Operation Qualification (OQ)

PTWS x30 Series
Dissolution Testing Instruments

Version 1.0

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Section 1.0 Scope Introduction

Table of Contents

Document History

Revision	Valid from	Author	Change	Remark
1.0	10.03.2026	Pharma Test	N	First release

Table 1:Document History

Index Information - Change:

N = New Document
C = Correction
R = Revision

Introduction

Objective

Operational qualification (OQ) is the process by which all functions of the Pharma Test PTWS x30 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 x30 Dissolution Instrument is composed of:

- PTWS x30 dissolution testing instrument
- Separate Pump & Heater Box (230VAC or 115VAC)
- All required accessories
- Options supplied as specified by customer

The PTWS x30 Dissolution Tester contains six to twelve sample vessels and six to twelve stirrer positions. It is used for the dissolution testing of a variety of pharmaceutical compounds including; tablets, capsules, transdermal patches and membranes. The PTWS x30 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 x30 is supplied with a thermostatically controlled water heater/circulator system. The heater temperature can be controlled by the PTWS x30 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 x30 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 Epson TM-U220 ticket 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 x30 dissolution instrument.

Optional installation accessories for the PTWS x30 are:

- TM-x30 manual tablet drop magazine
- TMA-x30 automated tablet drop magazine
- EPE-x30 movable, automated sampling system (requires TM-x30 or TMA-x30)
- ITM-x30 individual media temperature monitoring device

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 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 minor 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 Scope Introduction

This section explains the purpose and use of this document and the general operation qualification procedure.

Section 2 General Information and Document Settings

This section has the purpose of identifying the instrument at hand, including parts and accessories, required documentation, and installation site requirements.

Section 3 Instrument Identification

In this section the equipment in this system, the required documentation and side installation requirements are identified.

Section 4 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 Result and Comments

This section is used to document the result of the installation and for comments regarding the installation procedure.

Section 2.0 General Information and Document settings

In this section the general format setting of this document is described.

Section 2.1 General Date Format of this Document

Please select the date format you want to use in this document.

Date Format	Selected	NA
dd.mm.yyyy		
mm/dd/yyyy		
Other:		

Table 2: General Date Format of this document (d=day, m=month, y=year)

Section 2.2 Personnel Identification

Installation Engineer (1):

Name (print) _____ Initials _____

Signature _____ Date (Section 2.1) _____

Installation Engineer (2): (optional)

Name (print) _____ Initials _____

Signature _____ Date (Section 2.1) _____

Released by:

Name (print) _____ Initials _____

Signature _____ Date (Section 2.1) _____

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 2.3 Required Qualification Equipment and Materials Identification

Part-No.	Description	Serial No.	Calibr. until	OK	NA	miss.
30-31005	Digital laser tachometer					
30-31007	Digital thermometer					
10-61000	Stopwatch					
30-31080	Digital goniometer					
30-31050	Vibration Meter					
307-1205	Precision dial gauge for SWT					
30-31206	Axial Position testing Gauge SCT					
46-01810	Digital caliper					
315-0200	Depth adjustment balls, 25mm					
N/A	Measuring Cup, min 2l	NA	NA			
N/A	Appr. 1m silicone hose, ID=12mm	NA	NA			

Table 3: Calibration Tools

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 2.4 End User Information

Company Name: _____

Address: _____

_____

_____

Department: _____

Location: _____

Contact: _____

Telephone: _____

E-Mail: _____

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 3.0 Instrument Identification

Check if the PTWS x30 according to the completed IQ is present. 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	OK	NA	Serial No.
33-41000	Dissolution Testing Instrument	PTWS 130D			
33-41100	Dissolution Testing Instrument	PTWS 130S			
33-48000	Dissolution Testing Instrument	PTWS 830D			
33-41200	Dissolution Testing Instrument	PTWS 1230			
33-46600	Dissolution Testing Instrument	PTWS D630			

Table 4: Instrument Identification

PTWS x30 Details

Serial No. Heater Unit	
Voltage Heater Unit	☐ 230V 50 cycl.
	☐ 115V 60 cycl.
Asset No. or Lab ID No.	

