PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Analyst Qualification	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a procedure for Qualifying the Analyst before assigning them the analytical work.

2.0 SCOPE:

This SOP shall be applicable for Qualification of Analyst in Quality Control Department.

3.0 RESPONSIBILITY - Execution -Executive QC

Checking - Assistant Manager QC

4.0 ACCOUNTABILITY - Manager Quality Control

5.0 PROCEDURE

5.1 Identify approved Raw Material and Finish Product and prepare a list or use standard or Reference standard.

5.2 Keep the record of Material /Product Name, Batch No., A.R. No, Code No. and analytical value of sample along with acceptance limit.

5.3 Assign appropriate code No. to each sample identified for qualification.

5.4 Give sample for analysis appropriately coded in polybags / glass vials to Analyst.

5.5 Provide detail Standard Test Procedure to Analyst.

5.6 Evaluate the Analyst either one or more, in following areas of analysis.

1. Assay (Analysis to be carried out in triplicate)
2. Identification by IR Spectrophotometer (Analysis to be carried out in triplicate)
3. Microbiology

5.7 Evaluate the Analyst for one or more of the following analytical method

1. HPLC
2. U.V. Spectrophotometer
3. Titration
4. IR Spectrophotometer

5.8 Evaluate the capability of the Analyst in terms of its precision to perform the tests and GLP followed by the Analyst.

5.9 The capability to perform tests by Analyst shall be considered satisfactory if the results reported by the Analyst.

1. Are within the acceptable limits as per Annexure-I
2. The Analyst complies with GLP
3. Documents the results as per requirement

5.10 Acceptance Limit for Qualification.

5.10.1. In case of assay for Raw material and Finished Product, compare all three results with previous Results and find out RSD of all four results. The limit for RSD shall not be more than 1% for Raw Material and not more than 2% for Finished Product.

5.10.2. In case of IR analysis all three spectra shall match with Reference Spectra.

5.10.3. For Qualification of Microbiologist, evaluate the microbiologist w.r.t practices followed in the respective area like carrying out Microbiological Limit Test, Preparation of Culture, Settle Plate etc.

5.11 Qualify each new Analyst with in three months of the area of work given to them.

5.12 Keep the details like calculations, chromatograms, and strip chart along with comments of department head in training file to be maintained separately for each Analyst.

5.13 In case of Analyst found not qualified, re-train the Analyst and do not allot subjected work until he or she is qualified.

5.14 Maintain records related to Training /Re-training and Re-qualification in training file.

5.15 Prepare the final report as per Annexure-II

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

HPLC : High Performance Liquid Chromatography

A.R. No.: Analytical Report Number

RSD : Relative Standard Deviation

USP : United States Pharmacopoeia

w.r.t : With Respect to

ANNEXURES

Annexure-I : Acceptance Criteria of Analyst Qualification

Annexure-II : Qualification Of Analyst Record

Annexure-III : Qualification Of Analyst

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Issue Date:	**Page No.:**

ANNEXURE-I

ACCEPTANCE CRITERIA OF ANALYST QUALIFICATION

1. In case of assay for Raw material and finished product, compare all three results with previous Results and find out RSD of all four results. The limit for RSD shall not be more than 1% for raw Material and not more than 2% for finished product.
2. In case of I.R analysis all three spectra shall match with reference spectra.
3. For qualification of microbiologist, evaluate the microbiologist w.r.t practices followed in the respective area like carrying out sterility testing, microbiological limit test, preparation of culture, settle plate etc.

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Issue Date:	**Page No.:**

ANNEXURE-II

QUALIFICATION OF ANALYST RECORD FOR ASSAY

Initial value of coded sample:	1. _____

1) Name of Analyst :	2) Designation :
3) Performed Date :	4) Name of sample:
5) Batch No. given :	6) Code No.:
7) Assay by :	8) STP No.:

Present value of coded sample :	1._____ 2._____ 3._____ R.S.D : _____(all 4 values) Limit : Not more than 1.0 % for raw material. Not more than 2.0 % for finished product.
Overall Remarks:	
Checked by :	
Date :	

Verified by: _____
(QC Section In charge)
Sign & Date

Approved by: _____
(QC Head)
Sign & Date

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ANNEXURE-III
QUALIFICATION OF ANALYST

FOR INFRA RED SPECTROPHOTOMETER

1) Name of Analyst :	**2) Designation :**
3) Performed Date :	**4) Name of sample:**
5) Batch No. given :	
RESULTS	
Over all remarks:	
Checked by	
Date :	

Verified by: _____
(QC Section In charge)
Sign & Date

Approved by: _____
(QC Head)
Sign & Date