenance and filing of Production logbooks. Production logbooks form part of the documentation system required by the Code of GMP to provide complete and up-to-date histories of all batches of product. The logbook provides a key link in the process of traceability.

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MAN-035 Packaging Configuration for Production Line

This SOP provides an alphabetically indexed diagram of shipper packing and pallet packing configurations for any packaging process. This procedure contains schematic diagrams of different packaging configurations and calculations of total unit to be packed per container which can be useable into your packing lines.

[MAN-045 Checking of Components Prior to Use](#)

This SOP sets out a procedure to ensure that only components of correct code and batch number are issued for a batch and only issued components will be used in a finished product batch. This SOP also describes the procedure to be followed during returning of components to warehouse from the production lines.

[MAN-050 Tag Out Procedure](#)

This SOP describes how to prevent the risk of personal injury or damage to equipment likely to be caused by operating or attempting to operate machinery or equipment diagnosed as being unsafe, in need of repair or maintenance or formally removed from service. The SOP covers all isolation, condemning, repair or maintenance work that necessitates a device or machine to be taken out of service. This SOP applies to any situation where energy (either supplied to equipment, or stored within it) needs to be isolated to ensure the safety of any person working on or near equipment, processes or services - for any reason whatsoever.

[MAN-055 Procedures for Line Clearance, Line Opening and Line Cleaning](#)

This SOP describes the procedure and order to be followed when performing a Line clearance, Line opening and Line cleaning for a batch production. The procedure has been established to prevent mix-ups of products, containers, components, labels and mistakes in documentations. Mix-ups and mistakes can occur when correct procedure and GMP are not followed. Particular care should be taken when starting a new operation, at the change of shift and when additional components are needed. In this procedure you will find example of line clearance, opening and cleaning checklist based on an example of tablet packing line.

[MAN-060 Reconciliation of Component and Product](#)

This simple SOP describes the concept of reconciliation, how to reconcile finished goods and determine the allowable discrepancies of components and products when reconciled.

[MAN-065 Example-Operation of Barcode Reader](#)

This SOP describes the set up and operation of a standard barcode reader for carton components used in the packing lines.

[MAN-070 Example-IBC Operation and Cleaning](#)

This SOP describes the operation and cleaning procedures that relate to the use of the Intermediate Bulk Containers (IBC's) used to store and transfer of raw material on the process lines. The procedure instruction covers how to receive the bins from warehouse dispensary, movement towards the process lines, lifting and emptying the contents from the bin, cleaning and returning the bins back to warehouse dispensary.

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[MAN-075 Example-Tablet Packing Machine and Cartoner-construction, operation and cleaning](#)

This procedure describes the machine construction and operation, machine start up and cleaning of a typical tablet Blistering machine and the Cartoner for tablet packing. You will be able to create a new procedure for your packing line based on the format of this SOP.

[MAN-080 Example-Manufacturing Instruction for Tablet Packing](#)

This procedure describes how to create a complete manufacturing instruction for your process line to be followed by your manufacturing employees. To make the instruction more practical and easy to understand, a sample instruction is added in the form of a protocol for a typical tablet packing process. All the related blank forms are attached at the end of the procedure for a better understanding.

[MAN-085 Mop Cleaning Procedure](#)

This simple procedure outlines the operation of the factory laundry in a safe and hazard-free manner. This procedure can be used in any manufacturing site for the purpose of mop cleaning.

[MAN-090 Scheduling Production Lines](#)

This procedure describes how to produce a monthly manufacturing schedule following an agreed 12 months plan, to provide a sequence of work that will enable the scheduling of support groups (i.e. Quality, Technical and Warehousing), incorporate any planned engineering down time (i.e. project work, calibration and preventative maintenance), create and release batches according to the agreed weekly schedule, provide key dates for product supply to support Customer Service.

[MAN-095 Vacuum Leak Testing Procedure](#)

This SOP describes the set up and operation of a standard vacuum Leak Tester for the very popular vacuum leak testing used in a typical packing line.

[MAN-100 Weighing Equipment - Checking and Calibration](#)

This SOP outlines the procedures required for the checking/calibration and repair of balances, scales, checkweighers and load cells typically used in the standard packing lines.

[MAN-110 Example-Operation of Checkweigher](#)

This SOP describes the set up and operation of a standard checkweigher used in a typical packing line for weight checks of each packed unit.

[MAN-115 Example-Tablet Packing-Start up and In-process Testing](#)

This procedure contains instructions that enable the production operators working in a typical packing line to carry out Start-Up and In-Process Tests required in order to produce quality products and to ensure in-process controls. A typical tablet packing process is used here as an example.

