PTG-M100
Manuel Powder Characterization Instrument

Operation Qualification (OQ)

Version 1.0

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bsi. ISO 9001 Quality-management ISO 14001 Environmental-managment
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Document History

Version	Valid from	Author	Change	Remark
1.0	18.03.2024	PT	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 PTG-M100 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 PTG-M100 Powder Characterization Instrument is composed of:

- The PTG-M100 powder tester with funnel and nozzles
- A digital height gauge
- The required standard accessories
- Optionally delivered accessories as per customer order

The PTG-M100 instrument is used to determine the angle of repose and flowability of bulk solids. It fulfills the requirements of USP <1174>, EP <2.9.16> & <2.9.36> Pharmacopoeias and ISO <4324> for the determination of the angle of repose.

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 PT-SV100. The serial number is printed on the type plate on the underside of the instrument:

Part-No.	Description	Type	Rec.	Miss.	NA	Serial No.
42-07100	Powder tester	PTG-M100				

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
30-31080	Digital goniometer (protractor)				
46-01810	Digital caliper				
307-1205	Precision dial gauge, 20mm				
411-0200	Sea sand type 1.0711	[1]			

The validity of the calibration of the measuring tools has already been documented in the IQ, including copies of the calibration certificates. It is not necessary to attach the certificates here again.

[1] Enter lot no. of sea sand used here

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.0 Personnel Identification

Installation Engineer (1):

Name (print)	Initials
Signature	Date (MM/DD/YYYY)

Installation Engineer (2): (optional)

Name (print)	Initials
Signature	Date (MM/DD/YYYY)

Installation Engineer (3): (optional)

Name (print)	Initials
Signature	Date (MM/DD/YYYY)

Approved by:

Name (print)	Initials
Signature	Date (MM/DD/YYYY)

Released by:

Name (print)	Initials
Signature	Date (MM/DD/YYYY)

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 3.2 End User Information

Company Name: _____

Address: _____

_____

_____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature MM/DD/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 Align the PTG-M100

Check the levelness of the PTG-M100 using the spirit level on the base plate of the instrument. Use the digital goniometer to check the levelness of the PTG-M100. The inclination to the horizontal must not be greater than 0.2° in both the left-right and front-back directions.

OK	NOK	NA

Section 4.2 Calibrate the Height Gauge

Use the dial gauge holder supplied with the height measuring device and the calibrated dial gauge to check the measuring accuracy of the height measuring device. Place the measuring sensor of the dial gauge vertically on a suitable platform.

Zero the dial gauge and the height measuring device.

Then move the height gauge by 5mm, 10mm and 15mm and compare the display with the dial gauge measurement.

Nominal value (mm)	Measured value (mm)	Tolerance range (mm)	OK	NOK	NA
5.00		4.95 – 5.05			
10.00		9.95 – 10.05			
15.00		14.95 – 15.05			

Section 4.3 Adjust Falling Height

Use the height measuring device and adjust the nozzle holding arm of the base frame so that the distance between the top of the powder receiving table and the top of the nozzle sealing plate is 100 mm.

Nominal value (mm)	Measured value (mm)	Tolerance range (mm)	OK	NOK	NA
100		99 - 101			

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.4 Calibrate Nozzle Openings

Use the digital caliper and check the openings of the three nozzles supplied.

Nominal value (mm)	Measured value (mm)	Tolerance range (mm)	OK	NOK	NA
10.00		9.99 – 10.01			
15.00		14.99 – 15.01			
25.00		24.99 – 25.01			

Section 4.5 Perform Test Run with Sea Sand

Use the USP/EP outlet nozzle with the 10 mm opening. Fill the conical funnel with 140 ± 2g of sea sand. Place the powder test table and start the test to check the angle of repose. Use the height measuring device and save the table surface as the zero value. Open the cover plate and allow the sea sand to flow onto the receiving table. Carefully(!) measure the height of the resulting cone with the height measuring device.

Experience has shown that using sea sand with a grain size of 0.06mm - 0.3mm, a 10mm nozzle and a drop height of 100mm results in a powder cone with an angle between 27.5° and 30.5°. The receiving dish has a radius of 50mm. The resulting cone heights are therefore (according to the formula$\tan\alpha = \frac{counter-cathode}{anchort\ cathode}$): 26.0mm - 29.5mm.

Nozzle opening (mm)	Nominal cone height (mm)	Measured cone height (mm)	Nominal cone angle (degrees)	OK	NOK	NA
10	26.0 – 29.5		27.5 – 30.5			

Performed by: _____ Date: _____

Signature MM/DD/YYYY

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

Comments

This completes the operation qualification of the PTG-M100 powder tester.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Approved by: _____ Date: _____

Signature DD/MM/YYYY

Released by: _____ Date: _____

Signature DD/MM/YYYY