



**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
NUTSCHE FILTER**

Protocol No.	
Supersedes	
Effective Date	
No. of Pages	19



PERFORMANCE QUALIFICATION PROTOCOL FOR NUTSCHE FILTER

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1.0 Protocol Approval

This is a specific protocol for Qualification of Nutsche Filter (**Tag 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 a documented evidence that the Qualification of Nutsche Filter (**Tag No.:**) have been performed as per the approved protocol.

2.2 Purpose and Scope

2.3 The purpose of the protocol is to demonstrate that the Nutsche Filter 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 qualification exercise is limited to the Qualification of Nutsche Filter of Plant.

2.4 Responsibility

- **Protocol / Report Preparation:** Quality Assurance (QA) Executive.
- **Protocol / Report Preparation:** Manager Production / Manager Engineering / Manager Quality Assurance (QA).
- **Approval of Protocol / Report:** Quality Assurance (QA) AVP / Nominee.



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3.0 Training Record

3.1 Purpose

The purpose of this training is to familiarize the trainees with the strategy of Qualification of Nutsche Filter of Plant.

3.2 Scope

This training is applicable to Nutsche Filter.

3.3 Topics

The following topics shall be covered during training:

- Principle of working of Nutsche Filter.
- Technical specifications of the Nutsche Filter.
- Overall strategy of Qualification process.
- General precautions / guidelines to be followed during Qualification.
- *Training record shall be attached with the report as Annexure - 01*



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4.0 Pre Qualification Requirements

Following instruments shall be required for the Qualification of Nutsche Filter at Plant.

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

Calibration certificates of master instruments shall be attached as **Annexure No-02**.



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5.0 System/Equipment Description

5.1 System/Equipment details

The Nutsche filter (**Tag No. :**) shall be used to separate solid & liquid by filtration under pressure or vacuum.

Description

- Equipment Tag Number :
- Location : Sterile Plant
- Name of the system : Nutsche filter
- Manufacturer's Name / Address :
- Model : Detachable Bottom (cGMP)
- Overall Dimensions
 - Height : 1070 mm
 - Diameter : 780 mm
- Hold up Volume : 150 Litres
- Filter Disc Pore Size : 10 Micron



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5.2 Generic Design

5.2.1 Working Principle

Nutsche Filter is a closed vessel designed to separate solid and liquid by filtration under pressure or vacuum. The closed operation ensures compatible, contamination free and non polluting working conditions maintaining product purity and hygiene.

5.2.2 Brief Machine Description

The Nutsche Filter comprises of following parts:

- **Shell**

The shell is fabricated from SS-316 Plate. Shell is supported by four legs with castors and PU wheels. Shell of Nutsche filter is tested at 3 Kg/cm² and designed temperature of the shell is 130 °C at 60 minutes duration. Hold up volume 150 Litre and nominal filtration area is 0.47 m²

- **Detachable Bottom**

Detachable bottom is fabricated from SS-316 Plate. It holds filter cloth as a filter media (10 micron filter holes). Sealing rubber ring is provided in between grooves of detachable bottom & shell to provide leak proof joint while operation. Detachable bottom is lowered by shell cylinder attached to the vessel at one end and the bottom at the other end.

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 Pressure Gauge

Compound gauge is provided to measure the shell pressure.



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6.0 Qualification Procedure

Following procedure shall be used for the Qualification of the Nutsche filter is installed in Plant.

- 6.1 The connected utility shall be checked before starting Qualification. The observations 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 shall be checked. The observations shall be recorded as per **Exhibit –E03**.
- 6.4 The Nutsche filter shall be run for 60.0 minutes to check the Qualification performance of Nutsche filter and the observation shall be recorded as per **Exhibit-E04A & 4B**.
- 6.5 All instrument calibration certificates shall be attached as per **Annexure – 02**.
- 6.6 Any deviation observed during qualification shall be recorded in the observed deviation, corrective action and justification report section.
- 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.



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7.0 Acceptance Criteria

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

8.0 Qualification Report

This report shall include the related documents and attachments / annexure which shall be 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

- Location of the System
- The design of the System
- Major part of the System
- Regulatory requirement, or
- 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	Calibration Certificates & Equipment Checklist	01
E03	Control Panel Interface Operation Verification	01
E04A	Equipment Performance Test (Vacuum Test)	01
E04B	Equipment Performance Test (Leakage Test with Water)	01
Total No. of Pages		05

12.2 List of Annexure

Annexure No.	Annexure Title	No. of Pages
01	Training Record	01
02	Calibration Certificates of Master Instruments	01
Total No. of Pages		02

13.0 Reference Documents

13.1 Manual of Equipment



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Exhibit – E01

Connected Utilities Verification Check List

Equipment Name / Description : Nutsche Filter

Equipment Number :

Location : Plant

Date: Time:

S. No.	Utility Description	Specifications	Actual Observations
1.	Dry Nitrogen		
	Pressure	2 – 4 Kg/cm ²	
	Vacuum	600 – 700 mmHg	

Remarks: Observation Comply / Not Comply with the specification.

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

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



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Exhibit – E02

Calibration Certificate Availability Verification Checklist

Equipment Name / Description : Nutsche Filter

Equipment No. :

Location : Plant

Date: Time:

S.No.	Name of the Instrument / Component	Instrument Calibration Range	Instrument No.	Calibration Done on
1.	Vacuum Gauge			

Remarks: Observation Comply / Not Comply with the specification.

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

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



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Exhibit – E03

Control Panel Interface Operation Verification

Equipment Name / Description : Nutsche Filter

Equipment Number :

Location : Plant

Date: Time:

S. No.	Item	Action	Expected Result	Pass / Fail / Result
	Dry Nitrogen valve	Open the valve of dry Nitrogen	Nutsche filter shall get on	

Remarks: Observation Comply / Not Comply with the specification.

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

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



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Exhibit – E04A

Equipment Performance Test

(Vacuum Test)

Equipment Name / Description : Nutsche Filter

Equipment Number :

Location : Plant

Date: Time:

S.No.	Time	Vacuum On Vacuum Ejector Pump	Vacuum On Nutsche Filter	Remarks Pass/Fail
1.0	10 Min			
2.0	20 Min			
3.0	30 Min			
4.0	40 Min			
5.0	50 Min			
6.0	60 Min			

Remarks: Observation Comply / Not Comply with the specification.

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

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



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Exhibit – E04B

Equipment Performance Test (Leakage Test with Water)

(Dry Nitrogen Pressure)

Equipment Name / Description : Nutsche Filter

Equipment Number :

Location : Plant

Date: Time:

S.No.	Time	Pressure On Nutsche Filter	Observation of Leakage	Remarks Pass/Fail
1.0	10 Min			
2.0	20 Min			
3.0	30 Min			
4.0	40 Min			
5.0	50 Min			
6.0	60 Min			

Remarks: Observation Comply / Not Comply with the specification.

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

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



Annexure – 01
Training Record

Equipment Name:	Nutsche Filter
Equipment Tag No.:	
Location:	Plant
No. of Pages:	01



Annexure – 02

Instruments Calibration Certificates

Equipment Name:	Nutsche Filter
Equipment Tag No.:	
Location:	Plant
No. of Pages:	01