DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

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.

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