# Operation Qualification (OQ)

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

Version 1.0

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# Document History

| Version | Valid from | Author | Change | Remark |
|---|---|---|---|---|
| 1.0 | 31.07.2025 | Pharma Test | N | First release |
| | | | | |

**Index Information - Change:**

N = New Document
C = Correction
R = Revision

# Section 1.0 Scope Introduction

## Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PTF instrument are 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 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:

Complete all items on a form in full.

Document any deviation from defined protocols and accepted results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.

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:

1. Write down your initials
2. Write down the date of the additions
3. Number the addendum pages alphanumerically
4. Insert the addendum sheet behind the original page
5. Make all entries in permanent ink.

### Correcting Entries

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

### Correcting Short Entries

To correct a short entry (such as a single word or test result) on a form follow this procedure:

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write down the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Write down your initial
5. Write down the date of the change

### Correcting Long Entries

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

1. Draw a diagonal line, bottom left to upper right, through the miss-entered or incorrect information
2. Write the correction on a separate addendum sheet
3. Give a brief explanation of the change.
4. Write down your initial
5. Write down the date of the change
6. Number the addendum pages alphanumerically
7. Insert the addendum sheet behind the original page

### 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, bottom left to upper right corner, 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, check 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 an 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 service has been done
- After any parts have been replaced
- When this system is being removed from where it was originally installed

# Operation Qualification Program

This document is divided in sections.

### Section 1.0 Scope Introduction

This section explains the purpose and use of this document and the general installation qualification procedure.

### Section 2.0 Instrument Identification

This section has the purpose of identifying the instrument at hand, including parts and accessories, required documentation, and installation site requirements.

### Section 3.0 Personnel Identification

In this section the user of the equipment, the equipment required for qualification is identified and the end user information is written down to complete the qualification.

### 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. Where accreditation is held for the calibration of the equipment being qualified, this procedure will be referenced. Where applicable, copies of these procedures are available from Pharma Test upon request.

### Section 5.0 Result and Comments

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

## Section 2.0 Instrument Identification

The completed IQ document is present. Enter the serial number of the PTF. 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

| | |
|---|---|
| Asset No. or Lab ID No. | |

## Section 2.1 Required Qualification Equipment and Materials Identification

| Part-No. | Description | Serial No. | Rec. | Miss. | NA |
|---|---|---|---|---|---|
| 30-31006 | Digital speed meter | | | | |
| 10-61000 | Stopwatch | | | | |
| 307-1205 | Wobble/stroke height gauge | | | | |
| 30-31080 | Digital goniometer | | | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

## Section 3.0 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 3.2 End User Information

Company Name: _____

Address: _____

_____

_____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature DD/MM/YYYY

# Section 4.0 Operation Qualification Procedure

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

## Section 4.1 Turn on the Instrument

Check that the external power supply is connected to the 24 VDC power port on the backside of the instrument. Check that the mains cable is connected to the external power supply and to the mains. Use the power switch on the backside of the instrument to turn it on. Confirm that the screen lights up.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.2 Perform Self-Test

Press the click wheel to start the self-test. Confirm that the self-test passes without any error.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.3 Check Buttons and Click Wheel

Verify that all buttons and the click wheel work well.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.4 Log In to the Instrument

From the main menu select “Select user”. From the list of users select “ADMIN”. Enter the default password: “ADMIN” and select “Continue”.

| OK | NOK | NA |
|---|---|---|
| | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

## Section 4.5 Create a New User

From the main menu select "Edit user". Then select "Add new user". Enter a name for the new user and select "Continue". Enter a password for the new user and select "Continue". Confirm the new password by entering the same password again and select "Continue". You will get a confirmation message that the password has been set. Select "Continue". Otherwise, retry entering the password and make sure you enter it exactly the same twice. Note down this user password. Change the user permissions to "Method user" and select "Continue". On the next screen, select "Continue" again to create the new user.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.6 Change Administrator Password

From the main menu, select "Edit password". Change the default administrator password to your personal password. You need to enter the new password a second time to confirm the change.

**Make sure to note down your password and to secure this information.**

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.7 Set General Settings

From the main menu select "Settings". The settings menu offers the possibility to load and save files from and to a USB flash drive, to adjust date, time and PQ interval, to display the actual run time and to set the install date. Furthermore, the option to perform a quick test without login can be deactivated here. You can select to show the password during entering or to hide the characters. You can enter a department and a device ID. These will be included on the printouts. The instrument language can be selected here as well. Additional language files can be installed using the load files function. Refer to the user manual for more information about this. The info displays information about the instrument such as model, serial number, firmware version and more. The last menu item leads to the device settings menu, this will be used later.

Now, set date and time in the relevant menu and change any of the settings mentioned above as per your requirements.

| OK | NOK | NA |
|---|---|---|
| | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

## Section 4.8 Set and Restart PQ Interval

From the settings menu, select "PQ interval". Select "Set PQ interval". Set the PQ interval in months to the desired setting and select "Continue". Pharma Test recommends performing a performance qualification (PQ) every six months. Confirm that you want to start the PQ interval from today by selecting "Continue" on the following screen. Once the set PQ interval has elapsed, the instrument will remind the operator that the PQ is due. Note however, that use of the instrument will in no way be limited even in case the PQ is overdue. It is a reminder only.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.9 Set Device Settings

From the settings menu select "Device settings". From here you can perform calibration of the instrument, select which vacuum unit to be used and select types of balance and printer connected to the instrument.

