[PTB 311E/311E-500/311E-800
Series of Automated Tablet Testing Instruments

Installation Qualification (IQ)

Version 7.0

From firmware version 4.02

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Table of Contents

Document History

Version	Valid from [dd.mm.yyyy]	Author	Change	Remark
6.0	29.05.2016	PTAG	N	
6.1	06.02.2017	PTAG	R	Instructions for Document revised
6.2	27.10.2017	PTAG	R	PTB311E-800 added
6.3	15.10.2021	PTAG	R	Epson printer TM-U220 added
7.0	16.12.2022	PTAG	R	New features added (CAL functions and additional width measurement station)

Table 1: Document History

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 PTB 311E/ 311E-500/ 311E-800 series tablet testing instrument is composed of:

- The PTB 311E, PTB311E-500 or PTB 311E-800 tester
- All required accessories
- Options supplied as specified by customer
- Options as per customer order

The PTB 311E/ 311E-500/ 311E-800 series automated tablet tester is used to test the hardness (tablet breaking force), thickness, width and diameter of solid dosage forms, such as tablets, sweets and catalysts. The PTB 311E/ 311E-500/ 311E-800 can be used in several configurations that satisfy USP/EP criteria including a printer to report the results. The instrument meets the USP <1217> and EP <2.9.8> monographs and is in strict compliance with the valid EEC norms for EMC and CE standards. It fulfills the DIN EN61010- ICE 1010 instrument safety requirements.

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 three 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

Installation 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

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

Section 3.0 Required Calibration Tools, Substances and Standards for the Operation Qualification (OQ)

This section includes information about the calibration tools, substances and standards required to perform the Operations Qualification (OQ) and the corresponding calibration certificates.

Section 4.0 Documentation and Installation Procedure

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

Section 5.0 Instrument identification, supplied components, optional accessories

This section is used to control the completeness of the supply scope and optional accessories which are needed for the later use of the instrument/system.

Section 6.0 Results and Comments

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

Section 1.0 General Documentation Settings

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

Section 1.1 General 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)

Section 1.2 Personnel 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 1.3 Place of Installation

Company Name: _____

Address: _____

_____

_____

Department/Bldg.: _____

Location/Bldg.: _____

Contact: _____

Telephone: _____

E-Mail: _____

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.0 Instrument Identification

Section 2.1 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

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

Section 2.2 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.

Electrical Conditions at Installation Site

Voltage:	100/115V	☐	230/240V	☐
Frequency:	60 Hz.	☐	50 Hz.	☐

Section 2.3 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):		26 **x** 50 **x** 26 cm	

Section 2.4 Clearance

A minimum of **10cm** of the rear and sides of the instrument is required.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.5 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.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 2.6 Main Instrument

Check if the instrument/system 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:

Part-No.	Instrument Description	Serial No.	OK	NA
29-02860	PTB 311E Automated Tablet Testing Instrument 300N			
29-02870	PTB 311E-500 Automated Tablet Testing Instrument 500N			
29-02875	PTB 311E-800 Automated Tablet Testing Instrument 800N			

Section 2.7 Instrument Identification – Thickness Jaws and Printer (Option)

Part-No.	Instrument Description	Serial No.	OK	NA
29-2853x	Thickness testing jaw size = _____			

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 3.0 Required Calibration Tools, Substances and Standards for the Operation Qualification (OQ)

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!
- One of the following combinations of calibration tools must be available for the hardness sections of the OQ:
  - **PT-MT3 with PT-MT support for PTB111/311/411/311-500/311-800 and printer:** This is the recommended procedure by Pharma Test. Using a PT-MT3, no calibration weight is needed anymore because the PT-MT3 fulfills the hardness calibration completely. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.
    - If the hardness calibration shows a discrepancy, the “Adjustment via PT-MT3” function on the Hardness Tester can be used for correction.
  - **PT-MT2 with PT-MT support for PTB111/311/411/311-500/311-800, static weights and printer:**
    - If an obsolete PT-MT2 is available, the usage is valid as long as the calibration is valid. Pharma Test recommends the load cell adjustment with at least 5kg, 10kg and 15kg static weights, too. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.

Static weights and printer: If no electro-magnetic test tablet is available, the Hardness calibration can be done only with static weights. In this case, the PTB311E should be calibrated at least to 15kg, the PTB311E-500 at least to 30kg and the PTB311E-800 at least to 50kg. Furthermore the force increase curve must be recorded to check the linearity up to the maximum hardness.

Section 3.2 Required Qualification Equipment and Calibration Tools

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
10-61000	Stop watch				
004-3402	1 kg weight				
28-00290	5/10/15 kg weight				
28-00300	30 kg weight				
28-00500	50 kg weight				
29-18000	PT-MT2 magnetic test tablet or				
29-18050	PT-MT3 magnetic test tablet				
285-1755	10 mm calibration block				
002-0450	digital multimeter				
80-75109	Reference block 1-10.0 mm				
80-75111	Reference block 10-20.0 mm				
002-6035	Feeler gauge				

Mark NA when not required.

Section 3.3 Other Equipment Used – Not Calibrated

Part-No.	Description	Serial No.	OK	NA
29-18001	Support for PT-MT3 (used for PTB111E, 311E, PTB 311E-500 and PTB 311E-800)	NA		

Mark NA when not required.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 4.0 Documentation and Installation Procedure

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

Full information about the use and operation of the instrument/system is available from the supplied Operating Manual.

Section 4.1 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 4.2 Unpacking

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

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 5.0 Instrument Identification, Supplied Components, Optional Components

All parts required for the standard operation of the instrument are listed at the supplied delivery note (invoice). Each part is labeled with its part-no. Please check the completeness of the delivery scope using the delivery-note (or invoice) attached.

Description	OK	NOK
All items as per attached delivery note have been fully supplied		

In case any item is missing, please be so kind and inform Pharma Test AG 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 part has been received.

Section 5.1 Mains Cord

These parts are included in the standard supply scope of the Instrument

Part-No.	No.	Description	Rec.	Miss.	NA
34-08500	1	IEC/EUR mains cord			
34-08510	1	CH mains cable			
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			

Section 5.2 Complete the Instrument/System

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

OK	NOK	NA

Section 5.3 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

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Section 5.4 Turn on the Instrument

Turn on the instrument following the description of the manual. Use the mains power switch at the rear side of the instrument. All displays will light up.

OK	NOK	NA

Section 5.5 Verify Firmware Version

After the instrument is turned on some instrument show the installed Firmware Version Number. Check that the displayed version number is the same as noted in the QC/DQ document for this instrument. Not valid for instruments having a LE Display - mark NA.

Firmware Version Number:

OK	NOK	NA

Section 5.6 Turn off the Instrument

Turn off the instrument using the power switch on the rear left side of the instrument.

OK	NOK	NA

Section 5.7 Connect the Printer Cable

Keep main power switch of the instrument at off position. Connect the supplied printer cable with the port at the instruments signed "Printer", and the other end with the supplied printer

OK	NOK	NA

Section 5.8 Connect the Serial Cable

Keep main power switch of the instrument at off position. Connect the supplied serial PC cable with the port at the instruments signed "RS232", and the other end with the PC port

OK	NOK	NA

Performed by: _____ Date: _____

Section 1.2 Section 1.1

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Section 6.0 Result and Comments

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 installation 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 installation qualification have to be repeated once the reason for failure has been eliminated.

Comments

This completes the installation qualification of the tested instrument.

Performed by: _____ Date: _____

Section 1.2 Section 1.1

Released by: _____ Date: _____

Section 1.2 Section 1.1