



## Installation Qualification (IQ)

### PTWS x30 Series Dissolution Testing Instruments



Version 1.0

Pharma Test Apparatebau AG  
Siemensstr. 5  
63512 HAINBURG  
GERMANY  
T: +49 6182 9532-600  
F: +49 6182 9532-650  
[info@pharma-test.de](mailto:info@pharma-test.de)  
[www.pharma-test.com](http://www.pharma-test.com)



## Section 1.0 Scope Introduction

### Table of Contents

Installation Qualification (IQ).....	1
PTWS x30 Series Dissolution Testing Instruments.....	1
Section 1.0 Scope Introduction .....	2
Table of Contents .....	2
Introduction.....	3
Document History.....	4
Section 2.0 General Information and Document settings .....	8
Section 3.0 Instrument Identification .....	11
Section 4.0 Unpack the PTWS x30 from the Wooden Crate .....	15
Section 5.0 Installation Procedure .....	19
Section 6.0 Result and Comments .....	22

## Introduction

### Objective

Installation Qualification (IQ) is used to verify that the Pharma Test PTWS x30 instrument (or components where applicable) has been installed to the manufacturer's requirements and performs its functions as per specification.

### 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

## Document History

Revision	Valid from	Author	Change	Remark
1.0	10.03.2026	PTAG	N	First release

**Table 1: Document History**

### 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 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

## **Installation 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 installation qualification procedure.

### **Section 2 General Information and Document Settings**

In this section the date format, installation technician of the equipment, the equipment required for qualification is identified and the end user information is written down to complete the qualification.

### **Section 3 Instrument Identification and Installation Requirements**

In this section the instrument including details and serial number(s), the required documentation and site installation requirements are identified.

### **Section 4 Equipment Description**

This section has the purpose of identifying the equipment at hand, including all parts and accessories.

### **Section 5 Installation Procedure**

This section contains the installation procedure and test results in a pass/fail format for each test.

### **Section 6 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)

## Section 2.3 Required Qualification Equipment and Materials

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

Individual identification and verification of the validity of the calibration tools is part of the OQ.

Mark "miss." if a calibration tool is not available.

The caliper is only needed to verify the diameter of uncertified depth adjustment balls (25mm). In case the adjustment balls are certified, a caliper is not needed. Mark N/A in this case.

Part-No.	Description	OK	N/A	miss.
30-31005	Digital laser tachometer			
30-31007	Digital thermometer			
30-31080	Stopwatch			
30-31080	Digital goniometer			
30-31050	Vibration-Meter			
307-1205	Precision dial gauge for SWT/SCT			
30-31206	Axial Position testing Gauge SCT			
30-31210	SWT2-PTWS Test insert			
46-01810	Digital caliper			
315-0200	Depth adjustment balls, 25mm			
N/A	Measuring Cup, min 2l			
N/A	Appr. 1m silicone hose, ID=12mm			

**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 delivery note/packing list has been received. 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	rec.	NA	miss.	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

Asset No. or Lab ID No.

<input type="checkbox"/> 230V 50 cycl.
<input type="checkbox"/> 115V 60 cycl.

Performed by: \_\_\_\_\_

Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 3.1 Instrument Identification – Testing Positions

