PHARMA DEVILS

MICROBIOLOGY DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Microbiology	**SOP No.:**
Title: Analyst Qualification and Certification of Analyst	**Effective Date:**
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1.0 Objective

To lay down a procedure for qualification and certification of analyst.

2.0 Scope

This Standard Operating Procedure is applicable at Quality Control department of ……of ……

3.0 Responsibility

Executive	: Conduct the qualification procedure of analyst
Assistant Manager-QC	: Evaluate the analyst
Assistant/Deputy Manager-QC	: Maintain and update the analyst qualification, certification and re-certification record.
Head-QC/Designee	: Certify the analyst.

4.0 Abbreviations and Definitions

SOP	: Standard Operating Procedure
QC	: Quality Control
HPLC	: High Performance Liquid Chromatography
GC	: Gas Chromatography
FTIR	: Fourier Transform Infrared Spectrometer
TLC	: Thin Layer Chromatography
LOD	: Loss On Drying
RSD	: Relative Standard Deviation
cGMP	: Current Good Manufacturing Practice
%	: Percentage

5.0 Procedure

5.1 The qualification of analyst procedure shall be initiated only after successful completion of induction training, cGMP training and SOP training (e.g. operation and calibration

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procedure of equipment and instruments, handling of solutions, handling of reference standards / working standards, recording and reporting of results).

5.2 Before performing routine analysis, the analysts shall be qualified and certified in their respective working areas such as chemical analysis, instrumental analysis, microbiological analysis etc. as well as the tests, analyst will be assigned to perform during the course of analysis.

5.3 The analyst shall be qualified in performance of either one or more of the following test.

5.3.1 Assay by Titrimetric or Instrumental (HPLC, GC, UV) method.

5.3.2 Identification by FTIR.

5.3.3 Dissolution.

5.3.4 Disintegration

5.3.5 Friability

5.3.6 Viscosity

5.3.7 Water/LOD

5.3.8 Specific Optical Rotation

5.3.9 Limit Tests

5.3.10 Acidity and Alkalinity Tests

5.3.11 Melting Point

5.3.12 TLC

5.3.13 Sulphated ash

5.3.14 Residue on ignition

5.3.15 Loss on ignition

5.3.16 Sieve analysis

5.3.17 Standardization of volumetric solution

5.3.18 Microbial analysis

5.3.19 Bacterial endotoxin test

5.3.20 Sterility test

5.4 Select two previously analyzed and approved samples of raw material/s or drug product/s of similar identity (different batch numbers), for evaluation. Code these samples as (A)

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and (B) respectively. Quantity of samples sufficient for two times analysis shall be selected.

For Microbial testing of water analyst qualification shall be carried out on fresh sample.

5.5 Head-QC/ Designee shall identify the already approved samples.

5.6 Coded samples (A) and (B) shall be analyzed two times.

5.7 Samples shall be provided to the analyst undergoing the certification program along with the test protocol.

5.8 The analyst shall carry out sample analysis by following established specifications and test procedures for the drug product under analysis.

5.9 The analytical findings shall be recorded in Analytical Data Sheet as per Annexure-3. The summary of analytical results shall be recorded in the Analyst Qualification Report as per the Annexure-1 and shall be enclosed with Analytical Data Sheet along with all supporting documents.

5.10 The evaluation of analyst shall be based on his/her performance indicated by the analytical results obtained from his/her analysis.

5.11 The Asst. Manager/Executive-QC or his authorized nominee shall review and compare the analytical results obtained with the values/result (s) of the already analysed and approved samples.

5.12 The evaluation of analyst shall be based on his/her performance indicated by the analytical results obtained from his/her analysis.

5.13 The acceptance criteria for the analytical results will depend on the nature of test/s and range provided in the specifications.

5.14 The reported results shall be based on the following

5.14.1 For Assay % RSD of coded samples analysis shall not be more than ±1.0 % with respect to the initial results.

5.14.2 For Residual solvents and Dissolution test, % RSD shall not be more than 5.0%with respect to initial result and the results obtained from both the test sample shall not differ by more than 5.0%.

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5.14.3 For Water, LOD, Viscosity, Sulphated ash, Residue on ignition and Loss on ignition test , % RSD shall not be more than 10.0% with respect to initial results and the results obtained from both the test sample should not differ by more than 10.0%.

5.14.4 For microbiological analysis, Bacterial endotoxin test and Sterility test of samples, pass/ fail results shall be used as the acceptance criteria.

5.15 The analyst shall be considered as "Qualified and certified" if the analytical results reported by the analyst during the evaluation study meet the established acceptance criteria and are within the prescribed limits mentioned above.

5.16 In case the reported results vary from the known results by more than the above-prescribed limits, the analyst shall be re-trained and re-evaluated for qualification as analyst, as per the regular procedure of qualification.

5.17 The analyst shall be certified for carrying out only those "tests" in the respective area (i.e. Chemical/Instrumentation/Microbiology) for which he/she is certified.

5.18 Re-certification of the analyst shall be carried out in case where out of specification laboratory investigation indicates error due to the analyst.

5.19 A complete list of laboratory analysts shall be prepared as per the format in Annexure-2, which shall indicate their certification in respective areas.

6.0 Forms and Records

6.1	Analyst Qualification Report	:	Annexure-1
6.2	Analyst Qualification Record	:	Annexure-2
6.3	Analytical Data Sheet	:	Annexure-3
6.4	Analyst Competency List on Critical Analysis	:	Annexure-4

7.0 Reference

Nil

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8.0 Distribution

8.1 Master Copy : Documentation Cell (Quality Assurance)

8.2 Controlled Copies : Quality Control, Quality Assurance

9.0 History

Date	Revision Number	Reason for Revision
	00	New SOP

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ANNEXURE I

ANALYST QUALIFICATION REPORT/CERTIFICATION

NAME OF THE ANALYST:

TEST:

NAME OF INSTRUMENTS: **PRODUCT/SAMPLE NAME:**

MAKE:

Coded Samples Identity		Results obtained by Analyst		Mean	Previous Result (To be filled by Manager-QC during Evaluation)	% RSD	Evaluation of Data
		1	2				
A	Test:						
B	Test:						

CONCLUSION OF EVALUATION: **The above analyst is Certified/Not Certified and has Qualified/Not Qualified for carrying out the analytical tests independently in quality control.**

Date of Certification:

Evaluated by: **Approved by:**

Date: **Date:**

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ANNEXURE II

ANALYST QUALIFICATION RECORD

Name of Analyst	Areas of Certification				Date of Certification
	Chemical Analysis	Instrument Analysis	Microbiological Analysis	Packaging Material Analysis	

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ANNEXURE III

ANALYTICAL DATA SHEET

Material Name		**Item Code**	
Batch Number		**Issued By**	
Mfg. / Supplier Name		**Issued To**	
Mfg. Date		**Specification Number**	
Exp. Date		**Date of Analysis**	

Name of Test(s)	Observation(s)

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ANNEXURE IV

ANALYST COMPETENCY LIST ON CRITICAL INSTRUMENTS

Instruments										
Name of Analyst										

√ = Qualified to use the instruments

× = Not qualified to use the instruments