



PERFORMANCE QUALIFICATION PROTOCOL FOR DOUBLE CONE BLENDER

**PERFORMANCE QUALIFICATION PROTOCOL
FOR
DOUBLE CONE BLENDER**

EQUIPMENT No.:

Protocol No.	
Supersedes	
Effective Date	
No. of Pages	20



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Protocol Approval

This is a specific protocol for re-qualification of Double Cone Blender (**Equipment No.**) installed in Plant.

This protocol shall be approved by the following:

Prepared By:

Name	Designation	Department	Signature	Date

Checked By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date



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2.0 Overview

2.1 Objective

To provide documented evidence that the Qualification of Double Cone Blender (**Equipment No.:**) has been performed as per the approved protocol.

2.2 Purpose and Scope

The purpose of the protocol is to demonstrate that the Double Cone Blender installed in Plant shall operate reproducibly and consistently within its full dynamic range of operation according to Functional /Manufacturers/In house specifications.

The scope of this exercise is limited to the qualification of Double Cone Blender (**Equipment No.**).

2.3 Responsibility

- **Protocol / Report Preparation:** Quality Assurance (QA) Officer.
- **Review of Protocol / Report:** Manager Production / Manager Engineering / Manager Quality Assurance (QA).
- **Approval of Protocol / Report:** Quality Assurance (QA) Manager.

3.0 Training Record

3.1 Purpose

The purpose of this training is to familiarize the trainees with the overall strategy of Qualification of Double Cone Blender (**Equipment No.**).

3.2 Scope

This training is applicable to Double Cone Blender (**Equipment No.:**).

3.3 Topics

The following topics shall be covered during training:



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3.1 Principle of working of Double Cone Blender.

3.2 Overall strategy of Qualification process.

3.3 General precautions / guidelines to be followed during re-qualification.

Note:

3.4 *Training record shall be attached with the report as Annexure - 01*

4.0 Pre-Qualification Requirements

Following instruments shall be required for the Qualification of Double Cone Blender at Plant:

S.No.	Instrument Name	Instrument Code / S. No.	Calibration Certificate No.	Calibration Due On
1.	Tachometer			

5.0 System / Equipment Description

5.1 System / Equipment details

The Double Cone Blender shall be used for blending of two or more batches to get homogenous blend with bigger batch size as per the requirement.

Description

3.5 Equipment Tag Number :

3.6 Location : Ground Floor

3.7 Name of the system : Double Cone Blender

3.8 Manufacturer's Name / Address : M/s



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5.2 Generic Design

5.2.1 Working Principle

The double cone Blender is used for homogenous blending of sterile API's in aseptic area. Its blends materials precisely and quickly.

The Blender's double cone enclosure provides a clean, dust free operation. Its cone shaped design makes possible the emptying operation of the finished blend without any material hang-up very efficiently. Other desirable qualities are low maintenance.

Material during operating is rotated close to axis, which greatly reduces power requirement. The whole unit is mounted on solid fabricated stand, which houses drive and its control cabinet. The motor is provided with magnetic brake that enables blender's to stop instantaneously at any given position.

5.2.2 Brief Machine Description

The main components of the Double Cone Blender are –

- 3.9** Bearing housings are fixed on two trunions at ends.
- 3.10** A bottom outlet is provided with manual operated valve.
- 3.11** The shell is mounted on the SS fabricated side stands with the welded shaft.
- 3.12** The shell shaft one side is attached to gear reducer and spur gears, which is connected with 3 HP motor the shell.
- 3.13** Electric panel board with timer, reverse/forward switch, including with auto/manual operation and magnetic breaks.
- 3.14** A safety railing guard is provided with lock system for Blender.

5.2.3 Basic Design Concept

- 4.0** Equipment Contact surfaces are compatible with reactants coming in direct contact.
- 5.0** Smoothness of equipment surface for ease of cleaning
- 6.0** Feasible for in place cleaning.
- 7.0** To meet the current cGMP compliance level.



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5.3 Safety feature Description

5.3.1 All corners rounded off

All corners shall be rounded for the personnel safety of the human being to avoid any Accidentals cut during operation.

5.3.2 All electrical components are guarded

All electrical components are suitably guarded to restrict approach of personnel.

6.0 Qualification Procedure

Following procedure shall be used for the qualification of the Double Cone Blender
(Equipment No:) installed in Plant

- 6.1 The external utilities attached to the Double Cone Blender shall be verified and documented to be adequate. The details shall be recorded as per **Exhibit – E01**.
- 6.2 Calibration status of the instruments attached to the equipment shall be checked and observations shall be recorded as per **Exhibit –E02**.
- 6.3 The operating functions of control panel interface shall be checked. The observations shall be recorded as per **Exhibit – E03**.
- 6.4 The system shall be run for 30 minutes to check the operational performance of Double Cone Blender. The observations shall be recorded as per **Exhibit – E04**.
- 6.5 Qualification checks shall be performed to verify that Double Cone Blender has been installed with proper electrical connections and utilities. The observations shall be recorded as per **Exhibit – E05**.
- 6.6 Any deviation observed during qualification shall be recorded in the observed deviation, corrective action and justification report section.



