



PERFORMANCE QUALIFICATION PROTOCOL
FOR
VACUUM TRAY DRIER

Protocol No.	
Supersedes	
Effective Date	
No. of Pages	



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PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM TRAY DRYER

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1.0 Protocol Approval

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

2.2 Purpose and Scope

The purpose of this protocol is to demonstrate that the Vacuum Tray Drier 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 Vacuum Tray Drier in Plant.

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 Vacuum Tray Drier (**Tag No. :**) installed in Plant.

3.2 Scope

This training shall be applicable to Vacuum Tray Drier of Plant.

3.3 Topics



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The following topics shall be covered during training:

- Principle of working of Vacuum Tray Drier.
- 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*



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4.0 Pre Qualification Requirements

Following instruments shall be required for the Qualification of Vacuum Tray Drier at Plant

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

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 Vacuum Tray Dryer (Tag No.:.....) shall be used to dry the different Pharmaceutical Ingredients in a homogeneous manner and to heat /cool the API to appropriate temperatures, as per process requirements.

Description

- Equipment Tag Number :
- Location : Sterile Plant
- Name of the system : Vacuum Tray Dryer
- Manufacturer's Name / Address : M/s
- Model : GMP
- Dimension of Trays : 495mm x 495mm x 50mm
- Overall Dimension : 1150 x 1476x 1651mm
- No. of Trays : 66 Trays
- No. of Shelves : 11
- Drying Temperature Limit : 120 °C
- Heating Media : Hot Water
- Vacuum Pressure : -700mm Hg



PERFORMANCE QUALIFICATION PROTOCOL FOR VACUUM TRAY DRYER

5.2 Generic Design

5.2.1 Working Principle

The Vacuum Tray Dryer (**Tag No. :**) shall be used to dry the different Active Pharmaceutical Ingredients and to carry of the drying of API as per the process requirement. Vacuum Tray Dryer consists of a jacketed shelves fixed with the Inlet and outlet header of utility to dry the material efficiently.

The jacketed shelves are directly attached with the utility of supply and return header of utility.

5.2.2 Brief Machine Description

Vacuum tray dryer is consists the following:-

- SS-316 Chamber with jacketed shelves.
- SS Shelves with Inlet/Outlet Header attached and supported in the Chamber
- A vacuum source.
- A condenser with a receiver.
- SS door with silicon gasket and Clamp with Air vent
- SS trays

5.2.2.1 SS Chamber and Jacketed Shelves:

Vacuum tray dryer mounted on support of four SS pipes .The SS chamber is fabricated from SS-316 and jacket with SS-316 materials. Inlet and out let nozzles are provided in to the jacket to shelves to circulate hot water /cold water to the jacket .The thermo well is provided in the Vacuum Tray Dryer chamber wall to



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measure the temperature inside the chamber of Vacuum Tray Dryer. The

sight view glass is provided in to the equipment door to check the process status.

5.2.2.2 A Vacuum source & A Condenser with Receiver

A vacuum source is provided to the system from Vacuum Ejector. A Condenser, shell and tube type, mounted vertically to horizontal receiver through flanged connection. Receiver is used to collect the condensed moisture or liquid with inside partition, and connect with vacuum connection.

5.2.2.3 SS Door with silicon gasket and Clamp with Air vent

The vacuum tray Dryer is made of rectangular shape, having inner walls, which made of SS-316. SS 316 door with silicon rubber gasket approx 16sq.mm with an air vent which is provided in the system.

5.2.2.4 SS Trays

The Vacuum Trays Dryer contains 66 trays .All trays are made of SS-316. Each shelf contains 06 trays in each.

6.0 Qualification Procedure

Following procedure shall be used for the Qualification of the Vacuum Tray Drier, installed in Plant.

- 6.1 The external utilities attached to the Vacuum Tray Driers 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 equipments shall be checked and observations shall be recorded as per **Exhibit –E02**.
- 6.3 The operating functions of control panel, hot water, and vacuum pump, switches and button shall be checked .The observation of the test shall be recorded as per **Exhibit –E03**.



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6.4 Temperature Mapping procedure:

- 6.4.1 Temperature of VTD shall be set at desired level & allowed to acquire required temperature.
- 6.4.2 Temperature probes shall be pre calibrated by keeping together and from set temperature then noting down the temperature. Temperature variation from probe to probe and from standard set temperature shall not be more than $\pm 2^{\circ}\text{C}$. Observations shall be recorded in **Exhibit – E04A**.
- 6.4.3 Pre calibrated Temperature probes shall be placed at 12 places as per drawing attached in **Exhibit – E04B**.
- 6.4.4 Data logger shall be connected to the printer and temperature shall be recorded at the interval of 30 Minutes for 24 hrs at Temperature set at 35°C and at 90°C repeat the mapping for 24 hrs to complete the evaluation of operating range. Maximum, minimum and average temperature shall be recorded in **Exhibit – E04C & E04D**
- Printouts from data logger shall be attached as **Annexure – 03**.

