



**PERFORMANCE QUALIFICATION PROTOCOL
FOR
STAINLESS STEEL REACTOR**

Protocol No.	
Supersedes	
Effective Date	
No. of Pages	30



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1.0 Protocol Approval

This is a specific protocol for Qualification of Stainless Steel Reactor which have been installed in Plant.

This protocol shall be approved by the following:

Prepared By:

Name	Designation	Department	Signature	Date
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Checked By:

Name	Designation	Department	Signature	Date

Approved By:

Name	Designation	Department	Signature	Date

2.0 Overview

2.1 Objective

To provide a documented evidence that the Qualification of Stainless Steel Reactor (**Tag No.**) shall be performed as per the approved protocol.

2.2 Purpose and Scope

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



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The scope of this qualification exercise is limited to the Qualification of Stainless Steel Reactor of Plant.

2.3 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.

3.0 Training Record

3.1 Purpose

The purpose of this training is to familiarize the trainees with the strategy of Qualification of Stainless Steel Reactor (**Tag No.**) of Plant.

3.2 Scope

This training is applicable to Qualification of Stainless Steel Reactor.

3.3 Topics

The following topics shall be covered during training:



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- Principle of working of Stainless Steel Reactor
- 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 Qualification Requirements

Following instruments shall be required for the Qualification of Stainless Steel Reactor at Plant-D.

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

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

5.0 System / Equipment Description

5.1 System / Equipment details

The Reactor (**Tag No.**) shall be used to mix the different ingredients i.e liquids. Liquid act as a media in which reaction is carried out.



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Description

- Equipment Tag Number :
- Location : Sterile Manufacturing Area
- Name of the system : Reactor
- Manufacturer's Name / Address : M/S
- Model : Cap-3000 Ltr SS-316 Jacketed Reactor
- Dimensions :
 - Height of Shell : 1700 mm
 - Diameter of shell : 1500 mm
- Overall Dimension
 - Height : 3200 mm
 - Width : 1812 mm
- Capacity : 3000.0 Litre

5.2 Generic Design

5.2.1 Working Principle

The Reactor shall be used to mix the different ingredients and to carry out reactions as per the process requirements. The Reactor consists of a jacketed tank fixed with an agitator, to mix the material efficiently. The agitator is directly coupled with the motor via rod. The RPM of agitator is controlled by variable frequency drive.



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5.2.2 Brief Machine Description

The Manufacturing tank comprises of following parts:

- SS Tank with jacket
- Stirrer with rod
- Motor with drive

5.2.2.1 SS Tank

The SS tank is fabricated from SS316L plate, surrounded by jacketed with MS plate followed by SS cladding with insulated material. Inlet & outlet nozzles are provided in jacket to circulate the all utilities (steam, cooling water, chilled water, chilled brine, hot water, compressed air) to the jacket. The jacket is insulated with puff. The thermo well is provided in the tank wall to measure the temperature inside the tank. The bottom discharge valve is provided to remove liquid/slurry mass from the tank. The light & view glass is provided on the tank to check the process status. Product inlet is provided to feed product/solvent/dry solution to the tank. Pressure gauge is provided to measure tank pressure. The outer surface of manufacturing tank is matt polished & inside surface of the tank is mirror buffed. The Shape of the manufacturing Reactor is cylindrical shape having 10% torispherical shape at top & bottom. The working capacity of the manufacturing Reactor is 3000.0 litres & gross capacity of the manufacturing Reactor is 3446.0.litres. The minimum working capacity of the manufacturing Reactor is 106.0 litres. The operating pressure of the shell is within range 2.0 to 4.5 kg/ cm². The operating pressure of jacket is 4.5 kg/cm².

5.2.2.2 Stirrer with Shaft

The shaft & stirrer of tank is fabricated from SS 316 & is directly coupled with the motor via single mechanical seal. The RPM of Stirrer rod is variable. The stirrer is Anchor type.

5.2.2.3 Drive



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The variable frequency drive is attached with the motor to control the motor RPM which in turn control the RPM of stirrer

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.

5.3.3 Pressure Gauge

Pressure gauge is provided to tank& jacket to measure the pressure.



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6.0 Qualification Procedure

Following procedure shall be used for the Qualification of the Stainless Steel Reactor installed in Plant.

