



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM
REPORT
FOR
BIN BLENDER**

PROTOCOL 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 Operation Qualification protocol of Bin blender has been reviewed and approved by the following persons

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
PREPARED BY			QUALITY ASSURANCE		
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			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 Bin blender and define the qualification requirements and acceptance criteria for the machine and to prove that each operation proceeds as per design specification and the tolerances prescribed there in the document.

2.2 PURPOSE:

The purpose of this protocol is to establish documentary evidence to ensure that the Bin blender received matches the Design specification and also to ensure that it is properly and safely installed.

2.3 SCOPE:

The Scope of this protocol is limited to the operational Qualification of Bin blender at Granulation area of manufacturing facility.

Once the operational qualification of Bin blender has been completed successfully, the equipment shall be preceded for the performance qualification procedure.

2.4 RESPONSIBILITY:

In accordance with protocol, following functions shall be responsible for the qualification of system.

Execution Team (Comprising members from Production, Engineering and Quality Assurance) and their responsibilities are following:

- Prepares the qualification protocol.
- Ensures that the protocol is in compliance with current policies and procedures on system Qualification.
- Distributes the finalized protocol for review and approval signatures.
- Execution of Qualification protocol.
- Review of protocol, the completed qualification data package, and the final report.
- The operational checks, calibration, SOP verification, verification of safety features, verification of utility supply shall be carried out by engineering persons and production person.



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- The production operator / supervisor shall carry out the cleaning and operation of machine.

Head – Production/ Engineering:

- Review of protocol, the completed qualification data package, and the final report.
- Assist in the resolution of validation deficiencies.

Head – Operation and Quality Assurance:

- Review and approval of protocol, the completed qualification data package, and the final report.



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3.0 ACCEPTANCE CRITERIA:

- 3.1 The equipment shall be operational as per its specified operating instructions.
- 3.2 All SOPs for the equipment to be verified and checked.
- 3.3 Training is important to all the concerned personnel.
- 3.4 All the functionality of equipment components to be checked.
- 3.5 RPM of motor should be in the range of $\pm 5\%$ deviation.

4.0 REVALIDATION CRITERIA:

The machine shall be revalidated if

- There are any major changes, which affect the performance of equipment.
- During preventive maintenance or break down maintenance if any major components is replaced which affects the performance of equipment.
- As per revalidation date and schedule.



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5.0 OPERATIONAL QUALIFICATION PROCEDURE

5.1 EQUIPMENT DESCRIPTION:

Equipment Name	:	Bin blender
Supplier / Manufacturer	:	SAAN Engineers Pvt. Ltd.
Capacity	:	1200 L / 600 L
Serial No.	:	
Location	:	Blender-1200 Ltr.

Brief Description:

GMP model Bin blender is unique, versatile equipment used for lubricating/ blending the granules/ powder.

The equipment comprises main SS clad column, drive assembly, bearing housing, arm assembly, hydraulic cylinder & bin.

The main column is sandwiched between floors & slab. The double acting hydraulic cylinder is located centrally inside the column & bearing housing is mounted on hydraulic cylinder. Adapting this double acting hydraulic cylinder the bin can lift to & lower down to discharge the product after blending operation.

The main shaft i.e. drive shaft is located in the bearing housing, at rear end of drive shaft the direct mounting inline helical gear box of/ Siemens make is fixed & the motor is directly fastened on the gear box. Because of this drive assembly the chain sprocket & V belt pulley design is discarded & it saves the unwanted lubrication & frictional loss. At the other end i.e. front side of drive shaft the arm assembly is located where blender bin can easily be engaged & dis-engaged.

The prime mover will be coupled directly with in line helical gear box. The output shaft of gear box will be connected to blender drive shaft. By this coupling the blender output RPM will be achieved 5-10 RPM.



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The drive assembly is located inside the column & front opening of column is covered with nylon belt by which cGMP factor is maintained.

The arm assembly is provided with gate & locking bolt & wheel type nut. By maintaining the required height & proper level of the arm both bins can be slide easily & hold inside the arm with the help of the gate locking arrangement.

The main panel is located at service floor & all the related cables are routed through slab & column from main panel to operator panel. The operator panel is provided on machine column for easy approachability of operation.

The safety guards are provided around the blender with safety limit switch. The acting hydraulic cylinder is unique feature of this equipment & pilot operated anti-burst, non-return valve provided on cylinder port is a safety factor of this equipment. The power pack enclosure having hydraulic components & motor will be located inside the mast.

5.2 INSTRUCTION FOR FILLING THE CHECKLIST

- 5.2.1 In case of the compliance of the test actual observation should be written in specified location.
- 5.2.2 For identification of the components of the equipment and utilities actual observation should be written in specified location.
- 5.2.3 Give the detailed information in the summary and conclusion part of the Operational Qualification report.
- 5.2.4 Whichever column is blank or not used 'NA' shall be used.