PTWS x30 Installed Options:

Part-No.	Description	OK	NA
319-20x0	TM-x30 Manual Tablet Drop Magazine		
319-20x5	TMA-x30 Automated Tablet Drop Magazine		
319-20x0	EPE-x30 Automated Sampling Manifold		
319-20x0	ITM-x30 Individual Temperature Monitoring System		

Table 5: Installed Options

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 3.1 Instrument Identification – Testing Positions

Section 3.1.1 PTWS 130D/S:

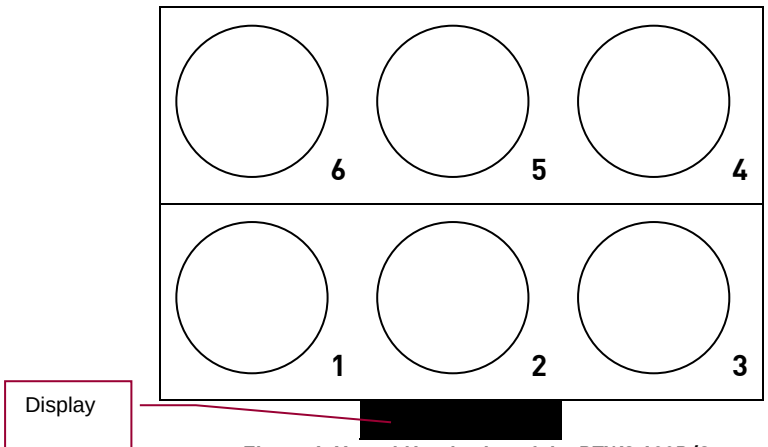


Figure 1: Vessel Numbering of the PTWS 130D/S

Section 3.1.2 PTWS 830:

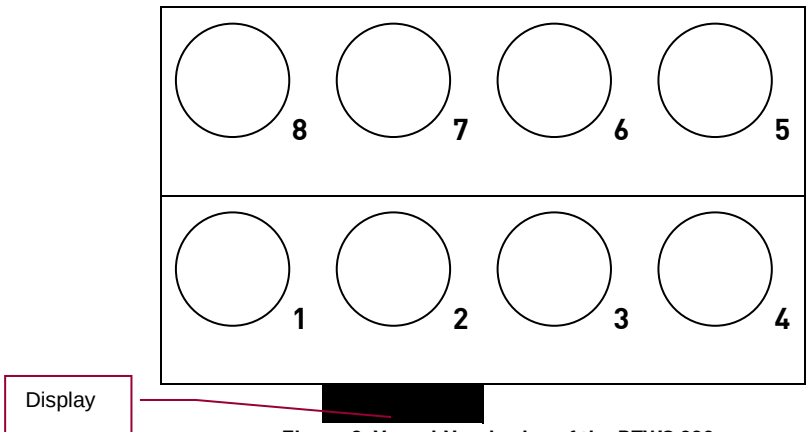


Figure 2: Vessel Numbering of the PTWS 830

Section 3.1.3 PTWS 1230/D630:

