PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation and Handling of Working standards	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for preparation and handling of working standards.

2.0 SCOPE:

This SOP is applicable to the working standards to be prepared in QC laboratory.

3.0 RESPONSIBILITY - Execution - Executive QC
Checking – Assistant Manager QC

4.0 ACCOUNTABILITY- Manager Quality Control

5.0 PROCEDURE:

5.1 Select latest approved batch of Raw material preferably having maximum purity and minimum impurity level.

5.2 Collect the required quantity of material from the selected batch as per Annexure -1.

5.3 Prepare at least 15 vials of working standards and each vial containing about 3 grams or minimum sufficient quantity of material.

5.4 Give the reference number to working standards as follows.

A-BBB/CC/DD

Where A : Corresponds to the first alphabet of name of raw material.

\- : Corresponds to separator.

BBB : Corresponds to serial number starting from 001,continuously to have details of total working standard in quality control laboratory.

CC : Corresponds to the last two digits of the year in which working standard is prepared.

DD : Corresponds to the no.of vials prepared for particular working standard starting from 01

5.5 If the second working standard of same material has to be prepared in the same current year then different serial number shall be assigned to this standard

5.6 Carry out the following test for preparation of working standard.

1. Assay (In six sets by two or more than two different analyst).

2. Loss on drying/Water content (In two sets by two different analyst)
3. Chromatographic purity/Related substances
4. I.R. (Where applicable)

5.7 Carry out Assay determination against reference standard wherever possible

5.8 For testing of working standard whose authentic reference standard, reference impurity, testing facility etc. is not available for testing in the laboratory, that material is sent to outside NABL accredited laboratory for testing.

5.9 Enter the results in the protocol of the respective material in any of the case mentioned above and attach the Photocopy of original C.O.A. with the protocol.

5.10 Calculate the average of six assay values obtained on as such basis. The RSD of these six values should not be more than 1.0% for chemical assay and 5.0% for microbial assay.

5.11 Store the material in light resistant glass vials, closed with rubber bungs and sealed with the Aluminium seals firmly.

5.12 Label the vials with the following details

1. Name of working standard
2. Ref. No.
3. Assay (On as such basis)
4. LOD/Water content
5. Date of preparation
6. Use before
7. Validity

5.13 Assign one year shelf life for working standard after six months check the stability of working standards (by duplicate analysis). The RSD should < 1% with the previous results.

5.14 Store all additional vials of working standard in refrigerator (Between 2 to 8°C) as per the list prepared in Annexure-II.(List of working standard).

5.15 Keep one vial of each working standard in the desiccators containing Silica.

5.16 Every month change the previous vial along with fresh vial for all working standards by

referring their respective records.

5.17 Maintain the issuance records as per Annexure – III

5.18 Destroy the expired vials of working standard after completion of shelf life and keep the record as per Annexure – III by using following procedure:

a) Empty the content in waste beaker containing water. After the material get soften, decant the water and transfer the paste in to the polythene bag and sent it to scrap management for further action.

b) Deface the labels of working standard vials / ampoules & discard the same into the waste bin.

5.19 Maintain the usage record of working standard as per Annexure – IV

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date
00	New	--------

8.0 DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0 REFERENCES:

Not Applicable

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

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No. : Number

Deptt : Department

RSD : Relative standard deviation

LOD : Loss on drying

COA : Certificate of Analysis

AC : Air conditioned

Ref . No. : Reference Number

IR : Infra-red

^{o} C : Degree Celsius

% : Percentage

Annexure- I : List of Working Standards

Annexure- II : Working Standards Records

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ANNEXURE- I
(LIST OF WORKING STANDARDS)

Prepared By: (Date & Sign)	Checked By: (Date & sign)	Approved By (Date & sign)

Sr. No	Name of Working std.	Sr. No.	Name of Working std.	Sr. No.	Name of Working std.

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ANNEXURE- II
(WORKING STANDARDS RECORDS)

Name of Working Standard	**:**	**Ref. No. of Working Standard**	**:**
Batch No. of Ref. standard	**:**		
Date of preparation	**:**	**% Assay (on as such basis)**	**:**
Use before	**:**	**LOD/Water Content**	**:**

S.No.	Vial Ref. No.	Date	Quantity issued	Quantity Balance	Issued by	Remark

No. of vials remaining on Expiry :
No. of vials destroyed :
Vials destroyed on :
Vials destroyed by :