Installation Qualification (IQ)

PTF 110, PTF 210, PTF 310 and PTF 610
Tablet Friability Testing Instruments

Version 1.0

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bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment
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Table of Contents

Document History

Version	Valid from	Author	Change	Remark
1.0	31.07.2025	Pharma Test	N	First Release

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 tablet friability testing instrument PTF 110, PTF 210, PTF 310 or PTF 610 (PTF x10) is composed of:

- PTF 110 / 210 / 310 / 610 instrument
- Test drum(s)
- Drum lock nut(s)
- Plastic collector(s)
- All required accessories
- Options supplied as specified by customer

The PTF x10 tablet friability testing instrument is used for the testing and evaluation of physical properties of a variety of solids, e.g. tablets, sweets, catalysts. The PTF x10 can be used in several configurations that satisfy USP/EP criteria.

During the mechanical process of coating, transportation and packing, tablets will lose some weight. In order to check this weight loss, a number of tablets (for example) are counted and weighed. The samples are then placed manually into the Drum of the instrument and a friability test performed following individual test methods described in various Pharmacopoeias.

When the test has finished the tablets are de-dusted and re-weighed. The "before and after" weights are compared and expressed as a percentage weight loss. This loss should not exceed 1 %.

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 into sections:

Section 1.0 Instrument Identification

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

Section 2.0 Personnel Identification

In this section the personnel performing the installation qualification, the user of the equipment and place of installation are defined.

Section 3.0 Required Calibration Tools for (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 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.
23-11100	Friability tester with 1 drum	PTF 110				
23-12100	Friability tester with 2 drums	PTF 210				
23-13100	Friability tester with 3 drums	PTF 310				
23-16100	Friability tester with 6 drums	PTF 610				

Instrument Details

Instrument voltage	24 VDC
External power supply voltage	100-240 Volt, 50/60 Hz
Asset no. or lab ID no.	

Section 1.1 Standard Scope of Delivery

Part-No.	Nos	Description	Rec.	Miss.	NA
283-0420	5	Thermal paper rolls for internal printer			
34-08400	1	Power supply, external			
34-08500	1	Mains cable, EUR or			
34-08510	1	Mains cable, CH or			
34-08511	1	Mains cable, US or			
34-08512	1	Mains cable, GB or			
34-08513	1	Mains cable, AR/AUS/NZ or			
34-08514	1	Mains cable, IN/ZA or			
34-08515	1	Mains cable, BR			

Performed By: _____ Date: _____

Signature MM/DD/YY

Section 1.2 Scope of Delivery – Drums and Related Parts

By default, the instrument is delivered with one full set of standard friability drums, unless ordered otherwise:

- PTF 110: one PTF standard friability drum, right side
- PTF 210: one PTF standard friability drum, right side and one left side
- PTF 310: three PTF standard friability drums, right side
- PTF 610: three PTF standard friability drums, right side and three left side

For each drum the delivery scope also includes one Plexiglas waste receipt, i.e. one, two, three or six. For each axis there is one drum axis fixing screw included, i.e. one or two.

Part-No.	Instrument Description	Nos	OK	NA
224-1100	PTF standard friability drum, left side			
224-1105	PTF standard friability drum, right side			
224-1115	PTF antistatic coated friability drum, left side			
224-1110	PTF antistatic coated friability drum, right side			
224-1125	PTF abrasion test drum with lamellas, left side			
224-1120	PTF abrasion test drum with lamellas, right side			
224-1210	Waste receipt, Plexiglas, magnetic			
224-1190	Drum axis fixing screw			

Section 1.3 Scope of Delivery - Optional Accessories

Part-No.	Instrument Description	Nos	OK	NA
224-0505	PTF 110/210/310/610 10° stand, set of two			

Section 1.4 Scope of Delivery – Optional Accessories – Balance

A balance can be connected to the PTF instrument. A suitable balance may also be supplied locally:

Part-No.	Model	Serial No.	OK	NA

Section 1.5 Scope of Delivery – Optional Accessories – External Printer

PTF feature an internal printer. An external printer can be used instead. A suitable external printer may also be supplied locally:

Part-No.	Model	Serial No.	OK	NA

Performed By: _____ Date: _____

Signature DD.MM.YYYY

Section 1.6 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-21-1x000	Operating manual			
IQ-21-1x100	Installation qualification			
OQ-21-1x100	Operation qualification			
NA	Instrument logbook			
QC-21-1x100	QC/DQ test report			
NA	Delivery note			

Section 1.7 Installation Requirements

NOTE: This instrument requires electrical installation with a quality, noise free ground (earth). 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. ☐

The Instrument must 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.

