PTS 3E Suppository Disintegration Testing Instrument

Operation Qualification (OQ)

PHARMA TEST APPARATEBAU AG
Siemensstrasse 5
D-63512 Hainburg (Germany)

Tel.: +49-6182-9532/600
Fax.: +49-6182-9532/650
Email: email@pharma-test.de
WEB: www.pharma-test.de
© Pharma-Test AG 2009/2010 V 5.0

ISO 9001 CERTIFIED
0393/97
NISZERT

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Scope
Introduction

Objectives:

Operational Qualification is the process by which all functions of the Pharma Test PTS 3E Suppository Tester being validated are tested with results recorded and pass/fail of all tests determined by comparing 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 PTS 3E Suppository Tester is composed of:

- PTS 3E Suppository Tester
- All required accessories
- Options supplied as specified by customer

The PTS 3E Suppository Tester can measure Suppository Disintegration Time of maximum three samples at the same time within a heated water bath following the existing EP/DAB criteria . The Instrument can be used in several configurations that satisfy EP/DAB criteria, e.g. for suppositories and ovule.

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Instructions For Documentation Completion

All performers and reviewers must complete qualification forms using the following guide lines:

- Fully complete all items on a form, except the optional comments section.

- Document any deviation from defined protocols and excepted 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. Number the page alphanumerically.

  2. Initial and date additions.

  3. Insert the addendum sheet behind the original page.

- Make all entries in permanent black ink.

Correcting Entries:

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

<u>Correcting Short Entries:</u>

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

1. Draw a diagonal line, bottom left to upper right, through the miss entered or incorrect information.

2. Write the correction to the upper right of the original entry.

3. Give brief explanation of change

4. Initial and date the change.

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Instructions For Documentation Completion

Correcting Long Entries

To correct a long entry or information block on a form:

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 page.

3. Give brief explanation of change.

4. Initial and date the changes.

5. Number the page alphanumerically

6. Place the addendum page behind the original page.

Marking Elements That Are Not Applicable

Some elements may not apply to your system configuration. The elements which 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 the letters NA (Not Applicable), your initials, and the date above the line. Include comments above the line or on the form to document the reason the element is not required.

3. Where NA is indicated as an option, select this field.

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.

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

CAUTION:

The following conditions require “re-qualification”;

- When a system modification has been completed, it affects the operation qualification
- When the software or firmware has been upgraded or changed
- When this system is being removed from where it was originally installed.

Re calibration/Re-certification Requirements

The following conditions require “re-calibration/re-certification;

- For a pre-determined period of time or use.
- After any minor service has been done or replacement of parts.
- When this system is being removed from where it was originally installed.

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Operational Qualification Program

Section (1)

This section includes identify the equipment in this system, and contains the qualification procedure, including the test protocols, 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 the procedure are available upon request at Pharma Test AG.

Section (2)

This section identifies the equipment in this system, the user of the equipment, personnel who have installed and that are approved for certification of this system being qualified, materials required and end user information to complete qualification.

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Table of Contents

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Section 1.0 Equipment Description

1. PTS 3E SuppositoryTester Check ☐

   Serial # _____

Section 1.1 Sub Components

		Options		Check	
1. Plexiglas Water bath incl. tubing	☐	1. Calibrateable digital thermometer	☐	N/A	☐
2. Plexiglas arm incl. 3 basket receipts	☐	2. DKD calibration certificate for thermometer	☐	N/A	☐
3. stainless steel suppository baskets	☐	3. Stop watch	☐	N/A	☐
4. glass testing rod	☐	4. calibration certificate for stop watch	☐	N/A	☐
5. round glass cover plates	☐				
6. control thermometer	☐	5. Others as specified below:			
7. 250 ml water preservative ALGEX	☐				
8. 100 ml cleaning oil	☐				
9. 2 Fuses	☐				
10. EUR mains cable					
11. Others, as below					

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY

Section 1.3 Qualification Procedure

1.2.1 Power Up Test

Before you are allowed to perform the power up test, fill the water bath with water and connect the tubes to water in- and outlet. For detailed Information please see the Operating Manual

Turn on power using AC power key on the rear side of the instrument. All displays will light on. The pump starts working, water is flowing through the system

Pass □ Fail □ N/A □

1.2.2 "SET °C" Key Test

Press "SET °C", to alter the pre-set temperature.

