

# CALIBRATION

**Prism Pharmatech Solutions**

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# PROCEDURES

**THE FOLLOWING ACTIVITIES ARE NORMALLY UNDERTAKEN :**

- 1. Documentation Programme**
- 2. Identification Systems**
- 3. General Calibration Control Mechanism**
- 4. SOPs for Calibration**
- 5. Calibration Data Sheet**
- 6. Handling & Maintenance of Test Standards**
- 7. Calibration Certification Requirement**
- 8. Pre-purchase Review of New Instrumentation**
- 9. Review of Calibration Programme**
- 10. Training of Technicians**

# CALIBRATION STANDARD

## 1. PRIMARY STANDARD

This standard is normally 4 times more accurate than transfer standard.

## 2. TRANSFER STANDARD OR SECONDARY STANDARD

This is a calibrating equipment used to calibrate instruments or measuring standard. Normally these are calibrating Equipment in the laboratories and are 4 times more accurate than measuring standard.

## 3. MEASURING STANDARD

It is the instrument used to measure process parameters.

# INSTRUMENTS CALIBRATION

- ❖ **TEMPERATURE CONTROLLER**
- ❖ **TIMER**
- ❖ **PRESSURE GAUGE**
- ❖ **MANOMETER**
- ❖ **FILTER**
- ❖ **MECHANICAL DISPLACEMENT**
- ❖ **TECHOMETER**
- ❖ **THERMOMETER**
- ❖ **HYGROMETER**
- ❖ **VACCUM GAUGE**
- ❖ **THERMOCOUPLE etc....**

# CALIBRATION DEPARTMENTS IDENTIFICATION SYSTEM

The identification number may contain three fields e.g. XX-YY-123

1. Field 1, namely XX consists of a group of letters which indicates the location or plant.
2. Field 2, namely YY consists of a group of letters which indicate the equipment on which the instrument is fitted.
3. Field 3, is alpha numeric and indicates the type of instrument and inventory number

e.g. PR – RT2 – TI6 will mean

Location/plant	-	product or plant designated as PR
Equipment	-	Reaction Tank No. 2 as RT2
Instrument	-	Temp. Indicator No. 6 as TI6

# CLASSIFICATION OF INSTRUMENTS

## 1. CRITICAL INSTRUMENTS

The performance of these instruments affects the process or the product

## 2. MAJOR INSTRUMENTS

The performance of these instruments affects or the product

## 3. REFERENCE INSTRUMENTS

These are for convenience only and do not affect the process and/or the product

1. **Aseptic core Instruments : Each calibration, minimum 3 months**
2. **Critical Instruments : 6 months**
3. **Major Instruments : 12 months**
4. **Reference Instruments : At the time of Installation**

# CALIBRATION DATA SHEET

## Type of Instrument :

1. Instrument Identification Number :  
Description :  
Model No. :  
Serial No. :  
Range/ Scale :
2. Instrument Standard Used :  
Description :  
Model No. :  
Serial No. :  
Precision / Accuracy :
3. SOP Procedure Number to be followed :
4. Calibration Date & Time :
5. Calibration Site :

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# CALIBRATION DATA SHEET

- 6. **Environmental Conditions** :

  - a. **Temperature** :
  - b. **Humidity** :
  - c. **Pressure** :

- 7. **Calibration Completion Date** :
- 8. **Calibration Status** : **Accepted**  
: **Rejected**
- 9. **Calibration Frequency** :
- 10. **Next Calibration Due Date** :
- 11. **Name & Signature of Calibrating Technician** :

# CALIBRATION CERTIFICATION REQUIREMENT

## VENDOR CALIBRATION CERTIFICATE REQUIREMENT

- **Vendor's name and address**
- **Calibration site**
- **Calibration completion date**
- **SOP or specification and its issue date**
- **Instrument standard**
  1. **Description**
  2. **Model No.**
  3. **Serial NO.**
  4. **Precision/ accuracy**
- 6. **Instrument being calibrated**
  1. **Description**
  2. **Model No.**
  3. **Serial NO.**
  4. **Range/ Scale**

**(Continue)**

# CALIBRATION CERTIFICATION REQUIREMENT

7. **Summary of data at various data collection intervals and the correction value for both instrument and standard**
8. **Environmental Conditions**
9. **Calibration Frequency, next due date and exceptional conditions**
10. **Name and signature of calibrating technicians**

# REVIEW OF CALIBRATION PROGRAMME

1. **Frequency of calibration and performance of instrument**
2. **Operating procedure for Calibration**

# TRAINING PROGRAMME FOR CALIBRATION TECHNICIANS

1. **General Specifications**
2. **Operations Training**
3. **On going Training**

# VALIDATION OF CALIBRATION EQUIPMENT

All calibration equipment have to be validated regularly from Authorized Government Undertakings like IDEMI (Institute for Design of Electrical Measuring Instruments), ERTL (Electronic Regional Test Laboratories)

Validation frequencies for various Calibration Equipment may vary from 6 months to 1 year depending on its type. Typical frequencies for some of the equipment are :

Electronic Calibrator	:	1 year
Temperature Bath	:	6 months
Dead Weight Tester	:	6 months
Digital Multimeter	:	1 year

# CALIBRATION FAILURES

If the error in the measurement observed during the calibration exceeds acceptable limits, it is reported to the user department. The instrument is then repaired/replaced & placed under observation for specified duration say 2 weeks. After this duration is over, the instrument is taken into regular operation.

# Prism Pharmatech Solutions

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Thanking You