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1 Objective

Process for operating and cleaning of Automatic Batch Printing Machine

2 Scope

Applicable for Automatic Batch Printing Machine for Packing department

3 Responsibility

Execution Operation

Quality Check Production Pharmacist

4 Accountability

Head of the Department

5 Procedure

5.1. Operation

- 5.1.1. Check the equipment for any leftover materials from previous product to make sure that equipment is clean.
- 5.1.2. Packing personnel should issue stereo to the operator as per the SOP, record this in the Stereo Record Register and get line clearance from the QA department.
- 5.1.3. As per the data received (Ex. Batch number, MRP, MFD, etc.?) adjust the block using flat rubber stereos.
- 5.1.4. Use a Book Black Ink for non-laminated cartons and Plast Black Ink for laminated cartons.
- 5.1.5. To achieve ink uniformity in the roller, rotate the roller by hand.
- 5.1.6. Fix the stereo by adjusting the master, allowing for a uniform printing and proper placement of the carton.
- 5.1.7. Switch the main "ON".
- 5.1.8. Remove the trial of overprinted matter on the carton.
- 5.1.9. If overprinting of the batch is satisfactory, request for a signature from the Packing personnel and QA department on overprinted cartons.
- 5.1.10. Continue and complete the batch.
- 5.1.11. Document the batch information in the Overprinting Log Book.
- 5.1.12. For reference, attach sample/specimen carton to BPR and provide one to the Printing department for future reference.
- 5.1.13. Collect the "overprinted" cartons in properly labelled container with the batch information.
- 5.1.14. Switch off the main and attach "to be cleaned" label to the equipment and document in the Equipment Log Book.
- 5.1.15. Seal the container until it is ready for packing. Place in the designated area for storage. After which, return the used stereo to the Packing personnel and destroy the used stereo in the presence of a QA personnel.

5.2. Cleaning

- 5.2.1. Use a thinner or an I.P.A to clean the roller, drying it with a dry lint free cloth.
- 5.2.2. If overprinting of laminated carton is done first, clean the roller with I.P.A, wipe with lint free cloth and apply Plast Black Ink to use for non-laminated carton.

6 Abbreviations

- **SOP** Standard Operating Procedure
- ${\bf BPR}\,$ Batch Packing Record
- **IPA** Isopropyl Alcohol
- **QA** Quality Assurance