Validation Plan (Ref.VAL-005)

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

PROGRAM INDEX

OBJECTIVE 2
DESCRIPTION OF EQUIPMENT / PROCESS / SYSTEM 2
DESIGN QUALIFICATION 2
LIST OF SYSTEMS / PROCESS SUBPARTS TO BE VALIDATED 2
INSTALLATION QUALIFICATION DOCUMENTATION 2
COMPUTER VALIDATION 3
CLEANING VALIDATION 3
OPERATIONAL QUALIFICATION TEST PLAN AND ACCEPTANCE CRITERIA 1
REQUIRED STANDARD OPERATING PROCEDURES (SOPS) 1
TRAINING 2
PROJECTED TIMELINE 2
PERFORMANCE QUALIFICATION PHASE 2
CHANGE CONTROL 2
RESPONSIBILITIES 2

Validation Plan Prepared By:			
Position	**Name**	**Signature**	**Date**
Project Coordinator			

APPROVAL OF THE VALIDATION PLAN			
Position	**Name**	**Signature**	**Date**
Validation Manager			
Quality Assurance Manager			
Operations Manager			

Additional approval that may be required depending on the size and importance of the project.

Validation Plan (Ref.VAL-005)

Objective

This document contains a prospective experimental plan that, when executed, is intended to produce documented evidence that the equipment/system has been validated in accordance with requirements.

(A general introduction or abstract explaining the location of the equipment/system and the purpose of this Validation Plan).

Description of Equipment / Process / System

The description serves to familiarise the responsible team members so that they may plan and review the test program

1. **Utilisation List: auxiliary equipment /services required by this process:**

   Include the serial number of equipment /services and the supply requirement based on the demand specification.

Equipment / Service requirement	Serial no	How equip./ service utilized in process/equipment/system	Supply requirement

2. **Impact List: i.e., systems/products directly influenced by this process**

   [Include Text]

Design Qualification

The Design Qualification (DQ) will be conducted for the project. The DQ activities undertaken for this project will be detailed in a Design Qualification Protocol.

List of Systems / Process Subparts to be Validated

The following systems are to be validated as part of the program.

Item	Serial no	Installation Qualification	Operational Qualification	Performance Qualification

Installation Qualification Documentation

- The Installation Qualification documentation package is to contain all of the IQ sub-documents listed in the Equipment Functional Specification and the Installation Qualification report. Details are stated in SOP VAL-030 Equipment Specification and Qualification.

IQ based on Demand Specifications	Applicable to this Project*
1. Equipment Functional Demand Specification	Yes/No
2. Mechanical / Design Specification	Yes/No
3. Electrical Demand Specification	Yes/No
4. Instrumentation Demand Specification	Yes/No
5. Operator's Control Panel Specification	Yes/No
7. Technical Documentation Specification	Yes/No
8. Environmental, Health and Safety Requirements	Yes/No

Computer Validation

Impact Assessment on the product Quality will be conducted for the proposed project.

Justify any computer validation activities in the plan being undertaken by this project.

Any Operational Qualification testing required as part of the validation requirement is to be included.

Cleaning Validation

Cleaning Validation is to be conducted in accordance with the requirements of SOP VAL-020.

Cleaning Validation is required for the process, equipment, or procedures.	Yes /No
Select the Worst-Case Product for Cleaning according to SOP VAL-020.	Yes / No
Analytical Method Validation required for Worst Case Product	Yes / No
Is analytical method validation complete? Include reference file for analytical method validation report.	Yes / No

Any Operational Qualification testing required as part of the validation requirement is to be included in the plan.

Validation Plan (Ref.VAL-005)

Schedule for Cleaning Validation Activities

	Expected Date of Completion	2024	2024	2024	2024	2025	2025	2025	2025	2025	2025
	Cleaning Proces	CIP	Manual	Manual	Manual	Manual	Manual	Manual	Manual	Manual	Manual
Formulation Type	Group Category	Tank 1	Mobil Vessel	Mobile Pump	Liquid Filler	Paste Filler	Other	Powder Filler	Mill	Mixer 1	Tablet Press
TABLET	T										
POWDER	P										
PASTE - Water Based	PST										
PASTE - Oil Based	PST										
GEL	GL										
CREAM	CRM										
OINTMENT	OT										
SUSPENSION	SUSP										
ORAL SOLUTION	ORSOL										
TOPICAL SOLUTION	SOL										
OILY SUSPENSION	OSUSP										
OILY SOLUTION	OSOL										
SHAMPOO	SH										
SHAMPOO WITH SPHERULITES	SHSP										

Key:

Completed	To be started	Not required	WIP

Validation Plan (Ref.VAL-005)

Schedule for Method Validation Activities

- Compendia absolute is defined as test methodology exactly as per compendia description.
- Compendia-based means that the assay is based on a certain portion or principle of a compendium.