Pass □ Fail □ N/A □

1.2.3 "⇑" Key Test

Press the key marked "⇑", the temperature shown in the LED Display increases

Pass □ Fail □ N/A □

1.2.4 "⇓ " Key Test

Press the "⇓ " the temperature shown in the LED Display decreases

Pass □ Fail □ N/A □

1.2.5 "h" Key Test

Press "h" key to adjust the testing time, the displayed time changes for maximum setting of 99 00

Pass □ Fail □ N/A □

1.2.6 "min" Key Test

Press the key marked "min", the displayed time changes for maximum 00 59

Pass □ Fail □ N/A □

1.2.7 "INT " Key Test

Press the "INT" marked key, the display shows "0"

Pass □ Fail □ N/A □

1.2.8 "START" Key Test

Press the key marked "START", starts a test for the pre-set total testing time, after 10 minutes the Plexiglas Arm holding the stainl. steel baskets will turn 180°

Pass □ Fail □ N/A □

1.2.9 "REC" Key Test

Press "REC", the display shows the programmed testing time, also when a test is activated

Pass □ Fail □ N/A □

1.2.10 "STOP " Key Test

Press the "STOP" marked key, the test is stopped the timer shows the elapsed testing
time

Pass □ Fail □ N/A □

1.2.11 "STOP" Key 2nd. time

Press the "STOP" for the second time, the test is aborted the display shows the programmed testing time

Pass □ Fail □ N/A □

1.2.12 Water bath temperature qualification

Check the water temperature within the bath after a 45 minutes pre-heating and equilibration time. The temperature variation should be within the limit of ± 0.5°C of the required testing temperature (36.5°C).

Pass □ Fail □ N/A □

1.2.13 Digital Timer qualification

Check the operation of the built-in digital timer. The displayed testing time should not differ within a limit of ± 5 seconds of the measured testing time.

Pass □ Fail □ N/A □

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY

Section 2.0 Identification of Equipment

Part Number	Description	Check		
39-00039	PTS 3E Disintegration Tester	☐	N/A	☐
391-7140	Plexiglas Water bath	☐	N/A	☐
391-7142/45	Plexiglas Arm incl. 3 basket receipts	☐	N/A	☐
391-7352	Stainl. steel testing baskets	☐	N/A	☐
105-0800	Control thermometer	☐	N/A	☐
391-3003	Glass testing rod	☐	N/A	☐
391-3002	Round glass cover plates	☐	N/A	☐

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY

Pharma Test Suppository Disintegration Testing Instrument
Operation Qualification

Section 2.1 Identifies Personnel

Installation Engineer: (1)

Name (Print)	Initials
Signature	Date

Installation Engineer: (2) (optional)

Name (Print)	Initials
Signature	Date

Installation Engineer: (3) (optional)

Name (Print)	Initials
Signature	Date

Approved By:

Title	
Name (Print)	Initial
Signature	Date

Section 2.2 Identifies Materials Required

Calibrated Digital Thermometer	Qty. of 1	_____	N/A ☐
Calibration Certificate	Qty. of 1	_____	N/A ☐
Stop Watch	Qty. of 1	_____	N/A ☐
Calibration certificate	Qty. of 1	_____	N/A ☐

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY

Section 2.3 End User Information

Company Name _____

Address _____

_____

_____

Department _____

Location _____

Contact _____

Telephone _____

Fax _____

E-mail _____

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY

Section 2.4 Comments:

This completes the operational Qualification of the Pharma Test PTS 3E Suppository Test Instrument.

Performer: _____ **Date:** _____
Signature MM/DD/YYYY

Approved By: _____ **Date:** _____
Signature MM/DD/YYYY