



STANDARD OPERATING PROCEDURE

Department: Quality Assurance	SOP No.:
Title: Preparation of Certificate of Analysis	Effective Date:
Supersedes: Nil	Review Date:
Issue Date:	Page No.:

1. PROCEDURE:

The objective of this procedure is to prepare the certificate of analysis after completion of the analysis.

2. SCOPE:

The procedure is applicable for

3. RESPONSIBILITY:

Head – QC & A and all Q.C.Chemists.

4. PROCEDURE:

- 4.1. During preparation of certificate of analysis check the following parameters against the Record of Results and Product Specifications.
- 4.2. Prepare the COA in the format as specified in Annexure – I.
- 4.3. After reviewing and approval of record of results against the product specification the data has to be transferred to COA correctly.
- 4.4. The following parameters (but not limited to) shall be verified for the correctness.
 - 4.4.1. Name of the product/material.
 - 4.4.2. Strength of the product.
 - 4.4.3. Batch Number.
 - 4.4.4. Manufacturing date.
 - 4.4.5. Sample particulars like:
 - Standard Batch Size.
 - Sample Quantity.
 - Sampled by.
 - 4.4.6. Expiry date.
 - 4.4.7. Sampling date.
 - 4.4.8. Date of analysis.
 - 4.4.9. Reporting date.
 - 4.4.10. A.R.Number.
 - 4.4.11. Specification Number.
 - 4.4.12. Market.
 - 4.4.13. Remarks.



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6. ENCLOSURES:

Annexure I: Certificate of Analysis - Raw Materials.

7. MASTER SOP – Retained by Head - QC & A/Management Representative.

8. NUMBER OF CONTROLLED COPIES: 03

9. DISTRIBUTION LIST:

Copy No.	Distributed To
01	Head – QC & A
02	GM- Operations
03	Reference to all Q.C.Chemist

10. REVISION HISTORY:

Date of Preparation	Revision History	Change Details	Reason for Revision
	00	New SOP	Not applicable