PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Preparation of Certificates of Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for preparation of Certificates of Analysis.

2.0 SCOPE:

This SOP is applicable to preparation of certificates of analysis for finished products, raw materials, and packaging materials and in process samples in quality control department. This also applicable for market sample and pre -shipment samples.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 For Finished, In process and semi finished sample:

5.1.1 After completion of analysis, analyst shall prepare the Certificates of analysis as per respective specification of the products as per Annexure-I.

5.1.2 Certificates of analysis shall be checked by a second person in QC (Officer/Executive).

5.1.3 Finally hand over the same documents to Quality Assurance Department for Approval.

5.2 For Raw materials and Packaging materials:

5.2.1 After completion of analysis, analyst shall prepare the certificate of analysis as per respective specification of the raw materials as per Annexure II and packaging materials as per Annexure-III.

5.2.2 Analytical test report shall be checked by a second person in QC (Officer/Executive) and

finally approved by QC Head.

5.2.3 The COA of market sample will be prepared same as that of Finished product /Raw material.

5.3 For Swab Sample Analysis:

5.3.1 After completion of swab analysis, analyst shall prepare the certificate of analysis as per Annexure IV.

Note: The copies of the COA for the requirement of other Department/agencies/Regulatory affairs shall be reproduced from the original report data and shall be checked and approved by concerned. This COA shall be prepared on the letterhead and shall be issued on current date.

6.0 ABBREVIATION (S):

QCD - Quality Control Department
SOP - Standard Operating Procedure
COA - Certificate of analysis
GRN- Good Received Note
STP- Standard Testing Procedure
A.R.No.-Analysis Request Number

7.0 REFERENCE (S):

NA

8.0 ANNEXURE (S):

Annexure –I Certificates of analysis.
Annexure –II Certificate of Analysis (Raw materials.)
Annexure –III Certificate of Analysis. (Packaging materials)
Annexure-IV Certificate of Analysis (Swab sample)

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9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION

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ANNEXURE I

ANALYTICAL REPORT (In-process and Semi-finished analytical test report)			
Product		**A.R. No.**	
Batch No.		**B. Size**	
Mfg. Date		**Exp. Date**	
Date of Report		**STP No.**	
Reference SOP No.:		**Page No.:** 4 of 6	

S.No.	Test	Specification	Result

Remark: The **Product Complies/ Does Not Comply** as per specification No.----------

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ANNEXURE II

CERTIFICATE OF ANALYSIS			
Product		**A.R. No.**	
Batch No.		**B. Size**	
Mfg. Date		**Exp. Date**	
Date of analysis		**Date of Report**	
STP No.			
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S.No.	Test	Specification	Result

Remark: The Product Complies/ Does Not Comply as per specification No.----------

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ANNEXURE III

ANALYTICAL REPORT (RAW MATERIAL)			
Name of the Item		**A.R. No.**	
Batch No.		**Quantity Received**	
Mfg. Date		**Exp. Date**	
Challan No.& Date		**Date of Sampling**	
Name of the Mfg.		**Date of Report**	
Name of supplier		**STP No.**	
Reference SOP No.:			**Page No.:** 6 of 6

S.No.	Test	Specification	Observation

Remark: The Sample **Complies/ Does Not Comply** as per specification No.----------