



DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

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

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.
- 6.5 Specimen signature contains the two signature i.e. one is short form signature and other is full form signature of the employee.



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- 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
No.	Number

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

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