

# Standard Operating Procedure

## Title: Preparation, Maintenance and Change Control of Master Documents

|                   |                           |                    |                |
|-------------------|---------------------------|--------------------|----------------|
| <b>Department</b> | <b>Quality Management</b> | <b>Document no</b> | <b>QMS-030</b> |
| Prepared by:      |                           | Date:              | Supersedes:    |
| Checked by:       |                           | Date:              | Date Issued:   |
| Approved by:      |                           | Date:              | Review Date:   |

### Document Owner

Technical Service Manager

### Affected Parties

All Technical/QA/Laboratory/Regulatory Department personnel involve in creating, updating and approving Master files documents.

### Purpose

To describe the preparation and responsibilities pertaining to Master Files, Technical SOP's, Specifications, Control Methods and Production Documents.

### Scope

This SOP is to provide instruction for the preparation and authorisation of Technical documentation residing in the Master Files.

### Definition

|             |  |
|-------------|--|
| Master File | Encompasses all documentation required for the manufacture and release of a product. The Master File encompasses both in-house and regulatory documentation, description of which is detailed in this SOP. |
|-------------|--|

### Related Documents

|          |  |
|----------|--|
| Form-365 | Master Document Change Control Form  |
| Form-505 | Document Creation or Cancel Request  |
| Form-415 | Library Log Form   |
| TEM-005  | Raw Material Specification and Test Report Template                                    |
| TEM-135  | Control Method Template  |
| TEM-140  | Formulation Template   |
| TEM-145  | Finished Product Specification and Test Report Template                                |
| TEM-150  | Packaging Material Specification and Test Report                                       |
| TEM-155  | Bill of Materials Template   |
| QMS-015  | Quality Documentation Management and Change Control                                    |
| QMS-010  | All Documents - Classification, Definition and Approval Matrix                         |
| QMS-115  | Criteria for Sourcing of RM, Critical Packaging Components and Imported Finished Goods |

### EHS Statement

There is no EHS impact.

# Standard Operating Procedure

## Title: Preparation, Maintenance and Change Control of Master Documents

|   |     |
|---|-----|
| 3. Formulation  | FLN |
| 4. Packaging Materials Specifications and Test Method | PMS |
| 5. Manufacturing Formula                              | MF  |
| 6. Manufacturing Instruction                          | MI  |
| 7. Bill of Materials                                  | BOM |
| 8. Stability Specification                            | SS  |
| 9. Finished Goods Specification and Test Method       | FGS |
| 10. Raw Material Specification and Test Method        | RMS |

### 3. Key Personnel and Responsibilities

The Master File documents are normally prepared by the Technical Service Department with the assistance given for Control Methods, Raw Material Specifications-Test Report, Finished goods Specification-Test Report and Stability Specifications from the Laboratory. The Technical Service Department is responsible for ensuring that testing methods have been properly validated, and that the associated report has been approved, before being incorporated into respective control methods and specifications. The documents are then authorised by responsible persons as listed in the SOP **QMS-010**.

### 4. Documentation Database

The Documentation Database is used to facilitate creation, control, maintenance and tracking of Quality, External, and Master file documents. These are also referred to as "Controlled Documents."

The Documentation Database is divided into three (3) of areas of control:

- "Quality Documents-In-house and external" - the area of the Documentation Database which stores data for controlling and maintaining Quality Documentation (**SOP QMS-015 and SOP QMS-025**).
- "Quality Audits" - the area of the Documentation Database, which facilitates control of the Quality Audit program including scheduling and auditor assignment. (See **SOP QMS-080**)
- "Master File Documents" - the area of the Documentation Database which stores data for controlling and maintaining Master file which is comprised of both Technical and quality documents needed for manufacturing a product (**covered in this SOP**).
- See SOP **QMS-010** for the structure of the Document Database.

The Quality Documents and Quality Audit section of the database is maintained by QA and EHS and accessible by all employees.

The Master file documents sections are maintained by Technical Service Departments.