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[MAN-120 Example-Packed Tablet Sampling by Production Personnel for Testing](#)

This procedure describes the process of sampling manufactured finished good required to be taken by production personnel for the laboratory testing. A typical tablet packing process is used here as an example.

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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).

Templates

[Cleaning Validation-Rinsing Test Template](#)

[Cleaning Validation-Swab Test Template](#)

[Cleaning Validation-Comparative Analysis Template](#)

[Example of Installation Qualification Report](#)

[Example of Operational Qualification Report](#)

[Example of Operational Qualification Test Protocol](#)

[Example of Performance Qualification Test Protocol](#)

[Example of Validation Plan](#)

[Example of Validation Report](#)

[Example of User Requirement Specification](#)

[Example of Commissioning Plan](#)

[Example of Design Qualification Protocol](#)
[Example of Installation Qualification Equipment](#)
[Example of Installation Qualification HVAC](#)
[Example of Installation Qualification Operating Environment](#)
[Example of Installation Qualification Pipe-work](#)
[Example of Installation Qualification Utilities](#)
[Example of Electrical Demand Specification](#)
[Example of Instrumentation Demand Specification](#)
[Example of Mechanical Demand Specification](#)
[Example of HAZOP Report](#)
[Example of Traceability Matrix Report](#)
[Example of Validation Discrepancy Form](#)
[Example of Validation Report Combined OQ_PQ](#)
[Example of Project Definition Report](#)
[Example of Project Evaluation and Closeout Report](#)
[Example of Test Protocol Change Request Form](#)

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Warehouse Management Procedures

In this episode you will find procedures and practical work instructions on warehousing in order to build up a highly effective warehousing and procurement System for your business.

In this area you will find procedures on Receipt of Incoming Goods, Raw Material and Components-Incoming-Handling by Sampler, procedure for Warehouse to Processing Issues, Returns and Rejects, Dispatch of Goods from Warehouse, Warehouse Inventory Management, Warehouse Locations and Storage Area, Finished Goods Transfer to Quarantine and Distribution Warehouse, Sampling of Raw Materials, Sampling of Components and Printed Materials, Work in Progress Area, Safety Procedure of Warehouse Racking, Forklift Operation in Warehouse, Tablet Dispensary Procedure as an example, Raw Material Tablet Sampling by Dispensary as an example, Material Purchasing Information Record and Source List, Generation of Purchase Order For Inventory and Consumables

All procedures have reference of prepared Forms for effective record keeping and reporting purposes. Forms are attached at the end of each procedure.

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[SOP List](#)

WAR-005 Receipt of Incoming Goods

This SOP contains step by step instruction on condition of accepting incoming goods in the warehouse, 'booking In' procedure of component and non component goods, how to complete movements of incoming goods into different storage locations within the warehouse maintaining full traceability. Here you will find generation and filing of documents related to receipt of incoming goods.

WAR-010 Raw Material and Components-Incoming-Handling by Sampler

This procedure describes quarantining, sampling, testing and releasing of incoming raw materials to Production. Here you will find the labeling requirement for component to be sampled, checking requirements of components, sampling and re-sampling of incoming goods for laboratory testing, generation of documentation during the movement of components in order to maintain complete traceability.

WAR-015 Warehouse Processing Issues Return and Rejects

This SOP contains step by step instruction on issue of tested and QC released components for batch production, documentation needed for capturing identification and traceability information during the picking, assembling and transferring of those components from warehouse to production. This procedure also has instruction to follow during the return and reject processing of raw materials and components from production to warehouse.

WAR-020 Dispatch of Goods from Warehouse

This SOP contains instruction and documentation on movement of finished goods to quarantine until release for sale, dispatching procedure and documentation needed for transferring of finished goods from quarantine to warehouse store and subsequently to out side the manufacturing site maintaining a complete traceability of finished goods.

WAR-025 Warehouse Inventory Management

In this procedure you will find a complete inventory management system by stock counting instruction, stock classification and reconciliation programs. Here you will find instruction on cycle counting by material code, counting by bin sheet information and reconciling/cross checking of those counts by physical counting of the stock, determination of material gain or loss and filing instruction.

WAR-030 Warehouse Locations and Storage Area

This SOP is designed to understand and draw an schematic diagram of ideal warehouse and production areas, identifying in-coming goods storage unit types and storage bin types, quarantines, reject cage, cool room, flammable storage, dispensary booths, production area, finished goods quarantine area and finished goods storage areas. This procedure defines how storage unit types and storage bins are numbered. This SOP is to be used as a guide to define the types of storage units and bins, movement direction within the warehouse and production areas.

