PT-SV100 Scott Volumeter

Operation Qualification (OQ)

Version 5.4

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Section 1.0 Scope Introduction

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Introduction

Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PT-SV100 Scott Volumeter 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 PT-SV100 Scott Volumeter is composed of:

- The PT-SV100 instrument
- A storage box

Document History

Version	Valid from	Author	Change	Remark
5.0	14.08.2013	PTAG	N	First release
5.1	26.08.2013	PTAG	R	Unnecessary qualification tool removed, various tests revised
5.2	05.11.2013	PTAG	R	Changed tolerances in section 4.11 to accommodate current lot of sea sand
5.3	27.07.2015	PTAG	R	Section 4.8 and 4.9 revised, matching to the QC
5.4	13.10.2017	PTAG	R	Section 4.4 revised, matching to the QC

Index Information - Change:

N = New Document
C = Correction
R = Revision

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.	NA	miss.	Serial No.
49-10000	Scott Volumeter	PT-SV100				

PT-SV100 Details

Asset No. or Lab ID No. [ ]

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 3.1 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	rec.	N/A	miss.
29-03500	Analytical balance				
30-31080	Digital goniometer (protractor)				
411-0200	Sea sand type 1.0711	[1]			
46-01810	Digital caliper				

Section 3.2 End User Information

Company Name: _____

Address: _____

_____

_____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

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

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 Check Alignment of PT-SV100

Use the digital goniometer to check the levelness of the PT-SV100 instrument. Measure on the base plate. If necessary use the two screws on the base plate to correct the alignment.

TARG	MEAS	pass	fail	N/A
0.0 – 0.1°				

Section 4.2 Check Alignment of Loading Funnel

Use the digital goniometer to check the levelness of the loading funnel.

TARG	MEAS	pass	fail	N/A
0.0 – 0.1°				

Section 4.3 Measure the Height of the Measuring Cone

Use the digital caliper to measure the height of the stainless steel measuring cone (part no. 495-0035)

TARG	MEAS	pass	fail	N/A
18.50 – 19.50mm				

Section 4.4 Check the Distance Between Outlet and Receiving Cup

Place the measuring cone on the receiving cup and adjust the stand, so that the outlet rests on the measuring cone.

pass	fail	N/A

Section 4.5 Check Inner Diameter of Receiving Cup

Use the digital caliper to measure the inner diameter of the receiving cup.

TARG	MEAS	pass	fail	N/A
29.00 – 31.00mm				

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.6 Check Height of Receiving Cup

Use the digital caliper to measure the inner height (i.e. measure the height without the bottom of the cup).

TARG	MEAS	pass	fail	N/A
33.00 – 37.00mm				

Section 4.7 Check Volume of Receiving Cup

Calculate the radius (r). Then use the inner height of the receiving cup (h) to calculate the filling volume (V) of the receiving cup using this formula:

$$V = \frac{\pi * r^2 * h}{1000}$$

TARG	MEAS	pass	fail	N/A
24.95 – 25.05ml				

Section 4.8 Weigh Empty Receiving Cup

Use the analytical balance to weigh the empty receiving cup.

TARG	MEAS	pass	fail	N/A
QC-value +- 2gr				

Section 4.9 Check Sieve Inserts

The sieves were measured in the factory and comply with the stated size. Just do an optical check if the sieves aren´t damaged and free from kinks and bumps.

Sieve Insert	TARG	MEAS	pass	fail	N/A
10 mesh (part no. 495-0025)	undamaged				
18 mesh (part no. 495-0026)	undamaged				
Other sieve sizes	undamaged				

Section 4.10 Insert Sieve Insert

Insert the 18 mesh (1mm) sieve insert (part no. 495-0026) into the PT-SV100-

pass	fail	N/A

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Section 4.11 Measure Bulk Density of Sea Sand

The 18 mesh (1mm) sieve (part no. 495-0026) is inserted into the PT-SV100. Use the sea sand and perform three tests with the PT-SV100. Fill at least 35ml of sea sand type 1.0711 into the funnel each time. Determine the bulk density of the sea sand. Use this test report or an equivalent report to document the results:

www.pharma-test.de/wp-content/uploads/2013/07/CA-49-10000_PT-SV100_test_report.zip (10 KB)

Attach the filled out report hereto.

No.	TARG	MEAS	pass	fail	N/A
1	1.10 – 1.60 g/ml				
2	1.10 – 1.60 g/ml				
3	1.10 – 1.60 g/ml				

Calculate the standard deviation of the bulk density of the three tests.

TARG	MEAS	pass	fail	N/A
0 – 0.5				

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 PT-SV100 Scott Volumeter.

Performed by: _____ Date: _____

Signature MM/DD/YYYY

Approved by: _____ Date: _____

Signature MM/DD/YYYY