STANDARD OPERATING PROCEDURE

Title: Operating and Cleaning Procedure for Carton Coding Machine

SOP No.:		Department:	Production	
		Effective Date:		
Revision No.:	00	Revision Date:		
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1.0 OBJECTIVE:
To lay down a Procedure for Operation and Cleaning of Carton Coding Machine.

2.0 SCOPE:
This SOP is applicable for Operation and Cleaning of Carton Coding Machine at Production area.

3.0 RESPONSIBILITY:
Operating Person – Production

4.0 ACCOUNTABILITY:
Head – Production

5.0 ABBREVIATIONS:
BPR   Batch Packaging Record
IPA   Iso Propyl Alcohol
ID No.   Identification Number
Ltd.   Limited
No.   Number
SOP   Standard Operating Procedure
NVZ   Non Varnished Zone

6.0 PROCEDURE:

6.1 Operation:

6.1.1 Ensure that machine is clean.

6.1.2 Set the guide plates and pusher plate.

6.1.3 Move the side roller and check whether the cartons are moving freely or not.

6.1.4 Set the stereo having coded matter as per batch requirement; adjust printing at proper place by rotating the side roller.

6.1.5 Switch on the mains & switch on the coding machine.

6.1.6 For verification of MRP of particular product refer the MRP mentioned in the SAP at location 1100 in case of Loan License Product (LL) or 9700 in case of Principle to Principle (P2P) as well as the MRP mentioned in the Process Order & Conversion note.

6.1.7 Take one coded carton as specimen and get it approved by Production and QA personnel after that attach this carton in the respective BPR.

6.1.8 Start the machine for batch coding operation. Perform the sorting of printed carton to segregate the rejected carton.

6.1.9 During sorting the over printed carton segregate the rejected carton and keep into lock and key rejection bin.

	PHARMA DEVILS		
	PRODUCTION DEPARTMENT		

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6.1.10 After completion of packing destroy the rejected carton and also consider during reconciliation of the same.

6.1.11 After completion of batch, switch off the machine and remove the remaining ink from ink drum and stereo from stereo drum, collect and return the used stereo to production officer/executive. Destroy the used and unused stereo as per SOP.

6.1.12 Record the machine operation details in respective "**Equipment's /Instruments Usage Cleaning Log**" as per **SOP**.

6.1.13 Cartons those are not having NVZ area shall be printed in G-Block by using bar coding machine having equipment ID. Entry of operation shall be maintained in respective logbook of equipment.

6.1.14 After Operation clean the machine.

6.2 **Cleaning:**

6.2.1 **'Switch Off'** the Machine.

6.2.2 Remove the stereo from stereo drum.

6.2.3 Remove the guard plates from the machine and clean it.

6.2.4 Remove remaining ink from ink roller using thinner solution.

6.2.5 Wipe off the pusher plate, guard plate & stereo roller using lint free cloth by 70% IPA solution.

6.2.6 Check the cleanliness of surrounding area.

6.2.7 Clean the coding machine daily / or after batch change over.

6.2.8 Record the maintenance/ cleaning details in respective "**Equipment's /Instruments Usage Cleaning Log**" as per **SOP.**

7.0 **ANNEXURES:**
Not Applicable.

ENCLOSURES: SOP Training Record

8.0 **DISTRIBUTION:**
- Controlled Copy No. 01   Quality Assurance
- Controlled Copy No. 02   Production
- Master Copy   Quality Assurance

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9.0   REFERENCES:

- SOP: Product Packing Operation in Parenteral blocks.

10.0   REVISION HISTORY:

CHANGE HISTORY LOG

Revision No.	Change Control No.	Details of Changes	Reason for Change	Effective Date	Updated By