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

To lay down the procedure for Analyst Qualification.

2.0 SCOPE:

This SOP shall be applicable to procedure for Analyst Qualification in Quality Control Dept.

3.0 RESPONSIBILITY:

3.1 Associate Officer and above of QC Department shall be responsible for performing of Analyst Qualification.

3.2 Officer and above of QC Department shall be responsible for Analyst Qualification.

3.3 Head Concerned dept. shall be responsible for implementation of this SOP.

4.0 ACCOUNTABILITY:

Head QA

5.0 PROCEDURE:

5.1 Identify approved Raw Material and Finish Product and prepare a list.

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.

i. Assay (Analysis to be carried out in triplicate)

ii. Identification by IR Spectrophotometer (Analysis to be carried out in triplicate)

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

1. HPLC
2. UV 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 Dissolution, analysis of 6 tablets shall pass within the limit of USP reference tablet of Prednisone and Salicylic Acid. Qualification is to be carried out with both types of tablets once in a year covering all Analysts defined for the operation.

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

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

5.11 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.

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

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

5.14 Prepare the final report as per Annexure-I.

6.0 REFERENCES:

Not Applicable

7.0 ANNEXURES:

Annexure No.	Title of Annexure	Format No.
Annexure-I	Acceptance criteria	
Annexure-II	Final Report for Performance of Analyst	

8.0 ABBREVIATIONS

SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
A.R. No.	:	Analytical Report Number
Dept.	:	Department
Ltd	:	Limited
QC	:	Quality Control
IR	:	Infrared
HPLC	:	High Performance Liquid Chromatography
U V	:	Ultra Violet
GLP	:	Good Laboratory Practices
RSD	:	Relative Standard Deviation
%	:	Percent
USP	:	United State Pharmacopoeia
w.r.t.	:	With respect to

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ANNEXURE I

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 dissolution, analysis of 6 tablets shall pass within the limit of USP reference tablet of prednisone and salicylic acid. Qualification is to be carried out with both types of tablets once in a year covering all analysts defined for the operation.
3. In case of I.R analysis all three spectra shall match with reference spectra.

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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ANNEXURE II
FOR ASSAY

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.:
Results	
Initial value of coded sample:	1.
Present value of coded sample :	1. 2. 3. R.S.D. : _____ (All four values) Limit : Not more than 1.0% for Raw material Not more than 2.0% for finished product
Over all remarks:	
Checked by :	
Date :	

Verified by: _____ **Approved by : _____**

Sign & Date **Sign & Date**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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FOR DISSOLUTION TEST BY UV METHOD

1) Name of Analyst :	2) Designation :
3) Performed Date :	4) Name of sample:
5) Lot No. given :	6) Ref. S.O.P. No.
7) Paddle/Basket	
Results	
	1. 2. 3. 4. 5. 6. Mean **R.S.D.: _____** **Limit (As per certificates)** **[ ]**
Over all remarks:	
Checked by	
Date :	

Verified by: _____ **Approved by : _____**

Sign & Date **Sign & Date**

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

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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: _____ **Approved by : _____**

Sign & Date **Sign & Date**