PT-SV110
Scott Volumeter

Installation Qualification (IQ)

Version 1.1

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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	13.02.2024	Pharma Test	N	New document
1.1	08.01.2024	Pharma Test	C	Mesh size in section 1.1

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 PT-SV110 instrument is composed of:

- The PT-SV110 main instrument
- Standard supply scope
- Optional equipment and accessories according to customer order

The PT-SV110 Scott Volumeter determines bulk density of powders according to the following standard Monographs: ISO 3923-2 (metallic powders): determination of apparent density, EP <2.9.34.1> USP <616, Method II> bulk density and tapped density of powders and method II, ASTM 32990 standard test method for apparent density of metal powders and compounds.

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 Instruments, Substances and Standards

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 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.
49-11000	Scott Volumeter	PT-SV110				

Instrument Details

Asset No. or Lab ID No.	

Section 1.1 Standard Scope of Delivery of PT-SV110

Part-No.	Nos	Description	Rec.	Miss.	NA
496-0320	1	Funnel sieve, 16 Mesh			
496-0325	1	Funnel sieve, 10 Mesh			
412-0100	1	Powder receipt plate, stainless steel			
496-0250	1	Baffle box support, complete			
496-0400	1	Spacer, 19mm			
496-0405	1	Receiving cup, 25ml			
4	1	Allen key, DIN 911			
495-0030	1	Scraper, stainless steel			
495-0021	1	Set of spatulas			
495-0022	1	Set of brushes			

Section 1.2 Optional Accessories

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

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.3 Required Documentation and Information

Ordering Information

Customer Order Number	
Supplier Delivery-Note or Invoice Number	

Equipment Documentation

Part-No.	Description	Rec.	Miss.	NA
B-49-11000	Operating Manual			
IQ-49-11000	Installation Qualification			
OQ-40-11000	Operation Qualification			
NA	Instrument Log Book			
QC-49-11000	QC/DQ Test Report			
NA	Delivery Note			

Section 1.4 Installation Requirements

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.

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 1.5 Operating Environment

Temperature:	15-40°C	Rel. Humidity:	20-80%
Physical Site:	Clean, dry and levelled bench	Weight Support:	Approx. 25 kg/m²
Required Bench Space (Length/Depth/ Height):		30 **x** 30 **x** 40 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 (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 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 Instruments, Substances and Standards

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
30-31080	Digit. Goniometer				
411-0200	Sea Sand 1.07711				
46-01810	Digital Caliper				
NA	Precision Balance				

Section 3.1 Certificates for the Instruments, Standards and Substances

PartNo.	Description	Calibration Date	Rec.	Miss.	NA
320-1071	DKD certificate for goniometer				
320-2004	DKD certificate for caliper				
NA	Calibration certificate for balance				

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

Section 4.2 Check for Completeness

All parts required for the standard operation of the instrument are listed at the supplied delivery note. 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 corresponding delivery note have been fully supplied.

OK	NOK	NA

In case any item is missing, please be so kind and inform Pharma Test 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 4.3 Assemble the Instrument

Assemble the instrument with its components as per supplied operating manual.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.4 Adjust the Instrument on the Bench

Adjust the instrument on the bench using the spirit level built into the base plate of the PT-SV110 and the goniometer to be levelled precisely. Use the two adjustment screws in the base plate to adjust the levelness. Secure them once the instrument is correctly positioned.

OK	NOK	NA

Section 4.5 Qualify the Goniometer

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 goniometer is used to qualify the levelled installation of the instrument.

OK	NOK	NA

Section 4.6 Qualify the Sea Sand

The sea sand is supplied with a certificate of analysis (COA) by the manufacturer, it is attached to the supply scope

The sea sand is used to qualify the bulk density.

OK	NOK	NA

Section 4.7 Qualify the Caliper

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 caliper is used to qualify various accessories and distances while installing the unit.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

Section 4.8 Qualify the Balance

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 balance is used to qualify bulk density.

OK	NOK	NA

Performed by: _____ Date: _____

Signature DD/MM/YYYY

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Section 5.0 Result and Comments

Type	PT-SV110	Serial Number	

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