



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



# PHARMA DEVILS

## QUALITY CONTROL DEPARTMENT

### PERFORMANCE QUALIFICATION OF DT APPARATUS

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#### 1.0 Pre-Approval:

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

Written By	Signature	Date
Production		

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 verify the performance attributes of the *Disintegration Tester (USP) Model ED – 2AL* critical to serve the intended purpose.
- To document the observations for future reference.
- To provide documented evidence that the *Disintegration Tester (USP) Model ED – 2AL* is operated and performed as per the Standard Operating Procedure.

#### 2.2 Scope:

This protocol covers the performance qualification of Disintegration Tester (USP) Model ED - 2AL. (PR-DTA-001).



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#### 2.3 Responsibility:

The 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

The Production and In Process Quality Control shall be responsible for Performing as well as the checking of the Performance Qualification along with the Quality Assurance and recording data as per the procedures outlined in this protocol.

Manager 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 Manager Quality Assurance.

The Manager-Quality Assurance and Plant Head shall finally approve the Qualification report.

#### 2.4 Requalification:

##### **Performance 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 subjected instrument is identified as **Tablet Disintegration Tester,**  
**Model ED – 2AL**

Serial No. : \_\_\_\_\_

In-house Instrument No. : \_\_\_\_\_

Name of the Supplier : \_\_\_\_\_

Purchase Order No. : \_\_\_\_\_



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#### **3.0 Performance Qualification:**

#### **3.1 Performance Qualification Procedure:**

Perform the Qualification as per the following procedure.

- 3.1.1 Note the number of cycles of the shaft holding the tube basket for one minute and record the observations in Section 3.2
- 3.1.2 Measure the distance traveled by the shaft and record the observations in Section 3.2
- 3.1.3 Check the integrity of the SS wire mesh and visually check for any damages for all the baskets. Record the observations in Section 3.2
- 3.1.4 Check that wire mesh of the basket at highest point is at least 2.5 cm below surface of the liquid and at lower point it is at least 2.5 cm above the bottom of the beaker. Record the observations in Section 3.2
- 3.1.5 Report the deficiency from the specified function, if any in the section 3.3.



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#### 3.2 Performance Qualification Test Data Sheet:

##### 3.2.1 Cycles of the shaft holding the tube basket (Reference: USP) (Acceptance criteria = 29 to 32 cycles / min.)

S.No.	CYCLES / MIN.	
	Right Shaft	Left Shaft
1		
2		
3		
Mean		

Verified By:

Name : \_\_\_\_\_ Signature : \_\_\_\_\_ Date : \_\_\_\_\_





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S.No.	DISTANCE TRAVELLED (cm)	
	RIGHT	LEFT
1		
2		
3		
Mean		

**3.2.2 Distance covered by the shaft. (Reference: USP)**  
**(Acceptance criteria = 5.3 to 5.7 cm)**

Verified By :

Name : \_\_\_\_\_ Signature : \_\_\_\_\_ Date : \_\_\_\_\_



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#### 3.2.3 Wire mesh Location of the basket at highest point and lowest point.

Highest point	Lowest point
The distance between the wire mesh and the surface of water when the basket is at the highest point.	The distance between the wire mesh and the bottom of beaker when the basket is at the lowest point.

Observation	Observation
-------------	-------------

S.No.	Right Basket (Distance In Cm)		Left Basket (Distance In Cm)	
	Highest Point	Lowest Point	Highest Point	Lowest Point
1				
2				
3				
Mean				
(Acceptance criteria = At least 2.5 cm) (Reference: USP)		(Acceptance criteria = At least 2.5 cm) (Reference: USP)		

Verified By :

Name : \_\_\_\_\_ Signature : \_\_\_\_\_ Date : \_\_\_\_\_



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#### 3.2.4 SS Wire Mesh Integrity Test:

TEST	OBSERVATION
Visual inspection of SS wire mesh.	

Verified By:

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_

**3.3**



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#### 3.4 Deficiency (if any) and Corrective Action Report:

If there is no deficiency, then write NA.

Description of deficiency and date observed:

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Person, responsible for corrective action and date assigned:

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Corrective actions taken and date conducted:

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Conducted By: \_\_\_\_\_ Approved By: \_\_\_\_\_

Date: \_\_\_\_\_ Date: \_\_\_\_\_

Comments (if any):

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Verified By:

Name: \_\_\_\_\_ Signature: \_\_\_\_\_ Date: \_\_\_\_\_



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#### 4.0 Acceptance Criteria:

Performance 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 Instrument No....., **is / is not** qualifying the Performance Qualification tests as per the Protocol No. .... The Instrument **can / cannot** be used for the routine analysis.

#### 5.2 Post-Approval:

Name	Signature	Date
Production		
Plant Head		
Quality Assurance		



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#### 6.0 Appendix:

#### 6.1 Abbreviations and Definitions

PQ	- Performance Qualification
mm	- Millimeter
Min	- Minutes
V	- Volt
Hz	- Hertz
Kg.	- Kilogram
cm	- Centimeter
N.A.	- Not Applicable
Sr.	- Senior
S. No.	- Serial Number
mV	- milli Volt
°C	- Degree Centigrade
AC	- Alternate Current
DC	- Direct Current
g	- Gram
RH	- Relative Humidity
USP	- United States Pharmacopoeia

**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.

**Performance Qualification** : The documented verification that all aspects of a facility, utility, or equipment that can affect product quality perform as intended meeting predetermined acceptance criteria.

**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