

## PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE								
<b>Department:</b> Production (External Preparation)	SOP No.:							
Title: Tubes Crimp Coding / Printing System	<b>Effective Date:</b>							
Supersedes: Nil	Review Date:							
Issue Date:	Page No.:							

#### 1.0 OBJECTIVE:

To lay down a Procedure for Batch coding / Embossing, Engraving on Tubes.

#### 2.0 SCOPE:

This SOP is applicable for Batch coding / Embossing, Engraving on Tubes crimp before start of filling & sealing process Packaging Section of Ointment Section.

#### 3.0 RESPONSIBILITY:

Officer/Executive Production

#### 4.0 ACCOUNTABILITY:

Head Production

#### **5.0 ABBREVIATIONS:**

BPCR Batch Production Control Record

MRP Maximum Retail Price

Mfg. Manufacturing

No. Number

PVC Poly vinyl chloride

SOP Standard Operating Procedure

#### 6.0 PROCEDURE:

#### **6.1 LAMINATED OR SEAMLESS TUBES: (ON-LINE)**

- **6.1.1** During filling & sealing operation of tubes, On-line embossing of batch number/Mfg date/ Expiry date shall be ensured on crimp of the tube.
- **6.1.2** Depending upon the size of tube and space availability on crimp for batch coding SS stereo letter size shall be decided.
- As per text matter of tube the information required e.g. Batch no. and Mfg. date shall be embossed on either side of tube crimp the emboss coding pattern on crimp shall be separated with letter slash i.e. "/", Batch No./Mfg date or Batch No./Exp. Date. E.g. ABAB01/04/22, where ABAB01 is the batch number and 04/22 is Mfg. date. Conjugated with slash. For manufacturing date the last two digit of the year shall be considered. If the space for embossing the coding not sufficient then 2<sup>nd</sup> side of the crimp the remaining information can be embossed.
- **6.1.4** Batch coding pattern on crimp of tube shall be followed as per the party requirement and approval.



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- 6.1.5 Two sides "I" mark tube shall be used if the two side (front side or rare side of tube) embossing on tube crimp is required.
- 6.1.6 Make an entry in "Tube Crimp Coding Approval Record" As per Annexure No. I.

#### **6.2 FOR ALUMINUM TUBES:**

- **6.2.1** In case of Aluminum tube only single side batch coding pattern engrave/Ink jet print on crimp of the tube.
- 6.2.2 Make an entry in "Tube Crimp Coding Approval Record" As per Annexure No. I.

#### 7.0 ANNEXURES:

ANNEXURES NO.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Tube Crimp Coding Approval Record	

**ENCLOSURE:** SOP Training Record

#### **8.0 DISTRIBUTION:**

• Controlled Copy No.01 Quality Assurance

• Controlled Copy No.02 Production

• Master Copy Quality Assurance

#### 9.0 REFERENCES:

Not applicable.

### 10.0 REVISION HISTORY:

#### **CHANGE HISTORY LOG**

Revision No.	Change control No.	<b>Details of Changes</b>	Reason for Change	Effective Date	Updated By



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## ANNEXURE – I TUBE CRIMP CODING APPROVAL RECORD

Department: Production Month & Year:

Date	Product Name	Batch No.	Batch Size	Mfg. Date	Exp. Date	Pack Size	Packing Material (Alu. Or Lami or Plastic Tube/ Other)	Coding Details	Done By Operator	Checked By Production	Verified By QA	Remark