Packaging Validation Protocol

(Reference: SOP _____)

Project Name		**Project Number**	
Equipment		**Serial Number**	
Manufacturer		**Model Number**	
Process Line/Location		**Protocol number**	

	WRITTEN BY:	REVIEWED BY:
Name:		
Position		
Signature:		
Date:		

	APPROVAL TO EXECUTE:		
Name:			
Position:			
Signature:			
Date:			

	PROTOCOL COMPLETION APPROVAL:		
Name:			
Position:			
Signature:			
Date:			

1 OBJECTIVE

The objective of this protocol is to define the procedure used and the acceptance criteria for validation of [insert full product description (eg. concentration, format, market)] on the [insert packaging line details] in the packaging area at site [insert site name].

Successful completion of the qualification study will provide a high degree of assurance and documented evidence that the packaged product meets its predetermined specifications and quality characteristics.

2 BACKGROUND

[insert brief description of reason for this validation]
Eg. The packaging process for product X, currently packed on line X, is being transferred to line Y packaging machine, therefore packaging validation of this product on the line Y must be completed.

- Cartonning, Leafletting

Sample evaluation and acceptance criteria will be based on [refer SOP no].

Two categories of defects will be identified: Major and Minor:

Major
A defect that is likely to result in failure or reduce the usability of the products for its intended purpose eg. Illegible batch number and expiration date

Acceptable Limit: 1%

Minor
A departure from established standards that has little bearing on the effective use of the product eg. Crooked label.

Acceptable Limit: 4%

6 REFERENCED DOCUMENTS

SOP [SOP No]

[Insert all document that is relevant e.g. SOPs, Previous qualification documents if this is a requalification, standards etc]

7 RESPONSIBILITY

7.1 Validation Engineer / Project Chemist

The individual who prepared this document is responsible for ensuring that the document has been created in compliance with all relevant procedures and accurately reflects the system. The author is responsible for executing / coordinating execution of the validation study and preparing a summary report upon completion to indicate validation status.

7.2 Technical Services

Technical Services approves the validation protocol and report and reviews the executed test scripts and any validation deviations. This individual is responsible for ensuring that the validation study is practical, follows sound validation principles and methodology and is in accordance with requirements and all applicable policies.

7.3 Packaging

Packaging is the owner of the system. Packaging is responsible for ensuring that the system as described covers the functionality required for production operations and that all stated production resources are committed for the validation study.

7.4 Quality Assurance

Quality Assurance is responsible for authorization to proceed with the validation study and authorization of completion of the validation report and release to manufacturing. Quality Assurance approves any validation deviations raised during the study and are responsible for ensuring that the regulatory and cGMP aspects of the system are in accordance with relevant procedures and that critical parameters and report conclusions are supported.

8 GENERAL DOCUMENTATION REQUIREMENTS

A summary of the execution and status of the validation shall be prepared in the form of a summary report. Release of the system for routine use shall be by means of an approved qualification report.

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Appendix No. 2 Packaging Instruction (PI) Verification

1. Objective
The objective of this test is: 1. To verify the correct PI has been issued to this packaging job. 2. To verify the correct bulk and packaging components as per PI have been issued and approved by Quality Control
2. Procedure
Refer to the PI and verify that the correct PI has been issued by checking: product name, product code and packaging line. Also, verify the correct bulk and components have been supplied as per PI and approved by Quality Control. Attach a copy of the PI.
3. Acceptance Criteria
The correct PI has been issued for the batch and the correct bulk and packaging components have been issued and approved by QC

Component	Item No.	Pharma Code	Lot No.	Component QC Approved (Yes/No)	Verified By Initial & Date
[Insert description of components to be supplied as outlined in PI]					

Comments:

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(Reference: SOP _____)

Appendix No. 6 - Table 6.1 Critical Process Parameters

		Initial & Date		Initial & Date		Initial & Date		Initial & Date		Initial & Date	
Setting Recorded at Interval (Time) →											
Critical Parameter ↓	**Validated Range**	**Current Set point**	**Actual Value**	**Current Set point**	**Actual Value**	**Current Set point**	**Actual Value**	**Current Set point**	**Actual Value**	**Current Set point**	**Actual Value**
Blister Machine Speed (cycles/min)			Blank out ACTUAL if only the SET value and no actual reading displayed								
Cartoner Machine Speed (cartons/min)											
Upper Forming Plate Temperature (oC)											
Lower Forming Plate Temperature (oC)											
Upper Sealing Plate Temperature (oC)											
Lower Sealing Plate Temperature (oC)											

All Acceptance Criteria Met (yes/no): _____ Report all discrepancies/further actions in Appendix [insert Discrepancy appendix no] (Discrepancy ref _____)	Initial/Date
Reviewed By:	**Date:**

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(Reference: SOP _____)

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Manufacturer		**Model Number**	
Process Line/Location		**Protocol number**	

	WRITTEN BY:	REVIEWED BY:
Name:		
Position		
Signature:		
Date:		

	APPROVAL TO EXECUTE:		
Name:			
Position:			
Signature:			
Date:			

	PROTOCOL COMPLETION APPROVAL:		
Name:			
Position:			
Signature:			
Date:			

1 OBJECTIVE

The objective of this protocol is to define the procedure used and the acceptance criteria for validation of [insert full product description (eg. concentration, format, market)] on the [insert packaging line details] in the packaging area at site [insert site name].

Successful completion of the qualification study will provide a high degree of assurance and documented evidence that the packaged product meets its predetermined specifications and quality characteristics.

2 BACKGROUND

[insert brief description of reason for this validation]
Eg. The packaging process for product X, currently packed on line X, is being transferred to line Y packaging machine, therefore packaging validation of this product on the line Y must be completed.

Packaging Validation Protocol
(Reference: SOP _____)

3 SCOPE

The scope of this packaging validation is to evaluate the ruggedness of the packaging process on the [insert packaging line name] for the following product:

- [insert full product description (eg. concentration, format, market)]

Validation of the packaging process for [insert full product description (eg. concentration, format, market)] covers the following products according to the product grouping strategy outlined in the Packaging Validation Plan:

- [insert list of products which are covered under the grouping strategy for this packaging line]

The packaging validation will be performed as per the requirements of [insert policy no].

4 SYSTEM AND PROCESS DESCRIPTION

4.1 System Description

The [insert packaging line name] is comprised of the following equipment:

- [list all equipment components of the packaging line, eg. Cartonner, Labeller, Sealer, Laser coder, Vision Systems etc.]

4.2 Process Description

[Enter a brief overview of the packaging process including a description of any vision systems or defect detectors in place]

Eg. The line X is a Blister Packaging Line employed to package tablets into sealed PVC/Aluminium foil blisters coded with a batch number and expiry date. The blisters are then packed into cartons, the cartons are then printed with a batch number and expiry date with a PLC controlled laser. The cartons are then sealed with a tamper evident seal using a PLC controlled labelling machine, stacked and shrink-wrapped, and placed in a shipper, which is sealed and inkjet coded with a batch number and expiry date.

Detectors on the machine are designed to reject blisters with an insufficient number of tablets, loose tablets and damaged tablets, and cartons with an insufficient number of blisters, missing leaflet, the incorrect or missing pharma-code, and missing tamper evident label.

4.3 Critical Process Parameters

[Tabulate process steps, process parameters, process ranges and criticality of step]

Process Step	Process Parameter	Process Range	Critical Step (Yes/No)
Eg. Blister forming/sealing, line speeds	Eg. Temperature, blisters or cartons/min	Eg. 135°C – 180°C	Yes/No/For information only