



RRT 10 BioDis

Multiple media pH-change dissolution testing
for USP 3 and 7



ERWEKA

Multiple media pH-change testing with a touch

With the ERWEKA RRT 10, automatic dissolution testing of different extended and sustained release dosage forms has become easier than ever before. This unit is perfectly suited for simulating the pH-changes within the human body. By placing different media in each row, the device echoes varying in vivo gastrointestinal conditions of the body. An automatic sample transport between the rows allows the reliable testing of the extended or sustained release from different dosage forms in various pH-zones. The simple to program RRT 10 thus, is the perfect unit for multiple media pH-changes for IV/IVC testing and dissolution profiling of a variety of release dosage forms (e.g. tablets, coated tablets and oblongs).

The RRT 10 is 100 % compliant to the USP/EP/JP standards and available as either USP method 3, USP method 7 or as a combination device of both USP methods 3 and 7. It comes with an external flow-through heater, which minimizes vibrations to the device. Moreover, the unit offers a mobile touch display, which is easy to use and provides convenient control. Vessels are placed inside an acrylic water bath with an outlet valve for easy cleaning and the automatic cover system of the RRT 10 reduces media evaporation.

Three configurations available:

USP 3 Dissolution Tester RRT 10

Configuration for USP 3 means the shafts dip by 100 mm again and again. Only reciprocating cylinder tool is available.

USP 7 Dissolution Tester RRT 10

Configuration for USP 7 uses a shorter dip length of 20 mm. Different tools are available.

Combination of USP 3 & USP 7

With a few simple steps, the RRT 10 can be easily switched by the user from USP 3 to USP 7 or vice versa.



External flow-through heater

The industry-proven external ERWEKA flow-through heater maintains a constant temperature with a heating range and accuracy of 0.02 °C.



Adjustable to your needs: USP 3 or 7

The RRT 10 is available as a fixed USP 3 or USP 7 device. If you need to test both methods, the user changeable USP 3 & USP 7 combination device is the right choice.

Touch display for comfortable control

The detachable touch display allows easy and convenient control of the device. It is equipped with advanced user management, broad documentation features, stores up to 100 products, media and methods and stores the last ten test protocols.

Automated evaporation cover

The evaporation cover automatically closes unused vessel rack rows to reduce media evaporation.

low-through heater guarantees a
range of 30° to 50° celsius with an

RRT 10

Highlights

The ERWEKA RRT 10 is available with eight vessel racks, six (or seven) test stations and two reference positions. It is offered with a wide range of vessel versions and provides the flexibility to use 50 ml, 100 ml, 300 ml (standard) and 1000 ml vessels.

An automatically running transport and a quick coupling on the tools allow for a fast exchange of samples. Together with additional features as the PT 100 temperature sensor and the USP printer and LAN interface, the RRT 10 thus is a comprehensive package for USP method 3 and USP method 7 testing.



Highlights

- Automated multiple pH-change, e.g. for IV/IVC testing
- 8 vessel racks
- Portable touch display with intuitive operation
- Simple and quick switch from USP method 3 to USP method 7
- Easy testing of enteric coated formulations
- Suitable for different vessel sizes:
50 ml, 100 ml, 300 ml (standard), 1000 ml
- Two reference positions for each row with 6 (or 7) test stations
- Quick coupling for fast exchange of sample tools
- Reduced evaporation losses due to automated covering system
- Filter for glass reciprocating cylinders with different available mesh screens
- Water bath with clear acrylic glass and outlet valve for easy draining and cleaning
- Formulation holder made of inert material, e.g. 316 stainless steel, Fluoropolymer coated
- USP 3 cylinders automatically centred inside vessels
- PT 100 temperature sensor for temperature checking
- USB printer and LAN interface
- External flow-through heater



Intuitive menu operation via Touch display



RRT 10 touch display

During the development of the ERWEKA RRT 10 touch display we focused on the features which users find most important: Easy and fast creation of methods, quick launching of tests and documentation of test runs. The intuitive portable colour-touch display enables easy operation of all functions.

Safe working with extensive feature set and large storage capacity

The RRT 10 provides a password protected access to the firmware with OQ functions and product memory. The unit is equipped with a memory capacity that allows the user to store up to 100 different methods/media/products as well as to access the latest ten test protocols, which can be documented by printing out the data using the USB or LAN interface. Comprehensive integrated calibration functions guarantee accurate results and document each calibration process: High convenience combined with a broad feature set.