### 5. Master File

- 5.1. In addition to the documents listed in section two, Master File includes references to official standards, procedures (SOP's) and Compendia.
- 5.2. The Product Description and Product Code number is unique and is allocated by the QA.
- 5.3. For new components, (Packaging and Raw Materials), their descriptions and Code Numbers are allocated by the QA Department.
- 5.4. Where a change needs to be made to an In-house Master File document, which is of an urgent nature, then the change may be made directly on to the original and authorised by the Technical Service Manager or delegate. The circumstances under which these changes can occur are restricted to changes that do NOT affect the registered details and those which are

# Standard Operating Procedure

## Title: Preparation, Maintenance and Change Control of Master Documents

- 6.2.6. Print the draft document, review comments, and incorporate any additional amendments into the electronic file. Write new status in the status box. Recirculate the final document for the appropriate approval signature according to section 4 of SOP **QMS-010**.
- 6.2.7. When signed, make appropriate number of official masters as specified in the following table and stamped with "This is an official master if stamp is in red" sign and date. Distribute the authorised copies in the satellite files of relevant departments as listed in the table below.

| Satellite File Location No. | Location   | Document Type  |
|-----------------------------|--|--|
| 01                          | QC Laboratory  | CM (Control Method), FGS (Finished Goods Specifications- Test Report), RMS (Raw Material Specification-Test Report), SPC (Specifications), SS (Stability Specifications), (PMS) Packaging Material Specification and Test Report |
| 02                          | Production   | CM (Control Method), FGS (Finished Goods Specifications-Test Report), RMS (Raw Material Specification-Test Report)   |
| 03                          | Regulatory   | FLN (Formulation)  |
| 04                          | Dispensary (first page outlining sampling requirements only) | RMS (Raw Material Specification-Test Report)   |
| 05                          | Warehouse  | (PMS) Packaging Material Specification and Test Report   |
| 06                          | Planning   | (BOM) Bill of Materials  |

- 6.2.8. Update master document list. File the electronic master document in the Live folder of the database.
- 6.2.9. File one approved hard copy in the master document file.

### 6.3. Changes to Master File Documents

6.3.1. A request to Master Document Change Control Form (**Form-365**) can be initiated by anyone in the manufacturing. Technical Service Staff receives the request with all relevant information attached for the change of the document, assigned a change control number in the under review folder of the database.

6.3.2. Change control numbers are alphanumeric figured allocated using the following format: **ID-XXYY-ZZ**

Where, Prefix ID is chosen for the type of master document to be changed

XX is the last two digits of the current year

YY is the month in which the change is initiated

ZZ is the consecutive number of changes for the specified document

6.3.3. Ensure document number and the change control number does not interchange.

6.3.4. The request is then evaluated for the following

# Standard Operating Procedure

## Title: Preparation, Maintenance and Change Control of Master Documents

6.3.17. Remove the original electronic version in the Superseded folder from Live folder of the database. Replace it with the changed file with appropriate version number from Draft folder.

6.3.18. Update master document list. Retrieve the hard superseded copy from the master document file, stamp with "Superseded" and place it in the superseded master document file.

