



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Distribution and Dispatch of Batch	Effective Date:
Supersedes: Nil	Review Date:
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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.



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- 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