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5.3 TEST INSTRUMENT DETAILS

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard which is to be used for the verification of the operation

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration Due date	Certificate Number

Checked by Date:

Remark: -----

Reviewed by (Sign/Date)



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5.4 Verification of Calibrated Component:

This test is intended to describe the equipments/instruments and its complete details to have a traceability to the national standard, which is to be used for the verification of the operation of the Bin blender.

S.No.	Name of Instrument	Inst. ID. Number	Calibration done on	Calibration valid up to	Certificate number

Remarks:

.....
.....
.....

Done By & Date:

Verified By & Date:



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5.5 VERIFICATION OF FUNCTIONAL CHECKS:

Describe each critical component and check them and fill the inspection checklist

5.5.1 Verification of functionality major component

Function of Component	Procedure for verification	Specification	Observation	Verified By Sign/Date
Movement of bin on trolley	Move trolley in left right forward backward and circular way	Bin should not sleep over holding base on trolley and trolley should smoothly move in all direction		
Operation of discharge valve of bin manually	Close discharge valve and pour 5 liter of water After some time start opening valve slowly and observe discharge of water	Discharge valve should properly cover and no leakage should observe Valve should control discharge of material		
Fitting of blender bin to rotating arm	Fix the blender bin with rotation arm and start for ten time at interval of 10 second	Blender should properly fixed over rotation arm and should not slip in any position		
Operation of manhole lid of bin	Tightly close man hole with lid, clamp, and gasket	Lid properly close manhole and should not loose or slip in		



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Function of Component	Procedure for verification	Specification	Observation	Verified By Sign/Date
	Attach to blender arm and rotate at full set RPM	any position while rotation		
Up and down movement hydraulic cylinder assembly	Make full up and down movement of hydraulic cylinder for five time	Movement should be smooth without noise and jerk		
	Make up movement in five position in inching mode And observe each position	Bin moves upward and stay in each position firmly without sliding down or tilting in positioning		
	Make down movement in five position in inching mode And observe each position	Bin moves downward and stay in each position firmly without sliding down or tilting in positioning		
Working of main motor	Set speed controller at 100% and observe motor for smooth running, without noise and jerk and remain properly coupled with gear	Motor should smoothly run, without noise , jerk and remain properly coupled with gear		



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Function of Component	Procedure for verification	Specification	Observation	Verified By Sign/Date
Main motor gear functioning	Set speed controller at 100% and observe Main motor gear for smooth running, without noise and jerk and remain properly coupled with side arm	Main motor gear should smoothly run, without noise and jerk remain properly coupled with side arm		
Working of motor for lifting	Make up, down movement of blender and observe motor for lifting for smooth running, without noise and jerk and remain properly coupled with pump	Power pack motor should smooth running, without noise, jerk and remain properly coupled with pump		

Remark: -----

Reviewed by (Sign/Date)



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5.5.2 Verification of operation key functionality

Component of Control Panel	Procedure for Verification	Specified Function	Observation	Verified By Sign/Date
Main supply ON/OFF selector switch	Manually Turn ON/OFF selector switch to ON position	Power supply to control panel should start. And RYB indicator should glow		
	Manually Turn ON/OFF selector switch to OFF position	Power supply to control panel should stop. And RYB indicator should stop glowing		
Setting of timer	Press SET / ENT push button	Timer one digit start blinking for setting time		
	Press UP push button five time	Timer blinking digit increase by one unit at each pressing		
	Press next (<) push button three time	Timer blinking digit shifted by one digit at each pressing and toggle in four digit		
	Set time 99:59 min. by using above three keys	Timer should display set time		
	Press SET / ENT push button	Set time of 99:59 min. should save in timer		



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Component of Control Panel	Procedure for Verification	Specified Function	Observation	Verified By Sign/Date
Lifting UP selector switch	Turn selector switch & hold constantly until bin holding arm stops further lifting	Bin holding arm should start lifting correspond to selector switch after reaching upper safe lift position stops further lifting even up selector switch hold.		
DOWN selector switch	Turn DOWN selector switch and hold constantly until bin holding arm stops further coming down	Bin holding arm should start coming down correspond to selector switch after reaching lower safe down position stops further coming down even down selector switch hold.		



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Component of Control Panel	Procedure for Verification	Specified Function	Observation	Verified By Sign/Date
RUN push button	Lift the blender up to blending position and press blender RUN green push button	Blender should start rotating		
Speed regulating rotary switch	Turn speed regulating rotary switch position slowly	Blender rotating RPM should increase corresponding to switch position		
	Turn rotating speed controlling rotating knob position slowly in reverse direction	Blender rotating RPM should decrease corresponding to switch position		
STOP push button	Lift the blender up to blending position and press blender press RUN green push button after timer setting and now press STOP red push button.	Blender starts rotation at set speed. Blender rotating RPM decrease and blender should stop rotating after coming in the safe position of bin.		



