PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Verification of Assay & LOD for API	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for verification of Assay and LOD for active pharmaceutical ingredient (API) prior to dispensing of batch.

2.0 SCOPE:

The procedure is applicable to verification of Assay and LOD for active pharmaceutical ingredient (API) before calculation for active drug.

3.0 RESPONSIBILITY:

Officer/ Executive : Production Department

Officer/ Executive : Store

Officer/ Executive : Quality control and Quality Assurance

Head Production : Shall ensure compliance and implementation of the SOP.

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 On receipt of BMR for QA, production shall initiate dispensing of batch.

5.2 Store dept note down the AR No. of API as per FEFO in to BMR/BPR requisition slip as per Reference SOP.

5.3 Note down the Assay, LOD/ moisture % value of API on Annexure – I

5.4 The value shall be verified by QC.

5.5 After verification from QC, proceed for availability status of Active materials as per Annexure-II then proceed for calculation part as per BMR.

6.0 ABBREVIATION(S):

API : Active pharmaceutical ingredient

LOD : Loss on drying

QC : Quality Control

QA : Quality Assurance

FEFO : First Expiry First Out

7.0 REFERENCE(S)

SOP: Requisition, issuance and archival of batch manufacturing and packing records.

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Verification of Assay & LOD for API	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

8.0 ANNEXURE(S):

Annexure-I : Verification of assay for active drugs

Annexure -II : Status of Active Pharmaceutical Ingredient

9.0 DISTRIBUTION:

Master copy : Quality Assurance

Controlled copy (S) : Production Department, Store Dept, Quality Control, Quality Assurance.

Reference copy (s) : Production department, store dept, Quality Control

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Verification of Assay & LOD for API	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure I

Verification of Assay for Active drugs

Section: **Date:**

S. No.	Material	Item code	A.R.No.	Assay on dried basis/ anhydrous	LOD/ Moisture content (% w/w)	Recorded by Production	Checked By (QC)

PHARMA DEVILS

PRODUCTION DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Production	**SOP No.:**
Title: Verification of Assay & LOD for API	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Annexure II

Status of Active Pharmaceutical Ingredients

Active Pharmaceutical Ingredients						**Item Code**				
S.No.	**Date**	**Use in Product**	**B. No.**	**A.R. No.**	**Qty. Available**	**Qty. Issued**	**Qty. Remaining**	**Record By**	**Ckd. By**	**Verified By**