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Signature DD.MM.YYYY

Section 1.8 Operating Environment

Temperature:	15-40°C	Rel. humidity:	20-80%
Physical site:	Clean, dry and levelled bench	Weight support:	Approx. 30 kg/m²
Required bench space (width x depth x height):		PTF 110:	39 **x** 42 **x** 42 cm
		PTF 210:	46 **x** 42 **x** 42 cm
		PTF 310:	51 **x** 42 **x** 42 cm
		PTF 610:	75 **x** 42 **x** 42 cm

Section 1.9 Clearance

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

Notes:

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)

Approved by:

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 End User Information

Company Name: _____

Address: _____

_____

_____

Department/Bldg.: _____

Location/Bldg.: _____

Contact: _____

Telephone: _____

E-Mail: _____

Performed By: _____ Date: _____

Signature DD.MM.YYYY

Section 3.0 Required Calibration Tools for OQ

This section lists all calibration tools, standards and/or substances required to perform the operation qualification (OQ) of this instrument.

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
30-31006	Digital speed meter				
10-61000	Stopwatch				
307-1205	Wobble/stroke height gauge				
30-31080	Digital goniometer, certified				

Section 3.1 Calibration Certificates for the Tools, Standards and Substances

Part-No.	Description	Calibration Date	Rec.	Miss.	NA
320-2000	DKD certificate for the digit. speed meter				
101-3200	DKD certificate for the stopwatch				
320-2001	DKD certificate for the wobble/stroke height gauge				
320-1071	DKD certificate for the digit. goniometer				

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 (IQ) 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 of mishandling during transport. In case any defects or signs are found, document them by pictures and check whether this has already been reported to the forwarder by the shipment'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

Section 4.3 Check for Completeness

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

Confirm that all items as per the corresponding delivery note have been fully supplied.

OK	NOK

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

Performed By: _____ Date: _____

Signature DD.MM.YYYY

Section 4.4 Assemble the Instrument

Install the instrument at its intended place of use and assemble the instrument with its components as per the supplied operating manual.

OK	NOK	NA

Section 4.5 Connect Mains

Keep the power switch on the backside of the instrument at off. Check that the mains cable, external power supply cable and the socket do not show any visible damage. Connect the external power supply to the 24 VDC power port on the backside of the instrument. Connect the mains cable to the external power supply and to the mains.

OK	NOK	NA

Section 4.6 Turn on the Instrument

Use the power switch on the backside of the instrument to turn it on. Confirm that the screen lights up.

OK	NOK	NA

Section 4.7 Verify Firmware Version

After power on, the installed firmware version is displayed. Verify that the version displayed matches the version noted in the supplied QC protocol. Enter the firmware version on the last page of this document.

OK	NOK	NA

Section 4.8 Verify the 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.

OK	NOK	NA

Performed By: _____ Date: _____

Signature DD.MM.YYYY

Section 4.9 Turn off the Instrument

Turn off the instrument using the power switch on the backside of the instrument.

OK	NOK	NA

Section 4.10 Qualify the Speed Meter

Each calibration tool has been tested and qualified by the factory. A calibration certificate issued by an accredited laboratory is only supplied in case it has been ordered.

The digital speed meter is used to qualify the drum rotation speed.

OK	NOK	NA

Section 4.11 Qualify the Stopwatch

Each calibration tool has been tested and qualified by the factory. A calibration certificate issued by an accredited laboratory is only supplied in case it has been ordered.

The stopwatch is used to qualify the instrument timer.

OK	NOK	NA

Section 4.12 Qualify the SWT Wobble/Stroke Height Gauge

Each calibration tool has been tested and qualified by the factory. A calibration certificate issued by an accredited laboratory is only supplied in case it has been ordered.

The SWT wobble/stroke height gauge is used to qualify the drum displacement.

OK	NOK	NA

Section 4.13 Qualify the Digital Goniometer

Each calibration tool has been tested and qualified by the factory. A calibration certificate issued by an accredited laboratory is only supplied in case it has been ordered.

The digital goniometer is used to qualify the 10° operating angle.

OK	NOK	NA

Performed By: _____ Date: _____

Signature DD.MM.YYYY

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Section 5.0 Result and Comments

Type		Serial Number	
Mains Voltage		Firmware Version	

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 must 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