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

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

OPERATIONAL QUALIFICATION OF DISINTEGRATION APPARATUS

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1.0 Pre-Approval:

Signing of this Approval page of Operational Qualification Protocol No. ..... indicates agreement with the Operational Qualification approach described in this document. Should Modifications to the Operational 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		

OPERATIONAL QUALIFICATION OF DISINTEGRATION APPARATUS

2.0 Overview:

2.1 Purpose:

The purpose of this protocol is:

- To verify the operational attributes of *Disintegration Tester (USP)* *Model ED-2AL*, critical to serve the intended purpose.
- To establish the suitability of the draft SOP prepared for the operation of System.
- To document the observations for future reference.

2.2 Scope:

This protocol covers the operational qualification of Disintegration Tester (USP) Model ED – 2 AL.

2.3 Responsibility:

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

- Production Department
- Quality Assurance Department
- Engineering Department

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

Production, Quality Assurance shall collect all the test data and shall compile the results to make the reports of qualification studies.

The Reports shall be checked by Production and Quality Assurance.

The post approval of the qualification shall be done by the Quality Assurance and plant Head.

2.4 Requalification:

Operational Qualification to be repeated incase of

- Replacement of any major component -
- Major modification in the existing instrument -
- During monitoring if instrument. is found to be malfunctioning -
- Shifting of the instrument from one location to another -

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2.5 Instrument Identification

The Instrument is identified as ***Tablet Disintegration Tester,***

Model ED – 2AL

Serial No. :

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

Name of the Supplier : **Electrolab**

Purchase Order No. :

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3.0 Operational Qualification Procedure

1) A draft SOP shall be prepared on the basis of manufacturer guide / instrument manual for operation before the Qualification testing.
2) Prior to the Qualification test, the Personnel shall be trained by the Engineer from the Manufacturer / supplier on the operational features of the instrument. This training shall be recorded in Section 3.1.
3) The trained personnel shall carry out the Operational Qualification along with the Service Engineer, following the Procedures mentioned under Section 3.2.1 for Key Functionality and Safety Features. Record the observations of Qualification Test in Test Data Sheet of Section 3.2.1. Checkpoints designed for the purpose of OQ are also aimed at verification of these draft SOP's.
4) Operate the instrument as per the draft SOP. Record the change if any and confirm the SOP. Report the confirmation of SOP in the Section 3.3.
5) Report the deficiency from the specified function, if any in the section 3.4

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3.1 Training **Date:**

Title: Disintegration Tester (USP) Model ED – 2AL

Name of the Trainer(s:_____

S.No.	Name of the Trainee	Employee Number	Signature
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

Signature of Trainer(s): _____

Date : _____

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3.2. Key Functionality & Safety Features:

A. Purpose:

The purpose of this procedure is to demonstrate that the control panel and other manual operations (if any) of Disintegration Tester **(Equipment No. .....)** function as specified by the manufacturer.

B. Testing:

1. Check all the displays on the panel are identified.
2. Turn on the power from the electrical panel.
3. Set the control(s) on the panel.
4. Verify functionality of each component on the panel against its Specified functions.
5. Observe and record the responses in the Test Data Sheet, under section 3.2.1.

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3.2.1 TEST DATA SHEET (Confirmation of Services Connection):

S.No	Test Particulars	Specified Function	Observations	Checked By
A	**SETTINGS**			
1	Switch ‘ON’ the Instrument	Both the baskets should operate and rest at the top position if are at top position before switching the power ‘ON’ Press all the keys on the front Panel & check for the buzzer beeps Display of timer and temperature should be ‘ON’		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No.	Test Particulars	Specified Function	Observations	Checked By
2.	Timer mode setting : There are two mode of operation	Timer Mode Manual Mode		
3.	Press the Timer . Manual key to change from Timer mode to Manual mode or from Manual mode to Timer mode	Initially when power supply is switched 'ON' the instrument is in Timer mode. If the Timer LED is ON then timer mode is selected, if Timer LED is OFF and Timer display shows ' ----' then MANUAL mode is selected.		

Verified By:

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S.No	Test Particulars	Specified Function	Observations	Checked By
4	Timer SettingRange Setting Hours and Minutes b. Press ▼ key followed by . Timer 1 / Timer 2 key c. Press ▲ key followed by Timer 1 / Timer 2 key	If this range is selected then the display will show '----' before time Time range in minutes and seconds should be selected Time range in hours and minutes should be selected		

Verified By:

Name: _____ Signature: _____ Date: _____

S.No	Test Particulars	Specified Function	Observations	Checked By

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S.No	Test Particulars	Specified Function	Observations	Checked By
5	Time Setting a) Press the ▶ [set] key followed by timer key	The display shows previously set time with extreme right digit flashing		
	b) Set the Time by pressing [▼] or [▲] key	Time will get increased or decreased with every key pressed		
	c) Press ▶ [SET] key	The position of the number to be changed will be shifted		
	d) Press [ENTER]	The value set will get registered		

Verified By:

Name: _____ Signature: _____ Date: _____

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S.No	Test Particulars	Specified Function	Observations	Checked By
6	Temperature setting a) Press PROBE SEL key b) Press SET key followed by TEMP key c) Set the temperature by pressing ▼ or ▲ key d) Press SET key e) Press ENTER	Bath probe will get set Temperature display shows previous set temperature and the right digit on the display starts flashy Temperature will get increased or decreased with every key pressed The position of the number to be changed will be shifted The value set will be registered		
7	Confirm the set value of temperature by pressing SET key followed By TEMP key	Display should show the set value		

Verified By:

Name: _____ Signature: _____ Date: _____

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S. No	Test Particulars	Specified Function	Observations	Checked By
8	After pressing the SET key start setting within 10 sec.	The mode gets terminated if starting setting exceeds 10 secs.		
9	Check the temperature of the bath and water in the Beaker is 37.9° and 37.0 ± 2°C respectively. By shifting the prope to required location.	The temperature display will show the temperature respective to the location of the probe after pressing PROBE SEL key		
10	Press TEMP key	Temperature controller will start		
B	OPERATION			
1	Put one tablet each in individual tube of the basket assembly (total six) followed by rises and assemble the basket on the extended arms. Press START STOP key .	The instrument will start operating		

Verified By:

Name: _____ Signature: _____ Date: _____

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S. No	Test Particulars	Specified Function	Observations	Checked By
2	Press the TIMER 1 and / or TIMER 2	The up and down movement of the basket will start and continue till the set time		
3	Press TIMER 1 or TIMER 2 key before completion of the set time	The operation will halt		
4	Check for complete passing of the granules through the mesh at the bottom of the basket by lifting the basket out of water and note the time displayed on the board Press START STOP key .	The apparatus will stop its operation		
C	BOTTOM ILLUMINATION CHECK Put ON the switch provided at right side of the bottom of the apparatus	The green light shall be observed in the bath		

Verified By:

Name: _____ Signature: _____ Date: _____

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3.3 SOP Verification:

Draft SOP No. : .....

Title : Disintegration Tester (USP) Model ED – 2AL

Operate the instrument. as per the draft SOP and record the details given below:

Operated By : ……

Checked By : ……...

The operating personnel understand and follow the SOP description (Yes/No) : YES

Changes required in draft SOP (If any) : _____

_____NO_____

_____

SOP to be revised (Yes/No) : NO

If yes, Review No. _____

Remarks: SOP Confirmed / Not Confirmed

Verified By:

Name : _____ Signature : _____ Date : _____

3.3 Deficiency (if any) and Corrective Action Report

If there is no deficiency, then write N. A

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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4.0 Acceptance Criteria:

Operational Qualification shall be considered acceptable when all the conditions specified in various data sheets under section 3.0 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.

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5.0 Summary:

Checks	Observations Yes / No	Remarks (if any)
Whether the acceptance criteria of the protocol and specific checkpoints are met.		

5.1 Conclusion:

The Disintegration Tester (USP) Model – ED-2AL **is / is not** qualifying the Operational Qualification tests as per Protocol No. ..... The Instrument **can / cannot** be tested for its Performance Qualification as per Protocol No. .....

5.2 Post-Approval:

Name	Signature	Date
Quality Control		
Plant Head		
Quality Assurance		

6.0 Appendix:

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6.1 Abbreviations and Definitions

OQ	- Operation 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
g	- Gram
RH	- Relative Humidity
USP	- United States Pharmacopoeia
SOP	- Standard Operating Procedure

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.
Operational qualification	The documented verification that all aspects of a facility, utility, or equipment that can affect product quality operate as intended throughout all anticipated ranges.
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