Installation Qualification Protocol for Bin Washer	
Identification No.:	**Document Number:**
Effective Date:	**Revision No.:** 00

Installation Qualification Protocol

Bin Washer

Equipment ID: ……..

Revision index

Revision	Date	Reason for revision
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1.0 Pre-Approval:

This document is prepared by the validation team of……. for the project "Oral Solid Dosage Formulation Facility" of …… under the authority of their Project Manager. Hence this document before being effective shall be approved by the Head QA of ……..

PREPARED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Validation & QA		

CHECKED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Validation & QA		
Production		
Engineering		
Quality Assurance		

APPROVED BY		
NAME/ FUNCTIONAL AREA	**SIGNATURE**	**DATE**
Head - Quality Assurance		

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2.0 Objective:

The purpose of carrying out Installation Qualification is to establish documented evidence that,

a) The equipment and its critical components are installed appropriately as per requirement and in accordance with new installation plan.

b) The installed equipments are in accordance with the requirements of approved design documents.

3.0 Scope

The document includes the installation qualification procedure of the equipment as per details given below:

In-house name of the equipment	Bin Washer
Equipment identification number	……..
Purchase order reference	……..
Supplier Name and address	……..
Installation location	
Facility	……..
Floor	Second Floor
Room name and number	Bin Washing Station

This protocol is generated to qualify the initial installation of the equipment. In case of further modification or relocation, some part of the same protocol can be used or separate protocol or addendum can be generated.

4.0 Reference Document:

Following documents are referred during preparation of the protocol

Document Name	Document Number
Validation Master Plan	….
Project Validation Plan	….
Design Qualification Document	….
Risk Analysis	….
Supplier design document	….
Drawings	GA drawing P & ID
Equipment Manual	Operational Manual for Bin Washer

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5.0 Equipment description:

5.1 Use

The Bin washer is used for cleaning of bins.

5.2 Capacity

Suitable for washing 500 L Bins.

5.3 Operation & Design Feature

Used bin is oriented in the closed cabinet over the pneumatically operated skid and closed entrance main door for washing. Washing cycle time can be set as per requirements for Plain water, Hot water, Hot Detergent, Process hot water, purified water, Hot air blowing for pre-set time and cold air blowing for pre-set time. In auto mode Bin shall be washed automatically as per sets cycles. There is nos. of spraying nozzles for washing at all corners & all side walls for outer washing. Top mounting spraying nozzle is fitted with pneumatic cylinder to wash inner surface of the bin, Inner washing nozzle move upward & downward during washing for completely washing of bin. The cabinet is having drain pot with recirculation of water connection with pump. After complete washing cycles bin is dry by passed filtered hot and then cold air circulation by air handling unit. Closed washing system for bin have following component:

- Hot water Storage tank
- Air Handling Unit
- Detergent tank

6.0 Installation Qualification Test Plan:

Installation qualification shall include following test:

i) Verification of signatures/participants as per test Sheet #1

ii) Verification of Documents and drawings as per test Sheet #2

iii) Verification of components as per test Sheet #3

iv) Verification of Installation as per test Sheet #4

v) Verification of measures identified in risk analysis as per test Sheet #5

vi) Identification of Standard Operating Procedure as per test Sheet #6

6.1 Identification of Components to be Tested:

The components taken from the technical document or P&ID are listed in the Appendix-I. In every case where the decision for GMP relevance is yes, (“Y”), a test has to be performed. If the decision is no, (“N”) no test is to be performed. The decision will be justified. However some components may be critical with respect to EHS and/or Operational requirement that can be considered for test performance. Though all components listed shall be identified and verified for the presence in accordance to P&ID or relevant drawings as per test sheet #2.

Each GMP relevant component shall be verified against the checklist given in test sheet #3. Specific test ID number for specific component is mentioned in the Appendix-I. After verification of the component the checker and verifier should sign the respective sheet.

The non-compliance should be highlighted in the used document. The annotated document should be identified by a serial number, which should appear in both test sheet and the annotated document. The annotated document must be attached with report as raw data.

7.0 Responsibility:

Responsibilities of different department/ personnel involved in different activities related to the installation qualification of the equipment are defined below:

Functions	Responsible
Preparation of IQ protocol	…….
Review of the protocol	…….
Approval of the protocol	…….
Clearance of the equipment for execution	…….
Execution of IQ protocol	…….
Preparation of IQ report	…….
Review of executed IQ protocol and report	…….
Approval of the Executed IQ protocol and report	…….