Touch display benefits

- Intuitive navigation due to a user-friendly menu structure
- Memory for saving up to 100 methods, media and products each
- Support for currently up to 20 users (in future: 50 users)
- Automatic storing of the 10 latest test protocols
- OQ functions
- Extensive calibration and adjustment capabilities
- 6.5" touch display
- USB A and LAN printer interface



Different sizes of spring holders and other methods available for USP 7

RRT 10

Customizable to your needs

The ERWEKA RRT 10 is available in three configurations: As a standalone device for either USP 3 or USP 7 or as an adjustable combination device for USP 3 and USP 7. Additionally, several options for vessels and tools are available.

The three different configurations

| | USP 3 | USP 7 | USP 3 & USP 7 |
|------------------------|---|--|--|
| Height of stroke | 100 mm | 20 mm | 100 mm & 20 mm (changeable) |
| Vessel types | 300 ml & 1000 ml for reciprocating cylinder | 50 ml, 100 ml, 300 ml, 1000 ml for different types of tools, see next page | 50 ml, 100 ml, 300 ml, 1000 ml for different types of tools, see next page |
| User changeable method | - | - | ✓ |

Options

- + 4 racks with 3 test stations each for 1000 ml vessels (USP 3)
- + 8 racks for 6 test stations for 50 - 300 ml vessels (+ 2 reference positions)
- + 8 racks for 7 test stations for 50 - 300 ml vessels
- + Different vessel sizes: 50 ml, 100 ml, 300 ml, 1000 ml
- + Evaporation covers for different vessels
- + Vessel 50 ml for Nifedipine, amber glass & adaption ring for 300 ml rack
- + Several sample holders (see table on right) for both methods
- + IQ/OQ documents



300 ml vessel with vessel holder



300 ml vessel with vessel holder



1000 ml vessel with vessel holder

Tools and vessels for USP/EP 3 and 7

We offer different kinds of tools and vessels. Not all tools and vessels work for both dissolution methods. Here is an overview for all recommended tool/vessel combinations.

| Formulation adaptor | 50 ml | 100 ml | 300 ml | 1000 ml |
|---|------------------------|--------|--------|---------|
| USP/EP 3 | | | | |
| Reciprocating Cylinder | - | - | ✓ | ✓ |
| USP/EP 7 | | | | |
| Spring Holder 0.60 inch, Ø 6.35 x 15.2 mm 0.96 inch, Ø 8.38 x 24.4 mm 1.40 inch, Ø 7.87 x 35.6 mm 1.45 inch, Ø 14.7 x 36.8 mm | ✓ | ✓ | ✓ | ✓ |
| Acrylic Rod Ø 3.175 mm | ✓ | ✓ | ✓ | ✓ |
| Cylinder Transdermal Holder Ø 34.9 x 92 mm | - | - | ✓ | ✓ |
| Reciprocating Disc 1.6 cm ² , Ø 14.3 mm | ✓ | ✓ | ✓ | ✓ |
| Reciprocating Disc 2.5 cm ² , Ø 17.8 mm | ✓ (Nife- dipine) | ✓ | ✓ | ✓ |
| Reciprocating Disc 5.0 cm ² , Ø 26.9 mm | - | - | ✓ | ✓ |
| Reciprocating Disc 7.0 cm ² , Ø 31.75 mm | - | - | ✓ | ✓ |
| Reciprocating Disc 10 cm ² , Ø 50.3 mm | - | - | - | ✓ |
| Angled Disc 1.42 inch, Ø 36.1 mm | - | - | ✓ | ✓ |
| Angled Disc 1.98 inch, Ø 50.3 mm | - | - | - | ✓ |



Reciprocating Discs



Cylinder Transdermal Holder



Acryl Rod

Technical data

| | |
|-----------------------------------|--|
| Test stations | 8 rows with 6 stations (standard configuration) and 2 vials for reference purposes or 7 test stations without reference positions |
| Water bath | Water bath of 30 litres volume, clear acrylic glass |
| Thermostat | Heating rate 1500 w, 30-50° C, accuracy +/- 0.2° C |
| Temperature control | External PT 100 temperature sensor |
| Test vessels (standard) | 300 ml USP-compliant cylindrical flat bottomed glass vessels (standard configuration) |
| Test cylinders (USP method 3) | USP-compliant glass reciprocating cylinders fitted with mesh screens of stainless steel or synthetic material (automated centring inside the vessel) |
| Formulation holder (USP method 7) | Whole range of USP-compliant holders for non-eroding formulations made of stainless steel or polytetrafluoroethylene |
| Speed | Speed adjustable from 5-40 strokes/min., accuracy better than +/- 5 % |
| Height of stroke | 100 mm (USP method 3) 20 mm (USP method 7) |
| Evaporation | Vessels protected by automated covering system |
| Control of the unit | Operation by color-touchscreen, password protected access to firmware with OQ functions and product memory |



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Product specifications are subject to change and are subject to change without notice. v.1.1.2.23

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