Test Origin (P or M)	Test Method Description/Name	Procedure Number	Compendia			Validated (Yes/No)	Validation Document Reference	Validation Required (Yes/No)	Risk Order	Planned Validation Time Frame
			Absolute (Yes/No)	Based On (Yes/No)	Reference (if applicable)					

Operational Qualification Test Plan and Acceptance Criteria

- Validation activities are to be conducted in accordance with the requirements of SOP VAL-005 Validation – Concept and Procedure.

  All documentation is to follow the requirements stipulated in SOP VAL-005. Templates for the various documents are to be sourced from the Templates.

  List of Operational Qualification tests that are to be conducted.

  TEMPLATE-270 Installation and Operational Qualification Protocol Template

  TEMPLATE-275 Installation and Operational Qualification Report Template

  The acceptance criteria for the operational qualification tests should be clear and unambiguous so that review and approval of the final qualification reports is expedited.

  It may be more appropriate to record the Operational Qualification Tests and the Acceptance Criteria for each test separately. In that case, include a separate section in the plan for the Acceptance Criteria and update the Program Index.

Required Standard Operating Procedures (SOPs)

Include the full SOP no. Ensure you reference the current version. Relevant SOPs required to conduct the validation activities are to be listed.

SOP #	Title	Date issued

List of current SOPs requiring modification during the Operational Qualification phase.

SOP #	Title	Responsible

List SOPs to be developed for the equipment/process during the Installation and Operational Qualification phases.

SOP #	Title	Responsible

Training

The following identified personnel will be trained in the system requirements in accordance with the relevant SOPs during the project's Operational Qualification phase.

Personnel	Training Requirement	SOP #

Projected Timeline

Produce a Gantt chart of the validation project. Include all the activities identified in the plan's Responsibilities table.

Performance Qualification Phase

[Fill in the details].

The Performance Qualification will consist of any additional tests determined to be necessary during the Operational Qualification phase.

Change Control

According to SOP QMS-030, the Change Control Procedure will be enacted after the commencement of this project's Operational Qualification phase.

Responsibilities

List of personnel who have been allocated as resources for the validation project and their responsibilities.

NB. The understanding and acceptance of the personnel listed must be obtained in advance.

	Activity	Position
1.	Validation Plan Prepared by: Authorized by:	Project Co-ordinator Validation Manager Quality Assurance Manager Operations Manager
2.	Training needs assessment	
3.	Modifying current SOPs Writing required SOP's,	
4.	Preparation of Installation Qualification Reports for approval to execute. Prepared by: Checked by: Authorized by:	 QA or Validation Manager

5.	Review of completed IQ Report Prepared by: Checked by: Authorized by:	 Electrical Mechanical Project Co-ordinator Validation Manager Quality Assurance Manager Operations Manager
6.	Writing Operational Qualification Test Protocols Prepared by: Checked by: Authorized by:	 QA or Validation Manager
7.	Conducting OQ tests	
8.	Completed OQ Test Protocols Documented by: Checked by: Approved by:	 QA or Validation Manager
9.	Writing Operational Qualification Report Documented by: Checked by:	
10.	Review of completed OQ Report Approved by:	Validation Committee Project Co-ordinator Production Manager Validation Manager Quality Assurance Manager Operations Manager
11.	Conducting Safety Audit	EHS Manager
12.	Close-off of issues raised in the Safety Audit	
13.	Conducting of training activities	
14.	Conducting of a Quality Audit for New Process Lines	Required YES/NO
15.	Writing Performance Qualification Test Protocols Prepared by:	
16.	Approval of PQ Test Protocols Checked by: Authorized by:	 QA or Validation Manager
17.	Conducting PQ tests	
18.	Completed PQ Test Protocols Documented by: Checked by: Approved by:	 QA or Validation Manager
19.	Writing Validation Report Prepared by: Checked by:	
20.	Compiling the validation file and circulation for approval.	Project Coordinator

21.	Approval of the Validation Report.	Validation Committee Project Co-ordinator Production Manager Validation Manager Quality Assurance Manager Operations Manager

Note: In all cases, the parties nominated for the approval process must be appropriate for the project being undertaken.

Document Revision History

Revision #	Date	Reason for Revision	Author Initial for Retrieval of Outdated Documents