#### Section 3.1.1 PTWS 130D/S:

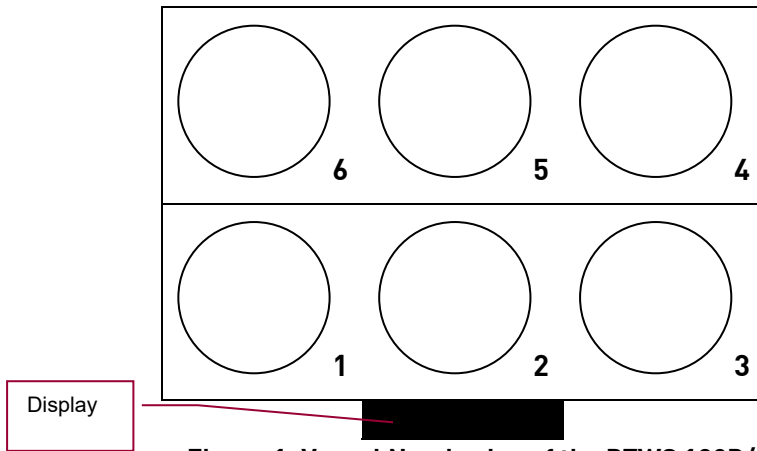


Figure 1: Vessel Numbering of the PTWS 130D/S

#### Section 3.1.2 PTWS 830:

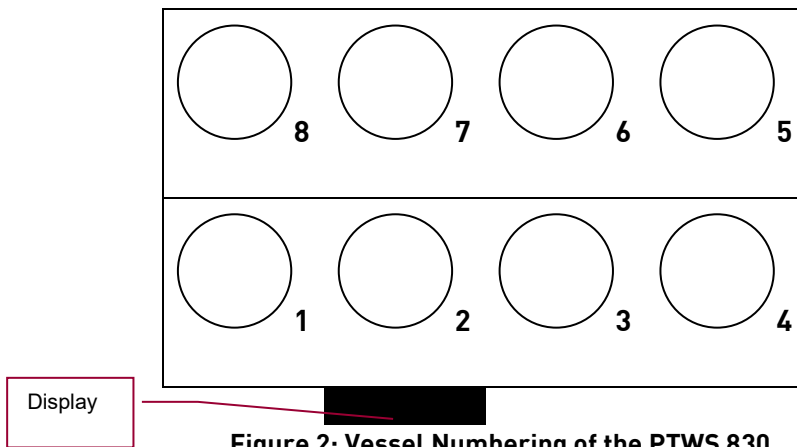


Figure 2: Vessel Numbering of the PTWS 830

#### Section 3.1.3 PTWS 1230/D630:

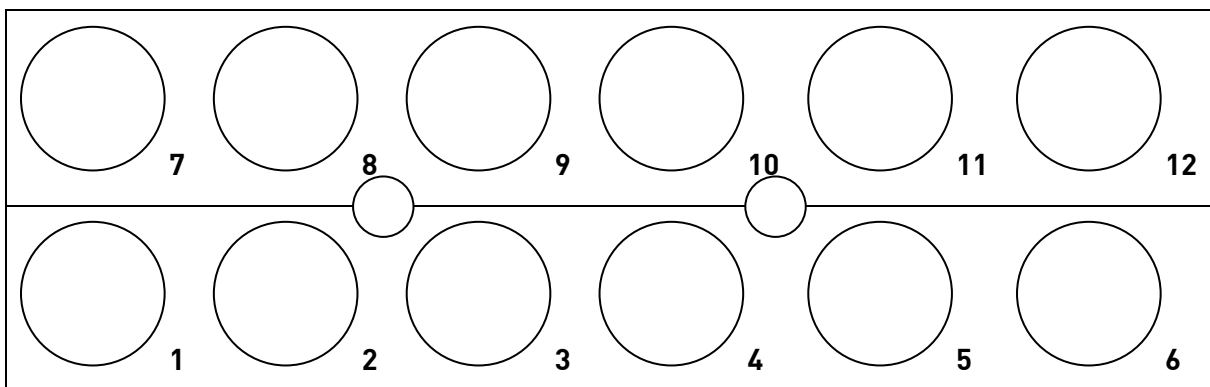


Figure 3: Vessel Numbering of the PTWS 1230 and PTWS D630

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 3.2 Instrument Identification – Supply Scope

Check if all items according to the delivery note/packing list have been received:

pass	fail	NA

If not all items have been received list the missing items below:

Part-No.	No.	Description	miss.

### Section 3.3 Required Documentation

#### Ordering Information

Customer Order Number	
Supplier Invoice Number	
Supplier Delivery Note	

#### Equipment Documentation

Part-No.	Description	rec.	NA	miss.
B-30-4xxxx	PTWS x30 Operating Manual			
IQ-30-4xxxx	PTWS x30 Installation Qualification			
OQ-30-4xxxx	PTWS x30 Operation Qualification			
NA	Instrument Log Book			
QC-30-4xxxx	QC/DQ Test Report			
NA	Delivery Note			

Table 5: Documentation

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 3.4 Instrument Installation Site Requirements

**NOTE:** This instrument requires electrical installation with a quality, noise free ground (earth). In this case, as in all electrical installations where liquid handling is an integral part of the instrument function, all mains (line) supplies should be protected with an RCD (Residual Current Detector) which typically trips out when current leakage to ground (earth) of approx. 30mA is detected.

#### Electrical Conditions at Installation Site

Voltage: 115V  230V  Frequency: 60Hz  50Hz

### Section 3.5 Operating Environment

Note: This dissolution instrument MUST be installed on a level surface. The supporting bench MUST be able to take at least 150kg of weight continuously. The parallel operation of the tester head with the water bath and the resulting perpendicular placement of the dissolution tools are all part of the USP / EP requirements for qualified instrument operation. Failure to comply with this will ultimately lead to failed Performance Qualifications (PQ) and non-compliance of the instrument for GMP use. Pharma Test Apparatebau AG is not responsible for inadequate site planning and installation. We are however, happy to advise if help is required.

Remarks (optional):

---



---



---



---

This instrument requires solid laboratory bench and needs to be installed in a laboratory environment.

Temperature: 10-40°C	Rel. Humidity: 20-80% (non condensing)
Physical Site: Clean, dry and level bench	Weight Support: Approx. 150 kg
Dimensions (Depending on instrument Type and orientation (Width x Depth x Height):	1000 x 750 x 1000mm for PTWS 130 & 830 1400 x 600 x 1000mm for PTWS 1230 & D630

### Section 3.6 Clearance

A minimum of 10cm of the rear and sides of the instrument is required. Approximately 90 cm of total bench space is required for the PTWS x30 (does not include space for options such as pump and fraction collector or spectrophotometer).

