PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Calibration of instrument from out side agency	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure / guidelines for the calibration of identified Quality Control instruments from outside agency.

2.0 SCOPE:

This SOP is applicable to Quality Control laboratory.

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

4.0 ACCOUNTABILITY - Manager Quality Control.

5.0 PROCEDURE;

5.1 Preparation of Calibration schedule:

5.1.1 Calibration schedule shall be prepared for all instruments/ Equipments which are required for the third party calibration.

5.1.2 Calibration schedule shall be prepared at every last month of the financial year or can be revised as per the requirement.

5.1.3 Calibration schedule shall be prepared as per Annexure -I

5.2 Procedure for calibration to be carried out at plant by third party:

5.2.1 Instrument/Equipment shall be calibrated by third party in the presence of executives and above of QC Deptt. of the company .

5.2.2 Calibration data shall be checked by the executives and Assistant Manager.

5.2.3 After the satisfaction of reviewed calibration data, third party shall affix the calibration label on the instrument /equipment with his initials and date.

5.2.4 If the instrument contains previous calibration label then it shall be torned by the third party and new calibration label shall be affixed.

5.2.5 Raw data of the calibration shall be maintained .

5.2.6 After the completion of calibration, executive and above shall make an entry in calibration schedule for actual performance.

5.2.7 If calibration is carried out after the due date, the deviation should be raised for the same

5.2.8 If the instrument performs unsatisfactory results during its use and if it is affecting the parameters of calibration, the executive and above should intimate the third party for the calibration of same instrument.

5.2.9 Any out of calibration results should be informed to Manager QC

5.3 Procedure for calibration to be carried out at outside the Laboratory:

5.3.1 Prior to one month time of the due date for calibration, executive and above shall send the instrument / equipment for calibration.

5.3.2 At the time of calibration, responsible analyst shall send the instrument to the third party with the calibration intimation (Annexure –II).

5.3.3 Executive and above shall make the necessary entry into calibration intimation in outside testing register.

5.3.4 After the filling of above, Assistant Manager and above shall verify the calibration intimation and put the initials and date.

5.3.5 Outside laboratory shall calibrate the instrument and affix the calibration label on it, return it to Promed along with calibration certificate duly certified.

5.3.5 Calibration data shall be reviewed by the executive and above and shall fill in the calibration intimation form, shall be verified by the Assistant Manager and above**.**

5.3.6 Executive and above shall make an entry for the date of calibration and due date of the calibration in the calibration intimation form.

5.3.7 On receiving back the calibrated instrument, executive and above shall make necessary entry in the outside testing register and in the calibration schedule

5.3.8 Any out of the calibration parameter shall be informed to the Manager QC

5.4 General:

5.4.1 Standard & Equipment used for calibration shall be calibrated and party shall submit the certificate with national traceability.

5.4.2 Annual contract with all details shall be signed.

5.4.3 In case of out of calibration, SOP on “Out of Calibration” shall be followed.

6.0 SAFETY & PRECAUTIONS:

Not Applicable.

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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:

SOP on “Out of Calibration”

10.0 ABBREVIATIONS & ANNEXURES

SOP : Standard Operating Procedure

No. : Number

QC : Quality Control

QA : Quality Assurance

RM : Raw Material

Deptt. : Department

Annexure - I: Calibration Schedule

Annexure –II: Calibration intimation

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ANNEXURE - I
CALIBRATION SCHEDULE BY THIRD PARTY

S.No.	Instrument/Equipment	Quantity	Frequency	Parameter to be calibrated	Acceptance Criteria

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ANNEXURE – II
CALIBRATION INTIMATION

Instrument/ Equipment				
Code No.				
Third party Name				
Calibration Parameter/Tolerance				
S.No.	**Type of Calibration**	**Range**	**Findings**	**Tolerance**

Remarks:

Prepared by/Date	**Verified by/Date**
Date of Calibration	**Due date of calibration**
Traceability of certificate No.	
Reviewed By/Date (After Calibration)	**Verified By/Date (After Calibration)**