



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance

SOP No.:

Title: Tolerance in the Calibration of Equipment/Instruments Schedule

Effective Date:

Supersedes: Nil

Review Date:

Issue Date:

Page No.:

1.0. OBJECTIVE:

The objective of this SOP is:

- 1.1 To describe a procedure for acceptable tolerance limit for the frequency of calibration of instruments.

2.0. RESPONSIBILITY:

- 2.1 Officer of Concerned Department shall be:

Responsible for calibration of the instrument in co-ordination with the Engineering Department.

- 2.2 Executive - Quality Assurance shall be:

Responsible for ensuring the timely calibration of the instruments.

3.0. ACCOUNTABILITY:

Head – Quality Assurance

4.0. PROCEDURE:

- 4.1 All the instruments shall be calibrated as per Schedule in the SOP of respective instruments.

- 4.2 The following tolerance limits shall be considered acceptable in the frequency of calibration of instruments.

Daily	:	-- Nil --
Weekly	:	± 01 days
Monthly	:	± 03 days
Quarterly	:	± 05 days
Six monthly	:	± 10 days
Yearly	:	± 15 days

- 4.3 Additional calibration shall be performed if instrument is shifted from one location to another location.

- 4.4 Affix the Calibration Tag on the instrument after the calibration is done.

- 4.5 Affix the label 'Under Maintenance' in case the instrument is not working properly, and report section in charge /Head of Department

- 4.6 Record the calibration results in the Standard format and in the Annexures of respective SOP.



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5.0 REASON FOR REVISION

5.1 Harmonization of format

6.0 TRAINING:

Trainer	--	Head – Quality Assurance
Trainee	--	All departmental Heads/Quality Assurance Personnel
Period	--	One day

7.0 DISTRIBUTION:

Certified Copy No. 1 :	Head of Department – Quality Control
Certified Copy No. 2 :	Head of Department – Oral Dosage Form
Certified Copy No. 3 :	Head of Department – Injection
Certified Copy No. 4 :	Head of Department – Engineering
Certified Copy No. 5 :	Head of Department – Warehouse
Original Copy :	Head – Quality Assurance

8.0 ANNEXURE:

None.

9.0 REFERENCE:

In-House