



**PERFORMANCE QUALIFICATION
REPORT
FOR
NUTSCHE FILTER**

| | |
|--------------------------|-----------|
| Report No. | |
| Supersedes | |
| Ref. Protocol No. | |
| Completion Date | |
| No. of Pages | 19 |

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1.0 Report Approval

This is a specific Report for Qualification of Nutsche Filter (**Tag No.**) installed in Plant, PDL-1, Derabassi.

This Report 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 Report.

2.2 Purpose and Scope

2.3 The purpose of the Report 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

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

| Sr. 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:

| Sr. 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 |