6.3.19. File one changed and approved hard copy in the master document file.

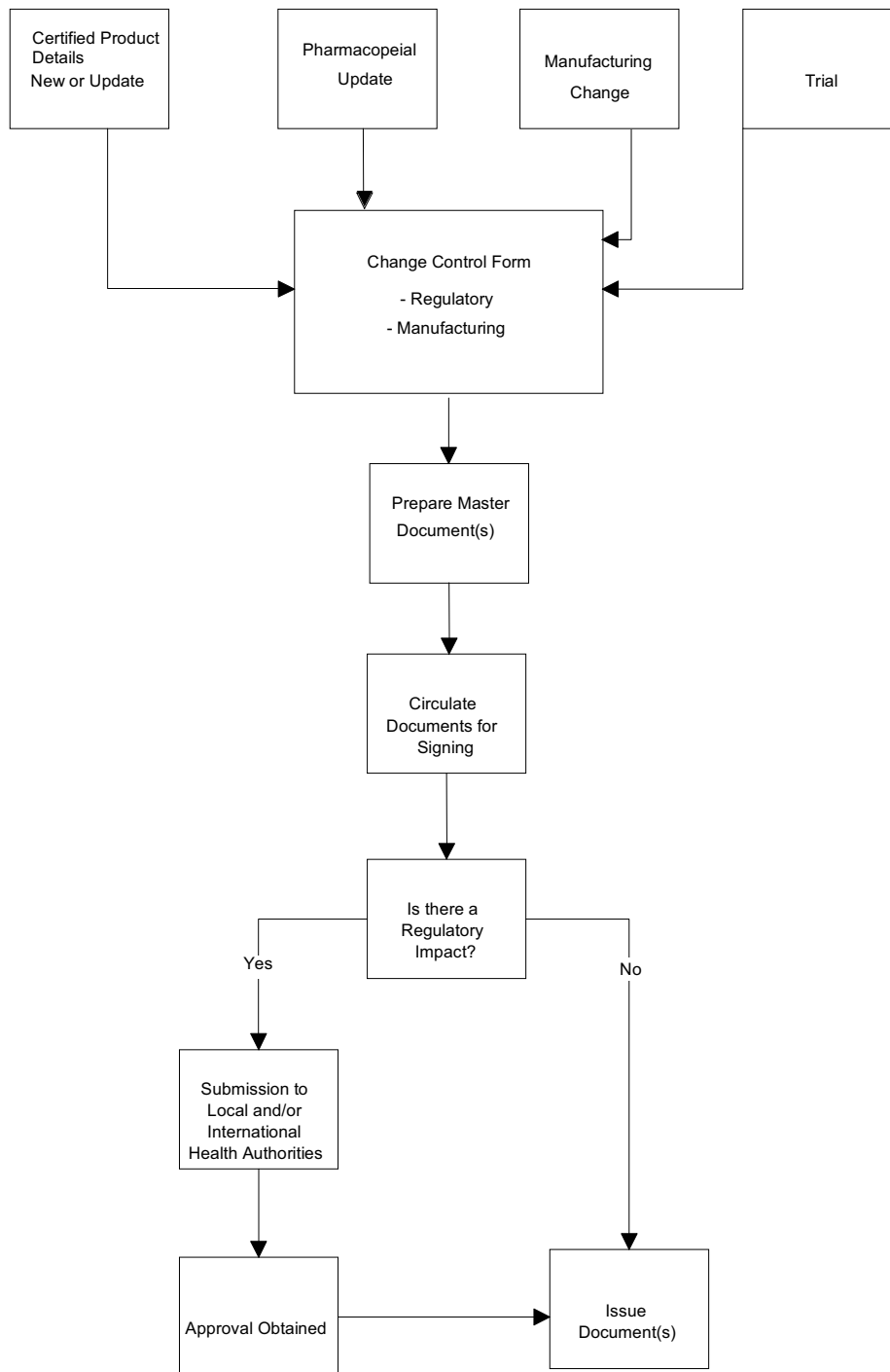
### 7. Category and Examples of Changes

|                                     |   |
|-------------------------------------|---|
| <b>Specification change</b>         | Any change to a specification, BOM or data sets. This includes but is not limited to: <ul style="list-style-type: none"><li>➤ Raw materials, Packaging components, In process testing, Packaged product and equipment specifications</li><li>➤ BOM for bulk and finished products</li><li>➤ Data sets for starting materials or finished products</li></ul>   |
| <b>Analytical method change</b>     | Any change to or deletion of a testing procedure or inclusion of a reduced testing schedule. This includes but not limited to: <ul style="list-style-type: none"><li>➤ Raw materials, packaging components, in process products, packaged products and calibration tests</li></ul>  |
| <b>Raw materials change</b>         | <ul style="list-style-type: none"><li>➤ Any change to a raw material supplier, manufacturing site, manufacturing process, mode of transport or storage of containers.</li></ul>   |
| <b>Packaging components</b>         | Any change other than artwork to a packaging component. This includes but is not limited to: <ul style="list-style-type: none"><li>➤ Bottles, caps, tubes, foils etc (e.g. thickness, materials, dimensions)</li></ul>  |
| <b>Manufacturing process change</b> | Any change to the processing procedure. This includes but is not limited to: <ul style="list-style-type: none"><li>➤ Manufacturing process (e.g. stirring time, blending time, order of addition drying time or temperature where variation is not specifically covered in the manufacturing instructions)</li><li>➤ Packaging process (e.g. cap torque, filling temperature, line set up and shut down procedure, fill volume, blister seal temperature etc)</li><li>➤ Cleaning process (e.g. time, temperature, method, cleaning agents etc)</li><li>➤ Introduction of a new product to the manufacturing facility.</li><li>➤ Transfer of an in-house manufactured product to an alternate manufacturing site.</li></ul>  |
| <b>Equipment /Computer change</b>   | Any modification or alteration to equipment or the environment where the equipment operates, or the relocation of the equipment from one place to another or the introduction of new equipments or consumables to existing equipments. This include but is not limited to: <ul style="list-style-type: none"><li>➤ Manufacturing equipments (e.g. manufacturing and storage tanks, blenders, stirrers, compressing machine, drying oven, granulators, fluid bed dryers, storage hoppers, transfer lines etc)</li><li>➤ Purified water system (e.g. Pumps, valves, dosing mechanism etc)</li><li>➤ Packaging equipment (vision system, capper, labeller, bottle blower, shrink wrapper, cartonner, case packer etc)</li><li>➤ Testing equipments ( e.g. pH meter, viscometer, scales, Thermometer, HPLC, balance, Spectrophotometer etc)</li><li>➤ Environment (e.g. air conditioning, humidity, pest control, lighting etc)</li></ul> |

