POLICY ON PROCESS VALIDATION

INTRODUCTION:

The objective of this policy is to provide the approach to be followed for Process validation

SCOPE:

Applicable to process validation of finished dosage forms for human and veterinary use and active pharmaceutical ingredients (API) manufactured at all ……. and associated units.

POLICY DETAILS:

- ✧ All manufacturing processes should be validated.
- ✧ A Validation Master Plan should be available with a schedule for all processes to be validated/ verified. Written procedures for Process Validation should be available.
- ✧ Principles of Quality Risk Management should be applied throughout the product life cycle to decide on the degree of control on attributes and parameters, extent and the scope of validation.
- ✧ Process Validation should cover the product and process life cycle and should involve the following stages:

Stage 1: Process Design- The commercial manufacturing process is defined during this stage based on knowledge gained through the development and scale-up activities.

- ▪ Building and Capturing process knowledge and Understanding
- ▪ Establishing a strategy for Process Control.

Stage 2: Process Qualification- The process design is evaluated in this stage to determine if the process is capable of reproducible commercial manufacturing.

- ▪ Design of Facility and qualification of utilities and Equipment
- ▪ Process Performance qualification

Stage 3: Continued Process Verification- Ongoing assurance is gained during routine production that the process remains in a state of control.

- ✧ Legacy products and processes should be assessed by Continued Process Verification.
- ✧ An integrated team approach should be followed for process validation with expertise from various disciplines. The team should have adequate training in the respective field to be a part of process validation.
- ✧ All facilities, instruments, equipment, systems, utilities and analytical testing procedures used for the validation should be qualified and validated before the Process Performance Qualification.
- ✧ A bracketing approach may be used for selection of products for validation.
- ✧ Process Validation should be performed in accordance to approved Validation Protocol and results should be recorded in an approved Validation Report.

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- ✧ Summary of Validation and conclusions shall be prepared, evaluated and approved.
- ✧ Critical Process Parameters, Critical Material Attributes, and Critical Quality Attributes should be assessed during validation activities using appropriate statistical tools.
- ✧ Deviations or Failures encountered during validation should be

  investigation and documented. Validation documents should be reviewed

  and approved by competent personnel.
- ✧ Change Control Procedure should be followed for any change to process, operating parameters, materials, equipment and the Impact Assessment of Change Control should decide the need for Validation.

AMENDMENT AND WAIVER:

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

DEFINITION:

Process Validation is defined as collection and evaluation of data from the Process Design stage, Process Qualification stage and Continued process verification stage, which establishes scientific evidence that a process is capable of consistently delivering quality products.

ABBREVIATIONS:

API	:	Active Pharmaceutical Ingredient
EMA	:	European Medicines Agency
EU	:	European Union
ICH	:	International Conference on Harmonization
USFDA	:	United States Food and Drug Administration

REFERENCES:

Annex 15 to the EU Guide to Good Manufacturing Practice:
Qualification and Validation ICH Q7 Good Manufacturing Practice
Guide for Active Pharmaceutical Ingredients
EMA Guideline on Process Validation for finished products
USFDA Guidance for Industry - Process Validation: General Principles and Practices
Health Canada validation guidelines for Pharmaceutical Dosage Forms