PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Preparation of Master Updation form	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1. **Purpose:** The purpose of this SOP (Standard Operating Procedure) is to generate product code and pack code for formulations of following dosage forms

   (1) Tablet (2) Capsule (3) Powder

1. **Scope:** This procedure is applicable under the following conditions.
   - 1.1. Whenever the new product launch is scheduled.
   - 1.2. Whenever the change in brand name of existing product.
   - 1.3. Whenever the generic name is changed due to change in pharmacopoeial status.
   - 1.4. Change in pack style.
   - 1.5. Change in price.
   - 1.6. Change in shelf life.

2. **References, Attachments and Annexures :**
   - 2.1. **References:**
     - 2.1.1. In house
   - 2.2. **Attachments:**
     - 2.2.1. Attachment-1: Product Master updation form
     - 2.2.2. Attachment-2: Product Pack Master updation form
     - 2.2.3. Attachment-3: Product Price Master updation form
   - 2.3. **Annexures :** NA

3. **Responsibilities:**
   - 3.1. **User Department:**
     - 3.1.1. To fill up the MUF form as per requirement.
   - 3.2. **Quality Assurance Head or Designee:**
     - 3.2.1. To review the filled MUF in case of new Product Launch.
     - 3.2.2. To review the filled MUF in case of change in brand name, change in generic name due to change in pharmacopoeial status, change in pack style & change in Shelf life.
   - 3.3. **Information & Technology :**
     - 3.3.1. To check the filled MUF and forward to Corporate Information & Technology Dept.
   - 3.4. **Quality Head:**
     - 3.4.1. Approve the new or revised code.

4. **Distribution:**
   - 4.1. Quality Assurance (QA) Department
   - 4.2. All user

5. **Abbreviations & Definition of terms:**
   - 5.1. **Abbreviations:**
     - 5.1.1. **MUF:** Master Updation Form

5.1.2. **PIF:** Project Identification Form

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6. Procedure:

6.1. Master Updation form (MUF) is a form consisting of 3 formats (A) Product Master Updation form (B) Product Pack Master Updation form (C) Product Price Master Updation form.

6.2. From the data provided by concern user department and location Information and Technology Department, Corporate Information and Technology dept. will provide product code, price code and pack code to the concerned locations.

6.3. On receipt of the duly approved project identification form (PIF), Production Head shall initiate the MUF filling activity as per Attachment-1 for new Product Launch.

6.4. In case of change in Pack Profile, after receiving the approved project identification form (PIF), Production Head shall initiate the MUF filling activity as per Attachment-2 for change in Pack Profile.

6.5. In case of Change in Price, Production Head shall initiate the MUF filling activity as per Attachment-3 for change in Price.

6.6. MUF filling activity, related to change in brand name of existing product, when generic name is changed due to change in pharmacopoeial status, change in shelf life, shall be handled through Attachment – 1.

6.7. Filled MUF shall be reviewed by QA and the location Information and Technology dept. shall send this to Corporate Information and Technology dept. for updation in Item Master.

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Attachment - 1
Product Master Updation Form

BF_CODE: $ up to 10 Characters	
Item Description: $ up to 120 Characters	
ITEM_SERIES: $ up to 5 Character	
ITEM_TYPE: $ upto 10 Characters (TABLETS / CAPSULES**)**	
GROUP_ CODE: $ upto 5 Characters	
SUB-GROUP_CODE: $ upto 5 Characters	
UNIT: $ upto 3 Characters	
INTEGRAL_QTY:$ upto 1 Character	
LOC_CODE: $ upto 8 Characters	
TRACK_SHELF_LIFE: $ upto 1 Character (Y / N **)**	
MIN_SHELF_LIFE: $ upto 4 Numbers (In Month**)**	
SHELF_LIFE: $ upto 5 Numbers (In Month**)**	
POTENCY_PERCENTAGE: $ upto 3 Numbers	
QC_CYCLE_TIME: $ upto 3 Numbers	
MFG_DATE_ON: $ upto 1 Character	
MFG_LEAD_TIME: $ upto 2 Numbers (In Day)	
QC_LEAD_TIME: $ upto 2 Numbers (In Day)	
PACK_CODE: $ upto 5 Characters	
GENERIC_DESCR: $ upto 100 Characters	

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Attachment – 2
Product Pack Master Updation Form

PRODUCT NAME	PRODUCT CODE	BATCH No.	PACK SIZE	SHIPPER CODE FOR OUTER SHIPPER	REMARK

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Attachment – 3
Product Price Master Updation Form

PRODUCT NAME	PRODUCT CODE	EFFECTIVE BATCH No.	PACK SIZE	MAXIMUM RETAIL PRICE	REMARK

7. History

Version No.		Effective Date	