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1.0 OBJECTIVE:

To describe the procedure for the preparing and numbering of the protocol for Method Validation, Verification and Study protocol.

2.0 SCOPE:

This procedure is applicable to the Method Validation and other respective section in the Quality control Department.

3.0 RESPONSIBILITY:

Officer – preparation of protocol

Section head / Executive – Review of protocol

Head Quality control – Review and approval of protocol

Head Quality Assurance – Approval of protocol and Compliance of SOP.

4.0 PROCEDURE:

4.1 Validation,verification and study Protocol:

4.1.1 On receiving the Validation, verification and study samples from R&D, the analyst will check for analytical pre-requisites from STP and specification and prepare the Validation, verification and study protocol.

Validation, verification and study protocol shall be given a unique number for traceability as follows:

XVP/YY/Year/Instrument/ZZZ/version.

Where X indicates the type of test under validation/verification

X for different tests is abbreviated as follows:

- Assay: A
- Dissolution: D
- Related substances: R
- Residual solvent: RS
- Forced degradation: FD

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- Identification: I
- Preservative: P
- Content Uniformity: CU
- Enantiomer: E

VP: indicates which type of activity carried out for sample.

- VP : Indicates validation protocol
- VEP: Indicates verification protocol.
- MEJ: Method equivalency justification
- SP: Indicates study protocol.

- YY indicates the chemical nature of the substance under analysis. YY for different substances are abbreviated as follows:

- Drug product: DP
- Drug substance: DS
- Intermediate: IN

- Year indicates the year of the validation, verification and study.
- Instrument shall be abbreviated as follows:

- HPLC = High performance chromatography
- GC = Gas chromatography
- UV = UV spectrophotometer
- IR = Infrared spectrophotometer
- TIT = Titration
- TLC = Thin layer chromatography

- ZZZ indicates the number of the protocol in the serial order of respective year. For example the first protocol prepared is numbered as 00 in every year.
- Version indicates the version of the protocol and subsequent changes made.
  For example the first protocol will have a version number as 00. If any changes are made, then subsequent protocol shall address as addendum as 00/A and onward as B, C, D…
- If any changes are made in method/ formula, then version of the protocol shall be addressed as 01.

For example, the first protocol made for assay test of a drug product in the year 2021 using HPLC instrument will get the number as AVP/DP/2021/HPLC/001/00.

For study protocol shall be given a unique number for traceability as follows:

SP/YY/Year/Instrument/ZZZ/version

Where SP indicates the study protocol, remaining numbering procedure are same as per point no. 4.1.3.

Validation, verification and study protocol shall contain the following on Front page: as per Annexure -I

- Company name, address & logo
- Product Name
- Title of the protocol

Contents of validation, verification and study protocol on next page are as below:

- Company name, address and logo
- Product name
- Title
- Protocol number
- Prepared by name, designation, sign and date
- Checked by name, designation, sign and date
- Reviewed by name, designation, sign and date
- Approved by name, designation, sign and date

Next page of Validation,verification and study protocol shall contain Header & footer as follows as:

- Header shall contain:

  - Company logo
  - Title

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- Name of product
- Validation, verification and study protocol number
- Page number X of Y

Where X presents the current page and Y presents the total pages.

- Footer shall contain:
  - Prepared by sign and date
  - Checked by sign and date
  - Reviewed by sign and date

- Validation, verification and study protocol shall contain 'INDEX' which describes the title, table of contents and respective page number.

- Validation, verification and study protocol shall clearly specify the objective and scope of Validation, verification and study.

- Validation, verification and study protocol shall specify the requirement of reagents, standards, samples, equipments and instruments.

- Validation, verification and study protocol shall specify the detailed methodology including all the standard and sample preparations, calculation, mobile phase preparation, chromatographic condition, whichever is applicable.

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- Validation, verification and study protocol shall specify the experimental details for Validation, verification and study/verification/study parameters along with its acceptance criteria.

- Duly signed validation, verification and study protocol shall be given to the analyst before start of the activity. Validation, verification protocol details shall be entered in a register as shown in Annexure-II and for study details shall be entered Annexure-III before starting activity. Any deviation from the signed validation, verification and study protocol shall be recorded and justified.

- If approved protocol received from R & D or any other site then analysis to be carried out accordingly to the methodology mentioned in the protocol.

ANNEXURE (S):

Annexure–I : Format for Analytical method validation / Verification / study protocol.
Annexure – II: Validation/Verification protocol entry Book.
Annexure – III: Study protocol entry Book.

REFERENCE (S):

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

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ABBREVIATION (S)/DEFINITION (S):

Sr. No.: Serial Number

SOP : Standard operating procedure

STP : Standard Test Procedure

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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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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ANNEXURE I

FORMAT FOR ANALYTICAL METHOD VALIDATION/VERIFICATION/STUDY PROTOCOL

For first page only:

ANALYTICAL METHOD VALIDATION/VERIFICATION/STUDY PROTOCOL

PRODUCT NAME

ANALYTICAL METHOD VALIDATION

PROTOCOL FOR TEST

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From Second page-Header part:

ANALYTICAL METHOD VALIDATION/VERIFICATION/STUDY PROTOCOL		
PRODUCT NAME:		
Title	**<Title>**	
Protocol No.	**<XVP/YY/Year/Instrument/ZZZ/version>**	**<Page X of Y>**

INDEX

From Second page-Footer part:

	Prepared By	Checked By	Reviewed By
Signature			
Date			

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ANNEXURE II

VALIDATION / VERIFICATION PROTOCOL ENTRY BOOK

S.No.	Product	Protocol Number	Remarks

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ANNEXURE III

STUDY PROTOCOL ENTRY BOOK

Reference SOP No.:

S.No.	Product	Protocol Number	Remarks