STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Development & Procurement of Change Parts	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE

To provide a procedure for development, purchase, receipt, issue, maintenance, retrieval and destruction of change parts of Blister/Strip packing machine.

2.0 SCOPE

Applicable while developing, purchase, receipt, storage, issue, maintaining, retrieval and destruction of change parts of Blister/Strip packing machine.

3.0 RESPONSIBILITY

All production officer and Engineering personnel.

4.0 ACCOUNTABILITY

Production Head and Engineering Head.

5.0 PROCEDURE

5.1 Development of new change parts for blister/ Strip machine:

5.1.1 Based on the product design, the Engineering department in co-ordination with General Manager works and F & D the product development shall arrive at the packing style and shape of the Blister/Strip pack.

5.1.2 The details of shape, size, along with the sample capsules/tablets (if available) shall be forwarded to the manufacturer of change parts.

5.2 Purchase:

5.2.1 Based on the product design, the engineering department has to raise CER with the details of shape, size and to be send to purchase department for raising P.O.

5.2.2 Purchase requisition is made in duplicate, Original copy is sent to the supplier and carbon copy retained with Eng. Dept.

5.2.3 The vendor has to deliver change parts to the factory.

5.3 Receipt and Checking:

5.3.1 On receipt of the blister change parts, the engineering personnel have to check the change parts against invoice description and the purchase requisition and raise the GRN for the above said.

5.3.2 The following data are to be recorded while checking the change parts:

A) Cavity size of forming and sealing roller.

B) Die length

C) Change part lay out number.

5.3.3 Production personnel shall visually check the change parts for dimension with the available instruments.

5.3.4 The change parts are then run on machine for trial and checked for forming sealing and cutting of the dummy strips. These strips are then checked for quality attributes and if found satisfactory the GRN is approved.

5.3.5 If any change parts fails to match with specification or damage it shall be destroyed or send for repairing after approval of the Location Head.

5.4 Storage:

5.4.1 The change parts should be kept covered in poly bags after cleaning.

5.4.2 The change parts are to be stored in the racks provided in the tool room.

5.4.3 Change parts are segregated and stored as per the layout no.

5.5 Issue:

5.5.1 Issue the change parts to the Production department.

5.5.2 The change parts shall be checked against the specification or layout number mentioned in the batch packing record prior to taking any batches for packing.

5.5.3 The change parts should be issued in sets along with the gears specific to it.

5.6 Scraping and Destruction of change parts:

5.6.1 After 1.0 million capsules/tablets the change parts are to be visually checked for any damage.
After 10.0 million capsules/tablets the change parts are to be scraped

5.6.2 If any change parts is found to be worn out or damage, the same has to be send to the maintenance dept for sending to repairing to the party.

5.6.3 If it is not repairable it is to be scraped and destroyed by engineering after getting approval from the Location Head.

6.0 REFERENCE

In-House

7.0 ANNEXURE(S)

Nil

8.0 ABBREVIATION(S)

GRN : Good Receiving Note
F & D : Formulation And Deplopment
P.O : Purchase Order
CER : Capital expenditure request.

9.0 REVISION CARD

S.No.	Date	Details of Revision	Reason for Revision	Issue No.	Rev. No./Date	Approved By/Date