XYZ Pharmaceuticals	
INSTALLATION QUALIFICATION	
Equipment Name: Automatic High Speed Linear Vial Washing Machine.	**Equipment No.:**

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1.0	**PROTOCOL APPROVAL:**

Signing of this approval page of Protocol indicates agreement with the qualification approach described in this document. If modification to the qualification approach becomes necessary, an addendum shall be prepared and approved .The protocol cannot be used for execution unless approved by the following authorities.

This Installation Qualification protocol of Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) has been reviewed and approved by the following persons:

FUNCTION	NAME	DEPARTMENT	SIGNATURE	DATE
PREPARED BY		QUALITY ASSURANCE		
REVIEWED BY		PROJECTS / ENGINEERING		
REVIEWED BY		PRODUCTION		
APPROVED BY		QUALITY ASSURANCE		

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2.0	OVERVIEW:

2.1	OBJECTIVE:
	The objective of developing and executing this protocol is to collect sufficient data pertaining to the Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) and define the qualification requirements and acceptance criteria for the unit. Successful completion of these qualification requirements will provide assurance that the Automatic High Speed Linear Vial Washing Machine AHLVW-150 was installed as required in the manufacturing area.
2.2	PURPOSE:
	The purpose of this protocol is to establish documentary evidence to ensure that the Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) received matches the Design specification and also to ensure that it is properly and safely installed.
2.3	SCOPE:
	This Protocol is applicable to installation of Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) at the Dry injection manufacturing facility in XYZ Pharmaceuticals & the subsequent documentation.
2.4	RESPONSIBILITY:
	The following shall be responsible; Quality Assurance officer / Executive – For preparation of protocol / Execution Projects / Engineering Head – For execution Production Head – For execution support Quality Assurance Head – For adequacy and final approval

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2.5	EXECUTION TEAM:
	The satisfactory installation of the Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) shall be verified by executing the qualification studies described in this protocol. The successfully executed protocol documents that the Automatic High Speed Linear Vial Washing Machine AHLVW-150 with two conveyor belt (one for loading the vials to washing machine and another for unloading from washing machine) is installed and is satisfactorily integrated. Execution team is responsible for the execution and installation of Automatic High Speed Linear Vial Washing Machine AHLVW-150 Execution team comprises of:

DEPARTMENT	DESIGNATION	NAME	SIGNATURE	DATE
PROJECTS / ENGINEERING				
PRODUCTION				
QUALITY ASSURANCE				

3.0	**ACCEPTANCE CRITERIA:**
3.1	The equipment shall fulfill all the selection criteria and its individual application
3.2	The equipment shall be complying with the specification mention in user requirement specification.
3.3	It shall be complying with all the designed specifications.
3.4	The Material of Construction (MOC) shall be complying with the test certificate.
3.5	All supporting electrical and non-electrical utilities of specified capacities are to be near the place of installation.

4.0	**REVALIDATION CRITERIA:**
	The machine has to be revalidated if
	• There are any major changes in system components which affect the performance of the system • After major breakdown maintenance is carried out. • As per revalidation date and schedule

5.0	INSTALLATION QUALIFICATION PROCEDURE:
5.1	SYSTEM DESCRIPTION

The Principle of Automatic High Speed Linear Vial Washing Machine AHLVW-150 is designed for washing of vials (5ml to 30ml) and these two conveyor for loading of vials to washing machine and unloading from washing machine.

1. The Automatic High Speed Linear Vial Washing Machine AHLVW-150 works on the principle of jet washing of the individual vials in a mouth down position by a series of jets.
2. The vials are loaded on the unloading station by placing a tray of vials on it. The complete layer of the vials are pushed out to the machine platform through loading conveyor.
3. The vials go to in feed lifter by the help of in feed conveyer. Then this in feed lifter carries the vials in to the individual pockets.
4. After vials going in to pockets channel run to the backside (Anticlockwise). During this process the in feed lifter come back and carry other vials for washing continuously.
5. The index channel of vials carries forward at a time. During each stoppage of this movement, nozzles manifold raises up and a nozzle enters the mouth of each individual vial.
6. A solenoid valve in the water and air lines is now activated and a jet of air / water hits the inside of the vial to thoroughly clean it.
7. An external cleaning station is also provided. The standard washing sequence provided is as under:

1st wash : Compressed air.
2nd wash : Re-circulated water.
3rd wash : Re-circulated water.
4th wash : Compressed air.
5th wash : Purified water.
6th wash : Compressed air.

7th wash : Purified Water.

8th wash : Compressed air.

9th wash : WFI.

10th wash : Compressed air.

8. These washed vials are then taken away from the pockets with support of vial guide plate and come out on the out feed lifter.

