PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Procedure for assuring the Quality of test and Calibration results	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for monitoring the validity of test and/or calibration results and the Verification practices for checking the validity of the test/ calibration results and for Estimation of the component of precision of the result.

2.0 SCOPE:

This SOP shall be applicable in Quality Control Laboratory.

3.0 RESPONSIBILITY:

3.1 Execution- Executive QC.

3.2 Checking - Assistant Manager QC.

3.3 Manager QC

4.0 PROCEDURE:

4.1 Executive and above or designated persons from Raw Material Section (for Active Material Only), Finished Product Section, Microbiology Section & Stability Section shall prepare the Material/ product specific results trend for their respective sections.

4.2 The trend shall be maintained in computer on Annexure - I.

4.3 When any 'Out of Trend' results come, they shall be intimated to their respective Section Head or Quality Control Manager.

4.4 Quality Control Manager shall check the results and ask the Section Head for the investigation for the root cause for the same. The Procedure for Control of Non-conforming Work, Corrective Action Preventive Action shall be followed.

4.5 The calibration results trend of instrument shall be prepared in computer on Annexure II.

4.6 Whenever any 'Out of Calibration' results found, 4.3 & 4.4 shall be followed.

4.7 Executive QC shall check the website of USP, BP, EP for the current status of reference Material lot number.

4.8 Whenever any new lot number of reference material/ standard, under scope is released by respective body, the same shall be purchased immediately .

4.9 The concerned person shall prepare the new Working Standard against the new Reference Standard within 15 days from the receipt of the reference standard.

4.10 The Manager Quality Control shall assure the periodic Retesting of the Retained items

4.11 The Manager Quality Control shall assure the participation in the Proficiency Testing Program/ Inter Laboratory Comparison and monitor the results.

4.12 If the PT Program/ ILC results do not come within satisfactory limits, 4.3 & 4.4 shall be followed.

4.13 The Manager Quality Control shall assure the proper training of QC personnel for the activities assigned.

4.14 The Section In charge of all sections shall maintain the environmental conditions with the Engineering Department.

4.15 The Manager Quality Control shall assure the use validated method for analysis.

4.16 The trend format shall be password protected and only authorized person shall take the print of the same.

4.17 The trend results are valid when the print out is signed for Prepared By, Checked By and Approved By.

5.0 SAFETY AND PRECAUTION:

5.1 Always use hand gloves, facemask and other required safety measures.

6.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date

7.0 REFERENCES:

Procedure for Control of Non-conforming Work SOP.

8.0 ABBREVIATIONS:

SOP : Standard Operating Procedure

QA : Quality Assurance

No. : Number

QC : Quality Control

STP : Standard Test Procedure

USP : United States Pharmacopoeia

BP : British Pharmacopoeia

EP : European Pharmacopoeia

Sr. : Serial

ILC : Inter Laboratory Comparison

PT : Proficiency Testing

9.0 ANNEXURE

Annexure-I : Format for trend data for Raw Material / Finished products
Annexure II : Format for trend data of calibration.

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Annexure-I

FORMAT FOR TREND DATA FOR RAW MATERIAL / FINISHED PRODUCTS

Name of the Product/ Material: _____

Mfg. Name (in case of RM) : _____

B.No.	Test						

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ANNEXURE II
FORMAT FOR TREND DATA OF CALIBRATION

Name of Instrument : _____

Instrument ID No. : _____

Date	**Test**						