INSTALLATION QUALIFICATION

FOR

MOISTURE ANALYZER

(Sartorius – MA 50)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION FOR MOISTURE ANALYZER

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1.0 Pre-Approval:

Signing of this Approval page of Installation Qualification Protocol No..... indicates agreement with the Installation Qualification approach described in this document. Should Modifications to the Installation Qualification become necessary; an addendum will be prepared and approved.

Written By	Signature	Date
Quality Control		

Checked By	Signature	Date
Production		
Quality Assurance		

Approved By	Signature	Date
Quality Assurance		
Plant Head		

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2.0 Overview:

2.1 Purpose:

The purpose of this protocol is to provide an outline for the Installation Qualification of the instrument for static attributes to verify that:

- Each installed sub component complies with the instrument data sheets / specifications, agreed upon with the manufacturer.
- All supporting utilities are connected.
- The instrument is installed as per the laid down specifications.
- No unauthorized or unrecorded modifications have taken place.
- Required testing reports are available.
- A *draft* Standard Operating Procedures (SOP) have been identified and listed.

2.2 Scope:

This protocol covers the Installation Qualifications of the Moisture Analyzer.

2.3 Responsibility:

The validation group comprising of a representative from each of the following departments shall be responsible for the overall compliance with this protocol:

- Quality Control Department
- Production Department
- Quality Assurance Department

Quality Control shall be responsible for checking proper installation and recording installation data as per the procedures outlined in this protocol.

The Quality Assurance shall be responsible for the final review of the qualification documents and its compliance to meet the acceptance criteria of the Installation Qualification protocol.

The summary report shall be approved by the Plant Head, and Head Quality Assurance.

2.4 Requalification:

Installation Qualification to be requalified on:

- Replacement of major component of the Instrument with a new component.
- Any major modification in the existing Instrument.
- Shifting of the Instrument from one location to another.

2.5 System Description:

Now more than ever, rapid and accurate analysis of the moisture content plays a decisive role in the pharmaceutical industries.

Fast production processes needs analytical methods with shorter measuring times to enhance and even replace the traditional oven drying methods.

Sartorius Moisture analyzer is a new standard in Infrared Moisture measuring instrument, a compact design with ceramic IR heating element (MA 50 C) or Halogen heating element (MA 50 H).

The motorized heating unit is semi automatic and fully automatic determination of drying parameters with **ASAP** features.

The data interface port is a menu-driven software for operator guidance, keypad with 10 numeric keys, 50g weighing capacity.

In conjugation with the YDP01 MA data printer it can generate the printouts in compliance with quality management / assurance guidelines.

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3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
Dryer functions:	
Heating element	**Ceramic IR heater** or round Halogen lamp
Temperature range	30 – 230°C / 86 – 392°F
Temperature increments	Adjustable in 1°C increments
Temperature adjustment	With YTM03MA temperature adjustment set
Weighing Function:	
Weighing capacity	50g
Readability	1 mg, 0.01% Moisture Content
Repeatability	Sample weight = 1g : 0.2% Sample weight = 5g : 0.05%
External calibration weight (of at least accuracy)	50 g (F1)
Sample Pan Dimensions	Ø 90 mm
Drying Parameters:	
Drying Programs	Standard, Quick
Drying Time	6 sec. To 999 min
Number of programs	5
Shutoff criteria	Fully automatic, semi automatic, asap, time (1 x 999 min), manual
Display for analysis results	Moisture, dry weight, RATIO, weight loss, residual weight (g or g/kg)
Analyzing Hardware	
Dimensions (L x W x H)	350 x 453 x 156 mm
Net Weight (approx.)	6.5 kg

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ITEM	SPECIFICATIONS
Voltage	230V or 115 V selectable by replacing the heating unit, -15%/ +10%
Frequency	48 – 60 Hz
Fuses	2 (neutral conductor / phase), 6.3 AT, 5 x 20mm
Operating temperature range	10 – 30°C (50 – 86°F)
Power consumption	700 VA max.
Built-in interface **Format** **Parity** **Transmission rates** **Handshake**	RS 232C 7or 8 bit ASCII, 1 start bit, 1 or 2 stop bit Space, odd or even 150 to 19200 baud Software or Hardware
Digital Input	1, adjustable function
Digital output	4, operating state of analysis

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4.0 Instrument Identification:

The subjected instrument is identified as ***IR Moisture Balance***

Serial No. : _____

In-house Instrument No. : **.....**

Name of the Supplier : ----------

Purchase Order No. : ---------- Dated ----------

5.0 Instrument Location:

Facility	:	Manufacturing
Area	:	Process Area
Room / Lab. Identification	:	In Process Quality Control

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6.0 Installation Qualification Procedure:

6.1 Inspection Checklist:

Instructions:

6.1.1 Check the Instrument physically for any damage and record the observation in the Data Sheet of section 6.2.

6.1.2 Identify the utility supplies required for instrument operation. Verify that utilities are as per the specification mentioned in the Check Point and record the observation in the Data Sheet of section 6.2.

6.1.3 Identify the critical accessories supplied with the instrument or installed on the utility supply line. Verify that instruments are as per the desired specifications.

6.1.4 Check the installation of instrument:

- To verify the proper assembly of the components as per the instrument manual. Record the installation location and verification of assembly in Test Data section 6.2.