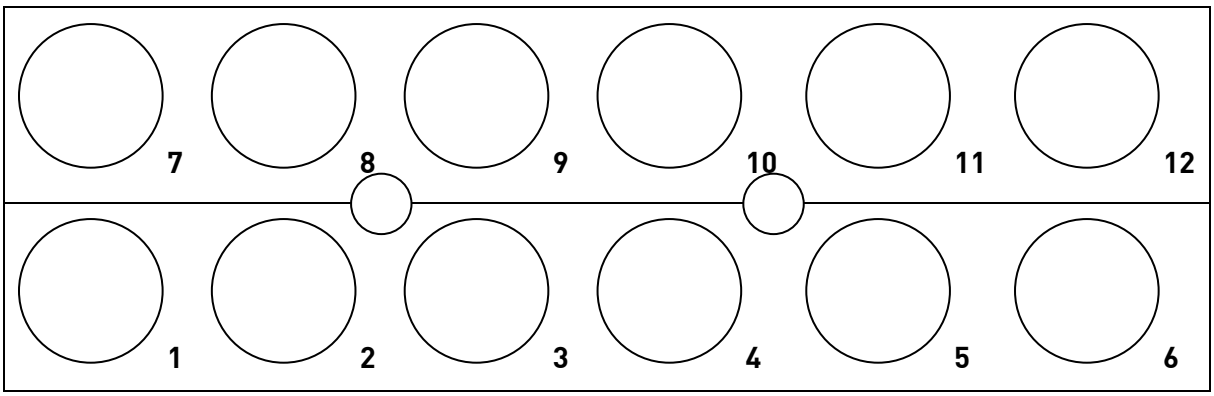


Figure 3: Vessel Numbering of the PTWS 1230 and PTWS D630

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.0 Operation Qualification Procedure

This section provides the operational procedure to qualify the instrument. Complete each subsection as described. For more detailed information on the general usage of the instrument refer to the instruction manual. Make sure to go through the instruction manual before starting the OQ procedure to be familiar with the usage of the instrument beforehand.

Section 4.1 Level the Instrument

Use the adjustable stands to level the instrument horizontally and verify the leveling with the digital goniometer.

pass	fail	N/A

Section 4.2 Doublecheck Mains voltage

If not already done during the IQ, make sure that the Heater Box´s mains voltage matches to the customer mains supply.

pass	fail	N/A

Section 4.3 Switch on the instrument

If not already done, startup the instrument:

First turn on the heater box, followed by the stirring head. Check that it starts up correctly.

If you are logged in already, logout to the instrument to perform the next two sections.

pass	fail	N/A

Section 4.4 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.

pass	fail	N/A

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.5 Verify Installed Firmware Version

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

pass	fail	N/A

Section 4.6 Login and Reference the Lift

Select "LOGIN", select the user "Administrator" and enter the password "12admin34".

Push "REFERENCE LIFT" and release the button. The lift will automatically drive into its upper reference position.

pass	Fail	N/A

Section 4.7 Install Paddle Stirrer Assembly

In case the instrument is supplied with paddles, attach the paddle blade adapters to the stirrer shafts. The drive shafts are numbered. Install the assembled stirrers into their corresponding spindle positions, noted in the IQ.

pass	Fail	N/A

Section 4.8 Install Basket Stirrer Adapter (alternatively)

In case the instrument is supplied with baskets only, unscrew the paddle blade adapters from the drive shafts if necessary. If already installed, the drive shafts may remain in the spindle positions. Attach the baskets and basket adapters to the drive shafts. The drive shafts are numbered. Install the assembled stirrers into their corresponding spindle positions, noted in the IQ

pass	fail	N/A

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.9 Install Additional Tools (alternatively)

In case the instrument is supplied with another type of tools, install them according to the type and usage of the tool.

pass	fail	N/A

Section 4.10 Attach the Stirrer Shaft Clamp Screws

If not already done during IQ, 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	N/A

Section 4.11 Indicate the Installed Stirring Tool Set

Indicate the installed stirring tool set:

Installed stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Section 4.12 Install the Dissolution Vessels

If not already done, insert the vessels in the order noted in the IQ. Secure the bayonet locks properly.

pass	fail	N/A

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.13 Adjust the Stirrer Immersion Depth

Place a depth adjustment ball into each dissolution vessel. Either use a certified depth adjustment ball or check the dimensions of the depth adjustment ball before the test with the certified digital caliper. Note dimensions of the depth adjustment balls below and confirm that they are within the given range.

Drive the instrument head into the USP1..2 Position.

