DECODING PHARMA

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.

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