PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for Procurement, Standardization, Storage and Usage of Reference Standard and Working Standard	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for procurement, Qualification, storage & usage of Reference standard and Working standard in Quality Control Department.

2.0 SCOPE:

This SOP is applicable to

2.1.1 Procurement and storage of Reference Standard.

2.1.2 Usage and destruction of Reference Standard.

2.1.3 Development and Qualification of working standard (WS)

2.1.4 Usage and Destruction of working standard.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head -- Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 Reference standard are categorized in two types:

A Pharmacopoeial Reference Standard: These are for the products mentioned in the Pharmacopoeia i.e. USP, BP, Ph.Eur and Indian pharmacopoeia.

B Non Pharmacopoeial Reference Standard: These are for the products, which are not mentioned in the Pharmacopoeia

5.1.1 Working Standard (WS): WS shall be developed in-house and qualified against the Reference Standard.

5.2 Procurement and storage of Reference standard:

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for Procurement, Standardization, Storage and Usage of Reference Standard and Working Standard	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

5.2.1 Pharmacopoeial Reference Standards shall be procured from the respective agencies or representative of agencies.

5.2.2 Non-Pharmacopoeia Reference standards are procured from the manufacturer of specific substance or from AMD.

5.2.3 Reference standard are procured whenever

a. New lot number of pharmacopoeial reference standard is released by the agencies.
b. Non-pharmacopoeial reference standard is expired.
c. New product is introduced in the facility.

5.2.4 Keep track of the release of new lots number of reference standard in the publications of agencies or in web site of respective agencies.

5.2.5 After receiving the reference standard, record the detail in the reference standard inward register as per Annexure –I.

5.2.6 Receive reference standard (Non-pharmacopoeial) from manufacturer along with certificate of analysis.

5.2.7 On receipt, check the integrity of seal of reference standard vial and label details.

5.2.8 Whenever the potency/purity is not mentioned on the label consider the same as 100%.

5.2.9 Store the reference standard vial in a closed box or desiccators and keep at temperature 2-8°C or as specified on the label.

5.3 Usage & Destruction of Reference Standard:

5.3.1 Record the date of opening for the testing or for the Qualification of working standard in reference standard logbook as per Annexure-I

5.3.2 During usage of reference standard, precautions should be taken such that contents of the vial are not contaminated with other products or any spillage should not occur.

5.3.3 Seal the reference standard vial after usage & keep in the designated place.

5.3.4 Ensure that reference standard quantity is sufficient for next qualification. If not indent for further procurement.

5.3.5 If the reference standard is expired (for non-pharmacopoeial) and /or replaced (for pharmacopoeial) by a new lot of reference standard dispose off the previous lot by solubilizing in a suitable solvent and discarding the solution and record the same in usage book.

5.3.6 Consumption records of reference standard should be recorded in Annexure VII.

5.4 Development & Qualification of working standards:

5.4.1 Pharmacopoeia reference standard is received in less quantity therefore working standard is developed against pharmacopoeial reference standard.

5.4.2 If non-Pharmacopoeial reference standard is received in sufficient quantity same standard can be used for routine analysis, otherwise working standard shall be developed against this standard.

5.4.3 For development of WS, select approved manufacturing batch, tested as per respective pharmacopoeia. Incase of nonavailability of approved batch in stock, material from approved vendor source may be used by simultaneously analyzing against reference standard.

5.4.4 Collect approximately 50gm sample from the selected batch. The sample quantity may changed as per requirement.

5.4.5 Perform the following test.

a. Description

b. Identification (IR and / or HPLC or as specified in the respective specification if IR or HPLC not mentioned in the respective specification as Identification test).

c. Water Content / Loss on drying

d. Assay / Potency

e. Any additional test, if required.

5.4.6 Above tests shall be carried out as per the standard testing procedure mentioned for respective material.

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for Procurement, Standardization, Storage and Usage of Reference Standard and Working Standard	**Effective Date:**
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Issue Date:	**Page No.:**

5.4.7 Record the analysis in the working standard test data sheet as per Annexure-II

5.4.8 In the test of assay, prepare one reference standard solution and three working standard solution as per the respective standard testing procedure.

5.4.9 System suitability shall be performed, as per respective pharmacopoeia / specification / STP and each WS preparation shall be injected in duplicate.

5.4.10 The area variation between two injections of individual sample preparation should not be more than 1.0 %.

5.4.11 Calculate the average of 3 assay values obtained on as is basis. The RSD of these 3 assay values should not be more than 1.0 %.

5.4.12 WS is given a unique serial number having nine characters.

A typical example is as given below.

WS	-	xxx	/	01

Where as

WS is a working standard

\- Dash

xxx indicates code for particular item.

/ Slash

01 serial number of working standard

5.4.13 Prepare certificate of analysis for the test performed for the qualification of WS. The format of COA should be as per the Annexure-III.

5.4.14 Preserve the working standard in clean & dry vial below 25°C or in freeze as per material requirement.

5.4.15 Transfer the WS in to six / twelve amber coloured glass vials, under the sampling booth area, each vials containing minimum 2 gm of sample. In case of Rifampicin 24 vial shall be prepared under sampling booth area by purging / flushing nitrogen.

5.4.16 In case of unavailability of material, costly material or not frequently manufacturing product material vial may contain less than 2 g of sample.

5.4.16 Each vial shall be properly sealed and labeled as per Annexure-IV.

5.4.17 The remaining quantity is kept in one vial and labeled. If WS is required by any customer, material from this shall be supplied.

5.4.18 Keep all the vials of working standard in a desicator or as per storage conditions mentioned on the labels.

5.5 Usage and destruction of WS:

5.5.1 One vial shall be issued by the Executive QC, to the analyst for its use for not more than 30 days. For Rifampicin working standard vial shall be issue for its use for not more than 7 days.

5.5.2 Issuance of WS vial shall be recorded in working standard logbook as per the format given in Annexure-V.

5.5.3 Take required WS vial from dessicator, weigh the required quantity of the WS and close the vial immediately and keep in the dessicator.

5.5.4 In case of vials stored at 2-8°C, Take required WS vial and keep it in the desiccator for about 15 to 20 minutes to attain room temperature. After attaining room temperature weigh the required quantity of the WS and seal the vial immediately and keep in the designated place again.

5.5.5 Remaining quantity (if any) of issued vial at the end of one month shall be destroyed by dissolving in suitable solvent & thereafter discarding the solution.

5.5.6 Destroy all remaining amount of WS at the end of the validity period and after development of the new WS. Record the destruction in the working standard log book (as per Annexure-V). Consumption of working standard should be recorded in Annexure VI. 0.

5.6 Frequency of WS development:

5.6.1 Validity period of WS shall be six months or as per label.

5.6.2 Validity period of WS for new material shall be six months or as per label.

5.6.3 The validity of a newly developed material shall be extended after proper stability study.

5.6.4 The preparation of Inhouse WS after the validity period shall be done from the

respective previous WS if the vendors are unable to supply WS within the specified time period. The previous WS shall be use as reference standard after proper characterization.

6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP - Standard Operating Procedure

WS- Working standard

QCD - Quality Control Department

SOP - Standard Operating Procedure

WS- Working standard

RS- Reference standard

CRS-Certified Reference Standard

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure – I: RS Log book

Annexure –II: Record of Analysis of WS

Annexure – III: Certificate of Analysis of WS

Annexure –IV: Label of WS

Annexure –V: WS Log book

Annexure- VI: Working standard consumption record

Annexure-VII: Reference standard consumption record

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION