



PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Production	SOP No.:
Title: Procedure for indent, receipt issue, usage and destruction of rubber stereotypes.	Effective Date:
Supersedes: Nil	Review Date:
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1.0 OBJECTIVE:

To lay down the Procedure for indent, receipt issue, usage and destruction of rubber stereotypes.

2.0 SCOPE:

This procedure is applicable for indent, receipt issue, usage and destruction of rubber stereotypes.

3.0 RESPONSIBILITY:

Officer /Executive/Assistant Manager

Head Production: To ensure execution & compliance.

Head QA: To ensure the compliance.

4.0 PROCEDURE:

4.1 Stereos required for the overprinting is to be indented in Stereo Order by production as per Annexure- I.



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- 4.2 Write Product Name, Batch No., Text Matter, Size of Letter and No. of stereo required in Stereo Order in Duplicate Copy.
- 4.3 Take the details of Product name, Batch No. , Mfg. date, Exp. Date, Mfg. License No. (If applicable) from BMR to write in Stereo Order.
- 4.4 Take maximum retail price from controlled price list.
- 4.5 Take text matter detail from BPR For size of font refer bellow-
 - Keep 1.5 mm of font for blister stereo (Verdana).
 - Keep 2.0 mm of font for carton (Verdana).
 - Put type of stereo for groove or flat as per requirement.
- 4.6 Put order no. in stereo order like P/T/YY/XXXX, P/O/YY/XXXX, P/S/YY/XXXX, P/H/YY/XXXX where P-Pharmadevils, T-tablet, O-Ointment, S-soft gelatin capsule, H-Hard gelatin capsule, YY-year, XXXX-serial no. of form.
- 4.7 Suppose 1st order of stereo given to vendor from tablet then the order no. shall be P/T/15/0001.
- 4.8 Handover the 1st copy (white) of stereo order to vendor after signing by production.
- 4.9 Keep the duplicate copy (pink) in stereo order for reference and follow up.
After receipt of stereo, impression of each piece of stereo is to be taken in stereo register and record the same as per Annexure –II.
- 4.10 Impression of each piece of stereo shall be checked by Production (sign / Date) and compared with the BMR / BPR for its Batch coding details.
- 4.11 In case the impression is improper, make a new impression and cut the previous impression with signature and date.
- 4.12 After approval the stereotypes shall be stored under lock and key in the appropriate stereo cupboard. Key of the cupboard shall be in the custody of production officer/ in-charge.
- 4.13 If the matter of the stereo procured is incorrect or improper, then the stereotypes shall be destroyed and fresh stereotypes are to be indented as per the format given in Annexure-I.
- 4.14 Issue the required number of stereo to technician for packing and record in the stereo register with signature of issued by officer and received by technician.



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- 4.15 After completing the packing activity, collect the used stereos, and verify that the quantity is same as the quantity is used / issued and put sign of returned by technician and received by officer.
- 4.16 Collect the issued and retained stereos and verify the quantity of both with the received quantity. Destroy them by cutting in to pieces.
- 4.17 Record the destruction details in the stereo register, which shall be checked by production and verified by Quality Assurance.
- 4.18 If there is any change in the production plan or the production for which is cancelled / postponed, the stereos procured during the period / plan shall be destroyed, and record in remark column as per the format given in Annexure - II.

5.0 ANNEXURE (S):

Annexure –I: Stereo order

Annexure –II : Stereo register

6.0 REFERENCE(S) :

Nil.

7.0 ABBREVIATION (S) /DEFINITION (S) :

BPR : Batch Packing Record

BMR : batch Manufacturing Record

QA : Quality Assurance

Mfg.: manufacturing

Exp.: expiry

NO.: Number

QTY.: Quantity



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REVISION CARD

S. No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	----	----	New SOP	---