WAR-040 Finished Goods Transfer to Quarantine and Distribution Warehouse

This simple SOP contains instruction and documentation on movement of finished goods from production to warehouse finished goods quarantine location until the samples are tested and released by the authorized persons.

WAR-045 Sampling of Raw Materials

This procedure primarily concerned with risk associated with sampling, precaution to be followed when sampling, general sampling procedures for raw materials, critical and non critical components, chemicals and secondary reference standards for laboratory.

WAR-050 Sampling of Components and Printed Materials

This procedure is an elaboration of SOP WAR-045 and mainly concerned with sampling plans and instructions of components and printed materials for quality testing before release for production use.

WAR-055 Work in Progress Area

This simple procedure describes the construction and locations of different work in progress areas between production and warehouse for temporary storage of raw materials, component and finished goods.

WAR-060 Safety Procedure of Warehouse Racking

This SOP outlines the measures to be taken to ensure the safety of all goods and personnel when using the storage racking system in order to avoid injury to staff or damage to property. This procedure concerned with the handling and storage of materials or products and to report any damage which may be occurred. This SOP particularly relates to the activities of the staff of the receiving and distribution warehouse.

WAR-065 Forklift Operation in Warehouse

This SOP gives instructions on operation requirements and maintenance of forklifts used in the warehouse, safety precaution to be taken during the operation of forklift under load.

WAR-075 Example-Tablet Dispensary Procedure

This procedure is mainly concerned with dispensing plans and instructions of released raw materials for production use. An example of tablet dispensary procedure is prepared for better explanation and understandings of dispensing. You will be able to follow the instruction for dispensing of any raw materials in your facility.

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WAR-080 Example-Raw Material Tablet Sampling by Dispensary

This procedure is an elaboration of SOP WAR-045 and mainly concerned with sampling plans and instructions of raw materials for quality testing before release for production use. An example

of tablet sampling procedure is prepared for better explanation and understandings. You will be able to follow the instruction for sampling of any raw materials in your facility.

PUR-005 Material Purchasing Information Record and Source List

This simple procedure describes how to keep purchasing information for approved materials, vendors, manufacturers, standard and current pricing and third party agreements.

PUR-010 Generation of Purchase Order for Inventory and Consumables

This procedure describes the steps to be followed by planning and procurement department to create purchase order for inventory items to be purchased from overseas and local suppliers.

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Environmental, Health and Safety Procedures

In this episode you will find procedures and practical work instructions on Environmental, Health and Safety Management to help you build up safe and secure work[place for your employees.

In this area you will find procedures on Hazardous Chemical Substance Management, Environmental, Health and Safety - Risk Management, Waste Removal Process, Identifying EHS Issues, Incident Management, First Aid Procedure etc.

All procedures have reference of prepared Forms for use of record keeping and reporting purposes. Forms are attached at the end of each procedure.

SOP List

EHS-005 Hazardous Chemical Substance Management

This SOP contains step by step instruction on approval process for the use of new chemicals, management of existing chemical substances that are classified as hazardous, assessment process for hazardous chemical substances, material safety data sheet management, elements of a hazardous substance induction & training program.

EHS-010 Environmental, Health and Safety - Risk Management

The purpose of this SOP is to describe the risk management process of identifying environmental, health and safety hazards, assessing risk of hazards, designing appropriate control systems and reviewing the systems. This procedure describes the steps to be taken and the tool that shall be used to undertake preliminary risk assessments (PRA) and outline the procedure for using the deviation report system for reporting EHS hazards that cannot be immediately and simply resolved by the observer.

EHS-015 Waste Removal Process

This simple procedure describes the types of bins/containers to be used for handling all types of wastes, recycling materials and wastes from the Manufacturing facilities.

EHS-020 Identifying EHS Issues

This simple procedure outlines the procedure for the identification and management of legal & statutory requirements related to Environmental, Health and Safety management. This procedure can be used to identify the EHS related issues and requirements that are applicable to all activities, products and services.

EHS-025 EHS Incident Management

This procedure defines and describes the requirements for immediate action, investigation, reporting, corrective action, follow-up and training associated with workplace incidents.

EHS-030 First Aid Procedure

The purpose of this SOP is to formalize the role of the nominated site first aider, to provide a clear understanding of the first aider's responsibilities and provide first aider's with information relating to the delivery of first aid.

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Pharmaceutical Audit Training Manuals

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Auditing a Calibration, Preventative Maintenance & Housekeeping System
Auditing Computerized Systems
Auditing Utilities System
Auditing Warehouse and Distribution System
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