Loosen the stirrer shaft clamps on top slightly but make sure the tools remain in position. Gently push each stirring shaft downwards until it touches the depth adjustment ball. Gently push each stirrer shaft clamps downwards until it rests into position and fix the position using the locking nut of the stirrer shaft clamps. The immersion depth is now equal to the dimensions of the depth adjustment ball.

Turn the black screw on top of the clamps medium tight by hand (clockwise). Take care that the positioning of the shaft to the clamp doesn´t change during this. Now tighten the headless screw in each clamp with the 2mm Allen key and finally tighten the black screws on top of the clamps completely by hand. Don´t use tools like a pliers1

Position	Target	Range	Measured	pass	fail	N/A
1	25.00mm	23.00 – 27.00mm				
2	25.00mm	23.00 – 27.00mm				
3	25.00mm	23.00 – 27.00mm				
4	25.00mm	23.00 – 27.00mm				
5	25.00mm	23.00 – 27.00mm				
6	25.00mm	23.00 – 27.00mm				
7	25.00mm	23.00 – 27.00mm				
8	25.00mm	23.00 – 27.00mm				
9	25.00mm	23.00 – 27.00mm				
10	25.00mm	23.00 – 27.00mm				
11	25.00mm	23.00 – 27.00mm				
12	25.00mm	23.00 – 27.00mm				

Remove the depth adjustment balls from the vessels.

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.14 Check the Vessel/Stirrer Shaft Centricity

Set the target stirring speed to 25RPM Check the vessel/stirrer shaft centricity. Use the centering cover, the SCT instrument or any suitable gauge. Note the values below. Check that all results are within the given range:

Indicate the installed stirring tool:

Installed stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Check that all results are within the given range:

Position	Range	Measured	pass	fail	N/A
1	0.00 – 1.00mm				
2	0.00 – 1.00mm				
3	0.00 – 1.00mm				
4	0.00 – 1.00mm				
5	0.00 – 1.00mm				
6	0.00 – 1.00mm				
7	0.00 – 1.00mm				
8	0.00 – 1.00mm				
9	0.00 – 1.00mm				
10	0.00 – 1.00mm				
11	0.00 – 1.00mm				
12	0.00 – 1.00mm				
13	0.00 – 1.00mm				
14	0.00 – 1.00mm				

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.15 Check the Stirrer Wobble

Wobble test with another stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Check the stirrer wobble (run out) of each stirring tool, use the SWT wobble meter with the precision dial gauge.

Indicate the tested stirring tool:

Tested stirring tool					
USP/EP App. 1 - Basket		USP/EP App. 2 - Paddle		Other	

Set the target stirring speed as per the table below. Measure the wobble at each stirring tool 2cm above the top of the paddle blade or basket holder. Document the displayed values below. Check that all results are within the given range:

Position	Target	Range	Measured	pass	fail	N/A
1	25 RPM	0.00 – 1.00mm				
2	25 RPM	0.00 – 1.00mm				
3	25 RPM	0.00 – 1.00mm				
4	25 RPM	0.00 – 1.00mm				
5	25 RPM	0.00 – 1.00mm				
6	25 RPM	0.00 – 1.00mm				
7	25 RPM	0.00 – 1.00mm				
8	25 RPM	0.00 – 1.00mm				
9	25 RPM	0.00 – 1.00mm				
10	25 RPM	0.00 – 1.00mm				
11	25 RPM	0.00 – 1.00mm				
12	25 RPM	0.00 – 1.00mm				
13	25 RPM	0.00 – 1.00mm				
14	25 RPM	0.00 – 1.00mm				

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Optional:

Position	Target	Range	Measured	pass	fail	N/A
1	25 RPM	0.00 – 1.00mm				
2	25 RPM	0.00 – 1.00mm				
3	25 RPM	0.00 – 1.00mm				
4	25 RPM	0.00 – 1.00mm				
5	25 RPM	0.00 – 1.00mm				
6	25 RPM	0.00 – 1.00mm				
7	25 RPM	0.00 – 1.00mm				
8	25 RPM	0.00 – 1.00mm				
9	25 RPM	0.00 – 1.00mm				
10	25 RPM	0.00 – 1.00mm				
11	25 RPM	0.00 – 1.00mm				
12	25 RPM	0.00 – 1.00mm				
13	25 RPM	0.00 – 1.00mm				
14	25 RPM	0.00 – 1.00mm				

Copy this page in case more tools are supplied. Attach and number the copies.

