PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Protocol for Working Standard	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for the Preparation, Numbering, Approval, Authorization,Control, and Revision of Protocols for working standards.

2.0 SCOPE:

This SOP shall be applicable for preparation and control of all working standard protocols of Quality control department.

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

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE:

5.1 QC Deptt. shall prepare working standard as per specific requirements.

5.2 Give the reference no. of working standards as per current version of SOP "Preparation and handling of working standard"

5.3 The front page, subsequent pages, and Certificate of Analysis of Data sheets shall be prepared on the approved format on A-4 size paper. (Refer: Annexure-I for front page and subsequent pages, Annexure-II Certificate of Analysis for working standard).

5.4 Each Protocol shall have a unique seven alphanumeric number. Once number is allocated to any Protocol the same number shall not be repeated to other Protocol.

NUMBERING SYSTEM						
First character	**Second character**	**Third character**	**Fourth character**	**Fifth character**	**Sixth character**	**Seventh character**
W	S	P	-	N	N	N

Where
W = Working

S = Standard

P = Protocol

\- = Separator

5th , 6th and 7th characters are the S. No. started from 001

5.5 After initiation, approval, and authorization of Protocol, the Master copy shall be submitted to QA documentation cell.

5.6 QA department shall issue a photocopy by stamping on the back side of each page as a "OPERATIONAL COPY FOR PHOTOCOPYING"

5.7 Take a photocopy of operational copy for use by authorized person (Section In-charge).

5.8 Maintain issuance record of working standard Protocol as per Annexure-II.

5.9 All the Protocols shall be reviewed whenever any change in specification or in testing procedure amended by the pharmacopoeia or relevant source.

5.10 Any change in Protocol shall be done through current version of Change Control Procedure

5.11 After revision, Master copy of Protocol shall be submitted to QA documentation cell for control and issuance.

6.0 SAFETY & PRECAUTIONS :

Not Applicable

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

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

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10.0 ABBREVIATIONS & ANNEXURES:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

STP : Standard Test Procedure

Annexure-I : Protocol Format For Working Standard

Annexure-II : Certificate Of Analysis Of Working Standard

Annexure-III: Working Standard Protocol Issuance Record

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ANNEXURE-I
PROTOCOL FORMAT FOR WORKING STANDARD

	PROTOCOL FOR WORKING STANDARD	**Page 1 of Y**
NAME OF WORKING STANDARD:		
REFERENCE No. :		

SPECIFICATION DETAILS	STANDARD TEST PROCEDURE DETAILS
Specification No. : Effective Date :	STP No. : Effective Date :

REFERENCE STANDARD DETAILS	MATERIAL DETAILS
Reference Lot No./ Batch No. : % Purity (on as such basis) :	Material Code No : A.R No : Mfg & Expiry :

	PROTOCOL FOR WORKING STANDARD	**Page Y of Y**
NAME OF WORKING STANDARD:		
REFERENCE No. :		

1) Test Name: Instrument ID. No.:

Remarks: Complies/Does not comply

Analysed by
& Date

Checked by
& Date

Remaining test will be follow in same manner

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ANNEXURE-II
CERTIFICATE OF ANALYSIS OF WORKING STANDARD

	PROTOCOL FOR WORKING STANDARD	**Format No. _____**

Working standard Name :	**Reference :**
AR No. of Materials used :	**Specification No. :**
Date of Preparation :	**Total Qty Sampled :**
Use Before	**No. of Vials :**
Report Date :	**Qty individual vial :**

Sr. No.	Tests	Release Limits	Results

Remarks: Complies / Does not comply as per IP/ BP/ USP/ IH specification.

Analyst :
Date :

Checked by:
Date:

Approved by:
Date :

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ANNEXURE-III

WORKING STANDARD PROTOCOL (OPERATION COPY) ISSUANCE RECORD

S.No.	Working Standard Ref. No.	Issued By/ Date	Received By /Date	Remarks