



# PHARMA DEVILS

PRODUCTION DEPARTMENT

## STANDARD OPERATING PROCEDURE

**Title:** Receipt and Handling of Rubber Stereos

<b>SOP No.:</b>		<b>Department:</b>	Production	
		<b>Effective Date:</b>		
<b>Revision No.:</b>	00	<b>Revision Date:</b>		
<b>Supersede Revision No.:</b>	Nil	<b>Page No.:</b>	1 of 10	

### 1.0 OBJECTIVE:

To lay down a Procedure for Receipt and Handling of Rubber Stereos.

### 2.0 SCOPE:

This SOP is applicable for Receipt and Handling of Rubber Stereos in Production.

### 3.0 RESPONSIBILITY:

Officer / Executive Production

### 4.0 ACCOUNTABILITY:

Head Production

### 5.0 ABBREVIATIONS:

B. No.	Batch Number
Exp.	Expiry
FG	Finished Goods
Pvt.	Private
Ltd.	Limited
M.L. No.	Manufacturing License Number
Mfg	Manufacturing
ml	Milliliter
MRP	Maximum Retail Price
NaCl	Sodium Chloride
No.	Number
QA	Quality Assurance
SOP	Standard Operating Procedure
SWFI	Sterile Water For Injection
Qty.	Quantity
Prod.	Production

### 6.0 PROCEDURE:

#### 6.1 STEREO ORDERING:

**6.1.1** Stereo ordered by Head Production or Officer / Executive Production as per the requirement of the Production monthly schedule or whenever required or after dispensing of the batch.

**6.1.2** For product, stereo order shall be raised with details of B. No., Mfg. Date, Exp. Date, MRP, Font Size & Quantity in a duplicate note book as shown in **Annexure- I, Titled "Stereo Indent Form For Product"**.

**6.1.3** For solvent NaCl & SWFI to be packed as combipack with product and for disposable syringe to be packed with product, stereo order shall be raised with details of B. No., M.L.No, Mfg. Date, Exp. Date, Manufactured By, Font Size & Quantity in a duplicate note book as shown in **Annexure- IV, titled "Stereo Indent Form for Solvent/Syringe"**.

**6.1.4** The MRP of particular product shall be confirmed from SAP.



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**6.1.5** Stereo indent form is finally checked and signed by production and send to QA.

**6.1.6** QA shall verify and sign Stereo Indent Form against Batch Record and approved MRP from SAP and return back to production.

**6.1.7** One copy of finalized Stereo Indent Form shall be handover to a stereo preparing agency and second copy shall be retaining by production.

*Note:* Rubber stereos ordered only approved stereo agency only.

### 6.2 RECEIVING OF STEREOS:

**6.2.1** After the stereo receipt, stereos are checked against the stereo indent form at receiving site.

**6.2.2** On receipt of stereo, individual word to word text matter impression shall be checked by putting the tick /dot mark with legible ink by production and verified by QA person on **Annexure -II, titled "Stereo Impression cum Approval Record"** in log book.

**6.2.3** No. of stereos noted and transfer the all stereo to production site.

**6.2.4** In case if stereos found with any impression discrepancy then complete set of stereo shall be destroyed in-presence of QA. New stereo indenting will be prepared as per stereo ordering and send to stereo agency along with observed discrepancy impression to prevent such occurrences

**6.2.5** Make the entry in stereo inward log book mentioning all details and quantity as per **Annexure-III, Titled "Stereo Receipt, Issuance, Retrieval and Destruction Record"**. Keep all the stereos labeled as per **Annexure- VI "stereo label"** in specified box under lock & key.

### 6.3 ISSUE AND REISSUE OF STEREOS:

**6.3.1** The required stereo is issued to the operator by production staff and quantity noted in "Stereo Receipt, Issuance, Retrieval and Destruction Record "and BPR. Balance stereos to be kept in lock and key.

**6.3.2** After issuance of stereo, the impression of stereos shall be done in format of **Annexure -II, titled "Stereo Impression cum Approval Record"** and individual word to word text matter impression shall be checked by putting the tick /dot mark with legible ink by production and verified by QA person. The verified impression sheet shall be attached with the BPR of respective batch/product.

**6.3.3** If there is damage of stereo while online using on the machine, stereos are reissued and quantity is noted in the log book titled as **"Stereo Receipt, Issuance, Retrieval and Destruction Record "**and in the BPR of respective batch/product.

**6.3.4** Maintain a logbook with details of issued stereos and balance stereos in the log book titled as **"Stereo Receipt, Issuance, Retrieval and Destruction Record"**



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### 6.4 DESTRUCTION OF STEREOS:

**6.4.1** After completion of packing of the batches issued stereo are returned to the production officer by the operator.

**6.4.2** Production and QA shall ensure that the all the issued stereos are returned back by the operator from packing machine. Reconciliation of stereos is done by the production staff after completion of the batch.

**6.4.3** Destroy rejected stereos by cutting into pieces in presence of QA and record the details in **Annexure III**, Titled “**Stereo Receipt, Issuance, Retrieval and Destruction Record**” and fill up scrap removal form for its disposal.

*Note:* Stereos which are not used change or cancellation or any of the reason are to be destroyed immediately after getting approval from HOD production and QA.

**6.4.4** Finally all unusable stereos destroyed and record the details in **Annexure III**, Titled “**Stereo Receipt, Issuance, Retrieval and Destruction Record**” and fill up scrap removal form for its disposal.

**6.4.5 In case of product stereo-**All the retrieved stereos along with the same batch no. in stock shall be verified and destroyed in presence of QA by cutting into pieces, placing in a polybag and to fill up the scrap disposal form for the same.

**6.4.6 In case of solvent stereo-** Use the rubber stereo of solvent (SWFI & Sodium chloride) having same batch no. for more than multiple product batches. Destroy the rubber stereo used for packing of any product. Keep the remaining stereo of solvent for next batches.

**6.4.7** At the same time make an entry in “**Stereo Receipt, Issuance, Retrieval and Destruction Record**” as per format shown in **Annexure-III**.

**6.4.8 Remark:** During indent of stereo it should be ensure that the use of new Symbol for Indian rupees i.e. “₹” in the products.

### 7.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Stereo Indent Form for Product	
Annexure-II	Stereo Impression cum Approval Record	
Annexure-III	Stereo Receipt, Issuance, Retrieval and Destruction Record	
Annexure-IV	Stereo Indent Form for Solvent/Syringe	
Annexure-V	Stereo Flow chart (I and Q -Block)	
Annexure-VI	Stereo Label	

**ENCLOSURES:** SOP Training Record



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### 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.	Details of Changes	Reason for Change	Effective Date	Updated By





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### ANNEXURE – II STEREO IMPRESSION CUM APPROVAL RECORD

**Block :** \_\_\_\_\_ **Department:** Production  
**Line :** \_\_\_\_\_ **Month :** \_\_\_\_\_  
**Section :** \_\_\_\_\_ **Year :** \_\_\_\_\_

Product Name	Mfg. Date	Batch No.	Exp. Date	Batch Size	Pack Size
<b>Packing Item: Label / Carton / Foil</b>					
<b>1. Stereo Impression</b>			<b>2. Stereo Impression</b>		
<b>3. Stereo Impression</b>			<b>4. Stereo Impression</b>		
<b>5. Stereo Impression</b>			<b>6. Stereo Impression</b>		
<b>7. Stereo Impression</b>			<b>8. Stereo Impression</b>		
<b>9. Stereo Impression</b>			<b>10. Stereo Impression</b>		
<b>11. Stereo Impression</b>			<b>12. Stereo Impression</b>		

