PT-TD300 Tap Density Tester
Installation Qualification (IQ)

Version 1.0

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Document History

Version	Valid from	Author	Change	Remark
1.0	13.10.2017	Pharma Test	N	New Release
1.1	29.10.2020	Pharma Test	R	Correction of false part numbers and descriptions

Index Information - Change:

N = New Document
C = Correction
R = Revision

Introduction

Objective

Installation Qualification (IQ) is used to verify that the Pharma Test Instrument/System (or components where applicable) has been installed according to the manufacturer's requirements. The results are documented and explained as passed (OK) or failed (NOK), compared to the requirements laid down in this form

Equipment

The Pharma Test instrument type PT-TD300 instrument is composed of:

- PT- TD300 Tap Density Tester
- 250 ml graduated cylinder and/or 100ml graduated cylinder (optional)
- Options supplied as specified by customer

The PT-TD300 Tap Density Tester is used for the testing tapping density of powders, granules, grains etc. in compliance with USP <616> methods 1 and methods 2 as well as with EP <2.9.34>, DIN EN ISO 787-11 and ASTM B527.

During powder development tapping density is one important characterization about the product. The instrument automatically calculates the tapped density, Hausner flowability ratio and Carr compressibility index after each test and documents the results via the integrated protocol printer.

The instrument and its technical design have also been described in valid international standards like DIN EN ISO and ASTM. In 1994 the tap-density tester became a part of the technical monographs in Europe's Pharmacopoeia.

Instructions for Documentation Completion

All performers and reviewers must complete qualification forms using the following guidelines:

1. Write down your initials
2. Complete all items on a form in full.
3. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
4. Write additional comments on an addendum sheet when there is not enough space on a form to accommodate all comments. Follow these three steps when adding an addendum sheet:
5. Write down your initials
6. Write down the date of the additions
7. Number the addendum pages numerically
8. Insert the addendum sheet behind the original page
9. Make all entries in permanent ink.

Correcting Entries

If you need to make corrections on a form, use the procedures described below:

Correcting Short and Long Entries

To correct a short entry (such as a single word or test result) or a long entry (information block, test description etc.) on a form follow this procedure:

1. Draw a diagonal line, through the false entered or incorrect information
2. Enter the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Confirm with your initial
5. Enter the date of the change

Marking Elements That Are Not Applicable

Some elements may not apply to your system's configuration. The elements that are not required may be a procedure or part of a procedure and/or a form or part of a form. Mark each element carefully according to the instructions below, so that it will be clear that the element is unnecessary and that you have not skipped or forgotten the element.

1. Draw a diagonal line, through the element that is not required
2. Write down the letters "NA" (for "Not Applicable"), your initials, and the current date above the line
3. Include comments above the line or on the form to document the reason the element is not required

4. Where NA is indicated as an option, mark this field
5. Mark the section "rec." (for "received") if the part has been identified
6. Mark the section "miss." (for "missing") if the part has not been identified and needs to be sent immediately to finish the installation; in that case make sure that the missing part has been ordered by you and has been confirmed by us for shipment

The performer and reviewer must sign and date all forms as usual, even when part or all of the form is marked "NA".

NOTE: All original entries must remain legible after any corrections have been made.

Conditions Requiring Re-Qualification

CAUTION: The following conditions require re-qualification:

- When a system modification has been completed which affects the installation qualification
- When this system is being removed from where it was originally installed

Re- calibration/ Re-certification Requirements

The following conditions require Operation Qualification (OQ) re-calibration/re-certification:

- When the software or firmware has been upgraded or changed
- A pre-determined period of time or use has passed
- After any minor service has been done
- After any parts have been replaced

Installation Qualification Program

This document is divided in sections.

Section 1.0 Instrument Identification

In this section the instrument including details and serial number(s), the supply scope, optional accessories as well as the required documentation are identified.

Section 2.0 Information User and Installation Place

In this section the user of the equipment and installation place are defined.

Section 3.0 Documentation and Installation Procedure

This section contains the installation procedure, test protocols and test results in a pass/fail format for each test.

Section 4.0 Result and Comments

This section is used to document the result of the installation and for comments regarding the installation procedure.

Section 1.0 Instrument Identification

Check if the PT-TD300 according to the order confirmation has been received and enter the serial number and the type name. The serial number is printed on the type plate on the back of the instrument:

Section 1.1 Main Instrument

Part-No.	No.	Type	Rec.	Miss.	NA	Serial No.
49-30000	1	Tap density tester				

Instrument Details

Voltage	100/115 V ☐ or 230/240 V ☐ 50/60 cycl.
Firmware Version	
Asset No. or Lab ID No.	

Section 1.2 Parts Included in Standard Scope of Supply

Part-No.	No.	Type	Rec.	Miss.	NA
490-0491	1	250 ml graduated cylinder includes the following:			
490-0020	1	Cylinder dish for 250 ml cylinder			
490-0015	1	Stainless steel dish			
490-0013	1	Securing ring			
490-5206	1	O-Ring 52x3			
003-4250	2	UL fuse 500 mA, 5x20			
10-60010	1	DAB cleaning oil, 1 bottle = 100ml.			
34-08500	1	IEC/EUR mains cord			
34-08510	1	CH mains cord			
34-08511	1	US mains cord			
34-08512	1	GB mains cord			
34-08513	1	ARG/AUS/NZ mains cord			
34-08514	1	IN/ZA mains cord			

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.3 Optional Accessories

Part-No.	No.	Type	Serial No.	Rec.	Miss.	NA
490-0112	1	100 ml graduated glass cylinder	NA			
490-0211	1	Support dish for a 100 ml graduated cylinder	NA			
490-0212	1	Securing ring to fix the 100ml cylinder	NA			
490-5207	1	O-Ring for 100ml cylinder	NA			
49-02100	1	Noise insulation bonnet	NA			
29-035x0	1	Analytical balance				

Section 1.4 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-49-30000	Operating Manual			
IQ-49-30000	Installation Qualification			
OQ-49-30000	Operation Qualification			
NA	Instrument Log Book			
QC-49-30000	QC/DQ Test Report			
NA	Delivery Note			

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.5 Instrument Installation Site Requirements

NOTE: This instrument requires electrical installation with a quality, noise free ground (earth). In this case, as in all electrical installations where liquid handling is an integral part of the instrument function, all mains (line) supplies should be protected with an RCD (Residual Current Detector) which typically trips out when current leakage to ground (earth) of approx. 30mA is detected.

Requirement Parameter	OK	NOK	NA
Laboratory mains voltage corresponds to instrument requirements noted above.			
A minimum of **10cm** of the rear and sides of the instrument is required.			

Section 1.6 Other Services Required

The Instrument has to be installed on a level surface. The supporting bench must be able to support the weight of the instrument, as well as other equipment installed on the same bench continuously.

NOTE: Pharma Test is not responsible for adequate site planning and installation. We are however, happy to advise if our help is requested.

Section 1.7 Operating Environment

Temperature:	15-40°C	Rel. Humidity:	20-80%
Physical Site:	Clean, dry and levelled bench	Weight Support:	Approx. 50 kg/m²
Required Bench Space (Length/Depth/ Height):		50 **x** 50 **x** 45 cm	

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 2.0 Personnel Identification

Installation Engineer (1):

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Installation Engineer (2): (optional)

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Installation Engineer (3): (optional)

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Released by:

Name (print)	Initials
Signature	Date (DD/MM/YYYY)

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 2.1 Place of Installation

Company Name: _____

Address: _____

_____

_____

Department/Bldg.: _____

Location/Bldg.: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 3.0 Documentation and Installation Procedure

This section describes the performance and documentation of the Installation Qualification (IQ) of the instrument/system. Complete each section as described.

Full information about the use and operation of the instrument/system is available in the supplied operating manual.

Section 3.1 Check Packaging Material

Check the packaging material the instrument/system has been delivered in for any defects or signs mishandling during transport. In case any defects or signs are found document them by picture and check whether this has already been reported to the forwarder by the good's recipient.

OK	NOK	NA

Section 3.2 Unpacking

Unpack the instrument/system. Make sure that there are no more parts left inside the packing material or box. Make sure that the instrument has not been damaged during transportation.

OK	NOK	NA

Section 3.3 Check Completeness of Delivery Scope

All parts required for the standard operation of the instrument are listed on the supplied delivery note (or invoice). Each part is labeled with its part-no. Check the completeness of the delivery scope compared to the delivery note (or invoice).

Confirm that all items as per attached delivery note have been supplied in full.

OK	NOK	NA

In case any item is missing, please inform Pharma Test immediately. Please mention your purchase order no., the instrument serial number, the part number which is missing, as well as the number of the delivery note. If the missed part is essential for the operation of the instrument, you can only proceed with the Installation Qualification after the missing part has been received.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 3.4 Complete the Instrument/System

Install and complete the instrument with its components as per supplied operating manual

OK	NOK	NA

Section 3.5 Connect Mains

Keep main power switch of the instrument at off position. Connect and verify connection of the power cable into the ground fault protection AC outlet. Check that the mains cord and socket do not show any visible damage.

OK	NOK	NA

Section 3.6 Install the Glass Cylinder

Insert the standard support dish into one of the testing position openings on the right side of the instrument's housing. The openings are marked 14mm (=14mm stroke height) and 3mm (=3mm stroke height). Take the O-ring and pull it over the glass cylinder down to the cylinder base. Use the plastic securing ring and also pull it over the glass cylinder down to the cylinder. Tighten the securing ring by screwing it onto the dish by hand to fix the glass cylinder.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 4.0 Result and Comments

Type		Serial Number	
Mains Voltage		Firmware Version	

The instrument has passed the Installation Qualification (IQ) procedure.

Yes ☐

No ☐

Check if all tests have passed. In case one or more tests failed check no and document the reason for the failure on this report. In this case the installation qualification has to be repeated once the reason for failure has been eliminated.

Comments

This completes the Installation Qualification of the Instrument.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Date:

Released by: _____ _____

Signature DD/MM/YYYY