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

To lay down a procedure for qualification of analysts, working in the Quality Control Laboratory.

2.0 SCOPE:

2.1 This SOP is applicable for all newly recruited analysts and existing analysts working in raw material, packing material, GLP, Stability and finished section in Quality control Laboratory.

3.0 RESPONSIBILITY:

Trainee, Officer, Sr. Officer - To undergo for qualification.

Section Head or his designee - To evaluate the qualification of analyst.

Head - QC or his designee - To ensure the compliance of SOP.

4.0 PROCEDURE :

4.1 The analyst shall be qualifying in tests/instruments prior to perform regular analysis. To qualify an analyst, the Head QC or respective section head shall ensure that the analyst has been trained in the SOP related to that instrument.

4.2 Respective section head shall identify the tests which shall be performed for qualification by analyst. Sample shall be collect from the approved batches of raw materials or finished product in a sufficient quantity as per requirement from respective department.

4.3 Enter the details of the collected approved sample in a format given as per Annexure – I.

4.4 Assign appropriate code no. to each of the sample to identify for qualification in Annexure – I

4.5 The code no. of sample shall be allotted as follows:

QCAQ/001/YY

QC : Quality Control

AQ : Analyst Qualification

001 : Serial number

YY : Current year last two decimal (i.e. 22 for year 2022)

4.6 Analyst shall be qualified for tests like Assay / Related substances/ Dissolution / Residual

solvents and Instruments like HPLC,GC, DISSOLUTION, UV (if required IR) etc.

4.7 Other than above tests/ Instruments on job training should be given to the analyst by section head or his designee as per respective analytical procedures or standard operating procedures.

4.8 Analyst need not to be qualified other than these instruments, however training should be given before operation of the instruments.

4.9 Analytical raw data sheet as per Annexure II shall be issued along with the coded sample with labeled details like sample name; code No., name of the test, instrument name and reference standard test procedure no etc. of the respective product /raw material to the analyst.

4.10 Record the details of the coded sample allotted to the analyst in a format given as per Annexure – I.

4.11 The analyst shall perform the test assay with triplicate sample preparation and other tests shall be performed as per the test procedure under the supervision of section Head or his designee and report the results in the analytical raw data sheet as per Annexure II.

4.12 The analyst shall submit the results along with the raw data like chromatograms, weight prints etc. to the section head or his designee for review and approval.

4.13 Evaluate the ability of the analyst in terms of precision to perform the tests and GLP followed by the analyst.

4.14 The ability to perform the test by an analyst shall be considered satisfactory if the results reported by the analyst.

i. Are within the acceptance limits
ii. The analyst complies with GLP.
iii. Documents the results as per requirements.

4.15 Acceptance Criteria:

4.15.1 Acceptance criteria for all test individual results should meet the respective material/product current specification.

4.15.2 **Acceptance criteria for raw material:**

4.15.2.1 For Assay test:

The % difference between the average of triplicate preparation and initial analysis result should not differ by ±1.5 % as per calculation 4.15.2.2 and individual result should be within specification limit and within 1.0% RSD.

4.15.2.2 For Related substances test (calculate):

- $\text{difference} = \frac{|\text{Final result} - \text{Initial result}|}{\text{Initial result}} \times 100$

Acceptance criteria: As per Below table.

Impurity	% Relative difference
$0.05\% < x \leq 0.1\%$	Not more than 50.0%
$0.1\% < x \leq 0.5\%$	Not more than 30.0%
$0.5\% < x < 1.0\%$	Not more than 20.0%
$x \geq 1.0\%$	Not more than 10.0%

4.15.2.3 For Residual solvents test:

The difference of the mean solvent should not be more than ±20 % if solvent is more than 50 ppm and not more than ±50 % if present less than or equal to 50 ppm.

4.15.3 **Acceptance criteria for finished product:**

4.15.3.1 For Assay test:

The % difference between the Average of triplicate preparation and initial analysis result should not differ than ± 3.0 % as per calculation 4.15.3.3 and should be within specification limit and within 1.0 % RSD.

4.15.3.2 For dissolution test:

The % difference of mean values of analyst result and initial result should not be differ by ± 5.0 % as per calculation 4.15.3.3

4.15.3.3 For Related substances test (calculate):

- $\text{Difference} = \frac{|\text{Final Result} - \text{Initial result}|}{\text{Initial result}} \times 100$

Acceptance criteria:

Impurity	% Relative difference
0.05 % < x ≤ 0.1 %	Not more than 50.0 %
0.1 % < x ≤ 0.5 %	Not more than 30.0 %
0.5 % < x < 1.0 %	Not more than 20.0 %
x ≥ 1.0 %	Not more than 10.0 %

4.15.3.4 The Head QC shall put the Qualification status with remarks that the analyst is qualified to perform the specified test using the instrument as per (Annexure -I).

4.15.3.6 In case analyst failed to meet the acceptance criteria on allotted sample, Analyst shall be retrained under the strict supervision of section head or his designee and requalify is respective test /Instruments.

4.16 Based on the instrument operated, analyst may qualify for analogous test.

4.17 If required and prior to perform other tests those analysts shall be qualified after proper training and qualification.

5.0 ANNEXURE (S) :

Annexure - I : Analyste Qualification log book

Annexure - II : Evaluation of Analyst Qualification and Raw data sheet

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S)/DEFINITION (S):

HPLC : High Performance Liquid Chromatography.

GC : Gas Chromatography.

UV : Ultraviolet.

ppm : parts per million.

SOP : Standard Operating Procedure.

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RSD : Related Standard Deviation.

GLP : Good Laboratory Practices.

IR : Infrared Spectrophotometer .

REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	-

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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ANNEXURE I

ANALYST QUALIFICATION LOGBOOK

S.No.	Date	Name of Analyst	Name of the Product /Material	A.R.No	Code No.	Test	Qualification status	Verified By	Approved By

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ANNEXURE II

EVALUATION OF ANALYST QUALIFICATION AND RAW DATA SHEET

Name of the Analyst						
Name of the Sample						
Reference code No.						
Test to be performed						
Sample Allocated on						
Date of test initiated						
Date of report						
Reference STP No.						
Instruments used :						
Name of Instrument						
Instrument ID						

S.No.	Test	Result	Initial result	%RSD	Specification Limit
Assay					
Dissolution					
Related Substance					
Residual Solvent					

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Summary & Conclusion by Head–QC :

- Analyst result complies /does not comply as per specification.
- Analyst result qualified / does not qualify as per SOP.

Remarks : The analyst is Qualified /not qualified to perform the _____ analysis using the instrument__ _____

(Head - QC):

Sign/Date: