INSTALLATION QUALIFICATION OF DISINTEGRATION TESTER (USP) (ELECTROLAB – MODEL ED-2AL)

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

INSTALLATION QUALIFICATION OF DT APPARATUS

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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 qualification of the Disintegration Tester (USP) model – ED – 2AL.(PR--000).

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 ControlDepartment
- 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 Quality Control, Production and 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:

Disintegration testing is a very essential step during tablets compression or capsule filing operations. Disintegration tester gives the time required for a tablet/ capsule to disintegrate into the Gastrointestinal Tract.

Electrolab's microprocessor based ED – 2AL is used for testing the Disintegration Time of the tablets, capsules. ED – 2AL is designed to meet the specifications of USP, DAB, EUR and IP.

The ED – 2AL design allows easy installation of the unit. A special cam drive ensures jerk – free movement. The instrument would stroke for 30 stroke / minute and with the stroke height of 55 mm. ED – 2AL offers easy loading of the baskets with swivel free movement through a simple yet unique Snap – Click loading mechanism for attaching and removal of baskets.

The ED – 2AL works in two different modes – Timer Mode and Manual Mode.

- Timer Mode: In this mode, the baskets stroke for the programmed time and park itself on the top position at the end of the test giving an alarm. The programmable Timer can be set from – Seconds to Minutes and Minutes to Hours. This ensures that a short and a long duration test can be conducted on the same unit.
- Manual Mode: In this mode, the display shows ' - - - -'. No time is displayed in this mode. The elapsed time can be viewed by pressing the Timer key. The display will display the elapsed Time for about 5 sec. When the test is over & the instrument is stopped, the total Disintegration Time can be seen by pressing the Timer key.

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An acrylic water bath is provided to give uniform temperature in the beaker. The temperature can be set from 20.0°C to 39.9°C and is controlled with accuracy of ± 0.5°C.

The base of the instrument is illuminated for viewing of the Disintegration process of the tablets.

The built – in RTD sensor monitors the bath temperature and the external probe monitors beaker temperature. A user – friendly designed splash proof panel is provided with membrane keys for settings.

3.0 Instrument Specification:

Detailed Instrument Specifications for instrument are as follows:

ITEM	SPECIFICATIONS
No. of Stroke	30 ± 0.5 Strokes / minute
Stroke Height	55 mm ± 2 mm
Motor	230 V AC Synchronous Motor 3.5 KG cm
No. Of Baskets	2 Nos. (Each carrying 6-test positions)
Water batch	6 mm thick Transparent Acrylic
Heater	400 – Watts, S.S. 304
Temperature Range	20.0°C to 39.9°C
Temperature Resolution	0.1°C
Temperature Control Accuracy	± 0.5°C
Timer	Range 1:1 Sec to 99 Min & 59 Sec Range 2:1 Min to 9 Hrs & 59 Min
Timer Resolution	Range 1:1 Sec Range 2:1 Min
Lamp	CFL 9 Watts
Lamp Fuse	250 mAmp
Choke	Suitable for 230/ 220 Volts CFL Lamps
Tube Voltage	230 Volts, 50 Hz
Power Supply	230 V AC, 50 Hz, 490 VA
Mains Fuse	2 Amp
Dimensions	350 mm x 390 mm x 510 mm (Approx.)
Weight	18 Kg (Approx.)

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4.0 Instrument Identification:

The subjected instrument is identified as ***Tablet Disintegration Tester,***

Model ED – 2AL

Serial No. : _____

In-house Instrument No. : _____

Name of the Supplier : _____

Purchase Order No. : _____

5.0 Instrument Location:

Facility	:	Manufacturing
Area	:	Process Area
Room / Lab. Identification	:	In-process Quality Control (IPQC)

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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.*
4. *Incase of multiple options; clearly identify the one, which has been supplied.*
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	15° C to 30°C		
2.	Relative Humidity	45% to 70%		
3.	Away from the Sunlight	-		
4.	Free from Vibrations	-		
5.	No corrosive Gases	-		
6.	Free from excess dust and moisture	-		
7.	Stability of input power (± 10% of 230 v AC 50 Hz)	-		

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

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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	Part No.	Qty. Supplied	Observation	Acceptance Yes / No
1	Basic Unit with bottom illumination		1		
2	Basket Assembly		2		
3.	Guided Discs		12		
4.	External Probe		1		
5.	Top Plate Assembly		1		
6.	Bath with Heater		1		
7.	Mains cord		1		
8.	Manual		1		

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, Calibration and Cleaning	SAP/0	Disintegration Tester (USP) – Model ED-2AL

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: _____

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:

Disintegration Tester (USP) Model – ED-2AL bearing Instrument No.....

is / is **not** qualifying the Installation Qualification tests as per the Protocol, 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		
Plant Head		
Quality Assurance		

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
S. No.	- Serial Number
Sr.	- Senior
mV	- Milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
gm	- Gram
RH	- Relative Humidity
UPS	- Uninterrupted Power Supply
Kg	- Kilogram
Hr.	- Hour
Sec	- Seconds
S.S.	- Stainless Steel
Nos.	- Numbers
mAmp	- Milli Amperes
Amp	- Amperes
Eq.	- Equipment
USP	- United States Pharmacopoeia
Ph Eur	- European Pharmacopoeia
IP	- Indian Pharmacopoeia

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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 are 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 manual

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

   _____

   Purchase Order No. ..... Dated ..... is attached.

3. Calibration Certificates

4. Draft SOP – No SAP / 0