



# PHARMA DEVILS

ENGINEERING DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Engineering	<b>SOP No.:</b>
<b>Title:</b> Approval of External Agency	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE

- 1.1 To lay down the procedure for Approval of External Calibration Agency.

### 2.0 SCOPE

- 2.1 This SOP is applicable at \_\_\_\_\_ in selecting the Agency for External Calibrations.

### 3.0 RESPONSIBILITY

- 3.1 Personnel of the engineering department shall responsible to ensure the selection of external calibration agency for performing the calibration of process control instruments.
- 3.2 Personnel of the Quality Control department shall responsible to ensure the selection of external calibration agency for performing the calibration of all analytical equipment/ instrument to be done as per schedule.

### 4.0 ACCOUNTABILITY

- 4.1 Head - Concerned User Department
- 4.2 Head - Quality Assurance.

### 5.0 PROCEDURE

- 5.1 External parties involved in calibration of instruments associated with the processing and testing of materials, shall be listed.
- 5.2 While selecting preference shall be given to the supplier of the instrument.
- 5.3 If the supplier is not authorized agency to perform the calibration, the Engineering Dept. personnel shall identify the external calibration agencies for calibrations.
- 5.4 After identifying the external calibration agencies, Engineering Dept. personnel shall approach the concerned party with the co-ordination of Quality assurance department.
- 5.5 The Engineering Dept. personnel shall send a questionnaire to the concerned agencies issued through Quality Assurance.



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- 5.6 The questionnaire (Annexure-I) consists of three pages:  
Page 1: Basic information (Site Details, Contact Numbers, Organization performance and Major Customers)  
Page 2 & 3: Technical information (Traceable to various regulatory bodies/type of calibration/ Fee structure/ Documentation details/ Duration for performing the calibration).
- 5.7 The filled questionnaire shall be obtain from the calibration agencies and forwarded to Concerned user Department Head and Head-Quality Assurance for final approval of vendor for performing the calibration of instruments.
- 5.8 The master instruments shall be sent for calibration to agencies, which are approved by regulatory authorities. eg: Electronic Test and Development Centre (ETDC), National Physical Laboratory (NPL).
- 5.9 The filled questionnaire shall reviewed by both Concerned user Department Head &Head of Quality Assurance in accordance with the current regulatory cGMP Requirements and then they shall conclude the selection criteria of External Calibration Parties with their comments.
- 5.10 Based on the compliance of both statutory and in-house requirements the calibration agency shall be qualified.
- 5.11 The qualified List of approved external calibration parties shall be prepared by Quality Assurance, and a copy of the same shall be forwarded to user department. This list shall be updated with the approval of new external calibration agency.
- 5.12 The instruments shall be sent to the approved external calibration party by hand or with their personnel. The instruments shall be sent with shock/water proof packing and make sure that, the instrument received from the party after calibration is packed with shock/water proof packing.

### 6.0 ABBREVIATIONS

- 6.1 cGMP – Current Good Manufacturing Practices.
- 6.2 NPL – National Physical Laboratories.
- 6.3 ETDC– Electronic Test and Development Centre.



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### 7.0 ANNEXURE

7.1 Annexure - I Approval of outside calibration questionnaire

CHANGE HISTORY		
Supersedes SOP No.	Change Control No.	Changes made
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### ANNEXURE - I

#### APPROVAL OF OUT SIDE CALIBRATION QUESTIONNAIRE

Name of the company			
Address of the company			
Address of the calibrating site			
Telephone Numbers	Office	Factory	
Name of the contact person			
Technical matter			
Commercial matter			
Major customers			
Issue of master documents of calibrations			
How do you rate yourself on the following attributes			
Price	Excellent	Good	Fair
Quality	Excellent	Good	Fair
Delivery	Excellent	Good	Fair
Service	Excellent	Good	Fair
Instrument collection/Delivery criteria			
Give three of your strong points			
1. _____			
2. _____			
3. _____			



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### APPROVAL OF OUT SIDE CALIBRATION QUESTIONNAIRE

1. Is the standards and instruments used for calibration traceable? If yes, to which standards ---Please specify.  
\_\_\_\_\_
2. Are all the technical persons trained with respect to ISO Standards?  
\_\_\_\_\_
3. Can the certificates of master instruments used for the specimen calibration be submitted to us?  
\_\_\_\_\_
4. In case of any discrepancies regarding the instruments received for calibration is damaged, what is the procedure to be followed.  
\_\_\_\_\_
5. Are all instruments used for calibration, calibrated and proper documentation maintained?  
\_\_\_\_\_
6. Is the calibration conducted at definite environmental conditions as per ISO guidelines.  
\_\_\_\_\_

<b>Out side Party Responsibilities</b>	<b>Aurobindo Responsibilities</b>
Issue and delivery of instruments	Verification of physical condition of instrument before and after delivery.
Issue of all traceable certificates	Verification of all related certificates
	Verification of results against internal calibration procedures, if available.

**Questionnaire filled by:**

**Designation:**



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**Sign & Date:**

**Seal:**

**COMMENTS:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Head Engg.  
Sign & Date**

**COMMENTS:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Head QA  
Sign & Date**

**CONCLUSION:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_