SOP for Verification of Assay & LOD for API

1.0 OBJECTIVE:

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

2.0 SCOPE:

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

3.0 RESPONSIBILITY:

3.1 Officer/ Executive : Production Department: Verification of assay and LOD for API

3.2 Officer/ Executive : Store: Verification of assay and LOD for API

3.3 Officer/ Executive : Quality control and Quality Assurance: SOP Compliance

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

4.0 DEFINITION(S):

4.1 NA

5.0 PROCEDURE:

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

5.2 Store department note down the AR No. of API as per FEFO in to BMR/BPR requisition slip as per Reference SOP **(**Requisition, issuance and archival of batch manufacturing and packing records)**.**

5.3 Note down the Assay, LOD, moister content/ water value of API on Annexure – I (Verification of assay for active drugs).

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 (Status of Active Pharmaceutical Ingredient) then proceed for calculation part as per BMR.

5.6 Assay value of API (raw material) shall be considering 100.00% in case it is observed more than 100.00% and LOD/water content will remain same.

6.0 ABBREVIATION(S):

6.1 API : Active pharmaceutical ingredient

6.2 LOD : Loss on drying

6.3 QC : Quality Control

6.4 QA : Quality Assurance

6.5 FEFO : First Expiry First Out

7.0 REFERENCE(S):

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

8.0 ANNEXURE(S):

Annexure no.	Title of Annexure	Format no.	Mode of Execution
Annexure I	Verification of assay for active drugs		
Annexure II	Status of Active Pharmaceutical Ingredient		

9.0 DISTRIBUTION:

9.1 **Master copy :** Quality Assurance

9.2 **Controlled copy (S) :** Production Department (01), Store Department (01), Quality Control (01), Quality Assurance (01)

9.3 **Reference copy (s) :** Production department (02), Store Department (01), Quality Control (01)

10.0 REVISION HISTORY:

Version No.	Change Control No.	Reason (s) for Revision	Details of Revision	Effective Date

SOP for Verification of Assay & LOD for API

ANNEXURE I
Verification of Assay for Active Drugs

Section:	**Date:**
Material:	**Item code:**

S.No.	A.R. No.	Assay on Dried Basis	Anhydrous Basis	LOD	Moisture Content (% w/w)	Recorded By Production	Checked By (QC)

SOP for Verification of Assay & LOD for API

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. Required	Qty. Remaining	Record By	Ckd By	Verified By