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- 6.7 Observed deviation shall be reported to the department head and quality head.
- 6.8 If the observed deviation does not have any major impact on the qualification, the final conclusion shall be provided.
- 6.9 If the observed deviation has major impact on the qualification, deviation shall be reported to the manufacturer for the corrective action and qualification activity shall be performed again.

7.0 Acceptance Criteria

Qualification shall be considered acceptable when requirements listed in section 6.0 of this document have been fulfilled.

8.0 Qualification Report

This report shall include the related documents and attachments / annexure which were completed at the time of qualification activity.

9.0 Approval of Qualification Report

The qualification report shall be evaluated and finally approved by Head Quality Assurance.

10.0 Qualification Criteria

- 7.1 Location of the equipment
- 7.2 The design of the equipment
- 7.3 Major part of the equipment
- 7.4 Regulatory requirement, or
- 7.5 Equipment is replaced with new one.

The above changes shall be done through change control procedure.



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11.0 Observed Deviation

S.No	Page No.	Point No.	Observed Deviation	Deviation Reported By	Deviation Approved By	Corrective Action Taken	Justification of Corrective Action	Corrective Action Taken and Justification Given By	

Report Approved By

Department Head

Quality Head



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12.0 List of Exhibits / Annexure

12.1 List of Exhibits

Exhibit No.	Exhibit Title	No. of Pages
E01	Attached Utilities Verification Checklist	01
E02	Critical Instrument List with Calibration Status	01
E03	Control Panel Interface Operation Verification	01
E04	Equipment Performance Test (Blank Trial)	01
E05	Checklist for Qualification	01
Total No. of pages		05

12.2 List of Annexure

Annexure No.	Annexure Title
01	Training Record
02	Calibration Certificates for Master Instruments

13.0 Reference Documents

13.1 Test Certificates of components



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Exhibit – E01

Attached Utilities Verification Checklist

Equipment Name / Description : Double Cone Blender

Equipment No. :

Location : Plant

S.No.	Utility Description	Specifications	Observation
1.	Power Supply		
	Voltage	395-435 Volts	
	Phase	3 Phase	
	Cycles	48-52 Hz	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E02

Critical Instrument List with Calibration Status

Equipment Name / Description : Double Cone Blender

Equipment No. :

Location : Plant

S.No.	Name of the Instrument / Component	Calibration Range	Instrument No.	Calibration Done On	Calibration Due On
1.	RPM Tachometer				

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E03

Control Panel Interface Operation Verification

Equipment Name/ Description: Double Cone Blender

Equipment no :

Location : Plant

Date:

Time:

S.No.	Activity	Action	Expected Result	Pass / Fail
1.	ON/OFF Red selector switch	Turn switch to ON position	The machine shall get ON	
		Turn switch to OFF position	The machine shall get OFF	
2.	Green Push Button	Push the button for rotate in clockwise direction.	Machine will run in clockwise direction	

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit-E04

Equipment Performance Test (Blank Trial)

Equipment Name/ Description : Double Cone Blender

Equipment no :

Location : Plant

Date : _____

Time (from – to) : _____

Qty. of water used : _____

Run time : _____

S.No.	Operation	Acceptance Criteria	Status
1.	Vibrations	No vibrations shall be observed.	
2.	Abnormal sound	No abnormal sound shall be observed.	
3.	RPM	0-20	

Remarks: Vibrations, abnormal noise observed/not observed after taking blank trial.

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Exhibit – E05

Checklist for Qualification

Equipment Name / Description : Double Cone Blender

Equipment No. :

Location : Plant

S.No	Checks to be performed	Specifications	Observation
1.	Utilities	All the utilities shall be properly connected	
2.	Electrical connection	No loose connection shall be there	
3.	Levelling of Machine	Shall be Levelled properly	
4.	Bolts	Check all bolts, if found loose tight it suitably	
5.	Safety Guard	Check that safety guard is provided	

Remarks:

Checked By: _____
(Name) (Sign) (Date)

Verified By: _____
(Name) (Sign) (Date)



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Annexure – 01

Training Record

Equipment Name:	Double Cone Blender
Equipment No.:	
Location:	Plant
No. of Pages:	01



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Annexure – 02

Calibration Certificates for Master Instruments

Equipment Name:	Double Cone Blender
Equipment No.:	
Location:	Plant
No. of Pages:	01