POLICY ON METHOD VALIDATION & METHOD VERIFICATION

INTRODUCTION:

This document provides the policy for validation/verification of analytical test procedure to assure the test procedures derived are adequate for evaluation of identity, strength, quality, purity and potency of drug substances and drug products.

SCOPE:

This policy is applicable to quantitative and semi quantitative analytical test procedure which are developed In- house, compendial or provided by customer and used for testing of registration and commercial batches (including assessment batch if commercialized) of drug substances and drug products analysed at ……...

POLICY DETAILS:

- ✧ All Analytical test procedure shall be validated/verified before use.
- ✧ A written procedure for method validation/verification shall be in place.
- ✧ Method validation or verification strategy shall be chosen based on the source of the test procedure. The compendial method and validated method received from customer shall be verified. In-house developed methods shall be validated.
- ✧ Parameters for the assessment of test method such as specificity, precision, linearity, accuracy etc. shall be selected as per defined procedure.
- ✧ The procedure should include acceptance criteria for validation parameters derived from regulatory guidelines, scientific rationale and statistical evaluations.
- ✧ Method validation/verification shall be executed as per approved protocol.
- ✧ The protocol shall describe objective, responsibilities, methodology and acceptance criteria at the minimum before initiating validation studies.
- ✧ Method validation and verification shall be conducted using qualified/calibrated instruments, trained/certified personnel, qualified standards and valid chemicals of required quality.
- ✧ Based on the learning from validation/verification studies executed, details described in test procedure shall be assessed and enriched as needed.
- ✧ Validation/verification documents shall be reviewed and approved by competent personnel.
- ✧ Review of the validation/verification shall be performed periodically, during transfer or whenever any change is made to the method as per defined procedure, need of revalidation shall be assessed upon the review
- ✧ Validation and verification documents along with supporting data shall be retained and shall not be destroyed.

AMENDMENT AND WAIVER:

The company reserves the right to amend, alter and/or terminate this policy at any time.

DEFINITION: Not Applicable

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ABBREVIATIONS:

ICH	:	International Conference in Harmonization
USP	:	United States Pharmacopoeia

REFERENCES:

ICH Q2 (R1): Validation of Analytical Procedure: Test and Methodology (March 1995), May 1997) Reviewer Guidance: Validation of chromatographic methods (November 1994)
USP <1225>: Validation of Compendial Procedures USP <1226>: Verification of Compendial Procedures
Guidance for Industry: Analytical Procedures and methods validation for Drugs and Biologics Draft Guidance February 2014