

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE			
Department: Quality Assurance	SOP No.:		
Title: Monitoring of Manufacturing activities	Effective Date:		
Supersedes: Nil	Review Date:		
Issue Date:	Page No.:		

1.0 OBJECTIVE:

To lay down the procedure for monitoring the manufacturing and the Related activities.

2.0 SCOPE:

This procedure is applicable to all the activities performed in production and raw material / packing material store.

3.0 RESPONSIBILITY:

Officer, Executive Quality Assurance.

Head – Quality Assurance.

4.0 **DEFINITION**(S):

NA

5.0 PROCEDURE:

- 5.1 Visit to manufacturing facility (Production) and check for the following:
 - (a) BMR/BPR online filling
 - (b) House keeping
 - (c) Record keeping and updating
 - (d) Activity performance as per SOP
 - (e) Material handling
 - (f) Calibration/checking of instruments
 - (g) Operation of equipment
 - (h) Cleaning of equipment
 - (I) Personal Hygiene
- 5.2 Visit to raw material/ packing material store and check for the following:
 - a) Raw material and packing material storage room monitoring record.
 - b) Labeling.
 - c) Label reconciliation record.



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- d) Weighing balance-checking record.
- e) Dispensing area.
- f) Storage area.
- g) House Keeping.
- 5.3 Monitor the activities and observe for compliance or non-compliance in terms of laid-down procedures.
- 5.4 Discuss the observations with HOD for corrective action.

6.0 ABBREVIATION(S):

BMR: Batch Manufacturing Record

BPR : Batch Packing Record HOD : Head Of Department

SOP: Standard Operating Procedure

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Nil

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION