PT-TD300
Tap Density Tester

Operation Qualification (OQ)

Version 1.3

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Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
1.0	17.10.2017	Pharma Test	N	New Release
1.1	22.10.2020	Pharma Test	N	Correction of Tolerances
1.2	29.07.2021	Pharma Test	C	Correction of Section 4.14 and new document format
1.3	16.04.2024	Pharma Test	R	Revision Section 3.4

Table 1: Document History

Index Explanation - Change:

N = New Document
C = Correction
R = Revision

Introduction

General

Operational qualification (OQ) is the process by which all functions of the Pharma Test instrument are being validated. For all tests performed, the results are recorded and the pass/fail evaluation of all tests is determined by comparing the results with pre-determined acceptance limits. The procedure used to certify performance and any certified/accredited procedure that forms the test and certification of the equipment will be identified and/or included in the protocol.

Equipment

The Pharma Test instrument type PT-TD300 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 signature
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 five steps when adding an addendum sheet:
    a. Write down your signature
    b. Write down the date of the additions
    c. Number the addendum pages numerically
    d. Insert the addendum sheet behind the original page
    e. Make all entries in permanent ink.

Correcting Entries

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

Correcting Entries, sections and parts which are now required or available

It is possible that certain information or requirements are not available or necessary for the instrument to be qualified. This information may be a full section, a part of it or procedure. Mark this element clearly, so that it is understood that it is not necessary in this case.

To correct a long entry or information block on a form follow this procedure:

1. Draw a diagonal line, through the wrong, invalid or incorrect information
2. Enter the correction
3. Give a brief explanation of the change.
4. Sign it using your initial
5. Enter the date of the change

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

Conditions Requiring Re-Qualification or re-calibration

The following conditions may require re-qualification or calibration:

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

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

The following conditions may require re-qualification or calibration:

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

Operation Qualification Program

This document is divided in sections.

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Section 2.0 Instrument Identification

This section includes the equipment description, part - and serial number

Section 3.0 Equipment Description

This section is used to enter the general information regarding the used calibration tools and validity

Section 4.0 Operation Qualification Procedure

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

Section 5.0 Result and Comments

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

Section 1.0 General Documentation Settings

In this section the general format setting of this document is described.

Sektion 2.1General Date Format of this Document

Please select the date format you want to use in this document.

Date Format	Selected	NA
dd.mm.yyyy		
dd/mm/yyyy		
mm.dd.yyyy		
mm/dd/yyyy		
Other:		

Table 2 General Date Format of this document (d=day, m=month, y=year)

Sektion 2.2Personnel Identification

Performer (1):

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performer (2):
(optional)

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Released by:

Name (print) _____ Initials _____

Signature _____ Date (Section 1.1) _____

Performed by: _____ Date: _____
Section 1.2 Section 1.1

Section 2.0 Instrument Identification

Check if the instrument/system according to the completed IQ is present. Enter the serial number of the instrument. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Serial No.	OK	NA
49-30000	PT-TD300			

Section 2.1 Instrument Identification – Printer (Option)

Part-No.	Printer Type	OK	NA	Serial No.

Sektion 2.2 Place of Installation

Company Name:	
Address:	
Department/Bldg.:	
Location/Bldg.:	
Contact:	
Telephone:	
E-Mail:	

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 3.0 Equipment Description

Section 3.1 Explanation

Not every single qualification tool in section 3.2 is necessary. Marking tools as "NA" is valid. To skip the mentioned section then by marking "NA" is valid, too.

Tools which are not marked as "optional" are obligatory!

Section 3.2 Required Qualification Equipment and Calibration Tools

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
30-31006	Digital Tachometer				
307-1205	Dial gauge for SWT				
801-2921	50g weight for balance (optional!)				
29-035x0	Precision Balance (optional!)				