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.16 Fill Up the Water Bath

Fill up the water bath until it covers the "900ml" print on the inserted vessels. Prime the pump system.

General information: the "Max Level"-sticker on the water bath is relevant only if no(!) vessels are inserted. If the water level isn´t higher than the "Max Level" line, there´s enough volume left that the bath doesn´t overflow when inserting the vessels!

pass	fail	N/A

Section 4.17 Enter Bath Control Menu

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

pass	fail	N/A

Section 4.18 Perform Pump Test

In the "**BATH CONTROL**" menu, select "**PUMP ON"** to turn on the pump. Check that the pump turns on and water without air bubbles is flowing.

pass	fail	N/A

Section 4.19 Check Pump Flow

The water bath is filled with ionized water. The pump is turned on.

Temporary remove two vessels at the right side of the water bath. Use a piece of hose (appr. 1m) with an inner diameter of 12mm and put it onto the short piece of pipe (inside the bath), where the water flows from the pump into the bath. Take care that the open end of the hose is placed in the water bath through the second vessel opening.

The water is now not flowing through the additional piece of hose (which is freely movable) into the bath. Turn off the pump.

Use a measuring cup holding at least 2 liters.

Select "Settings ➔ Qualification (OQ) ➔ Pump flow" and press "START TEST". Enter a time of 30s. Put the open end of the additional hose into the measuring cup and press "PUMP ON"

Check how much water is collected in the cylinder and double the amount to calculate the flow rate per minute. Check that the result is within the given range. Remove the additional piece of hose. Fill up the water bath again. Put the vessel back into position.

Document the flow rate below:

Time	Multiplied	Equals	Range	Measured	pass	fail	N/A
30s	by 2	1 minute	2.0 – 6.0l/min				

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.20 Temperature Setting

Join the "**BATH CONTROL**" menu again. In the upper left corner the target temperature is displayed. Click on the "pen" symbol and enter a target temperature of 37.5°C. Select "**HEATER ON**" to start the heating system **and simultaneously start the stopwatch. This calibration continues in section 4.27.**

Check that the temperature starts rising.

pass	fail	N/A

Section 4.21 Fill the vessels

Fill the vessels with 750ml-900ml deionized water and put the evaporation lids on top the vessels.

General information: To receive a good temperature in the medium, the water level of the water bath (outside the Vessels) must always be at least(!) as high as the medium level inside the vessels.

pass	fail	N/A

Section 4.25 Calibrate Vibration Levels

The vibration meter is placed on top of the vessel cover while the stirrers run at 50 RPM and the thermostat is on heating to 37.5°C.

Description	TARG	MEAS	OK	NA
Calibrate the vibration level at vessel position 1.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 2.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 3.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 4.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 5.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 6.	⩽ 0.20mil or ⩽ 5µm			

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Description	TARG	MEAS	OK	NA
Calibrate the vibration level at vessel position 7.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 8.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 9.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 10.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 11.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at vessel position 12.	⩽ 0.20mil or ⩽ 5µm			

The vibration meter is placed on top of the water bath on the below described positions, while the stirrers run at 50 RPM and the thermostat is on heating to 37.5°C.

Description	TARG	MEAS	OK	NA
Calibrate the vibration level at the front left corner of the bath.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the front right corner of the bath.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the back left corner of the bath.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the back right corner of the bath.	⩽ 0.20mil or ⩽ 5µm			

The vibration meter is placed on top of the dissolution head on the below described positions, while the stirrers run at 50 RPM and the thermostat is on heating to 37.5°C.