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

## Section 4.0 Unpack the PTWS x30 from the Wooden Crate

Unscrew the crate cover. Remove cardboard boxes where accessible. Unscrew and remove the crate front wall. Unscrew and remove the crate side wall. Unscrew and remove the remaining crate walls. Always lift the instrument with two people using the proper lifting points. Never lift the instrument from any other points (i.e. the head) as this may damage the instrument! Carefully place the instrument on the installation location. Remove the wrapping material and unpack all accessories. Assure that there has been no physical damage caused to the instrument or accessories during shipment.

pass	fail	NA

## Section 4.1 Equipment Description – Vessels

Check if the vessels as per the order confirmation have been received and note the serial numbers below. Refer to the numbers in the table below when installing the vessels in their positions later:

Vessel Pos.	Vessel SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

**Table 6: Vessels**

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 4.2 Equipment Description – Stirrer Shafts

Note the serial numbers of the stirrer shafts below. Refer to the numbers in the table below when installing the shafts in their positions later:

Shaft Pos.	Shaft SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

**Table 7: Stirrer Shafts**

### Section 4.3 Equipment Description – Paddles (USP/EP App. 2)

Note the serial numbers of the Paddles below. Refer to the numbers in the table below when installing the shafts in their positions later:

Paddle Pos.	Paddle SN.	rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

**Table 8: Paddles**

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 4.4 Equipment Description – Baskets (USP/EP App. 1 (optional))

Note the serial numbers of the Baskets below. Refer to the numbers in the table below when installing the shafts in their positions later:

Basket Pos.	Basket SN.	Adapter SN.	Rec.	NA	miss.
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

Table 9: Baskets

### Section 4.5 Equipment Description – Additional Vessels (optional)

In case additional vessels were ordered, note the serial numbers of the Vessels below. Refer to the numbers in the table below when installing the vessels in their positions later.  
 Vessel type: \_\_\_\_\_

Vessel Pos.	Vessel SN.	Rec.	NA	miss.
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

**Table 10: Additional vessels**

**Section 4.6 Equipment Description – Additional Tools (optional)**

In case additional tools were ordered, note the serial numbers below (mark NA in case field does not apply). Refer to the numbers in the table below when installing the tools in their positions later.

Tool type: \_\_\_\_\_

Tool Pos.	Tool SN.	Adapter SN.	Rec.	NA	miss.
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					
11					
12					

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

Performed by: \_\_\_\_\_

Date: \_\_\_\_\_

Section 2.2

Section 2.1

## Section 5.0 Installation Procedure

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

### Section 5.7 Check Mains Voltage

Check that the Heater box's mains voltage matches to the customer mains supply. Check that the correct main cable is available.

pass	fail	NA

### Section 5.1 Connect the Tubing Set (Optional)

In case the instrument is supplied as part of an automated system, connect the tubing set by following the labels on the tubing and the color coding of the "Luer"-connectors.

pass	fail	NA

### Section 5.2 Connect the Mains to the Heater Unit

Set the mains switch at the backside of the heater box to the "off"-position. Connect the first mains cable to the local power outlet and to the PTWS x30.

pass	fail	NA

### Section 5.3 Connect the Power Supply to the Stirring head

Set the mains switch at the backside of the stirring head to the "off"-position. Connect the second mains cable to the local power outlet and to the 24V table power supply. Put the hollow plug of the table power supply to the power port at the backside of the stirring head.

pass	fail	NA

### Section 5.4 Connect the Sensors and Actors

Connect the external temperature sensor and the automated tablet magazine (optional).

pass	fail	NA

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 5.5 Connect Stirring head and Heater Box with the Data Cable

Use the Sub-D-female cable to connect the head and the heater box at the ports labelled "CAN".

pass	fail	NA

### Section 5.6 Attach the Water Hoses between Heater Box and Waterbath

Connect the "outlet" port at the heater box to the right connector (view from the front) of the waterbath. The "inlet" port to the left connector (view from the front) to the waterbath.

pass	fail	NA

### Section 5.7 Switch on the Instrument

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

pass	fail	NA

### Section 5.8 Login as Administrator

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

pass	fail	NA

### Section 5.9 Move the stirring head up

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

pass	fail	NA

Performed by: \_\_\_\_\_ Date: \_\_\_\_\_

Section 2.2

Section 2.1

### Section 5.10 Insert the vessels

Insert the vessels in the order noted in Section 4.2. Secure the bayonet locks properly.

pass	fail	NA

### Section 5.11 Insert the stirrer shafts

Insert the stirrer shafts in the order noted in Section 4.3. Secure the shafts from falling down with the black stirrer fastening screws 316-2150.

pass	fail	NA

Performed by: \_\_\_\_\_

Date: \_\_\_\_\_

Section 2.2

Section 2.1

