



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

**OPERATIONAL QUALIFICATION
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Document Reference: IQ No.: _____

Issue Date: _____



PHARMA DEVILS

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FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

CONTENTS

S.No.	Title of sections	Page No.
1.0	Pre-approval	3
2.0	Objective	4
3.0	Scope	4
4.0	Reason for OQ	4
5.0	Refer attached Manufacturer/Supplier Operation Qualification No. (if applicable):	4
6.0	Responsibility	5
7.0	Training	5
8.0	Verification of instruments for calibration	6
9.0	Verification of SOP	6
10.0	Operational check of software	6
11.0	Details of parameter of DQ verified in OQ	7
12.0	Functional/ operational requirements of equipment	7-9
13.0	Reference documents	9
14.0	Abbreviations	9-10
15.0	Attachments	10
16.0	Deviations/ Changes (if any)	10
17.0	Recommendations/ Conclusion	10
18.0	Post approval	11



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

1.0 Pre-approval Protocol:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PREPARED BY				
User Department				
REVIEWED BY				
User Dept. Head				
Engineering Dept. Head				
Environment, health and safety				
Quality Control (if applicable)				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

2.0 OBJECTIVE: To ensure that the installed equipment / system operate according to the approved design, specification and manufacturers operating manual and to record all relevant information and data.

3.0 SCOPE: The scope of this Operation Qualification is for “**BIN BLENDER (PILLAR TYPE), Capacity: 600 Litres**”.

4.0 Reason for OQ:

The reason for preparing this document is:

Please tick any one (or multiple) option(s) from the following (☑):

- | | |
|---|-------------------------------------|
| Refurbished premises/equipment | <input type="checkbox"/> |
| Purchase of Utility Systems | <input type="checkbox"/> |
| Purchase of Process Equipment | <input checked="" type="checkbox"/> |
| Purchase of Laboratory Equipment | <input type="checkbox"/> |
| Bespoke or user configured computer systems | <input type="checkbox"/> |
| In-Use Systems that don't have a URS | <input type="checkbox"/> |
| Others (Specify) | <input type="checkbox"/> |

5.0 Refer attached Manufacturer/Supplier Operation Qualification No. (if applicable):

Refer attached OQ No.: _____.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

6.0 Responsibility: Personnel involved in qualification activity.

Department	Name	Activity
User		To prepare the qualification protocol and verify all the proposed operating parameters of the equipment.
Engineering		To verify the key functionalities and equipment parameters
Health Safety and Environment		To verify the safety requirements of equipment and facility
Quality Assurance		To be a part of team and review the documents
QA Head		To review and approve the requirement and Qualification document
Plant Head		To review and approve the requirement and Qualification document

7.0 Training: Personnel involved in qualification activity.

S.No.	Name	Training status	Training report availability	Checked by/ date
7.1				
7.2				
7.3				
7.4				



PHARMA DEVILS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)

PROTOCOL No.:

8.0 VERIFICATION OF INSTRUMENTS FOR CALIBRATION:

S.No.	Instrument Name	Instrument ID	Calibration done on	Calibration due on	Checked by/ Date
8.1					
8.2					
8.3					
8.4					
8.5					
8.6					
8.7					

9.0 VERIFICATION OF STANDARD OPERATING PROCEDURE (SOP) :

Required corrections shall be carried out on draft copy of SOP and SOP shall be finalized.

S.No.	SOP Name	SOP No.	Checked by/ Date
9.1			
9.2			
9.3			

10.0 OPERATIONAL CHECK OF SOFTWARE:

S.No.	Description of test	Expectation / Acceptance criteria	Result	Pass (Yes/ No)	Checked by/ Date
10.1	NA	NA	NA	NA	NA

11.0 DETAILS OF PARAMETER OF DQ VERIFIED IN OQ:

S.No.	Parameter Mentioned in DQ	Observation in OQ	Checked by/ Date
11.1	NA	NA	NA



PHARMA DEVILS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)

PROTOCOL No.:

12.0 Functional/ Operational Requirements of Equipment:

The desired functional/ operational requirements are listed under this section.

S.No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
Pillar type Blender:				
1.	Run the empty blender at slow RPM and check the speed	RPM shall be as per set RPM		
2.	Run the empty blender at fast RPM and check the speed	RPM shall be as per set RPM		
3.	Rotate the arm and stop it	It shall stop in Vertical position		
4.	Lift the arm up to the blending height	Machine shall get start		
5.	Start the Machine and press the Emergency stop button	Machine shall get stop		
6.	Press the start buttons to run the arm and after some time stop the button	The arm shall start and stop when start and stop buttons are pressed		
7.	Check the Up and Down movement of Trolley	Shall be smooth movement		
8.	Check the rotation of the arm	Shall be smooth rotation		
9.	Check the Operation of A.C. Drive by setting any two speeds and start/stop the machine on the preset speed.	The machine shall run as per set speed on drive.		



PHARMA DEVILS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)

PROTOCOL No.:

S.No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
10.	Noise level without load & with load: A. Start the machine without any load & check the noise level with the help of dB meter. B. Start the machine with load & check the noise level with the help of dB meter.	Noise level should not be more than 90 dB		
11.	Vibration without load & with load: A. Start the machine without any load and check for the vibration. B. Start the machine with load and check for the vibration.	Abnormal vibrations should not be observed.		
12.	Run the loaded blender at slow RPM and check the speed	RPM shall be as per set RPM		
13.	Run the loaded blender at fast RPM and check the speed	RPM shall be as per set RPM		
Square Bin and IPC Bin:				
1.	Open and close the butterfly valve and check the butterfly valve operates smoothly	Shall operate smoothly when it is closed and opened		
2.	Move the trolley with bin and check the trolley movement	Shall move smoothly		



PHARMA DEVILS

OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)

PROTOCOL No.:

S.No.	Operating Parameter & Test Procedure	Acceptance Criteria (Based on DQ/ Manual)	Observation	Remark
3.	Fill the bin with water and check for any leakages through butterfly valve	There shall not be any leakage of water.		

13.0 Reference Documents: Nil.

14.0 Abbreviations: Full forms of all abbreviations are listed here.

Abbreviation	Full form
DQ	: Design Qualification
OQ	: Operation Qualification
SOP	: Standard operating procedure
Dept.	: Department
QA	: Quality Assurance
Sr. No.	: Serial Number
ID	: Identification
e.g.	: Example
&	: And
RPM	: Rotation per minute
HMI	: Human machine interface
PLC	: Programmable logic controller
dB	: Decibel

15.0 Attachments: This section contains a list of all attachments referenced in the protocol.

S.No.	Attachment Details	Attachment No.



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
FOR
BIN BLENDER (PILLAR TYPE)**

PROTOCOL No.:

16.0 Deviations/ Changes (if any):

17.0 Recommendations/ Conclusion :



PHARMA DEVILS

**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT
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18.0 Post approval:

This document has been developed and the individuals listed below have reviewed the document and agree with its content and with their signature grant approval for its execution).

Functional area	Name	Designation	Signature	Date
PERFORMED BY				
User Department				
Engineering				
EHS				
Quality Control (if applicable)				
Validation QA				
REVIEWED BY				
User Dept. Head				
Quality Assurance				
APPROVED BY				
QA Head				
Plant Head				