8.0 Test Execution Method:

8.1 Pre –Requisites:

Prior to conducting/ executing the installation qualification protocol following conditions must be fulfilled:

- Equipment/ System should be safe for execution
- Facility should be ready for execution
- Area should be clean
- Approval of Design Qualification report

8.2 Signature Registration & Training:

All personnel who are executing or reviewing the protocol must enter his/her name and signature in signature registration page. Provide the location of training record or attach the appropriate training record with the report to indicate that the personnel are trained on the following:

- Execution of IQ protocol
- Writing GMP critical record
- Deviation handling procedure for validation related deviations
- Review of executed validation protocol and GMP critical records

A signature registration page is given as Test sheet # 01

8.3 General Recording Instruction:

- Execution will be carried out as per the SOP for Qualification protocol execution SOP.
- Recording of observation will follow good documentation practice as per SOP.
- In the test data sheet test parameter and criteria will be pre-defined. Other cells e.g. observation and signature will be completed by the person manually.
- Where observation is to be recorded as 'Y/N/NA', write 'Y' when the observation is in compliance with acceptance criteria, write 'N' when observation is a non-compliance. If it is not applicable write NA, if unobvious write suitable justification for being not applicable
- Any mistake in the approved protocol format if identified before or during execution shall be recorded as comment rather canceling it manually. This mistake will be verified during review of executed protocol.
- Comment summary sheet will be available separately as Data sheet # 7.
- Comments and deviation will be recorded as per the instruction given in the following section.
- If possible or required a digital photograph may be taken and print of the photograph may be presented as evidence of compliance or deviation from the acceptance criteria.

8.4 Deviation Handling:

- During execution the comments if any shall be noted in the respective datasheet.
- All comments shall be numbered as "X-YY" where "X" is test sheet no. and "YY" is the sequential serial no. for that particular test sheet; For example in test sheet no. 3, second comment shall be numbered as 3-02. Comment number shall be allotted on the test data sheet and comments shall be written on comment summary sheet.
- During review or execution all comments shall be verified and if any comment is made to specify non-compliance to that test acceptance criteria, comment shall be escalated as "Deviation".
- The deviation will be identified and it will be suitably numbered in the comment section of the comment summary sheet as per SOP for Handling of Deviation, SOP ……..

- The deviation will be assessed whether it has any GMP criticality. GMP non-critical deviations can be justified whereas GMP critical deviation may require investigation and corrective actions. Appropriate justification, investigation, corrective action and verification of effectiveness of corrective action will be performed and recorded as per SOP # …….. – Handling of Deviation.
- Analyze the deviations whether they can affect the Operational or Performance qualification test or not. If not, operational qualification test can be initiated before the deviations are resolved. The deviations, which are not resolved before Operational Qualification shall be listed as "Action List". The action list should be the part of IQ report, however all deviations shall be resolved before handing over the equipment for routine use.

8.5 General Safety Instruction for Execution:

Safety will be one of the key considerations during the execution of this protocol. The following guidelines must be observed during the execution stage.

- All personnel involved with the execution shall identify hazards associated with performance of IQ testing and precautions to be taken.
- All personnel involved with the execution shall inform to company management any hazard, to themselves or others, associated with the materials, equipment, method of working and the precautions to be taken.
- All personnel involved with the execution shall check that utilities are safely isolated when energizing or de-energizing.

9.0 Acceptance Criteria:

The individual parameters successfully pass the examination if all responses in the test sheets in the inspection result column are "Y" or those tests with an open response (i.e. because a check was not feasible) are justified, and acceptance of the justification must be recorded by the approvers of the report.
The system successfully passes IQ if all the test specifications are passed or open tests justified and accepted.
Thus it is shown that the system

- Meets the Specifications and Quality requirements identified by the User
- Is correctly installed and documented.

10.0 Summary Report and Conclusion:

In order to close the IQ, the tests results are evaluated and the IQ report (format enclosed) is formally approved. During the review of the report it is necessary to assess to what extent all tests were successfully completed. If individual tests could not be completed, the IQ report can be approved for the next test phase nevertheless, and the next test phase (OQ) commenced, if the functionality of the system is deemed suitable for the execution of the next test phase and the completion of any open tests is controlled. GMP critical deviations must be completely fulfilled.

11.0 Enclosed Documents:

Following documents are enclosed as part of installation qualification protocol and shall be preapproved as a part of the main protocol.

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S.No.	Document	Title	Document No.
1	Data Sheet # 1	Identification of Signatures / Participants	
2	Data Sheet # 2	Document Verification Sheet	
3	Data Sheet # 3	Component verification sheet*	
4	Data Sheet # 4	General Installation check	
5	Data Sheet # 5	Verification of measures identified in Risk Analysis	
6	Data Sheet # 6	Identification of Related standard Operating Procedure	
7	Data Sheet # 7	Comment Summary Sheet	
8	Appendix-I	List of components to be tested	
9	Report	Installation Qualification report	
10	Attached documents	List of attached document	

*There are separate datasheets for each critical component as per test ID's listed in Appendix-I.

12.0 Abbreviations:

Abbreviation	Detail
LLP	Limited Liability Partnership
VMP	Validation Master Plan
PVP	Project Validation Plan
P&ID	Piping and Instrumentation Diagram
SOP	Standard Operating Procedure
GMP	Good Manufacturing Practices
IQ	Installation Qualification
BIW	Bin Washer
GA	General Arrangement