PTWS 820-MA

Media Addition Station for USP/EP PTWS 820D Tablet Dissolution Testing Instrument

The Pharma Test media addition station PTWS 820-MA together with the PTWS 820D tablet dissolution testing instrument can be used to perform the automated media half change for delayed release dosage forms. The operation is performing according to the requirements from USP <711>, EP <2.9.3> and CP <931> for delayed release dosage forms (in CP, enteric coated dosage forms). The test will start with 750ml of 0.1N HCl. After 2 hours, 250ml of concentrated, pre-heated buffer solution will be dosed quickly into the dissolution vessels. The pH will change to 6.8 and the dosage form should then start to dissolve.

PTWS 820-MA Media Addition Station together with the PTWS 820D

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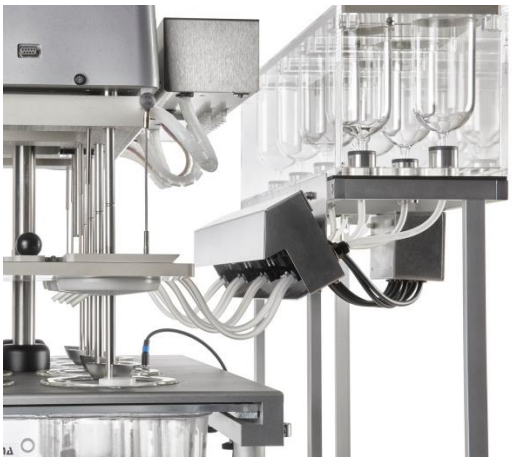
Current Challenges

The buffer change is usually done manually using cylinders with preheated buffer as USP, CP and EP recommends to perform the media change quickly. The main problems for the manual operation are:

- No simultaneous adding of buffer to all vessels possible
- Almost impossible to keep the temperature in the cylinders at 37°C
- The media adding is done in a non reproducible way and could differ from one vessel to the next
- An employee needs to wait 2h for the media change, needs to preheat the media and add the buffer to the vessels one by one.



Fully Compliant

Pharma Test has designed the automated media change station PTWS 820-MA which can preheat and dose 250ml of concentrated buffer very quickly and simultaneously to the vessels. A heated waterbath is used to preheat the concentrated buffer solutions. The correct temperature is important as the amount of liquid added to the vessel is about 250ml. It has to stay in the USP range of 37+/- 0.5°C. Therefor the added media should be heated up to 37 °C. This way the test can immediately continue as required by USP, CP and EP. It is also possible to operate the whole system over the ARGUS Dissolution Software.

Direct Delivery of the Additional Media Inside the Dissolution Tester

Advantages

» Very fast buffer adding (less than 30sec for 250ml). Corresponds to a pump flowrate of 500ml/min. According to USP <711> and EP 2.9.3 the test must be "proceeded immediately" after the 2h in 0,1N HCl. "all test times stated are observed within a tolerance of +/-2%".
» Includes an additional heating system which will preheat the buffer. The concentrated buffer (6x250ml) must be preheated to keep in the USP Tolerance of 37 +/-0.5°C
» No temperature change in the dissolution vessel as the preheated buffer will be transferred very quickly

Features

» Fully compliant with USP <711>, EP <2.9.3> and CP <931> recommendations for delayed release testing
» For automated operation of USP, EP and CP dissolution test for delayed release (CP enteric-coated preparations) dosage forms
» Unattended operation for the media change. Saves time. Customers can start the dissolution test in the evening. Not necessary to wait for the 2h.
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» Includes an additional heating system which will preheat the buffer. The concentrated buffer (6x250ml) must be preheated to keep in the USP Tolerance of 37 +/-0.5°C
  › No temperature change in the dissolution vessel as the preheated buffer will be transferred very quickly.
  › 6 vessels are simultaneously filled with the concentrated buffer. No time gap.
  » No Pumps are used or necessary
  » Gravity and a valve system are used for the fast media dosing
  » The valves will automatically open after 2h
  » The system can be operated by WinDiss ARGUS dissolution PC software

Standard Scope of Supply

The PTWS D620 comes ready to use with the following standard scope of supply:

- One set of stainless steel paddles
- One set of 1000ml Borosilicate glass vessels
- One set of depth adjustment balls
- One bottle of ALGEX water preservative
- Comprehensive documentation folder including:
  - User manual
  - DQ/QC instrument compliance test certificate
  - IQ documentation
  - OQ documentation
  - Instrument logbook
  - Compliance certificates for vessels and stirring tools

Technical Specifications

Parameter	Specification
Number Vessels	8
Standard Vessels	250 milliliter USP/EP Borosilicate glass vessel, each individually coded
Vessel Covers	Ultra-low evaporation design (< 0.7% within 24h)
Heating System	Pump for water circulation and 1500W heater for fast heating up (230/240V units only)
Heater Range	25 - 45°C
Heater Accuracy	± 0.2°C inside the water bath
Water Circulation	Water circulated from external heating system through special diffuser inside the water bath
Vibration Elimination	External heating system, spring loaded pump assembly
Instrument Dimensions	Bath: approx. 60cm x 25cm x 64cm (width x depth x height) Heater: approx. 26cm x 37cm x 21cm (width x depth x height)
Net Weight	Approx. 12kg waterbath, 5kg heater
Certification	All components certified to USP / EP requirements
CE / EMC Certification	All CE / EMC Certification provided
Validation	All IQ & OQ documents included

We reserve the right to make technical changes without any prior notice.