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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.

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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.

LAB-080 Preparation of Disinfectant Solution IPA

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