# Standard Operating Procedure

## Title: Master File Documentation: Preparation & Responsibilities

### 10. Appendix 1 - Flow Chart for Preparation and Change of Master Documents



## Master Document Change Control Form

(Ref. SOP QMS-030)

|                                   |
|-----------------------------------|
| Change Control Number: ID-XXYY-ZZ |
|-----------------------------------|

**Requester to Complete**

**1. Requester Information**

|                          |  |                |  |
|--------------------------|--|----------------|--|
| <b>Name of Requester</b> |  |                |  |
| <b>Department</b>        |  | <b>Contact</b> |  |
| <b>Urgency of change</b> |  | <b>Date</b>    |  |

**2. Change information**

|   |                     |
|---|---------------------|
| <b>Action</b>   |                     |
| <b>Document to be changed (if known)</b>                          |                     |
| <b>Document number to be changed (if known) i.e. SS-XXXX-00.A</b> |                     |
| <b>Raw material code or Finished Product code and description</b> | <b>Code:</b>        |
|   | <b>Description:</b> |
| <b>Other related information i.e. DR; Audit</b>                   |                     |

**3. Details of Change**

|                           |  |
|---------------------------|--|
| <b>Reason for Change</b>  |  |
| <b>Current value/text</b> |  |
|                           |  |

## Master Document Change Control Form

(Ref. SOP QMS-030)

**Other to Complete (If required)**

|   |             |             |
|---|-------------|-------------|
| <b>Laboratory Manager</b><br>(or delegate)        | <b>Name</b> |             |
|   | <b>Sign</b> | <b>Date</b> |
| <b>Comment</b>                                    |             |             |
| <b>QA Manager</b><br>(or delegate)                | <b>Name</b> |             |
|   | <b>Sign</b> | <b>Date</b> |
| <b>Comment</b>                                    |             |             |
| <b>Regulatory Manager</b><br>(or delegate)        | <b>Name</b> |             |
|   | <b>Sign</b> | <b>Date</b> |
| <b>Comment</b>                                    |             |             |
| <b>Associated Supply Manager</b><br>(or delegate) | <b>Name</b> |             |
|   | <b>Sign</b> | <b>Date</b> |
| <b>Comment</b>                                    |             |             |