Description	TARG	MEAS	OK	NA
Calibrate the vibration level at the front left corner of the dissolution head.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the front right corner of the dissolution head.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the back left corner of the dissolution head.	⩽ 0.20mil or ⩽ 5µm			
Calibrate the vibration level at the back right corner of the dissolution head.	⩽ 0.20mil or ⩽ 5µm			

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.26 Check the Stirrer Speed

The stirring tools are assembled and installed in their positions. They are held in place by the locking screw at the stirrer shaft clamps on top. Set the target stirring speed as per the tables below. Check the stirring speed at each stirrer using the calibrated tachometer. Measure approx. 15 seconds after turning on the stirrers. Measure for 1 minute. Document the displayed values below. Check that all results are within the given range.

Position	Target	Range	Measured	pass	fail	N/A
1	50 RPM	49 – 51 RPM				
2	50 RPM	49 – 51 RPM				
3	50 RPM	49 – 51 RPM				
4	50 RPM	49 – 51 RPM				
5	50 RPM	49 – 51 RPM				
6	50 RPM	49 – 51 RPM				
7	50 RPM	49 – 51 RPM				
8	50 RPM	49 – 51 RPM				
9	50 RPM	49 – 51 RPM				
10	50 RPM	49 – 51 RPM				
11	50 RPM	49 – 51 RPM				
12	50 RPM	49 – 51 RPM				
Position	**Target**	**Range**	**Measured**	**pass**	**fail**	**N/A**
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: _____

Section 2.2 Section 2.1

Position	Target	Range	Measured	pass	fail	N/A
1	150 RPM	148 – 152 RPM				
2	150 RPM	148 – 152 RPM				
3	150 RPM	148 – 152 RPM				
4	150 RPM	148 – 152 RPM				
5	150 RPM	148 – 152 RPM				
6	150 RPM	148 – 152 RPM				
7	150 RPM	148 – 152 RPM				
8	150 RPM	148 – 152 RPM				
9	150 RPM	148 – 152 RPM				
10	150 RPM	148 – 152 RPM				
11	150 RPM	148 – 152 RPM				
12	150 RPM	148 – 152 RPM				

Section 4.27 Check the Temperature Inside the Water Bath

A complete heat-up of the waterbath including filled vessels needs – depending on the start temperature – 30...45min usually. Once the temperature is reached, stop the stopwatch, note the warm-up time and the water bath temperature, measured by the calibrated reference thermometer, in the middle of the water bath.

Measurement	Target	Range	Measured	pass	fail	N/A
Heat-up time	~45min	30 – 75 min				
Water bath temperature	37.5°C	37.0 - 38.0°C				

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.28 Check the Vessel Temperature

Make sure that the water bath temperature (Section 4.27) has been reached for minimum 20 minutes. This means: after the water bath has reached 37.5°C, wait minimum 20 minute more before measuring the media temperature.

Depending on environmental temperature it might be necessary to adapt the water bath temperature. To receive 37.0°C inside the vessels, the waterbath temperature must be a little higher. The 0.5°C difference in this document (water bath: 37.5°C, medium temperature 37.0°C) are an experienced value. Depending on the conditions on site the water bath temperature may be changed a little.

Measure the temperature inside the vessels, midways between the water surface and the bottom of the vessel. Measure in the middle position of each vessel opening for at least 30 seconds at each position and document the displayed temperatures below. Check that all results are within the given range:

Position	Target	Range	Measured	pass	fail	N/A
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				

In one vessel free of choice, place both the reference thermometer as well as the external manual sensor of the PTWS instrument. Verify that the reading of the PTWS sensor doesn´t differ more than 0.5°C from the reference thermometer.

