PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procurement and Handling of Reference Standards & Impurity Standards	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for Procurement and Handling of Reference Standards & Impurity standards

2.0 SCOPE:

This SOP is applicable to the reference standards & impurity Standards in QC laboratory.

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

4.0 ACCOUNTABILITY- Manager Quality Control

5.0 PROCEDURE:

5.1 Get the latest list of the reference standards & impurity standards from the respective agencies for the current lot.

5.2 Procure the reference standards & impurity standards of U.S.P., B.P., E.P. and I.P. from respective agencies or as mentioned in the respective pharmacopoeia by placing a purchase order.

5.3 On receipt of the reference standard, check all the details on the label and enter the respective detail in the bin card to maintain a stock of the same as per Annexure-I (Reference standard) and Annexure-II (Impurity standard.)

5.4 Assign the Ref. number for Ref. std. and impurity std. as follows.

For Ref. Impurity standard:-

R	I	X	N	N

Where, RI = Reference impurity

X = Corresponding first alphabet of Ref. impurity

NN = Serial No. of Ref. Impurity Std. starting from 01

For Ref. standard:-

R	S	X	N	N

Where, RS = Reference standard

X = Corresponding first alphabet of Ref. standard

NN = Serial No. of Ref. standard starting from 01.

5.5 The Executive QC shall ensure that the bin card is maintained and entry is done after each withdrawal.

5.6 Working standard shall be prepared using the reference standard as per SOP. "Preparation and handling of working standard"

5.7 The Executive QC shall ensure the availability and procurement of reference standard well in advance.

5. 8 Reference standards shall be properly closed and stored in the refrigerator at 2° to 8° C temperature or other specified temperature.

5.9 Discard the old lot of reference standard on implementation of current lot as per following procedure

5.9.1 Empty the contents in waste beaker containing water. After the material gets soften, decant the water & transfer the paste in to the polyethylene bag. This paste is then sent to scrap yard.

5.9.2 Deface the labels of the reference standard vial or ampoules.

5.9.3 Discard the vial & ampoule in to the dust bin for broken glass ware.

5.9.4 Sent the defaced label and broken vials to scrap yard for disposal.

5.9.5 Record the destruction detail of reference standard in Annexure –I & Impurity standard in Annexure-II.

6.0 SAFETY & PRECAUTIONS:

Not Applicable

7.0 REVISION HISTORY:

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

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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:

"Preparation and handling of working standard "

10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

CQA : Corporate Quality Assurance

QA : Quality Assurance

No. : Number

Dept. :Department

B.P. : British Pharmacopoeia

U.S.P. : United State Pharmacopoeia

E.P : European Pharmacopoeia

Ref. : Reference

Std. : Standard

Annexure- I : Detail of Reference Standard

Annexure- II : Detail of Impurity Standard

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ANNEXURE – I
DETAIL OF REFERENCE STANDARD

Name of reference standard: _____ **Ref. No.: _____**

Current Lot No.:_____ **Procured From : _____**

S.No.	Date of Receipt	Qty. Received (mg)	Date of issue	Qty. issued (mg)	Balance Quantity (mg)	Issued by	Date of Discarding	Lot. No. Discarded	Qty. discarded (mg)	Discarded By

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ANNEXURE – II
DETAIL OF IMPURITY STANDARD

Name of impurity standard: _____ Ref. No.:_____

Current Lot No.:_____ Procured From : _____

S. No.	Date of Receipt	Qty. Received (mg)	Date of issue	Qty. issued (mg)	Balance Quantity (mg)	Issued by	Date of Discarding	Lot. No. Discarded	Qty. discarded (mg)	Discarded By