STANDARD OPERATING PROCEDURE

Department: Quality Control	**SOP No.:**
Title: Procedure for Proficiency Testing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0   OBJECTIVE:

To lay down a procedure for Proficiency Testing/ Inter Laboratory Comparison.

2.0   SCOPE:

This SOP shall be applicable to Quality Control Department.

3.0   RESPONSIBILITY – Execution - Executive QC.
                                   Checking - Assistant Manager QC.

4.0   ACCOUNTABILITY - Manager Quality Control

5.0   PROCEDURE:

5.1   The Manager Quality Control shall interact with the PT Coordinator, through letters, mails or telephone, for willingness to participate in PT Program.

5.2   The laboratory shall participate in any on-going program for the program related to our scope.

5.3   In the absence of any such program, the laboratory shall conduct an Inter Laboratory Comparison (ILC) Program and inform NABL for the same.

5.4   The ILC studies shall be conducted among minimum of 5 laboratories (including herself).

5.5   The laboratory prefers to perform Inter Laboratory Comparisons with NABL Accredited laboratories. In case, if it is not possible, for any reason, then other laboratory (s) with good Quality Management System, resources & facilities shall be considered.

5.6   The Manager Quality Control or the designated person shall collect the sample(s) for the ILC.

5.7   After sample collection, the concerned person shall distribute the samples to the participating laboratories along with protocol and result sheet. The requirements (like reference standard/ working standard, columns, impurity standards, etc.) of the participating laboratory(s), if any, shall be met by the laboratory itself.

5.8   After receiving the result from the participating laboratories, the Manager Quality Control shall calculate the Z-score.

5.9   After completion of the ILC programme, the laboratory shall communicate the information to NABL and all the participating laboratories.

5.10   The record of Proficiency Testing/ Inter Laboratory Comparison program shall be maintained with the laboratory on Annexure- I

6.0   SAFETY & PRECAUTIONS:

Not Applicable.

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7.0   REVISION HISTORY:

Revision No.	Reason for Revision	Superseded From & Date

8.0   DISTRIBUTION:

Copy No.	Issuance Record				Withdrawal Record		Destruction Record	
	Date	Dept. issued	Name / Signature of receiver	Issued By Name / Signature	By	Sign/ Date	By	Sign/ Date

9.0   REFERENCES:
Not Applicable

10.0   ABBREVIATIONS & ANNEXURES:

SOP   : Standard Operating Procedure

QA   : Quality Assurance

No.   :   Number

QC   :   Quality Control

STP   :   Standard Test Procedure

NABL :   National Accreditation Board for testing & calibration Laboratories

ILC   :   Inter Laboratory Comparison

PT   :   Proficiency Testing

Annexure 1: Record of Proficiency Testing/ Inter Laboratory Comparison

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ANNEXURE I

RECORD OF PROFICIENCY TESTING/ INTER LABORATORY COMPARISON

S.No.	Date	Name of program	Name of participating lab.	Z -Score	Remarks