Sektion 3.3 Standard supply scope of the PT-TD300

Part-No.	Description	OK	NA
490-0491	PT-TD300 Glass Measuring Cylinder, 250ml		
490-0015	PT-TD stainless steel cylinder dish for 250ml cylinder		
490-0013	PT-TD300 Plastic Holder w. Thread for 250ml. Cylinder		
490-5206	PT-TD300 O-Ring		
283-0420	Thermo Paper for Miniplus-Printer, 57/30/12		
34-08500	EUR Mains Cable, 1.8m, 250V/10A		
003-4250	UL fuse 500 mA, 5x20		
004-0921	Pharma Test USB Flash Drive		

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 3.4 Optionals

Please check that all ordered optionals (e.g. additional cylinders, external printer, PT-Node...) are present. In case of a 100ml glass cylinder, check that it has come with the corresponding conformity certificate.

Description	OK	Miss.	NA

Comments

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.0 Operation Qualification Procedure

This section provides the operational procedure to qualify the instrument. Complete each subsection as described.

For more detailed information on the general usage of the instrument refer to the instruction manual.

Section 4.1 Perform Power Up Test

Turn on the instrument by using the AC power key on the back side of the instrument. All displays will light on. The start screen is shown including instrument type, serial no. and firmware version.

OK	NOK	NA

Section 4.2 Verify the Firmware Version

After power on, the installed firmware version is displayed. Verify that the version is matching the version noted in the supplied QC protocol.

OK	NOK	NA

Section 4.3 Verify Instrument Serial Number

Note the serial number displayed on the start screen of the instrument. Check that this serial number corresponds to the serial number printed on the type plate on the back of the instrument.

pass	fail	N/A

Section 4.4 Check the Keyboard

Verify that all buttons and the click wheel work well.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.5 Log In to the Start Menu

Select the menu "SELECT USER" and select "ADMIN" to edit all information which is required to start a test. This information includes the entry of users, methods, products and the decision if tests can only be performed with the PT-TD300 instrument when a valid user and password have been entered or if the instrument can be used without logging on.

Enter the ADMIN password (see operating manual). The full menu can be accessed now.

Use the Click Wheel to move within the menu selection screen.

OK	NOK	NA

Section 4.6 Select Edit Password

Change the default administrator password to your personal password. You can enter from 1 to a maximum of 15 digits. Note down your password and secure the information.

OK	NOK	NA

Section 4.7 Enter a Method

Enter a testing description using the "Edit Method" menu. This method will be used for the forthcoming tests. First enter the method and product name. Then set the result evaluation to (yes). Leave the interval time setting at the default 0 (a logging interval is not applicable to the PT-TD300 instrument). The method includes information according to which norm the test should be performed (see operation manual for more information). Set mode to 14mm tapping height and 300 taps/min. Set the three tap sequences to 10, 50 and 100 taps. If a balance is used to the PT-TD300, select Weight: (Yes). Otherwise select Weight: (No).

OK	NOK	NA

Section 4.8 Enter a User

Edit User leads to some operations. Add a new user. Select a username, create a new password and confirm it. Select the user permissions and choose "Method User" and continue with adding the new user.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.9 Enter the Settings Menu

The Settings menu offers the possibility to load and save files on a USB flash drive, to adjust date, time and PQ interval, the actual run time can be seen and the install date. The Quick Menu option can be deactivated, the possibility to show the password can be set to yes and no, the actual department can be set, even the language. At least the info menu leads to all information about the device (SN, BN) and more. At last the device settings are shown.

Adjust time and date in the relevant menu.

OK	NOK	NA

Section 4.10 Set PQ Interval

Restart the time sequence (PQ Interval) to perform the instrument Performance Qualification

OK	NOK	NA

Section 4.11 Calibration 14mm Stroke Rate

Measure the USP Stroke Height by entering the Device Settings and PT-TD calibration. Choose "Calibrate Speed", Set Mode: 14 mm and continue with Frequency 1, 300 Taps. Print the calibration report.

TARG	MEAS	OK	NOK	NA
300 ± 5 strokes				

Section 4.12 Calibration 14mm Stroke Height

Measure the USP Stroke Height by entering the Device Settings and PT-TD calibration. Choose "Calibrate Height", Set Mode: 14 mm and continue with entering Tap 1 up to 4. Use a calibrated dial gauge for the measurement of the height. Print the calibration report.

