STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Method Validation/Verification Data Sheet Writing	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To describe the procedure for writing the datasheet for method validation and method verification activity.

2.0 SCOPE:

This procedure is applicable to writing the datasheet of method validation and method verification activity in Quality Control Department.

3.0 RESPONSIBILITY:

All analysts in validation group, Group Leader - Quality control

Head – Quality control

4.0 PROCEDURE:

4.1 Data sheet writing

4.1.1 On the basis of the Experimental Design given, prepare "Analytical/Cleaning Method Validation and Method Verification Data Sheet" as per Annexure- II for recording the raw data collected during the performance of the specified validation/verification parameters.

4.1.2 Method Validation/Verification data sheet shall be issued by section Head or his designee to the analyst.

4.1.3 Entry of issuance of Method Validation/Verification data sheet shall be made in to a'Data Sheet issuance register' as per Annexure - I.

4.1.4 Carryout the method validation/verification as per Experimental Design and record the Preparations, observations, conclusions ,experimental condition along with instrument used reagent used, in corresponding data sheet.

5.0 ANNEXURE (S):

Annexure - I -Method Validation/Verification Data Sheet issuance register'.

Annexure - II - Raw Datasheet of Method Validation/Verification.

6.0 REFERENCE (S):

	PHARMA DEVILS	
	QUALITY CONTROL DEPARTMENT	

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

7.0 ABBREVIATION (S)/DEFINITION (S):

SOP: Standard Operating Procedure

REVISION CARD

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

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METHOD VALIDATION/VERIFICATION DATA SHEET ISSUANCE REGISTER

S.No.	Product Name	Test	Parameters	Issued To /Date	Issued By /Date	Remarks

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For Header Part:

METHOD VALIDATION / VERIFICATION DATA SHEET	
Reference SOP No.:	

Product	:	
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Protocol No.	:	**Page**
Parameter	:	

For Footer Part:

Prepared by: Checked by
Date: Date: