



PTWS X20
Dissolution Testing Instrument

Operation Qualification (OQ)

ASTM Version 1.0

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Document History

Revision	Valid from	Author	Change	Remark
1.0		PTAG	N	New document

Table 1: Document History

Index Explanation - Change:

- N = New Document
- C = Correction
- R = Revision

Introduction

General

Operational qualification (OQ) is the process by which all functions of the Pharma Test instrument are being 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 PTWS x20 Dissolution Instrument is composed of:

- PTWS x20 dissolution testing instrument
- All required accessories
- Options supplied as specified by customer

The PTWS x20 Dissolution Tester contains eight sample vessels and eight stirrer positions. It is used for the dissolution testing of a variety of pharmaceutical compounds including; tablets, capsules, transdermal patches and membranes. The PTWS x20 can be used in several configurations that satisfy USP criteria e.g. rotating baskets or paddles (USP Apparatus 1 and 2), paddles over disk (USP Apparatus 5) and rotating cylinder for transdermal applications (USP Apparatus 6). The PTWS x20 is supplied with a thermostatically controlled water heater/circulator system. The heater temperature can be controlled by the PTWS x20 as are all other operating parameters such as paddle speed. Tablet (capsule) can be dropped into the vessel sequentially. The Pharma Test dissolution tester PTWS x20 is designed of two major instruments, the drive and heating system which is connected to the water bath and separated from the drive to prevent vibration transfer into the vessels.

A run time protocol can be printed, when the PT-RP80 report printer or any Pharma Test dissolution software is used with the instrument. The temperature sensing probe measures and records the actual temperature of the water bath. Temperature readings can be taken before, after, and periodically during a run to ensure complete compliance throughout the run by using an external certified thermometer. Bath temperature readings are displayed on the screen of the PTWS x20 dissolution instrument.

The instrument has been completed and installed in compliance with the IQ document, which is a part of the entire qualification process.

How to Fill Out This Document

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

1. Write down your initials
2. Complete all items on a form in full.
3. Document any deviation from defined protocols and expected results. Owner approval of protocol deviations must be documented before final approval signatures can be obtained.
4. 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:
 5. Write down your initials
 6. Write down the date of the additions
 7. Number the addendum pages numerically
8. Insert the addendum sheet behind the original page
9. Make all entries in permanent ink.

Correcting Entries

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

Correcting Short and Long Entries

To correct a short entry (such as a single word or test result) or a long entry (information block, test description etc.) on a form follow this procedure:

1. Draw a diagonal line, through the false entered or incorrect information
2. Enter the correction to the upper right of the original entry
3. Give a brief explanation of the change
4. Confirm with your initial
5. Enter the date of the change

NOTE: All original entries must remain legible after any corrections have been made.

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, 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, mark 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
- When the PC software or Instrument firmware has been upgraded or changed
- A pre-determined period of time or use has passed
- After a service has been done
- After any parts have been replaced

Operation Qualification Program

This document is divided in sections.

Section 1.0 Instrument Identification

This section includes the equipment description, part - and serial number

Section 2.0 Personnel Identification

This section is used to enter personal identification information of all person involved in the qualification process of this instrument

Section 3.0 Required Instrument Identification

This section includes the equipment and certificates required to perform the Operational Qualification

Section 4.0 End User Information

In this section the user and installation place is defined

Section 5.0 Operation Qualification Procedure - Instrument Functionality

This section contains the operation qualification procedure to ensure the correct function of the instrument, test protocols and test results in a pass/fail format for each test.

Section 6.0 Operation Qualification Procedure - Instrument Functionality and Compliance

This section contains the qualification procedure for the technical compliance of all relevant testing parameters to ensure the correct operation of the instrument, test protocols and test results in a pass/fail format for each test.

Section 7.0 Result and Comments

This section is used to document the result of the operation qualification and for comments regarding the qualification procedure

.

Section 1.0 Instrument Identification

Check if the instrument/system according to the completed IQ is present and completely installed including all accessories required to use the instrument. Enter the serial number of the instrument. The serial number is printed on the type plate on the back of the instrument:

Part-No.	Instrument Description	Type	Serial No.	OK	NA
30-41000	Pharma Test Dissolution Tester	PTWS 120D			
30-41100	Pharma Test Dissolution Tester	PTWS 120S			
30-48000	Pharma Test Dissolution Tester	PTWS 820D			
30-46000	Pharma Test Dissolution Tester	PTWS 620			
30-41200	Pharma Test Dissolution Tester	PTWS 1220			
30-46600	Pharma Test Dissolution Tester	PTWS D620			

Performed by: _____
Signature

Date: _____
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)

Performed by:

Signature

Date:

DD/MM/YYYY

Section 3.0 Required Qualification Equipment and Materials Identification

The listed equipment is required to perform the operation qualification of the instrument. Only if ordered the equipment and tools will be supplied with a certificate of an accredited office of standards. Instruments and tools used to qualify the instrument should be certified.

Part-No.	Description	Serial No.	Calibrated Until	OK	NA
30-31006	Digital Speed Meter				
30-31007	Digital Thermometer				
10-61000	Stop Watch				
307-1205	Wobble/Stroke Height Gauge SWT				
30-31080	Digital Geniometer				
30-31206	Axial Position Testing Gauge SCT				
30-31050	Vibration Meter				
313-0050	25mm Ball				

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

Section 4.0 End User Information

Company Name: _____

Address: _____

Department: _____

Location: _____

Contact: _____

Telephone: _____

Fax: _____

E-Mail: _____

Performed by: _____ Date: _____

Signature

DD/MM/YYYY

Section 5.0 Operation Qualification - Instrument Functionality

This section provides the operational procedure to qualify the correct functionality instrument. Complete each subsection as described.

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

Section 5.1 Fill the Water Bath

Fill up the water bath using de-ionized water up to the "Max. Level" mark (no glass vessel should be inserted). Prime the pump system.

pass	fail	NA

Section 5.2 Perform Power Up Test

Turn on the instrument by pressing the <Power>-key. Check that the display is evenly illuminated and that there are no dead pixels or other display defects.

pass	fail	NA

Section 5.3 Verify Instrument Serial Number

Note the serial number displayed on the start screen of the instrument. Check that this serial number corresponds to the serial number printed on the type plate on the back of the instrument. Not valid for instruments having a LE Display - mark NA

pass	fail	NA

Section 5.4 Verify installed Firmware Version

Verify the firmware version displayed on the start screen of the instrument. Check that this firmware version corresponds to the version noted in the IQ and supplied QC report for this instrument

pass	fail	NA

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

Section 5.5 Login as Administrator

To use the instrument you need to login first. Select "Login" from the start screen by touching the button and select "Administrator". Enter the default password "1234" for the Administrator and confirm with "Enter".

pass	fail	NA

Section 5.6 Test motorized Lift Function and all Key's

To test the correct lift function, select "LIFT CONTROL" from the main menu. The lift control menu will open. Use the <Reference>-key to move the lift to the upper home position. Keep your finger on the button until the lift stops automatically in the highest position and became green. Then move the lift down into the lower home position by touching the <down arrow>-key. Again, keep your finger on the button until the lift stops automatically in the lowest position.

pass	fail	NA

Section 5.7 Enter Instrument Control Menu

Select "BATH CONTROL" to control the pump and temperature settings.

In the "HEATER STATUS", the target temperature of the water bath is shown in the first line. In the middle line the actual temperature inside the water bath is displayed. In the third line the actual temperature of the hand sensor is displayed.

pass	fail	NA

Section 5.8 Test Pump Function

In the "BATH CONTROL" menu, select "PUMP OFF" to turn off the pump. Select "PUMP ON". Check that the pump turns on and that there is water flowing.

pass	fail	NA

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

Section 5.9 Test Pump Flow Rate

The water bath is filled with ionized water. The pump is turned on. In case there is no water flow detected an error message will appear on the screen.

Use a graduated cylinder holding at least 4 liters and the calibrated digital stop watch. Clamp the short tube from the pump outlet to the bath inlet to interrupt the water flow. Use the quick disconnect on the pump outlet to disconnect the tube. Pull the male part of the quick disconnect out of the tube. Use an additional tube of approx. 50cm length (or something similar) and insert the male part of the quick disconnect there. Put the other end of the additional tube into the water bath through a vessel opening after taking out the vessel there. Insert the end with the male part of the quick disconnect into the quick disconnect. The water is now flowing again from the pump into the water bath. Now, take the end of the additional tube out of the water bath and collect the water flowing from the pump in the cylinder for 30 seconds. Check how much water is collected in the cylinder and double the amount to calculate the flow rate per minute. In case no large enough cylinder is available, use a smaller cylinder and reduce the collection time accordingly, then again calculate the flow rate per minute. Check that the result is within the given range. Put the tubing back in as it was before this test and fill up the water bath again. Put the vessel back into position. Document the flow rate below:

Target	Range	Measured	pass	fail	NA
3.5 l/min	2.0-5.0 l/min.				

Section 5.10 Temperature Setting

In the "BATH CONTROL" menu, select "SET TEMP" and enter 37.0°C as target temperature. Select "HEATER ON" to start the heating system. Check that the temperature starts rising.

pass	fail	NA

Section 5.11 Paddle Stirrer Assembly Installation

Move the lift into the upper home position. The stirrers are still switched off.

In case the instrument is operated with paddle stirring tools, attach the paddle blade adapters to the stirring drive shafts. All parts of the complete assembly are individual batch coded. Install the assembled stirrers into their corresponding spindle positions. If no paddle stirring tools are used enter NA

pass	fail	NA

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

Section 5.12 Basket Stirrer Assembly Installation

Move the lift into the upper home position. The stirrers are still switched off.

In case the instrument is operated with basket stirring tools, attach the basket adapters to the stirring drive shafts. All parts of the complete assembly are individual batch coded. Install the assembled stirrers into their corresponding spindle positions. If no basket stirring tools are used enter NA

pass	fail	NA

Section 5.13 Attach the Stirrer Shaft Clamp (Locking) Screws

Attach each black stirrer shaft clamp screw onto each stirrer drive shaft to hold them in position. Tighten the clamp screw by hand so that the assembled stirrers remain in place in their spindle positions.

pass	fail	NA

Section 5.14 Install the Dissolution Vessels

The lift is still in the upper home position. The stirring drive are still switched off.

Place the dissolution vessels into their positions as per identified in the IQ document. Use the corresponding holes inside the water bath cover. Follow the numerical order as per IQ document. Use the three adjustment discs mounted on the underside of the water bath cover to lock the vessels. The center of each dissolution vessel can be individually adjusted against the stirrer. Use the fixing screws of the adjustment discs to fix and lock the centered position of each vessel.

pass	fail	NA

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

Section 6.0 Operation Qualification - Instrument Performance and Compliance

This section provides the operational procedure to qualify the performance and compliance of all relevant testing parameters of instrument. Complete each subsection as described. Wherever a certificate of compliance (COC) is required it is supplied as part of the delivery scope and has been qualified during the Installation Qualification Procedure as to be included.

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

Section 6.15 Vessel Dimension (COC is part of the supply scope)

In absence of a certificate of compliance measure the internal dimension. The vessel bottom should be smooth and without defects. The vessel needs to be fixed in its position to ensure stable operation and centering of the shaft inside the vessel

pass	fail	NA

Section 6.16 Basket and Shaft Dimension (COC is part of the supply scope)

In absence of a certificate of compliance measure the vent hole diameter, thickness of the wide portion of the basket adapter plate, total basket height, internal diameter of the top of the basket, outer diameter of the screen part of the basket, height of the open screen, outer diameter of the bottom of the basket, and screen mesh number

pass	fail	NA

Section 6.17 Paddle and Shaft Dimension (COC is part of the supply scope)

In absence of a certificate of compliance measure the relevant parameters of the paddle blade, blade height, blade thickness, total blade length, length of the flat portion of the blade, radius of the angle of the top outer edge of the blade, radius of the outside edge of the blade, difference between the distance of the midline of the shaft to the midline for the 2 sides, and the difference between the heights of both sides of the paddles at the outside top

pass	fail	NA

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

Section 6.18 Shaft Wobble

To measure the shaft wobble a runout gauge should be used. The gauge has to touch the shaft about 2 cm above the top of the Paddle Stirrer Plate or Basket assembly. Read the absolute value of the difference between the max. and min. readings which represents the total wobble

Position	Target	Range	Measured	pass	fail	NA
1	1 mm	0 - 1 mm				
2	1 mm	0 - 1 mm				
3	1 mm	0 - 1 mm				
4	1 mm	0 - 1 mm				
5	1 mm	0 - 1 mm				
6	1 mm	0 - 1 mm				
7	1 mm	0 - 1 mm				
8	1 mm	0 - 1 mm				
9	1 mm	0 - 1 mm				
10	1 mm	0 - 1 mm				
11	1 mm	0 - 1 mm				
12	1 mm	0 - 1 mm				

Performed by: _____

Date: _____

Signature

DD/MM/YYYY

Section 6.19 Paddle & Basket Shaft Verticality

The instrument drive unit is in its working position. The verticality has to be measured along the shaft using an accurate bubble or digital leveling device. The shafts have to be vertical at 2 points, 90° apart

Position	Target	Range	Measured	pass	fail	NA
1	90°	89° - 91°				
2	90°	89° - 91°				
3	90°	89° - 91°				
4	90°	89° - 91°				
5	90°	89° - 91°				
6	90°	89° - 91°				
7	90°	89° - 91°				
8	90°	89° - 91°				
9	90°	89° - 91°				
10	90°	89° - 91°				
11	90°	89° - 91°				
12	90°	89° - 91°				

Performed by: _____

Date: _____

Signature

DD/MM/YYYY

Section 6.20 Basket Wobble

To measure the basket wobble a runout gauge should be used. The gauge should be positioned to touch the bottom ring of the turning basket. Read the absolute value of the difference between the max. and min. readings which represents the total wobble

Position	Target	Range	Measured	pass	fail	NA
1	1 mm	0 - 1 mm				
2	1 mm	0 - 1 mm				
3	1 mm	0 - 1 mm				
4	1 mm	0 - 1 mm				
5	1 mm	0 - 1 mm				
6	1 mm	0 - 1 mm				
7	1 mm	0 - 1 mm				
8	1 mm	0 - 1 mm				
9	1 mm	0 - 1 mm				
10	1 mm	0 - 1 mm				
11	1 mm	0 - 1 mm				
12	1 mm	0 - 1 mm				

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

Section 6.21 Vessel Centering

The centering gauge is used to measure the centering inside the vessel. The gauge is used to center the vessel around the stirring shaft at 2 different positions, which are at the top rim of the vessel and above the basket of paddle position. The shaft should be slowly turned at both positions. The vessel should be centered at both positions. The tolerance has to be measured from the center line

Position	Target	Range	Measured	pass	fail	NA
1	1 mm	0 - 1 mm				
2	1 mm	0 - 1 mm				
3	1 mm	0 - 1 mm				
4	1 mm	0 - 1 mm				
5	1 mm	0 - 1 mm				
6	1 mm	0 - 1 mm				
7	1 mm	0 - 1 mm				
8	1 mm	0 - 1 mm				
9	1 mm	0 - 1 mm				
10	1 mm	0 - 1 mm				
11	1 mm	0 - 1 mm				
12	1 mm	0 - 1 mm				

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

Section 6.22 Vessel Verticality

The stirring shafts are outside the vessels. The leveling gauge is used to measure the inside the vessel at 2 points, 90° apart. The vessel must not be more than 1.0° from vertical at either position.

Position	Target	Range	Measured	pass	fail	NA
1	90°	89° - 91°				
2	90°	89° - 91°				
3	90°	89° - 91°				
4	90°	89° - 91°				
5	90°	89° - 91°				
6	90°	89° - 91°				
7	90°	89° - 91°				
8	90°	89° - 91°				
9	90°	89° - 91°				
10	90°	89° - 91°				
11	90°	89° - 91°				
12	90°	89° - 91°				

Performed by: _____

Signature

Date: _____

DD/MM/YYYY

Section 6.23 Basket Depth

Depth balls are used to set and qualify the stirring tool immersion depth. The height is within 8% of the desired height, for a basket at 25mm \pm 2mm from the bottom. Use the certified depth balls to set the distance between the bottom of each vessel and the bottom side of the basket. Place the ball into the vessel and lower the stirring tool until it touches the ball. Lock the stirring tool in this position. Repeat this action for all positions. If no basket stirring tools are used mark NA

Position	Target	Range	Measured	pass	fail	NA
1	25 mm	23 - 27 mm				
2	25 mm	23 - 27 mm				
3	25 mm	23 - 27 mm				
4	25 mm	23 - 27 mm				
5	25 mm	23 - 27 mm				
6	25 mm	23 - 27 mm				
7	25 mm	23 - 27 mm				
8	25 mm	23 - 27 mm				
9	25 mm	23 - 27 mm				
10	25 mm	23 - 27 mm				
11	25 mm	23 - 27 mm				
12	25 mm	23 - 27 mm				

Performed by: _____

Date: _____

Signature

DD/MM/YYYY

Section 6.24 Paddle Depth

Depth balls are used to set and qualify the stirring tool immersion depth. The height is within 8% of the desired height, for a paddle at 25mm \pm 2mm from the bottom. Use the certified depth balls to set the distance between the bottom of each vessel and the bottom side of the paddle blade. Place the ball into the vessel and lower the stirring tool until it touches the ball. Lock the stirring tool in this position. Repeat this action for all positions. If no paddle stirring tools are used mark NA

Position	Target	Range	Measured	pass	fail	NA
1	25 mm	23 - 27 mm				
2	25 mm	23 - 27 mm				
3	25 mm	23 - 27 mm				
4	25 mm	23 - 27 mm				
5	25 mm	23 - 27 mm				
6	25 mm	23 - 27 mm				
7	25 mm	23 - 27 mm				
8	25 mm	23 - 27 mm				
9	25 mm	23 - 27 mm				
10	25 mm	23 - 27 mm				
11	25 mm	23 - 27 mm				
12	25 mm	23 - 27 mm				

Section 6.25 Rotational Speed

Use the speed meter (tachometer) to measure the rotational speed of the paddle or basket stirring tool. The rotational speed must be within 2% or \pm 2 rpm of the stated speed rate, whichever is larger

Target	Range	Measured	pass	fail	NA
50 rpm	48 - 52 rpm				
100 rpm	98 - 102 rpm				
150 rpm	147 - 153 rpm				

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

Section 6.25.1 Measure at 50 rpm

Adjust the stirring speed to be 50 rpm. Use the speed meter to qualify the speed range for each stirring position. Positions not in use mark NA

Position	Target	Range	Measured	pass	fail	NA
1	50 rpm	48 - 52 rpm				
2	50 rpm	48 - 52 rpm				
3	50 rpm	48 - 52 rpm				
4	50 rpm	48 - 52 rpm				
5	50 rpm	48 - 52 rpm				
6	50 rpm	48 - 52 rpm				
7	50 rpm	48 - 52 rpm				
8	50 rpm	48 - 52 rpm				
9	50 rpm	48 - 52 rpm				
10	50 rpm	48 - 52 rpm				
11	50 rpm	48 - 52 rpm				
12	50 rpm	48 - 52 rpm				

Performed by: _____

Date: _____

Signature

DD/MM/YYYY

Section 6.25.2 Measure at 100 rpm

Adjust the stirring speed to be 100 rpm. Use the speed meter to qualify the speed range for each stirring position. Positions not in use mark NA