**Checked By:** .....  
**(Production)**  
**Date** :.....

**Verified By :**.....  
**(QA)**  
**Date** :.....









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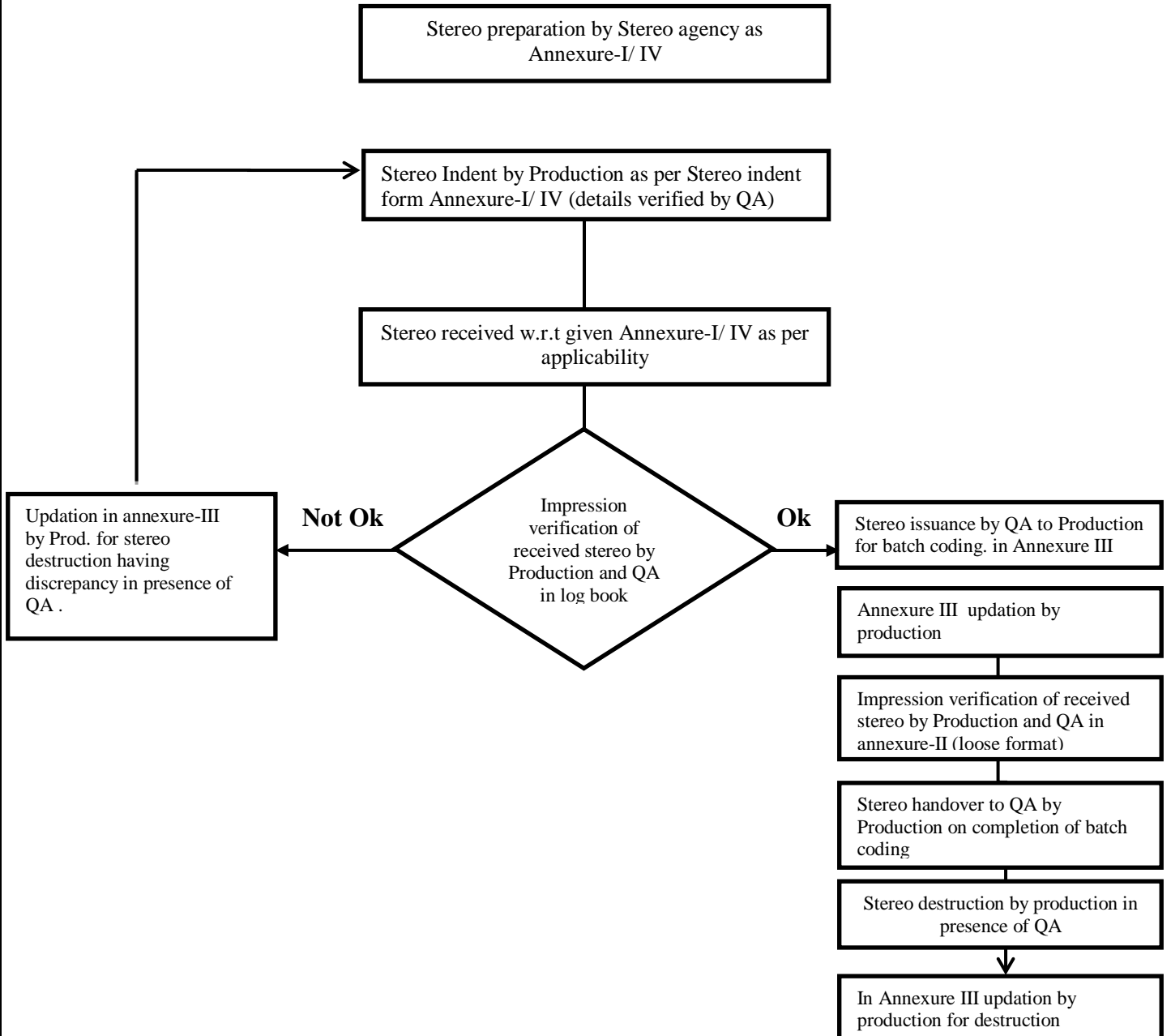
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### ANNEXURE- V STEREO FLOW CHART





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### ANNEXURE- VI STEREO LABEL

<b>Product Name</b>	
<b>Batch No.</b>	
<b>Mfg Date</b>	
<b>Exp. Date</b>	
<b>MRP</b>	
<b>Number of Stereos</b>	
<b>Checked By Prod. (Sign. &amp; Date)</b>	
<b>Verified By QA (Sign. &amp; Date)</b>	