Acceptance criteria – Temperature shall be within $33-37^{\circ}\text{C}$ at any of the place and temperature variation shall not be more than $\pm 2^{\circ}\text{C}$ among the points for temperature set at 35°C .

Temperature shall be within $88-92^{\circ}\text{C}$ at any of the place and temperature variation shall not be more than $\pm 2^{\circ}\text{C}$ among the points for temperature set at 90°C .

- 6.5 The VTD shall be subjected to blank trials and the results shall be recorded as per **Exhibit-E05**.
- 6.6 The Vacuum Tray Driers shall be run for 4 hrs as blank trial to check the operational performance of Vacuum Tray Drier. All the observations shall be recorded as per **Exhibit –E05A, E05B, E05C** for VTD Vacuum checking, cooling rate & heating rate respectively.
- 6.7 Qualification checks shall be performed to verify that VTD has been installed with proper electrical connections and utilities. The observations shall be recorded as per **Exhibit – E06**.



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- 6.8 Any deviation observed during qualification shall be recorded in the observed deviation, corrective action and justification report section.
- 6.9 Observed deviation shall be reported to the department head and quality head.
- 6.10 If the observed deviation does not have any major impact on the qualification, the final conclusion shall be provided.
- 6.11 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
- 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
E04A	Pre calibration and temperature verification check list	01
E04B	Location of probes	01
E04C	Temperature mapping record set at 35°C	01
E04D	Temperature mapping record set at 90°C	01
E05A	Cooling Rate	01
E05B	Heating Rate	01
E05C	Vacuum Test	01
E06	Checklist for Qualification	01
Total No of Pages		11

12.2 List of Annexure

Annexure No.	Annexure Title
01	Training Record
02	Calibration Certificates for Master Instruments
03	Print out of data logger

13.0

ference Documents

13.1 Test Certificates of components

Exhibit – E01

Attached Utilities Verification Checklist

Equipment Name / Description : Vacuum Tray Drier

Equipment No. :

Location : Plant

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S.No.	Utility Description	Specifications	Observations
1.	Power Supply		
	Voltage	395 – 435 Volts	
	Cycles	48 – 52 Hz	
	Phase	Three Phase	
5.	Hot Water		
	Pressure	2.0-2.5 Kg/cm sq	
	Flow Rate	1.5-2.5 Kg/cm sq	
6.	Cooling Water		
	Pressure	2.0-2.5 Kg/cm sq	
	Flow Rate	1.5-2.5 Kg/cm sq	

Remarks: Observations 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 : Vacuum Tray Drier

Equipment No. :

Location : Plant

S.No.	Name of the Instrument / Component	Calibration Range	Instrument No.	Calibration Required
1.	Pressure Gauge			
2.	Vacuum Gauge			
3.	Temperature Sensor			
4.	Temperature Indicator			

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 : Vacuum Tray Drier

Equipment No. :

Location : Plant

S.No.	Item	Action	Expected result	Pass/Fail
1.	Green Push Button On	Push the button	The Green colour switch shall & vacuum ejector pump motor start hot water pump start.	
2.	Red Push Button off	Turn the red switch	Both pump and motor shall stop.	
3.	Red colour switch On/Off	Turn the switch to On position	All the light indications shall glow when the power is on.	
		Turn the switch to Off position	All the light indications shall turn off when the power is Off	
4.	Temperature RTD	Set the temperature & check the functioning of RTD sensor	RTD Sensor shall control the temperature & shall keep temperature in the specified limit	

Remarks:

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

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



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Exhibit – E04A

Pre Calibration and Temperature Verification Checklist

Equipment Name / Description : Vacuum tray Drier

Equipment No. :

Location : Plant

Temperature attained within 33-37°C/88-92°C at:

Pre calibration study started at:

Probe Description	Temperature Observed (°C)	Probe Description	Temperature Observed (°C)
Probe 1		Probe 7	
Probe 2		Probe 8	
Probe 3		Probe 9	
Probe 4		Probe 10	
Probe 5		Probe 11	
Probe 6		Probe 12	

Acceptance Criteria: Set temperature difference among probe to probe shall not be more than $\pm 2^{\circ}\text{C}$.

