POLICY ON PACKAGING VALIDATION

INTRODUCTION:

Packaging validation provides an assurance that the packaging process meets the product quality and market requirements (i.e. quality attributes, consumer needs) consistently and is efficient to avoid defects in the final product throughout the operating range.

The objective of this policy is to outline the requirements for packaging validation

SCOPE:

This policy applies to the validation of packaging process performed in all ……. and associated units for commercial products.

POLICY DETAILS:

- A procedure shall be in place for packaging validation.
- Approved batch packing record and validation protocol shall be available for performing packaging validation.
- The critical process parameters impacting the robustness of the packaging process, in process test and challenge tests shall be considered, while developing the validation protocol.
- The validation protocol shall detail the objective, scope, responsibility, procedure to be validated, equipment, critical process parameters, critical quality attributes, sampling plan and acceptance criteria, at the minimum.
- The equipment, facilities, systems and analytical methods to be used in packaging validation shall be qualified and validated, prior to the validation.
- Staff involved in validation work shall have adequate training.
- When the primary packaging of the product is a part of the manufacturing process, the policy for process validation shall be followed, for e.g. FFS, MDI.
- Packaging validation shall be performed for all type of packing operations depending on the pack type. Bracketing and matrixing approach shall be applied for selection of products SKU's for packaging validation.
- Change request procedure shall be followed for any changes to packaging process and pack and impact on packaging validation shall be assessed.
- Number of validation run shall be decided based on the criticality of the packing process e.g. primary packing, secondary packing.
- Standard range of all process parameters of packing machines shall be decided based on the outcome of the validation exercise.

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

DEFINITION: Not Applicable

ABBREVIATIONS:

EU	:	European Union
FFS	:	Form Fill Seal
MDI	:	Metered Dose Inhaler

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TRS : Technical Report Series
WHO : World Health Organization
SKU’s : Stock Keeping Unit

REFERENCES:

EU guide to good manufacturing practices, annex 15, qualification and validation
Guidance for industry process validation: general principles and practices
WHO TRS 961 Annex 3 WHO good manufacturing practices for pharmaceutical products: main principles WHO TRS 902 Annex 9 Guidelines on packaging for pharmaceutical products