PTS 3E
Suppository Disintegration Test Instrument

Installation Qualification (IQ)

Version 4.1

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Document History

Revision	Valid from	Author	Change	Remark
4.0	02.12.2011	PTAG	N	New document
4.1	12.05.2017	PTAG	R	Design,

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 PTS 3E Suppository Disintegration Test instrument is composed of:

- The PTS 3E main instrument
- Standard Supply Scope
- Optional Equipment and Accessories

The PTS 3E Automated Suppository Disintegration Tester is used for the physical properties testing of a variety of Suppository forms, e.g. Suppositories and Vaginal Ovals. The PTS 3E can be used in several configurations that satisfy EP <2.9.2> criteria.

The PTS 3E can be used as a standalone device with visual definition of the disintegration time or measured the softness of the sample by hand using the supplied glass rod.

Instructions for Documentation Completion

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

1. Complete all items on a form in full.
2. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
3. 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:
4. Use your initials to confirm the entry
5. Enter the date of the additions (addendum)
6. Number the addendum pages numerically
7. Insert the addendum sheet behind the original page
8. 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. Write the correction on a separate addendum sheet
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

CAUTION: The following conditions 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

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), as well as the required documentation are identified.

Section 2.0 Information User and Installation Place

This section the user of the equipment and installation place are defined

Section 3.0 Required instrument, substances, and standards used for the Functional Qualification (OQ)

This section includes information about the equipment, tools and substances required to perform the Functional Qualification (OQ), as well as information of the place of installation.

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 Instrument Identification

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	Type	Rec.	Miss.	NA	Serial No.
39-00039	Suppository Disintegration Tester	PTS 3E				

Instrument Details

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

Section 1.1 Optional Accessories

Part-No.	Instrument Description	Type	Serial No.	Rec.	Miss.	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.2 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-39-00039	Operating Manual			
IQ-39-00039	Installation Qualification			
OQ-39-00039	Operation Qualification			
NA	Instrument Log Book			
QC-39-00039	QC/DQ Test Report			
NA	Delivery Note			

Section 1.3 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: 60cycl. ☐ 50cycl. ☐

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.4 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 1.5 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):	55 **x** 50 **x** 45 cm		

Section 1.6 Clearance

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

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 (2): (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 Required instrument, substances, and standards used for the Functional Qualification (OQ)

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
30-31007	digital Thermometer				
10-61000	Stop Watch				

Section 3.1 Certificates for the Standards, Instruments and Substances

PartNo.	Description	Calibration Date	Rec.	Miss.	NA
320-2002	DKD certificate for thermometer				
320-2125	DKD certificate for stop watch				

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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 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: _____

Signature DD/MM/YYYY

Section 5.0 Instrument identification, supplied components, optionals

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			
34-08511	1	US mains cord			
34-08512	1	GB mains cord			
34-08513	1	ARG/AUS/NZ mains cord			

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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

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 Turn off the Instrument

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

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 5.6 Qualify the Thermometer

Each instrument, which is used for the functional qualification (OQ) of this instrument has been tested and qualified at factory. A certificate issued from an authorized laboratory is only supplied when it has been ordered

The thermometer is used to calibrate and qualify the heating system

OK	NOK	NA

Section 5.7 Qualify the Stop Watch

Each instrument, which is used for the functional qualification (OQ) of this instrument has been tested and qualified at factory. A certificate issued from an authorized laboratory is only supplied when it has been ordered

The stop watch is used to qualify the timer function and time setting

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 6.0 Result and Comments

Type	PTS 3E	Serial Number	
Mains Voltage			

The instrument has passed the Installation Qualification (IQ) 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 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

Approved by: _____ Date: _____
Signature DD/MM/YYYY

Released by: _____ Date: _____
Signature DD/MM/YYYY