- 6.1 The power supply and connected utility shall be checked before starting Qualification and 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 switches and buttons shall be checked and observations shall be recorded as per **Exhibit-E03**.
- 6.4 The motor functioning test to be performed and observations shall be recorded in **Exhibit-04**.
- 6.5 The equipment Passivation shall be carried out and recorded as per **Exhibit-E05**.
- 6.6 The Reactor shall be calibrated for total volume range by using raw water and calibrated with water flow meter. The results shall be recorded as follows:
 - i) Reactor shall be calibrated for minimum steerable volume by water till the stirrer has touched with the water to ensure that stirring is effective by switch on the stirrer.
 - ii) Reactor shall be calibrated for minimum sensing volume when the tip of the sensor is dipped by the water and showing the initials temp.
 - iii) The Reactor shall be calibrated for working volume.
 - iv) The Reactor shall be calibrated for overflow volume and all activity shall be recorded in **Exhibit- E06**.
- 6.7 The Reactor shall be subjected to blank trial followed by verification of heating and cooling function for entire range required for the process. Procedure for the testing is as follows -
 - i) Water/solvent shall be charged into the system till working volume and equipment shall be run for 30 minutes to observe the vibrations, abnormal sound and other parameters and observations shall be recorded in the **Exhibit-E 07A**.
 - ii) Water/solvent shall be charged into the system till working volume, and cooling shall be done and activity shall be recorded in the **Exhibit-E 07B**.



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iii) Further more water/solvent shall be charged in to the system to ensure the heating rate and all activity shall be recorded in **Exhibit E 07C**.

6.8 Qualification checks shall be performed to verify that Reactor has been installed with proper electrical connections and utilities. The observations shall be recorded as per **Exhibit – E08**.

6.9 Any deviation observed during Qualification shall be recorded in the observed deviation, corrective action and justification report section.

6.10 Observed deviation shall be reported to the department head and quality head.

6.11 If the observed deviation does not have any major impact on the Qualification, the final conclusion shall be provided.

6.12 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

- Location of the equipment



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- The design of the equipment
- Major part of the equipment
- 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	Critical Instrument List with Calibration status	01
E03	Control Panel Interface Operation Verification	01
E04	Motor functioning Test	01
E05	Equipment Passivation Record	01
E06	Volume Verification Record	02
E07	Equipment Performance Record	
E07A	Equipment Performance Test – Trial Run	01
E07B	Equipment Performance Test – Cooling Rate	01
E07C	Equipment Performance Test – Heating Rate	01
E08	Checklist for Qualification	01
Total No of Pages		11

12.2 List of Annexure

Annexure No.	Annexure Title	Reference
01	Training Record	Ref ere nce
02	Equipment Passivation & pH Testing Record	
03	Calibration Certificates of Master Instruments	

Documents

13.1 Manual of Equipment

Exhibit – E01

Attached Utilities Verification Checklist

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :



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Location : Plant

Date: Time:

S.No.	Utility Description	Specifications	Observations
1.	Power Supply		
	Volts	415 Volts	
	Phase	3 Phase	
	Cycles	50 Hz	
5.	Steam		
	Pressure	3.0-3.5 Kg/cm sq	
	Flow rate	1.5-3.5 Kg/cm sq	
8.	Cooling Water		
	Pressure	2.5-3.0 Kg/cm sq	
	Flow rate	1.5-3.0 Kg/cm sq	

Remarks: Observation Comply / Not Comply with the specification.

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 : Stainless Steel Reactor

Equipment No. :

Location : Plant

Date: Time:

S.No.	Name of the Instrument / Component	Instrument Calibration Range	Instrument No.	Calibration Done on
1.	Pressure Gauge			
2.	Temperature Sensor			
3.	Temperature Indicator			
4.	RPM Meter			

Remarks: Observation Comply / Not Comply with the specification.

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

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

Exhibit – E03



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Control Panel Interface Operation Verification

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :

Location : Plant

Date:

Time:

S.No	Item	Action	Expected Result	Pass / Fail
1.	Green Push Button On	Push the button	The green color switch ON machine shall start.	
2.	Red Push Button Off	Turn the red switch to off position	The Machine shall stop	
3.	Red Color Switch On/Off	Turn the switch to ON position	All the light indication shall turn ON When the power is On	
		Turn the switch to OFF position	All the light indication shall turn off when the power is Off	
4.	VFD Knob setting	Turn right to increase the RPM of motor	The RPM is increased which display on indicator	
		Turn left to decrease the RPM of motor	The RPM is decreased which display on indicator	
5.	RPM display	Display the RPM of the motor	The set RPM will display after turn on the main control	

Remarks: Observation Comply / Not Comply with the specification.