6.1.5 Identify the SOP's and assign SOP Numbers, record the SOP Title and Number in Section No. 6.2.

6.1.6 Record the deficiency (if any) in section number 6.2 and report the details of action taken.

Note:

1. *Record all the observations against the respective specifications, mentioned in the specific checkpoints, under section 6.2 (The specifications are extracted from the Purchase order / Manual / Manufacturer's Recommendations).*
2. *Incase of non-compliance, give the explanation / justification in the Deficiency And Corrective Action report format under section 6.2.*
3. *When more than one unit of the same type exist, replicate the corresponding data sheet to match and uniquely identify each page or same protocol can be used separately.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*

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5. *The calibration certificates of the instruments shall be traceable to National / International standards.*
6. *Define all technical terms and abbreviations in the appendix under section 10.0.*

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6.2 Installation Qualification:

6.2.1 Physical verification of the instrument / Environment:

Objective: To verify that any physical damage of the instrument and Environmental condition for the operation of the Instrument.

S. No.	Test Particulars	Specifications	Observations	Acceptance Yes/No
Physical Verification				
1.	Check the Instrument for any damages.	There should not be any damages.		
Environmental Conditions				
1.	Room Temperature	10°C to 30°C		
2.	Relative Humidity	NMT 60% RH		
3.	Away from the Direct Sunlight	-		
4.	Away from Air Draft	-		
5.	Away from Vibrations	-		
6.	Disturbance due to magnetic field	-		
7.	No corrosive Gases	-		
8.	Free from dust	-		

Checked by
(Quality Control) _____ **Name** _____ **Sign.** _____ **Date**

Verified by
(Quality Assurance) _____ **Name** _____ **Sign.** _____ **Date**

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6.2.2 Major Component Verification:

Objective: To verify that major components as identified below are complying as per the desired specifications.

S.No.	Name	No.	Observations	Acceptance Yes/No
1	Moisture Analyzer [MA – 50] with YDP01MA Data Printer.	1 No.		
2.	Kit of Standard Accessories			
	Power cord	1 No.		
	Pan Support	1 No.		
	Shield disk	1 No.		
	Dust cover to keypad	1 No.		
	80 disposable aluminum sample pan	01 Pack		
	1 pair of forceps	1 No.		
	3 cards with brief instruction in six different languages.	1 Set.		
3.	3MA Temperature adjustment Set for MA 50 and MA 100	1 No.		
4.	Operator's Instruction Manuals	1 No.		

Checked by (Quality Control) _____ **Name** _____ **Sign.** _____ **Date**

Verified by (Quality Assurance) _____ **Name** _____ **Sign.** _____ **Date**

6.2.3 Verification of Utility Supply:

Objective: To verify that necessary utility supplies required for instrument operation are as per the desired specification and connected properly.

S.No.	Utility	Specifications	Observations	Connected and Identified (Yes/No)
1.	Power	Single Phase, 230V ± 10% 50 Hz		

Note: *Power Supply to be checked with a Multimeter.*

Checked by (Quality Control)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.4 Standard Operating Procedures (SOPs) Identification:

SOP's	Number	Title
Operation, cleaning and Calibration		Sartorius Moisture Analyzer (MA 50)

Checked by (Quality Control)	**Name**	**Sign.**	**Date**
Verified by (Quality Assurance)	**Name**	**Sign.**	**Date**

6.2.5 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

_____
_____
_____
_____
_____

Person, responsible for corrective action and date assigned:

_____
_____
_____
_____

Corrective actions taken and date conducted:

_____
_____
_____
_____
_____
_____

Conducted By : _____ Approved By : _____

Date : _____ Date : _____

Comments (if any):

_____

_____

Verified By:

Name: _____ Signature: _____ Date: _____

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7.0 Acceptance Criteria:

Installation Qualification shall be considered acceptable when all the conditions specified in various forms under section 6.0 have been met.

Any deviation from the acceptance criteria of the specific check point shall be reported and decision should be taken for the rejection, replacement or rectification of the instrument / component.

8.0 Remarks (if any):

_____

_____

_____

_____

_____

_____

_____

_____

_____

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9.0 Summary:

Checks	Observations	Remarks
Whether acceptance criteria of the protocol and Specific check points are met.	Yes/No	

9.1 Conclusion:

Sartorius MA 50 Moisture analyzer, bearing Instrument No..... **is / is not** qualifying the Installation Qualification tests as per the Protocol No....., hence the instrument **can / cannot** be tested for its Operational Qualification as per Protocol No.....

9.2 Post-Approval Signatures:

Name	Signature	Date
Quality Control		
Quality Assurance		
Plant Head		

10.0 Appendix:

10.1 Abbreviations and Definitions:

IQ	- Installation Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
cm	- Centimeter
N.A.	- Not Applicable
Sr.	- Senior
S.No.	- Serial Number
mV	- milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
g	- Gram
RH	- Relative Humidity

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Acceptance criteria	:	The product, instrument., and / or process specifications and limits, such as acceptable quality level and unacceptable quality level, that are necessary for making a decision to accept or reject.
Installation qualification	:	The documented verification that all aspects of a facility, utility or equipment that can affect product quality adhere to approved specifications (e.g., construction, materials) and is correctly installed?
Validation	:	Establishing documented evidence that a system does what it purports to do.
Revalidation	:	Repetition of the validation process or a specific portion of it

10.2 List of Documents:

1. Instrument manuals

2. Purchase Order Attached (Yes / No). If no, state Location.

   Purchase Order No. _____ Dated _____ is attached.

3. Calibration Certificates

4. Draft SOP No. .....