Remarks:

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

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



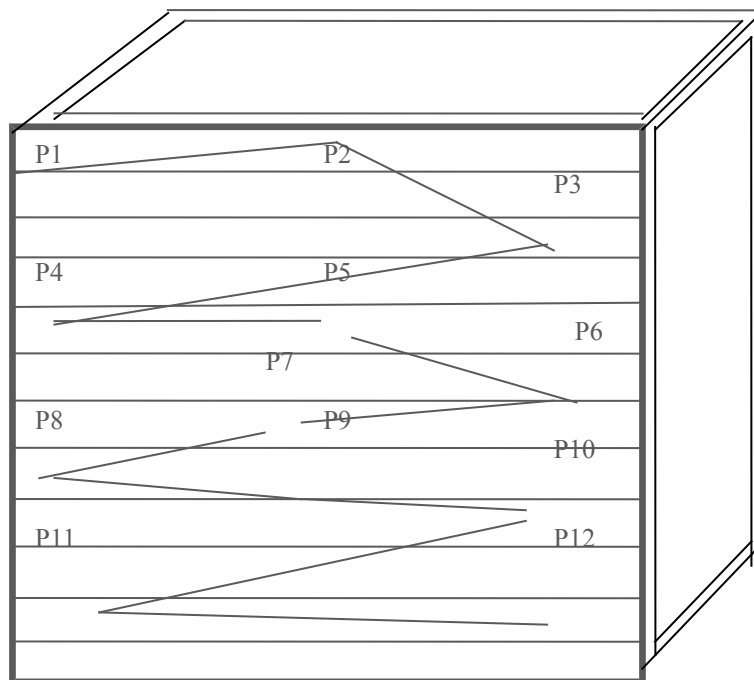
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Exhibit – E04B

Probes Location Diagram



Location:

P1: Tray-1 (Left Front)

P2: Tray-1(Middle Back)

P3: Tray-3 (Right Front)

P4: Tray-5 (Left Back)

P5: Tray-5 (Middle Front)

P6: Tray-6 (Right Back)

P7: Tray -7 (Middle Back)

P8: Tray- 8 (Left Front)

P9: Tray-8 (Middle Back)

P10: Tray-9 (Right Front)

P11: Tray-11 (Left Back)

P12: Tray-11 (Right Front)



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Exhibit – E04C

Temperature Mapping Record

Date of Mapping:

Set Temperature (°C): 35°C

Probe Description	Minimum Temperature (°C)	Maximum Temperature (°C)	Average Temperature (°C)	Remarks
Probe 1				
Probe 2				
Probe 3				
Probe 4				
Probe 5				
Probe 6				
Probe 7				
Probe 8				
Probe 9				
Probe 10				
Probe 11				
Probe 12				

Remarks: Set temperature monitoring record of 24 hrs shall be evaluated.

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

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



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Exhibit – E04D

Temperature Mapping Record

Date of Mapping:

Set Temperature (°C): 90°C

Probe Description	Minimum Temperature (°C)	Maximum Temperature (°C)	Average Temperature (°C)	Remarks
Probe 1				
Probe 2				
Probe 3				
Probe 4				
Probe 5				
Probe 6				
Probe 7				
Probe 8				
Probe 9				
Probe 10				
Probe 11				
Probe 12				

Remarks: Set temperature monitoring record of 24 hrs shall be evaluated.

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

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



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Exhibit-E05A

Equipment Performance Test

(Cooling Rate)

Equipment Name / Description : Vacuum Tray Drier

Equipment No. :

Location : Plant

Optimum Temperature (Range) : _____

Starting Date/Time : _____

Connected Utility : Cooling water

S.No.	Time	Temperature(°C)	Remarks
1.			
2.			
3.			
4.			
5.			
6.			
7.			

Remarks:

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

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



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Exhibit-E05B

Equipment Performance Test

(Heating Rate)

Equipment Name / Description : Vacuum Tray Drier

Equipment No. :

Location : Plant

Optimum Vacuum (Range) : _____

Starting Date/Time : _____

Connected Utility : Hot Water

S.No.	Time	Temperature(°C)	Remarks
1.			
2.			
3.			
4.			
5.			
6.			
7.			

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-E05C

Equipment Performance Test

(Vacuum Test)

Equipment Name / Description : Vacuum Tray Drier

Equipment No. :

Location : Plant

Optimum Temperature (Range) : _____

Starting Date/Time : _____

Connected Utility : Vacuum

S.No.	Time	Vacuum On Vacuum Ejector Pump	Vacuum On VTD	Remarks Pass/Fail
1.	10 Min			
2.	30 Min			
3.	60 Min			
4.	120 Min			
5.	180Min			
6.	240 Min			

Remarks:

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

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



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Exhibit – E06

Checklist for Qualification

Equipment Name / Description : Vacuum tray Drier

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 the all bolts, if found loose tight it suitably.	
5.	Abnormal Sound	Run the Tray Drier and check for any unusual sound	

Remarks:

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

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



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Annexure – 01

Training Record

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



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Annexure – 02

Calibration Certificates for Master Instrument

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



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Annexure – 03

Print out of Data logger

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