OPERATIONAL QUALIFICATION PROTOCOL

TIPPLING DEVICE 1000 KG

PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

OPERATIONAL QUALIFICATION FOR TIPPLING DEVICE

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OPERATIONAL QUALIFICATION FOR TIPPLING DEVICE

1.0 Pre-Approval

Signing of this Approval page of Operational Qualification Protocol, indicates agreement with the Operational Qualification approach described in this document. Should Modifications to the Operational Qualification become necessary; an addendum will be prepared and approved.

Written By	Signature	Date

Checked By	Signature	Date

Approved By	Signature	Date

OPERATIONAL QUALIFICATION FOR TIPPLING DEVICE

2.0 Overview

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of the **Conta Bin Blender** Critical to serve the intended purpose of the equipment.
- To establish the suitability of the draft SOP prepared for the operation of Equipment.
- To document the observations for future reference

2.2 Responsibility:

The validation group comprising of representatives from each of the following departments should be responsible for the overall compliance with this protocol:

- Production Department
- Quality Assurance Department
- Engineering Department

The Officer-Production and Officer-Engineering should be responsible for checking the operations and recording data as per the procedures outlined in this protocol.

Executive -Validation should collect all the test data and should compile the results to make the reports of qualification studies.

The Reports should be checked by Manager-Engineering and Manager-Plant.

The Senior Manager-QA, should finally approve the Validation report.

2.3 Requalification:
Operational Qualification to be repeated incase of:

- Replacement of any major component / instrument.
- Major modification in the existing equipment.
- During monitoring, if equipment is found to be malfunctioning.
- Shifting of the equipment from one location to another.

2.4 System Description

Technical Details

Motor	1.5+1.5 HP / 1440 RPM
Electrical Services	415 V/3 Phase, 50Hz AC supply
Foundation	Required
percentage of constituents	
Overall Dimension	H - 3225 mm L - 2900 mm W-1396 mm
Net Weight	800 Kgs Approx.

3.0 Operational Qualification Procedure

1) A draft SOP shall be prepared on the basis of supplier guide for operation before the Qualification testing.
2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the supplier on the operational features of the equipment / system. This training shall be recorded in Section 3.1.
3) The trained personnel shall carry out the Operational Qualification following the Procedures mentioned under Section 3.2 for Key Functionality and 3.3 for Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1 and 3.3.
4) Operate the equipment / system as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.4.
5) Report the deficiency from the specified function, if any in the section 3.5

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3.1 Training **Date:**

Title: Operational features of Tippling Device

Name of the Trainer(s) :

(M/s. SHEFA INDUSTRIES)

S.No.	Name of the Trainee	Employee Number	Signature
1.			

This certifies that the above said personnel for M/s._____., has undergone all the operations regarding the operating of machine which includes functioning of the machine, interaction of Control Panel and operator panel with the machine and all safety features functioning step by step under the presence of Vendor's trainer Mr._____

Signature of the Trainer (s) : _____

Date : _____

3.2 Key Functionality

A. Purpose:

The purpose of this procedure is to demonstrate that the control panel and other manual operations of CONTA BIN BLENDER (Tag No. -------) function as specified by the manufacturer.

B. Testing:

1. Check all the displays on the panel are identified.
2. Turn on the power from the electrical panel.
3. Set the control(s) on the panel.
4. Verify functionality of each component on the control panel against its Specified functions.
5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

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3.2.1 TEST DATA SHEET

S.No.	Test Particulars	Specified Function	Observations	Checked By
1	Switch ON the mains from front panel	3 Phase Indication lamp should come ON		
2				
3				
4				

Comment (If any):

All the test on Operator Panel was found OK & Satisfactory.

Verified By:

Name: _____ Signature: _____ Date: _____

3.3 Safety Features Test:

S. No.	Safety Feature Description	Specified Function	Observations	Checked By
1	Earth Fault	Machine will stop.		
2	Overload trip fault	Machine will stop		

Comments (if any):

3.4 SOP Verification

SOP No. Page No._____. (In operation and instruction manual)

Title:

Installation of Machine

Operate the equipment as per the draft SOP and record the details given below:

Operated By: _____

Checked By: _____

The operating personnel understand and follow the SOP description:

Yes

Changes required in draft SOP (If any):

_____No_____

_____

_____

SOP to be revised No.

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3 Deficiency (if any) and Corrective Actions Report:

Description of deficiency and date observed :

_____

_____

_____

_____

_____

Person, responsible for corrective action and date assigned:

_____

_____

_____

_____

Corrective actions taken and date conducted :

_____

_____

_____

_____

_____

_____

_____

Conducted By : _____ **Approved By:**_____

Date : _____ **Date :** _____

Comments (if any):

Verified By:

Name:_____ **Signature :**_____**Date :**_____

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4.0 Acceptance Criteria

Operational Qualification should be considered acceptable when all the conditions specified in various data sheets under section 3.0 have been met.

Any deviation from the acceptance criteria of the specific checkpoint should be reported and decision should be taken for the rejection, replacement or rectification of the equipment/component.

5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.	Yes.	----------

5.1 Conclusion:

The Tippling Device (Tag No. ----) **Is** qualifying the Operational Qualification test as per the guideline described in this Protocol No. 03. The Tippling device (Tag No. -----) **Can Be** tested for its Performance Qualification as per Protocol No. 04.

5.2 Post-Approval:

Name	Signature	Date

Verified By:

Name:_____ Signature :_____Date :_____