Position	Target	Range	Measured	pass	fail	NA
1	100 rpm	98 - 102 rpm				
2	100 rpm	98 - 102 rpm				
3	100 rpm	98 - 102 rpm				
4	100 rpm	98 - 102 rpm				
5	100 rpm	98 - 102 rpm				
6	100 rpm	98 - 102 rpm				
7	100 rpm	98 - 102 rpm				
8	100 rpm	98 - 102 rpm				
9	100 rpm	98 - 102 rpm				
10	100 rpm	98 - 102 rpm				
11	100 rpm	98 - 102 rpm				
12	100 rpm	98 - 102 rpm				

Performed by: _____ Date: _____

Signature

DD/MM/YYYY

Section 6.25.3 Measure at 150 rpm

Adjust the stirring speed to be 150 rpm. Use the speed meter to qualify the speed range for each stirring position. Positions not in use mark NA

Position	Target	Range	Measured	pass	fail	NA
1	150 rpm	147 - 153 rpm				
2	150 rpm	147 - 153 rpm				
3	150 rpm	147 - 153 rpm				
4	150 rpm	147 - 153 rpm				
5	150 rpm	147 - 153 rpm				
6	150 rpm	147 - 153 rpm				
7	150 rpm	147 - 153 rpm				
8	150 rpm	147 - 153 rpm				
9	150 rpm	147 - 153 rpm				
10	150 rpm	147 - 153 rpm				
11	150 rpm	147 - 153 rpm				
12	150 rpm	147 - 153 rpm				

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

Section 6.26 Bath Temperature

The water bath has been filled already. The heater is started and the target temperature of the media inside the water bath is set to 37.0°C. Wait until temperature inside the bath has been equalized. Measure the temperature of the medium inside water bath at 6 positions. The temperature must be $\pm 0.5^\circ$ from the target temperature

Position	Target	Range	Measured	pass	fail	NA
1	37.0°C	36.5°-37.5°C				
2	37.0°C	36.5°-37.5°C				
3	37.0°C	36.5°-37.5°C				
4	37.0°C	36.5°-37.5°C				
5	37.0°C	36.5°-37.5°C				
6	37.0°C	36.5°-37.5°C				

Section 6.27 Media Temperature inside the Vessels

The dissolution vessels are filled and inside the water bath. The vessel covers are attached to each vessel. Wait until temperature inside the vessels is equalized. Measure the temperature of the medium inside water bath at 6 positions. The temperature must be $\pm 0.5^\circ$ from the target temperature

Position	Target	Range	Measured	pass	fail	NA
1	37.0°C	36.5°-37.5°C				
2	37.0°C	36.5°-37.5°C				
3	37.0°C	36.5°-37.5°C				
4	37.0°C	36.5°-37.5°C				
5	37.0°C	36.5°-37.5°C				
6	37.0°C	36.5°-37.5°C				
7	37.0°C	36.5°-37.5°C				
8	37.0°C	36.5°-37.5°C				
9	37.0°C	36.5°-37.5°C				
10	37.0°C	36.5°-37.5°C				
11	37.0°C	36.5°-37.5°C				
12	37.0°C	36.5°-37.5°C				

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

Section 6.28 Vibration

Use the vibration meter to ensure that there is no significant vibration in the dissolution apparatus or medium.

pass	fail	NA

Section 6.29 Select a Method and start a Test

To use the instrument you need to select an existing method. The instrument is delivered with a factory set method named "PTAG". Select this method to perform one automated test sequence. Follow the on-screen instructions. The instrument will automatically start pump and heater. You need to drive the instruments head into the operating position by hand. When the lift drive is in its operating position and all test parameters have been met, press <DROP TABLET> and the stirrers will start. The programmed sampling intervals will start

pass	fail	NA

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

Section 7.0 Result and Comments

Instrument Type	<input type="text"/>	Serial Number	<input type="text"/>
Voltage	<input type="text"/>	Firmware Version	<input type="text"/>

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 tested instrument.

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

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

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