Reading PTWS manual sensor	Reading reference thermometer	Allowed deviation	Difference	pass	fail	N/A
		+- 0.5°C				

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.29 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 <Insert Samples>, followed by <START TEST>. The stirrers will start. The programmed sampling intervals will start.

pass	fail	N/A

Section 4.30 Automated tablet magazine (optional)

In case the PTWS x30 is equipped with an automated tablet magazine (ATM), confirm that it moves correctly at beginning of the method test above: It moves from <closed position> to <opened position> and back to <closed position>.

pass	fail	N/A

Section 4.31 Calibrate the ITM sensors (optional)

In case the PTWS x30 is equipped with the individual temperature measurement (ITM), check the readings of the ITM sensors after the first sampling of the example method happened. For this, join the "TEST STATUS" and go to the screen "Temperatures last sampling". Compare the temperature readings of the PTWS with the temperatures measured inside the vessels with the reference thermometer:

	Reading PTWS ITM sensor	Reading reference thermometer	Allowed deviation	Difference	pass	fail	N/A
1			+- 0.5°C				
2			+- 0.5°C				
3			+- 0.5°C				
4			+- 0.5°C				
5			+- 0.5°C				
6			+- 0.5°C				

Performed by: _____ Date: _____

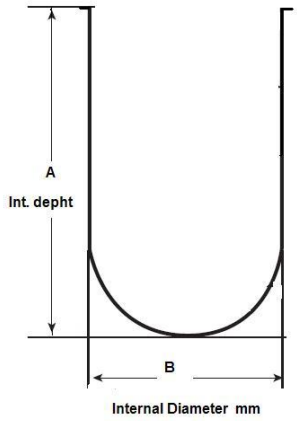
Section 2.2 Section 2.1

	Reading PTWS ITM sensor	Reading reference thermometer	Allowed deviation	Difference	pass	fail	N/A
7			+- 0.5°C				
8			+- 0.5°C				
9			+- 0.5°C				
10			+- 0.5°C				
11			+- 0.5°C				
12			+- 0.5°C				

Section 4.32 Check Vessel Dimensions

Pharma Test certifies that the supplied USP/EP 1l vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Vessel Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	Nominal Volume	Material
USP/EP	160 – 210	98 -106	1,000ml	Glass or other transparent material
USP	380 - 300	98 – 106	2,000ml	Glass or other transparent material

Confirm that the conformity of every glass is checked and documented in the tool certificate of the instrument-QC.

Pos.	OK	NOK	N/A
Vessel			

Copy this page in case more vessels are supplied. Attach and number the copies.

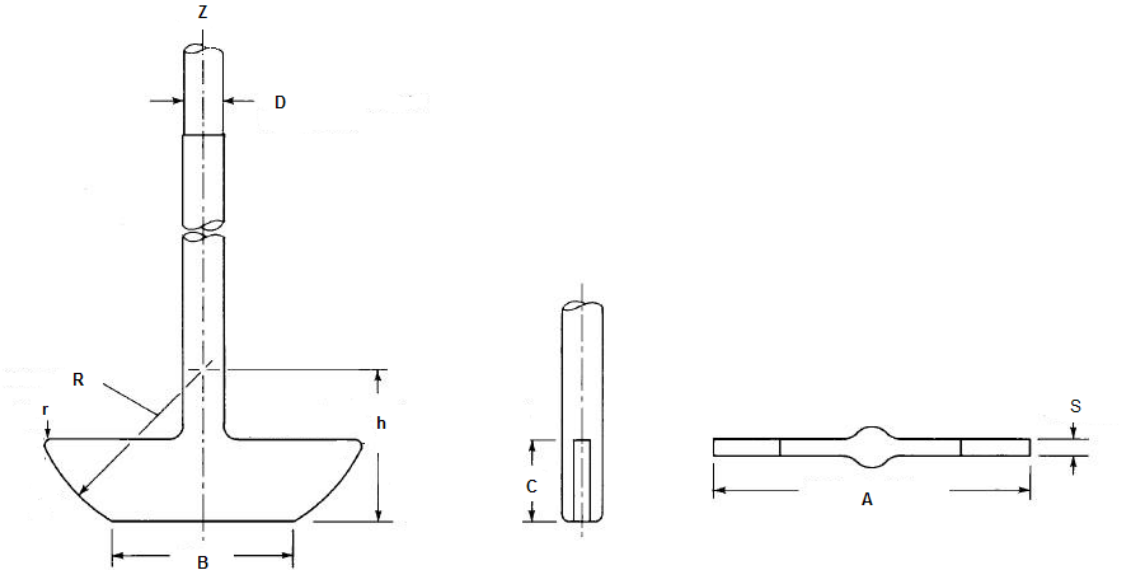
Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.33 Check Paddle Dimensions