9. Out feed lifter come down and the washed vials (12 vials at a time) transfer on the outfeed conveyor for further process.

Equipment Details:

Equipment Name : Automatic High Speed Linear Vial Washing Machine

Make : AMBICA ENGINEERING WORKS

Model No. : AHLVW-150

Capacity : 150 vials/Minute (5ml to 30ml vials)

5.2	INSTRUCTION FOR FILLING THE CHECKLIST
5.2.1	In case of the compliance of the test use the word ‘Complies’ otherwise use ‘Does not comply‘ to indicate non-compliance.
5.2.2	For identification of the components of the equipment and utilities use the word ‘’yes’’ to show its presence and use ‘No’ to indicate the absence of the identity
5.2.3	Give the detailed information in the summary and conclusion part of the Installation Qualification report.
5.2.4	Whichever column is blank or not used ‘NA’ shall be used.

5.3	INSTALLATION CHECKLIST:

	Installation checklist is as follows:

Sr. NO.	STATEMENT	YES / NO	CHECKED BY (SIGN)	DATE
1.	Verify that the “As Built” drawing is complete and represents the design concept.			
2.	Verify that major components are securely anchored and shock proof.			
3.	Verify that there is no observable physical damage.			
4.	Verify that there is sufficient room provided for servicing.			
5.	All access ports are examined and cleared of any debris.			
6.	Equipment identification nameplate visible.			
7.	Verify that all piping and electrical connections are done according to the drawings.			
8.	Safe electrical connections, Water line and Compressed air are fitted.			
9.	Wiring diagram affixed to inside section of control panel.			
10.	Units installed on foundation are secure in place as per manufacturer’s recommendations.			
11.	Check the dimensions for infeed conveyor: 1500 mm (L) X 345mm (W)			
12.	Check the dimensions for outfeed conveyor: 340 mm (L) X 900mm (W)			

5.4	**IDENTIFICATION OF MAJOR COMPONENTS:**
	To Verify that major components as identified below are complying as per the desired specifications.

System components	Design Specifications	Complies / does not comply	Checked By (Sign.)	Date
Equipment description	**Name:** Automatic High Speed Linear vial washing machine **Make:** Ambica Engineering works **Model:** AHLVW – 150 **Out put:** 150 vials/ minutes of 5ml to 30 ml			
Conveyor width	900 mm			
Pressure gauge	Qty: Five No., Range: 0 – 4kg/cm^2			
Main motor	3 Phase, 415Volt, 50Hz, 1 HP, 0.75KW, 1390 RPM, Make –Remi			
Pump motor	3 Phase, 415Volt, 50Hz, Each 350W, 960 RPM, Three no. Make– Grunfors			
Conveyor drive motor (Infeed)	3 Phase Induction motor, 415Volt, 0.5HP, 1365 RPM, Make– Sabar,			
Dimension of infeed conveyor	1500(L) x 345(W) mm, MOC – SS304			
Conveyor drive motor (outfeed)	3 Phase Induction motor, 415Volt, 0.5HP, 1365 RPM, Make– Sabar,			
Dimension of outfeed conveyor	340(L) x 900(W) mm, MOC – SS304			
PLC and MMI	Messung, VFD – T verter, 220V, 0.75KW, One no.			
Main drive gearbox	Reduction type with helical gear drives AMBICA make			
Conveyor drive gear motor	Make- Ambica, 0.5 HP			
Filter housing	Four no.			

System components	Design Specifications	Complies / does not comply	Checked By (Sign.)	Date
Washing Nozzle	12 x 10			
Vial pocket	12 x 40			
Limit switch	Four no., AC 15 at 415 volt, 1.5Amp., Make - Grunfors			

5.5	VERIFICATION OF MATERIAL OF CONSTRUCTION:
	Verify the material of construction from test certificates.

Sr. No.	Components	MOC	Method of verification	Checked By sign./Date
1.	Washing Needles	SS 316	Visually with test certificate	
2.	All Tanks ,	SS 316	Visually with test certificate	
3.	Machine frame and structure	SS 304	Visually with test certificate	
4.	All side covers	SS 304	Visually with test certificate	
5.	Vial pocket	HDPE	Visually with test certificate	
6.	All prism patty	UHMW	Visually with test certificate	
7.	Pusher	UHMW	Visually with test certificate	
8.	Loosening patty	UHMW	Visually with test certificate	
9.	Conveyor belt	SS 304 wire mesh type	Visually with test certificate	
10.	Pockets Channel	SS 304	Visually with test certificate	
11.	Main Pocket drive chain	SS 316	Visually with test certificate	

