STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Distribution and Dispatch of Batch	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for distribution and dispatch of given batch of a drug and arrangement of recording system for all distribution records.

2.0 SCOPE:

This SOP is applicable for all distribution records at ……..

3.0 RESPONSIBILITY:

Officer/Executive- Store/ Production

Officer/Executive- Quality Assurance

Head –Production

Head- Quality Assurance

4.0 DEFINITION(S):

Distribution Records: Document Related to dispatch of a drug to depot or market.

5.0 PROCEDURE:

5.1 Only approved batch shall be released for the market.

5.2 Appropriate storage conditions should be ensured before dispatch of drug product to the the market.

5.3 Personnels engaged in distribution of finished goods with receive training.

5.4 Periodic audit of warehousing practice followed at distribution center shall be carried out and records there of shall be maintained.

5.4 Records of distribution shall be maintained in such a manner that finished batch of a drug can be traced to the retain level to facilitate prompt and complete recall of the batch, if and when necessary.

5.5 Assessment of records pertaining to distribution of finished goods will be done by production and QA head jointly and will include all relevant factors including storage conditions, release status etc.

5.6 The distribution records shall be readily made available to the persons designated for recalls.

5.7 Records pertaining to distribution of drug product shall be retained up to the one year after the expiry of the product.

6.0 ABBREVIATION(S):

Dept. : Department

QAD : Quality Assurance Department

QC : Quality Control

SOP : Standard Operating Procedure

7.0 REFERENCE(S):

Schedule M, WHO guideline of Good Distribution Practices, TRS 937.

8.0 ANNEXURE(S):

Nil

9.0 REVISION CARD:

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