



## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Specimen Signature	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down a procedure for Specimen Signature of employees.

### 2.0 SCOPE:

This Standard Operating Procedure shall be applicable for Specimen Signature of all new recruit to be followed at formulation plant of .....

### 3.0 RESPONSIBILITY:

**Officer/Executive QA** shall be responsible for taking the Specimen signature of staff on Standard form.

**Head -Quality Assurance** or his/ her designee shall be responsible for compliance of SOP.

### 4.0 ACCOUNTABILITY:

**Head QA:** Approval of this SOP & ensure compliance of SOP.

### 5.0 DEFINITIONS:

**Specimen Signature:** Specimen signature is a signature to proof authenticity of a person who is signing the document. Signature shall provide the documentary evidence for signing the documents. Specimen signature shall also provide a traceability of the document signed by particular employee

### 6.0 PROCEDURE:

- 6.1 Specimen signature of every employee who is responsible to sign off the controlled document shall be maintained by QA department.
- 6.2 After completion of Induction program of new joinee, Specimen Signatures shall be taken in the Logbook.
- 6.3 Whenever a new recruit joins the company, then after completion of induction training, QA Officer/ Executive shall take his/her Specimen signature in the Log Book.
- 6.4 Specimen Signatures Log shall be signed off by all Employees of respective plant specific department.



# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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- 6.5 Specimen signature contains the two signature i.e. one is short form signature and other is full form signature of the employee.
- 6.6 Record of specimen signature shall be maintained by QA documentation cell, when need arise for verification of signature, same shall be verified from QA documentation cell.
- 6.7 Employee shall not change the specimen signature during the signing of documents.
- 6.8 Incase changes required in Specimen Signatures of an employee; Initiator (employee) shall raise the request to QA for “**Specimen Signatures Change Approval Form**” as per prescribed format in Annexure
- 6.9 “**Specimen Signatures Change Approval Form**” shall be initiated by the employee with appropriate justification & impact assessment and reviewed by Initiating Department Head. Further the same shall be approved by Head QA as per **Annexure-II**, Titled “**Specimen Signatures Change Approval Form**”.
- 6.10 After approval, new Specimen Signatures shall be signed off by employee in the “**Specimen Signatures Log**” and mention the effective date in the remark column **e.g. new signatures w.e.f. ....**
- 6.11 When any employee resign or transfer to other location then, QA Officer/Executive shall write the “Resign” or “Transfer” in remark column.

### 7.0 ABBREVIATIONS:

SOP Standard Operating Procedure

QA Quality Assurance

### 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Specimen Signature Record	
Annexure-II	Specimen Signatures Change Approval Form	

### 9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.



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### 10.0 REFERENCES:

In house

### 11.0 REVISION HISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		





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### ANNEXURE-II

### SPECIMEN SIGNATURES CHANGE APPROVAL FORM

**Date:**

To,

Head QA

<b>Name of Employee</b>		
<b>Employee Code</b>		
<b>Designation</b>		
<b>Department</b>		
<b>Reporting to</b>		
<b>Existing Specimen Signature</b>	<b>Initial Signature</b>	<b>Full Signature</b>
<b>New Specimen Signature</b>	<b>Initial Signature</b>	<b>Full Signature</b>
<b>Justification for Change</b>		
<b>Impact Assessment of Change</b>		
<b>Initiator (Employee) (Sign &amp; Date)</b>		
<b>Reviewed Comments By (Head of the Department) (Sign &amp; Date)</b>		
<b>Review Comments &amp; Approval by (Head QA)</b>		