Sr. No.	Components	MOC	Method of verification	Checked By sign./Date
12.	Pocket drive chain sprocket	Nylocast	Visually with test certificate	
13.	Drive cam	Harden material	Visually with test certificate	
14.	Indexing drive cam	Harden material	Visually with test certificate	
15.	All shaft	SS 304	Visually with test certificate	
16.	All pipe fittings for drain	SS 304	Visually with test certificate	
17.	All rubber gasket	Silicon	Visually with test certificate	
18.	All Tanks	SS 316	Visually with test certificate	
19.	All pipe fittings	SS 316 with Silicon	Visually with test certificate	

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5.6	IDENTIFICATION OF SUPPORTING UTILITIES:
	Identify and record the supporting utilities and their details in following tables:

UTILITY	PROPERLY IDENTIFIED & CONNECTED (YES/NO)	CHECKED BY (SIGN)	DATE
1) Electricity: Specification: 415 VAC, 3 Ph.			
2) Compressed air (20CFM) 0 – 4 Kg/cm^2			
3) Recycle water (400 Ltrs./hour) 0 – 4 Kg/cm^2			
4) Purified water (400 Ltrs../hour) 0 – 4 Kg/cm^2			
5) Purified water (400 Ltrs../hour) 0 - 4 Kg/cm^2			
6) WFI (300 Ltrs./hour) 0 – 4 Kg/cm^2			

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5.7	IDENTIFICATION OF SAFETY FEATURES:
	Identify and record the safety features (if any) and their function in following tables:

Sr.No.	Safety feature Description	Function	Identified By (Sign)	Date
1.	Check for the overload safety devices	The electric circuit should be provided with miniature circuit breaker. for motor safety.		
2.	Check for earth connection	Earth connection should be provided properly.		
3.	Two Emergency stop	One on main panel and another at backside cover for Equipment and operator safety.		
4.	Discharge vial jam	Limit switches should be provided inside the indexing drive box. For Equipment safety.		
5.	Pusher vial jam	Limit switch should be provided on pusher clutch. For Equipment and product safety.		
6.	Lifter vial jam	Limit switch should be provided on lifter clutch. For Equipment and product safety.		
7.	Infeed vial jam	Limit switch should be provided on Infeed drum clutch. For Equipment and product safety.		

5.8	IDENTIFICATION OF STANDARD OPERATING PROCEDURE (SOP)
The following standard operating procedure (sop) were identified as important for effective performance of Automatic High speed linear Vial washing machine.	
1.	Operation and cleaning of Automatic High speed linear Vial washing machine
2.	Preventive maintanance of Automatic High speed linear Vial washing machine

5.9	IDENTIFICATION OF COMPONENT TO BE CALIBRATED:
	Identify and record the instruments to be calibrated in following tables:

Sr. No.	Name of the Instrument	Location	Specification	Identified By (Sign	Date
1.	Pressure gauge	Compressed air supply line	0 – 4 kg/cm^2 Make: Micro		
2.	Pressure gauge	Recycle water supply line	0 – 4 kg/cm^2 Make: Micro		
3.	Pressure gauge	Purified water supply line	0 – 4 kg/cm^2 Make: Micro		
4.	Pressure gauge	Purified water supply line	0 – 4 kg/cm^2 Make: Micro		
5.	Pressure gauge	WFI supply line	0 – 4 kg/cm^2 Make: Micro		

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5.10	VERIFICATION OF DRAWING AND DOCUMENTS:
	Following documents are reviewed and attached as listed below:

Sr. No.	DRAWING AND DOCUMENT DETAIL	CHECKED BY (SIGN)	DATE

5.11	ABBREVIATIONS

Following Abbreviations are used in the installation qualification protocol of Automatic High speed linear Vial washing machine.

P & I: Piping and instrumentation

VFD: Variable frequency drive

UHMW: Ultra high molecular weight polyethylene

HDPE: High density polyethyne

VWM: Vial washing machine

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5.12	DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S)
Following deficiency was identified and corrective actions taken in consultation with the validation team.	

Description of deficiency:
Corrective action(s) taken:

Reviewed By:
Date

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5.13 Annexure(s):

Sr.No.	Annexure No.	Title of Annexure

6.0	INSTALLATION QUALIFICATION FINAL REPORT:

All the IQ data sheets and discrepancy report shall be reviewed by validation team to prepare summary report. The summary of IQ shall be used to draw conclusion for approval of installation qualification report.

6.1	SUMMARY

6.2	CONCLUSION

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6.3 FINAL REPORT APPROVAL

It has been verified that all tests required by this protocol are completed, reconciled and attached to this protocol or included in the qualification summary report. Verified that all amendments and discrepancies are documented, approved and attached to this protocol.

Signature in the block below indicate that all items in this qualification report of Automatic high speed linear Vial washing machine have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
		PROJECT / ENGINEERING		
		PRODUCTION		
		QUALITY ASSURANCE		