PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Uncertainty in Measurement	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down procedure for estimate the uncertainty in measurement of various procedures used in the Quality Control Department.

2.0 SCOPE:

This SOP is 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 uncertainty in measurement should be calculated for all quantitative determinations in the laboratory.

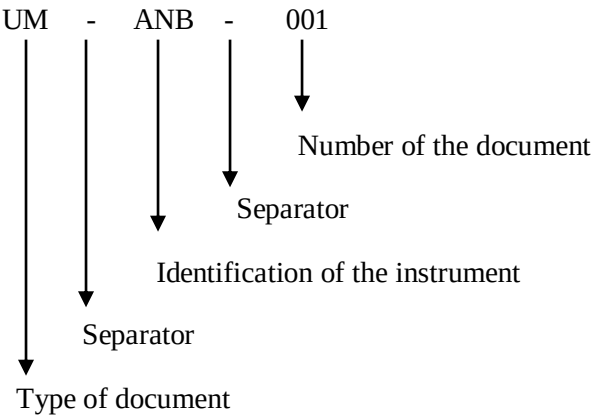
5.2 All the sources (Type A & Type B), which result to the uncertainty in measurement, should be identified.

5.3 Numbering of Uncertainty Documents:

5.3.1 All uncertainty documents shall be referred by 5 alphabetical, 3 numeric and 2 special characters, totaling to 10 characters.

5.3.2 The first 2 alphabetical characters denote the type of document, next 3 alphabetical characters denote the type of instrument/ test, which uncertainty shall be performed and the 3 numeric characters denote the number of the document.

For example,



5.4 After identifying the sources, calculate the Standard Uncertainty in measurement by making, minimum 5 and maximum10, observations for Type A uncertainty as per NABL 141.

5.5 Calculate the combined Standard Uncertainty for Type A uncertainties as per NABL 141.

5.6 Calculate the combined Standard Uncertainty for Type B uncertainties as per NABL 141.

5.7 Now calculate the total combined Standard Uncertainty (u) as per NABL 141.

5.8 Calculate the Expanded Uncertainty in Measurement (U), obtained by multiplying the combined Standard Uncertainty, u (y) of the output estimate, y, by a coverage factor, K as per NABL 141.

5.9 The record shall be maintained as Annexure - I.

6.0 SAFETY & PRECAUTIONS:

Not applicable.

7.0 REVISION HISTORY:

Revision No.	Reason for Revision	Superseded from & date
00	New	--------

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

QC : Quality Control

NABL : National Accreditation Board of calibration & testing Laboratories

Annexure - I: Record of Uncertainty

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ANNEXURE - I

RECORD OF UNCERTAINTY

Format No.:_____

S.No.	Type A/B	Name of method /Instrument	% Uncertainty	Remarks