STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Analyst's Validation	**Effective Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Analyst's validation.

2.0 SCOPE:

This SOP is applicable to Analytical chemist's who analyze samples by chemical methods and by using instruments.

3.0 RESPONSIBILITY:

Officer, Executive – Quality Control Department

Head – Quality Control Department

4.0 DEFINITION(S):

NA

5.0 PROCEDURE:

5.1 All the Quality Control Officers, Executives, need to be trained and qualified for handling of instruments & testing of samples & good laboratory practices.

5.2 All respective Officers, Executives shall perform the testing as per standard test procedures of the samples in triplicates with three different weights on any of the instruments or methods given below and it shall be recorded in raw data sheets.

5.3 Assay by HPLC

5.3.1 Purity or residual solvents by GC

5.3.2 Water content by KF

5.3.3 Assay by UV/VIS

5.3.4 SOR by Polarimeter

5.3.5 Results of the three sets of one sample (has been prior to approved) tested by individual Officers, Executives should comply the acceptance criteria as given in table-I

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Table-1

Test	Acceptance criteria
Assay By HPLC	RSD NMT 2.0% Individual & Within the group
Assay By UV/VIS	RSD NMT 2.0% Individual & Within the group
Water By KF	RSD NMT 2.0% Individual & Within the group
Purity By GC	RSD NMT 2.0% Individual & Within the group
Assay by Titrimetric	RSD NMT 2.0% Individual & Within the group
SOR by Polarimeter	RSD NMT 2.0% Individual & Within the group

5.4 Tested sample should comply with specification.

5.5 Qualified analysts shall be certified to perform the test.

5.6 The analysts validation shall be carried out once in two years

6.0 ABBREVIATION(S):

QCD – Quality Control Department

SOP – Standard Operating Procedure

HPLC: High performance liquid chromatography

GC: Gas chromatography

KF: Karl Fischer

SOR: Specific Optical Rotation

UV/VIS: Ultraviolet/Visible

RSD: Relative standard deviation

7.0 REFERENCE(S):

NA

8.0 ANNEXURE(S):

Annexure–I: Analytical test data sheet for analysts validation

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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 Test Data Sheets for Analysts Validation

Name of the Employee:

Designation:

Sample Name: **B.No.:**

Test Name:

Test write up:

Conclusion:

Analyzed By/Date **Checked By/Date**