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Component of Control Panel	Procedure for Verification	Specified Function	Observation	Verified By Sign/Date												
Emergency push button	Lift the blender up to blending position and press blender RUN green push button and now press Emergency push button	Blender start at rotation at set speed Blender stops immediately.														
Verification of timer	Set time 60:00 min and observe actual time with stop watch after 1 min. 10 min. 20 min. 45 min. 60 min. After starting blender bin	Displayed time and actual time should not vary	<table border="0"> <tr> <td>Displayed</td> <td>Actual</td> </tr> <tr> <td>-----Min.</td> <td>----- Min.</td> </tr> <tr> <td>-----Min.</td> <td>----- Min.</td> </tr> <tr> <td>-----Min.</td> <td>----- Min.</td> </tr> <tr> <td>-----Min.</td> <td>----- Min.</td> </tr> <tr> <td>-----Min.</td> <td>----- Min.</td> </tr> </table>	Displayed	Actual	-----Min.	----- Min.	-----Min.	----- Min.	-----Min.	----- Min.	-----Min.	----- Min.	-----Min.	----- Min.	
Displayed	Actual															
-----Min.	----- Min.															
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Component of Control Panel	Procedure for Verification	Specified Function	Observation	Verified By Sign/Date
Verification of RPM	Set Speed regulating rotary switch as mentioned below and observe displayed RPM on RPM indicator Displayed RPM and actual RPM with tachometer	RPM and frequency should increase with rotating knob and displayed RPM and actual observed RPM should not vary more than $\pm 5\%$	Display RPM. ----- Observed RPM ----- -----RPM -----RPM -----RPM -----RPM -----RPM -----RPM	
	05.00			
	08.00			
	10.00			

Remark: -----

Reviewed by (Sign/Date)



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5.6 VERIFICATION OF SUPPORTING UTILITIES:

Utility	Method of verification	Observation	Verified by Sign/ Date
Electricity: 3 phase, 415V AC, 50Hz supply with neutral and proper earthing	Physically with Clamp meter		
Compressed Air: 5-6 Kg/Cm ²	Physically		

Remark: -----

Reviewed by (Sign/Date)



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5.7 VERIFICATION OF SAFETY FEATURE:

Identify and record the safety features (if any) and their function in following tables:

Safety features description	Procedure for verification	Specification	Observation	Verified By Sign/Date
Machine emergency stop	Press the emergency stop push button during operation	Machine should stop immediately and alarm generates with hooter		
Up proximity switch	Lift the machine until it reaches its highest position	Machine should stop when it reaches its highest position		
Down proximity switch	Start the machine at its minimum lift & start the operation Start the machine in its down position	Machine should start its operation Machine should not start		
Position proxy	Start the machine at its minimum lift after setting the timer & stop the machine	The machine should stop with its blender bin in home position		
Earthing	Check whole body with multimeter for any current	No current leakage should be observed		



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	leakage			
Column guard cover	Run machine and observe column from back side	Guard should properly fix and all moving part should be properly covered		
Safety railing	Run machine and open safety railing	Machine should stop immediately and alarm generates with hooter		
Display of RPM & Time	Set Blender RPM 6 Blending time 10 minute	Set parameter should display		
Power failure study	Start Blender and run process for five minute and power off main supply	Blender should run on set parameter and as power supply cut machine stops		
	Wait for five minute and again power ON main supply and observe	Machine should start with set parameter and process should start with remaining time		

Remark: -----

Reviewed by (Sign/Date)



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5.8 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP):

The following Standard Operating Procedures were identified as important for effective performance of bin blender.

S.No.	SOP Title	SOP Number	Verified By Sign/Date

Remark: -----

Reviewed by (Sign/Date)

5.9 TRAINING RECORD OF PERSONNEL (S):

S.No.	Name of Personnel	Designation	Sign. & Date	Trained By	Remark

Remark: -----

Reviewed by (Sign/Date)



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5.11 DEFICIENCY AND CORRECTIVE ACTION (S) REPORT (S):

Following deficiency was identified and corrective actions taken in consultation with the Engineering Department.

Description of deficiency:

Corrective action(s) taken:

**Deviation accepted by
(Sign/Date)**

**Deviation Approved by:
(Sign/Date)**



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6.0 OPERATIONAL QUALIFICATION FINAL REPORT:

6.1 SUMMARY:

6.2 CONCLUSION:

**Prepared By
Sign/ Date**

**Checked By
Sign/ Date**



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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. If applicable signature in the block below indicates that all items in this Operational qualification report of Bin blender have been reviewed and found to be acceptable and that all variations or discrepancies have been satisfactorily resolved.

FUNCTION	NAME	DESIGNATION	DEPARTMENT	SIGNATURE	DATE
REVIEWED BY			QUALITY ASSURANCE		
			ENGINEERING		
			PRODUCTION		
APPROVED BY			HEAD OPERATION		
			QUALITY ASSURANCE		