STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Comparative study of Analytical method in Quality Control department	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down the procedure for Comparative study of Analytical method in Quality Control department.

2.0 SCOPE:

This SOP is applicable for Comparative study of Analytical method in Quality Control department.

3.0 RESPONSIBILITY:

Officer, Executive– Quality Control.

Head – Quality Control.

4.0 PROCEDURE:

4.1 For Comparative study of Analytical method in Quality control department analyst from originating laboratory should send sample along with COA of that concerned product to the receiving laboratory (Quality Control Department).

4.2 After receiving the samples analyst make necessary entry in inward register as per annexure -I

4.3 Generate the A.R. no. of Comparative study samples as follows.

CS-0001/15

CS Comparative Study

\- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016… etc)

4.4 Receiving laboratory analyst will perform the critical tests i.e. Assay, Dissolution as per the standard test procedure (Triplicate preparation for Assay and single preparation for Dissolution).

4.3 After completing the analysis, the analyst has to fill the data in Miscellaneous Analytical Raw data sheet as per annexure - XII of SOP and prepare summary report as per respective Protocol and Report of individual product.

4.4 The numbering system followed for all Comparative study protocols and reports shall be as

follows:

QCD/CS/001/ZZ

Where,

QCD: Stands for Department code.

CS: Stands for Comparative Study.

001 Serial number of the protocol

ZZ: Stands for the version starting from 00

5.0 ANNEXURE (S):

Annexure- I: Comparative study samples inward

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution control, revision and destruction of Standard Operating Procedure (SOP).

SOP: Preparation, Approval, Distribution, Control, Revision and Destruction of Specifications, Standard Test Procedure and Analytical Raw Data Sheets.

7.0 ABBREVIATION (S)/DEFINITION (S):

COA: Certificate of Analysis.

A.R. No.: Analytical Reference number.

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
01	00	---	---	New SOP	---

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ANNEXURE I
COMPARATIVE STUDY SAMPLES INWARD

S.No.	Date	Name of product	Batch No.	Mfg. Date	Exp. Date	AR No.	Date of Report	Analyzed By	Checked By