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

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



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Exhibit – E04

Motor functioning Test

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :

Location : Plant

Date:

Time:

S.No.	Item	Action	Expected Result	Pass / Fail
1.	General Functioning (Check Direction Of Motor)	Check the motor functioning while motor is ON.	The motor shall run without any unwanted noise & without objectionable vibration (Motor Direction should Be clockwise)	
2.	Motor RPM	RPM shall be measured by attaching tachometer on the center of the shaft of motor	150 ± 10%	
3.			1460 ± 10%	

Remarks:

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

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



PERFORMANCE QUALIFICATION PROTOCOL FOR STAINLESS STEEL REACTOR

Exhibit – E05

Equipment Passivation Record

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :

Location : Plant

Date: Time:

S.No	Nitric Acid Used %	Activity Performed	Expected Result	Pass / Fail
01	Nitric Acid shall be used with Water (Solution 2.5%) Volume of Water_____.Ltr Volume of HNO3 _____Ltr	Recycle the nitric acid solution for 60.0 Minutes and followed by Water Cleaning	Check the Reactor for its cleanliness it should be cleaned	
02	Flush the Reactor with Water* and collect the sample for pH checking	Collect sample in the sample bottle and pH shall be checked.	Ph shall be in the range pH 5 to pH 7	

Remarks: Observation Comply / Not Comply with the specification.



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

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

* Water quantity shall vary based on the requirement.



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Exhibit – E06

Volume Verification Record

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :

Location : Plant

Date:

Time:

S.No.	Calibration Point of the Equipment	Initials Reading of Water Flow Meter (I)	Final Reading of Water Flow Meter (F)	Difference of Reading (F-I)	Actual Volume in L

Remarks: Observation Comply / Not Comply with the specification

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

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



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Exhibit-E07A

Equipment Performance Test

Blank Trial

Equipment Name / Description: Stainless Steel Reactor

Equipment No :

Location : Plant

Date : _____

Time (from – to) : _____

Qty. of Water/Solvent used : _____

Working volume : _____

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	(0-90)	

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-E07B

Equipment Performance Test

Cooling Rate

Equipment Name/Description: Stainless Steel Reactor

Equipment No :

Location : Plant

Qty. of raw water/solvent used : _____

Optimum Temperature Range : Room Temperature to 0°C

Observed Temperature Range: _____

Date : _____

Time (from – to) : _____

Connected Utility : Chilled Water / Chilled Brine

S.No.	Time	Temperature (°C)	Remarks

Remarks: Cooling rate is ok/not ok as per process requirement.

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

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



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Exhibit-E07C

Equipment Performance Test

Heating Rate

Equipment Name/Description : Stainless Steel Reactor

Equipment no :

Location : Plant

Qty. of raw water/solvent used : _____

Optimum Temperature Range : 0°C to 40°C

Date : _____

Time (from – to) : _____

Connected Utility : Hot Water

S.No	Time	Temperature (°C)	Remarks
.			

Remarks: Heating rate is ok/not ok as per process requirement.

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

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



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Exhibit-E08

Checklist for Qualification

Equipment Name / Description : Stainless Steel Reactor

Equipment No. :

Location : Plant

S.No.	Checks to be performed	Specifications	Actual observation
1.	Utilities	All the utilities shall be properly connected	
2.	Electrical connection	No loose connection shall be there	
3.	Bolts	Check all the bolts, if loose tight it.	
4.	Safety Guard	Safety guard should be provided.	
5.	Abnormal Vibration & sound	Run the system & check the abnormal vibration & abnormal sound.	

Remarks: Observation Comply / Not Comply with the specification.

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

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



Annexure – 01
Training Record

Document No:	
Location:	Plant
No. of Pages:	01



Annexure – 02

Equipment Passivation & pH Testing Record

Document No:	
Location:	Plant
No. of Pages:	01



Annexure – 03

Calibration Certificates of Master Instruments

Document No:	
Location:	Plant
No. of Pages:	01