



PHARMADEVILS
QUALITY ASSURANCE DEPARTMENT

PERFORMANCE QUALIFICATION PROTOCOL FOR SPARKLER FILTER

**PERFORMANCE QUALIFICATION
PROTOCOL
FOR
SPARKLER FILTER**



PERFORMANCE QUALIFICATION PROTOCOL FOR SPARKLER FILTER

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1.0 Protocol Approval

This is a specific protocol for Qualification of Sparkler Filter which have been installed in the 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 Sparkler Filter shall be performed as per the approved protocol.

2.2 Purpose and Scope

2.3 The purpose of the protocol is to demonstrate that the Sparkler 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 Sparkler Filter in Plant.

2.4 Responsibility

Protocol / Report Preparation: Quality Assurance (QA) Executive.

Review of Protocol / Report: Manager Production / Manager Engineering / Asst.Manager /Manager Quality Assurance (QA).

Approval of Protocol / Report: Head QA.



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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 Sparkler Filter of Plant.

3.2 Scope

This Training is applicable to Sparkler Filter.

3.3 Topics

The following topics shall be covered during training:

- Principle of working of Sparkler Filter.
- Overall strategy of Qualification process.
- General precautions / guidelines to be followed during Qualification.

Note:

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

4.0 Re – Qualification Requirements

Following instruments shall be required for the Qualification of Sparkler Filter.

S.No.	Instrument Name	Instrument Code / S. No.	Calibration Certificate No.	Calibration Due On
1.	Water Flow Meter			

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



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5.0 System / Equipment Description

5.1 System / Equipment details

The Sparkler Filter shall be used to filter solid mass from slurry.

Description

- Equipment Tag Number :
- Location :
- Name of the system : Sparkler Filter
- Manufacturer's Name / Address :
- Model : Φ 14" x 11 Plates
- Dimensions

Overall Dimensions

- Height : 400 mm
- Width : 460 mm
- Length : 600 mm



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5.2 Generic Design

5.2.1 Working Principle

The liquid to be filtered enters the filter by the central passage of filter inlet, filter cartridge & flows over the filter plates on which suitable filter media is held uniformly under the force of circulating pump. The liquid gets filtered through filter media and clear filtrate goes out of the filter through outlet port. To provide large filtration area, the filter is having number of disks and flow is distributed on all the filter plates.

5.2.2 Brief Machine Description

The Sparkler Filter comprises of following parts:

- Top Dish
- Shell & Bottom Plate
- Filter Plate Assembly

5.2.2.1 Top Dish

Top Dish is fabricated from 4 mm SS sheet. It is directly coupled on Shell by wing nuts & bolts.

5.2.2.2 Shell & Bottom Plate

Shell is fabricated from 4 mm SS sheet & bottom plate is fabricated from 10 mm SS sheet. It holds the entire filter plate assembly.

5.2.2.3 Filter Plate Assembly

Filter plate assembly comprises of cartridge top dish, filter pad, supporting screen, filter plate ring, filter plate, interlocking cup & scavenger plate.

5.3 Safety feature Description

5.3.1 All corners are rounded off

All corners are rounded for the personnel safety of the human being to avoid any accidentals cut during operation.



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6.0 Re -Qualification Procedure

Following procedure shall be used for the Qualification of the Sparkler Filters installed in Plant-D.

- 6.1 The connected utility shall be checked before starting Qualification and observations shall be recorded as per **Exhibit –E01**.
- 6.2 Availability of calibration certificates of all the attached instruments shall be checked. The observations shall be recorded as per **Exhibit – E02**.
- 6.3 The operating function of control panel shall be checked. The observations shall be recorded as per **Exhibit-03**.
- 6.4 .The sparkler filter shall be subjected to blank trial and the results shall be recorded. The Sparkler filter shall run for 30 minutes to check the operational performance of Sparkler Filter, and the observations shall be recorded as per **Exhibit-04**.
- 6.5 Qualification checks shall be performed to verify that Sparkler filter have been installed with proper 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.
- 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 have been fulfilled.

8.0 Qualification Report

The 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

- Major change in equipment design.
- Relocation of the equipment.
- Any other regulatory requirement.



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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 Record (Blank trials)	01
E05	Checklist for Qualification	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 Instruments	01
Total No of Pages		02

13.0 Reference Documents

13.1 Test Certificates of components



PERFORMANCE QUALIFICATION PROTOCOL FOR SPARKLER FILTER

Exhibit – E01

Attached Utilities Verification Checklist

Equipment Name / Description : Sparkler Filter

Equipment No. :

Location : Plant

Date: Time:

S.No.	Utility Description	Specifications	Observations
1.	Dry Nitrogen Pressure	2-4 kg/cm ²	

Remarks : Observations Complies / Not Complies with the above specifications.

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 : Sparkler Filter

Equipment No. :

Location : Plant

Date:

Time:

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

Remarks: Observations Complies / Not Complies with the above specifications.

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

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



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Exhibit – E03

Control Panel Interface Operation Verification

Equipment Name / Description : Sparkler Filter

Equipment Number :

Location : Plant

Date: Time:

S. No.	Item	Action	Expected Result	Pass / Fail / Result
1.	Dry Nitrogen valve	Open the valve of dry Nitrogen	Nitrogen shall get out from vent of Sparkler Filter	

Remarks: Observation Comply / Not Comply with the specification.

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

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



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Exhibit – E04

Equipment Performance Record (Blank trials with Carbon and Purified Water)

Equipment Name / Description : Sparkler Filter

Equipment No. :

Location : Plant

Date: Time:

S.No	Operation	Activity Performed	Expected Result	Pass / Fail
1.	1.0% solution of Carbon shall be prepared in Purified Water.	Connect the Vessel outlet to the inlet point of Sparkler Filter, and allow the solution to enter into the filter, open nitrogen valve & removed air of the cartridge of filter, from the Air vent and, collect the filtrate in another Reactor and check the clarity.	Filtrate solution should be clear	
2.	To Check the equipment performance (Run the filter for 30 minutes)	Continuous running and recycle the filtrate for 30 minutes.	No Abnormal sound, no Vibration should be observed in Equipment during the filtration.	



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Exhibit – E04
Equipment Performance Record (Blank trials)

S.No	Operation	Activity Performed	Expected Result	Pass / Fail
3.	Dismantling the filter cartridge assembly and checking the hold up volume in the chamber	Apply the dry nitrogen in the system for 5 minutes before dismantling	There should be zero hold up in the filter chamber.	

Remarks: Observations Complies / Does Not Complies with the above specifications.

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

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



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Exhibit – E05

Checklist for Qualification

Equipment Name / Description : Sparkler Filter

Equipment No. :

Location : Plant

Date:

Time:

S. No.	Checks to be performed	Specifications	Observation
1.	Utilities	All the utilities shall be properly connected	
2.	Levelling of Machine	Shall be levelled properly	
3.	Bolts	Check all the bolts, if loose tight it.	
4.	Abnormal Vibration & sound	Run the system & check the abnormal vibration & abnormal sound.	

Remarks:

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

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



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Annexure – 01

Training Record

Equipment Name:	Sparkle Filter
Equipment No.:	
Location:	Plant
No. of Pages:	01



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Annexure – 02

Calibration Certificates of Master Instruments

Equipment Name:	Sparkle Filter
Equipment No.:	
Location:	Plant
No. of Pages:	01