Optionally a balance can be connected to the instrument and the type of balance can be set here. Refer to the user manual for information on supported balances and how to use them together with PTF. In case an external balance is to be used with this instrument, select the corresponding type now.

By default, the instrument is equipped with an internal printer, and it is set up to use this internal printer. So, this setting only needs to be changed in case an alternative, external printer is to be used. Refer to the user manual for more information about supported external printers. In case an external printer is to be used with this instrument, select the corresponding type now.

| OK | NOK | NA |
|---|---|---|
| | | |

## Section 4.10 Calibrate the Timer Function

This test is to confirm that the integrated timer of the instrument is working. From the "Device settings" menu enter the "PTF calibration" menu and select "Calibrate timer".

| No. | Description | TARG (sec) | MEAS | OK | NA |
|---|---|---|---|---|---|
| 4.10.1 | Set the timer to 60 seconds and start the calibration. Use the stopwatch. Enter the real time measured. | 60 ± 1 | | | |
| 4.10.2 | Print the calibration report and attach it to this document. | NA | NA | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

## Section 4.11 Calibrate the Drum Rotation Speed

From the PTF calibration menu select "Calibration -> Speed". Set the nominal rotation speed to the below described values and enter a runtime of 60 seconds. Use the speed meter to verify the actual rotation speed. Enter the individual speed results in the PTF calibration menu. Print the calibration reports and attach them to this document.

| No. | Description | TARG (rpm) | MEAS | OK | NA |
|---|---|---|---|---|---|
| 4.11.1 | Perform the rotation speed calibration with a nominal speed of 15 rpm. | 15 ± 1 | | | |
| 4.11.2 | Perform the rotation speed calibration with a nominal speed of 25 rpm. | 25 ± 1 | | | |
| 4.11.3 | Perform the rotation speed calibration with a nominal speed of 40 rpm. | 40 ± 1 | | | |
| 4.11.4 | Perform the rotation speed calibration with a nominal speed of 50 rpm. | 50 ± 1 | | | |
| 4.11.5 | Perform the rotation speed calibration with a nominal speed of 65 rpm. | 65 ± 1 | | | |
| 4.11.6 | Perform the rotation speed calibration with a nominal speed of 80 rpm. | 80 ± 1 | | | |
| 4.11.7 | Perform the rotation speed calibration with a nominal speed of 100 rpm. | 100 ± 1 | | | |

## Section 4.12 Calibrate the Drum Rotation Counter

From the PTF calibration menu select "Calibration -> Count". Set the number of revolutions to the amount as shown in the table below and the speed to 25 rpm. Count the revolutions using the speed meter. Enter the individual rotation results in the PTF calibration menu. Print the calibration reports and attach them to this document.

| No. | Description | TARG (revolutions) | MEAS | OK | NA |
|---|---|---|---|---|---|
| 4.12.1 | Perform the rotation counter calibration with nominal revolutions 25. | 25 ± 1 | | | |
| 4.12.2 | Perform the rotation counter calibration with nominal revolutions 100 | 100 ± 4 | | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

## Section 4.13 Calibrate the Run-Out of the Drum Bodies

Set the drum speed to 25 rpm and measure the run-out (axial) at the cover side of the drum. Use the wobble meter. The cover side is the outer side of each drum relative to the instrument body. For instruments with more than one drum on one side, start measuring with the innermost drum, then attach one drum after another moving outwards.

| No. | Description | TARG (mm) | MEAS | OK | NA |
|---|---|---|---|---|---|
| 4.13.1 | Measure the run-out of drum no. 1 | ≤ 1.50 | | | |
| 4.13.2 | Measure the run-out of drum no. 2 | ≤ 1.50 | | | |
| 4.13.3 | Measure the run-out of drum no. 3 | ≤ 1.50 | | | |
| 4.13.4 | Measure the run-out of drum no. 4 | ≤ 1.50 | | | |
| 4.13.5 | Measure the run-out of drum no. 5 | ≤ 1.50 | | | |
| 4.13.6 | Measure the run-out of drum no. 6 | ≤ 1.50 | | | |

## Section 4.14 Setup Fixed Speed

From the settings menu select “Fixed speed”. Here you can choose between “Yes” to set a fixed drum rotation speed, which will then be used for all tests with this instrument, or “No” to allow changing the speed settings in the quick test and methods.

| No. | Description | TARG | MEAS | OK | NA |
|---|---|---|---|---|---|
| 4.14.1 | Fixed speed setting is set to | (yes or no) | | | |
| 4.14.2 | In case it is set to yes, enter which fixed speed is set to | rpm | | | |

## Section 4.15 Test 10 ° Stand Position (optional)

Calibrate the degree of the optional PTF 10° stand in case the instrument is supplied with this. Use the goniometer.

| TARG (°) | MEAS | OK | NA |
|---|---|---|---|
| 10 ± 1.5 | | | |

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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## Section 5.0 Result and Comments

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 in this report. In this case the operation qualification must be repeated once the reason for failure has been eliminated.

**Comments**

This completes the operation qualification of the PTF friability testing instrument.

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

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

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