Pharma Test certifies that the supplied USP/EP 1l vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Paddle Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	C (mm)	D (mm)	S (mm)
USP/EP	74.0 – 75.0	41.0 – 43.0	18.5 – 19.5	9.4 – 10.1	3.0 – 5.0

Confirm that the conformity of every paddle is checked and documented in the tool certificate of the instrument-QC.

Pos.	OK	NOK	N/A
Shaft			
Paddle			

Copy this page in case more paddles are supplied. Attach and number the copies.

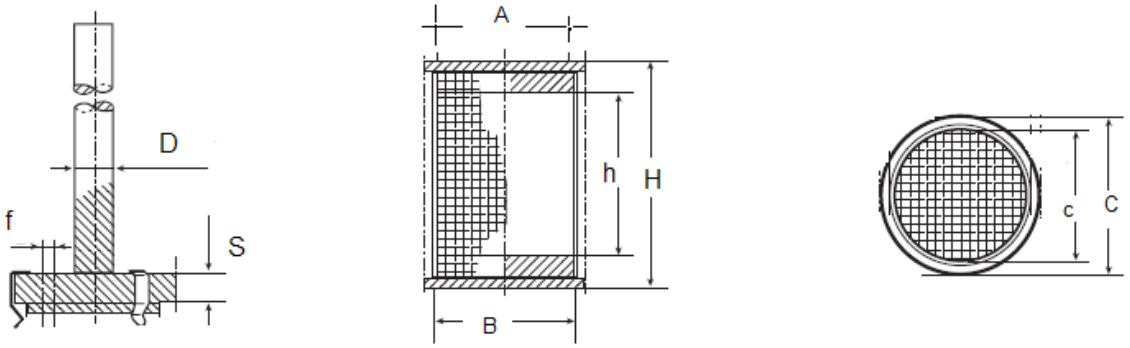
Performed by: _____ Date: _____

Section 2.2 Section 2.1

Section 4.34 Check Basket Dimensions

Pharma Test certifies that the supplied USP/EP 1l vessels, the stirring shafts and adapters have been carefully tested and that the dimensions comply with the valid EP/USP/JP Pharmacopoeia and or ISO norm.

Basket Specifications of the Valid USP <711> and EP <2.9.3> Monograph:



Norm	A (mm)	B (mm)	C (mm)	c (mm)	D (mm)	S (mm)	f (mm)	H (mm)	h (mm)
USP/EP	19.2 – 21.2	NA	22.0 – 28.0	19.2 – 21.2	9.4 – 10.1	4.6 – 5.6	1.5 – 2.5	34.0 – 40.0	26.0 – 28.0

Confirm that the conformity of every basket is checked and documented in the tool certificate of the instrument-QC.

Pos.	OK	NOK	N/A
Shaft			
Adapter			
Basket			

Copy this page in case more baskets are supplied. Attach and number the copies.

Performed by: _____ Date: _____

Section 2.2 Section 2.1

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 PTWS x30 instrument.

Performed by: _____ Date: _____

Section 2.2 Section 2.1

Released by: _____ Date: _____

Section 2.2 Section 2.1