TARG	MEAS	OK	NOK	NA
12.00 – 16.00 mm				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.13 Calibration 3mm Stroke Rate

Measure the EP Stroke by entering the Device Settings and PT-TD calibration. Choose "Calibrate Speed", Set Mode: 3 mm and continue with Frequency 1, 250 Taps. Print the calibration report.

TARG	MEAS	OK	NOK	NA
250 ± 5 strokes				

Section 4.14 Calibration 3mm Stroke Height

Measure the EP Stroke Height by entering the Device Settings and PT-TD calibration. Choose "Calibrate Speed", Set "Mode: 3 mm" and continue with entering Tap 1 up to 4. Use a calibrated dial gauge for the measurement of the height. Print the calibration report.

TARG	MEAS	OK	NOK	NA
2.80 – 3.20 mm				

Section 4.15 Calibrate the Balance (optional!)

Calibrate the balance by entering the Nominal weight and continue with taring the balance. Put the Nominal weight on the balance and wait until the PT-TD300 recognizes the weight. Print the calibration report.

TARG	MEAS	OK	NOK	NA
50 g ± 0.0001g				

Section 4.16 Calibration USP/EP Assembly Weight - Dish 250ml complete

Weigh the total 250ml dish assembly including the O-ring and securing ring.

TARG	MEAS	OK	NOK	NA
440 – 460g				

Section 4.17 Calibration USP/EP Assembly Weight – Cylinder 250ml

Weigh the 250ml graduated cylinder.

TARG	MEAS	OK	NOK	NA
176 - 264g				

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.18 Calibration USP/EP Assembly Weight - Dish 100ml complete

Weigh the total 100ml dish Assembly including the O-ring and securing ring

TARG	MEAS	OK	NOK	NA
228 – 252g				

Section 4.19 Calibration USP/EP Assembly Weight – Cylinder 100ml

Weigh the 100ml graduated cylinder

TARG	MEAS	OK	NOK	NA
114 - 146g				

Section 4.20 Fill up the Cylinder

Weigh the product to be tested and fill it into the graduated cylinder

OK	NOK	NA

Section 4.21 Run the Method you defined in section 4.7

Select the method you stored in section 4.7

OK	NOK	NA

Section 4.22 Run a Test

Enter a batch number and an initial volume of approx. 100ml. Insert the support and cylinder into the shown slot and run the Test. The PT-TD300 stops at the end of the first run after 10 taps.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.23 Enter the Volume after the first Run

Read the tapped volume from the graduated cylinder, enter the result and confirm the entry.

OK	NOK	NA

Section 4.24 Run the second Tap Sequence

Press <Continue>. The instrument will perform the second tap sequence and stops at the end of the 2nd run after 50 Taps. Read the tapped volume from the graduated cylinder, enter the result and confirm the entry.

OK	NOK	NA

Section 4.25 Run the third Tap Sequence

Press <Continue>. The instrument will perform the third tap sequence and stops at the end of the 3rd run after 100 Taps. Now enter a volume that is >2ml less than the volume after the second run. This will lead to another execution of of the 3rd Tap sequence.

OK	NOK	NA

Section 4.26 Repeat the third Tap Sequence

Press <Continue>. The instrument will perform the third tap sequence a second time and stops at the end of the 3rd run after 100 Taps. Now enter a volume that´s <2ml less than the volume after the third run. The test is finished and a printout appears.

OK	NOK	NA

Section 4.27 Check the Printout

Check that the printout is fully visible and contains all data you entered formerly. Check that the result volumes you entered appear on the printout correctly. Attach the printout to this document.

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

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Section 5.0 Result and Comments

Instrument Type		Serial Number	
Mains Voltage		Firmware Version	

Addendum Sheet/s attached to this document Yes ☐ No ☐

If yes, how many:

The instrument has passed the operation qualification procedure. Yes ☐ No ☐

Check "yes", 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 applicable sections of the operation qualification have to be repeated once the reason for failure has been eliminated

Comments

This completes the operation qualification of the tested instrument.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Released by: _____ Date: _____

Section 1.2 Section 1.1