PHARMA DEVILS

PRODUCTION DEPARTMENT

| STANDARD OPERATING PROCEDURE | |
|---|---|
| **Department:** Production (External Preparation) | **SOP No.:** |
| **Title:** Production Process and Control | **Effective Date:** |
| **Supersedes:** Nil | **Review Date:** |
| **Issue Date:** | **Page No.:** |

**1.0 OBJECTIVE:**

To lay down a Procedure "How to Control Production Process".

**2.0 SCOPE:**

This SOP is applicable for all Process & Control.

**3.0 RESPONSIBILITY:**

Production- Officer/Executive

**4.0 ACCOUNTABILITY:**

Head - Production

**5.0 ABBREVIATIONS:**

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| AR. No's | Analytical Report Numbers |
| BPCR | Batch Production Control Record |
| BPR | Batch Packing Record |
| BMR | Batch Manufacturing Record |
| QA | Quality Assurance |
| QC | Quality Control |
| SOP | Standard Operating Procedure |

**6.0 PROCEDURE:**

**6.1 INSTRUCTIONS:**

**6.1.1** Production In charge shall plan the daily production activities in consultation with Production Manager and Planning department.

**6.1.2** A copy of the weekly schedule is to be circulated to the in charge of the Production Departments.

**6.1.3** Everyday the plan to be inform to the Department In charge and the variance and priorities are to be discussed with the Production Manager. Details regarding machine utilization, manpower requirement absenteeism etc. is to be discussed with the Production Manager.

**6.1.4** The production process of a batch / product commences only after issue the BPCR by QA.

**6.2 MANUFACTURING**:

**6.2.1** Prior to the beginning of manufacturing operations, it is to be ensured that the machines and surroundings are clean and free from residues of previous products.

**6.2.2** Prior to the day's production, manufacturing chemist shall receive the dispensed materials from the store and ensure that all the equipment to be used for manufacturing of the product is clean.

**6.2.3** All cleaned equipments, utensils, and containers shall have a status tag/label indicating the cleanliness status.

**6.2.4** At any time of processing, all the equipments, utensils and containers shall have proper status label.

**6.2.5** Before affixing the labels to any equipment, processing or container of any other manufacturing accessory, it is to be ensured that all the previous and inappropriate labels are removed.

**6.2.6** Manufacturing chemist weighs each and every ingredient in presence of QA personnel before taking it for manufacturing and shall be recorded in relevant document.

**6.2.7** The clean poly bags contain the bulk product shall be tied and the container shall be pasted with duly signed label having the batch status.

**6.2.8** In process control, tests checks to be done strictly according to the BMR. Process data shall be recorded at the time of performance and duly signed.

**6.2.9** In case of any deviation from BPCR, manufacturing chemist inform to production in charge and QA for necessary action.

**6.2.10** If time limitations for any stages of processing are stated in the BPCR, the actual time taken for that stage shall be entered in the BPCR.

**6.2.11** At every stage of the process, the yield shall be calculated and recorded in the BPCR.

**6.2.12** In case of the intermediate stages of processing, a test requests form sent to quality control for clearance of the intermediate bulk before the processing of the next stage.

**6.2.13** Identification slips shall affix to the containers of the intermediate product with remarks.

**6.3 PACKAGING**:

**6.3.1** The manufacturing date for any batch of a product to be overprinted, from the month in which the ingredients are dispensed the expiry date is arrived at, from the shelf-life of the product.

**6.3.2** The price to be stamped on label/carton checked as per price list approved and circulated by QA.

**6.3.3** Required printing stereos organized well in advance before starting of overprinting of packing operations**.**

**6.3.4** The correctness of the stereos are to be checked (on the same day when received) by taking the impression, if any mistake is noticed, then reject the same and to be procure the new one.

**6.3.5** The quantity of the over-printed materials is to be reconciled with the quantity dispensed and recorded in the BPR any discrepancies in quantity of packing materials issued is to be investigated.

**6.3.6** Before starting the packing operations, it shall be ensured that the packing line is clear off from all the materials and products used for the previous operations.

**6.3.7** Packing is to be done as per the instructions defined in BPR.

**6.3.8** Finished goods are transferred to the store for distribution and sale after approval of QA Head.

**6.4 LABEL/CARTON MONITORING:**

**6.4.1** Accept only approved labels with A.R. No's from packing material store.

**6.4.2** Physically, check and verify the quantities and record.

**6.4.3** Production supervisor shall issue the instructions in writing for quantities, batch no., mfg date, exp. date, price and other necessary requirement etc. for overprinting. First few coded labels are to be sent to QA/QC for approval of batch details etc. and after approval, the entire batch quantity shall be printed.

**6.4.4** Coding to be certified by production and QA for batch details and other relevant details along with quality of printing.

**6.4.5** Maintain a register of coded labels duly certified and such label shall be attached to corresponding BPCR.

**6.4.6** All excess overprinted labels/cartons immediately be destroyed and the supervisor concerned maintain records of such label/cartons.

**6.4.7** At the end of the batch, proper reconciliation of the labels/cartons are to be done and completed BPCR handed over to QA Head.

## 7.0 ANNEXURES:

Not applicable.

**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.

## 10.0REVISION HISTOR:

**CHANGE HISTORY LOG**

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