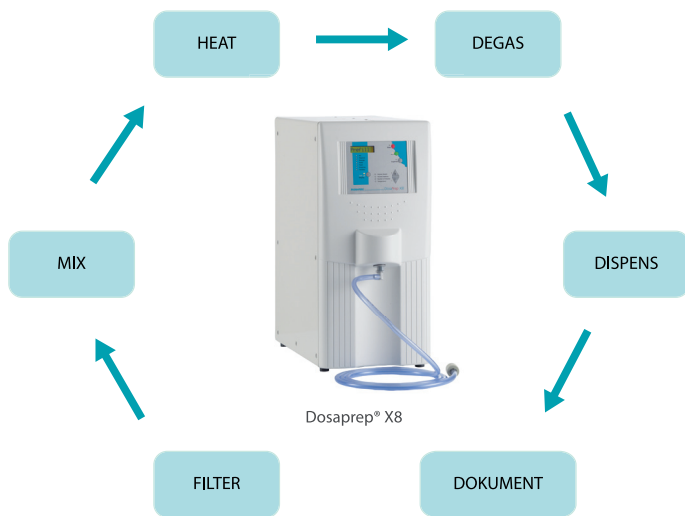


Automatic Media Preparation for Dissolution Test Systems



Media Preparation using Dosaprep X8



DosaPrep X8 allows for a volume of up to total 8.8 l to:

- filter the incoming water/media line.
- automatically prepare the media in the desired ratio of e.g. water and concentrated acid from two input lines, alternatively premixed media may be used.
- continuous stirring with a magnetic stirrer to achieve a homogeneous medium.
- increase the temperature to the desired value e.g. 37 °C;
- degas according to USP protocols.
- dispense precisely the required quantities.
- document the details of each preparation.

Dosaprep X8 has been designed for maximum accuracy and easy validation. It works in a batch mode.

Operation Details

Preparation of Media USP Conform

In document „Guidance for Industry, The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 ...“ CDER of January 2010 it is requested, that the medium should contain less than 60 % of the gas at ambient temperature. This requirement can be easily matched with Dosaprep X8 if the medium is heated.

Effective Deaeration

Deaeration is being carried out with the following measures:

- preheating;
- vacuum of lower than 200 mbar/hPa (absolute);
- continuous stirring;
- extra degassing time at the completion of
- the process may be chosen over a wide range

Accurate Preparation of Media

There are two inlet lines for medium e.g. water, and additive like concentrated hydrochloric acid or buffer. Both lines may be mixed in a wide range of concentration.

Alternatively also a ready prepared medium can be used.

Surfactant Capability

Can process dissolution media containing surfactants thus eliminating foaming.

Easy Filtering

A 20 µm filter is in the water/media line, and ensures that particles are being removed. This filter can be easily exchanged. The instrument has a built-in capacity control which requests an exchange if the maximum of the capacity is reached.

Precision Pondering Cell

The precision pondering cell is used for both an accurate mixing process and also for the dispensing the required quantities of the media. The measurement principle is gravimetric.

Continuous Stirring

The medium is continuously stirred with an electronic and non wearing stirring drive.

The stirring magnet is sealed and resistant against acid. This allows continuous mixing and ensures a homogeneous medium in respect to temperature, concentration and degassing.

Precise Heating

A special heater heats the media to the chosen temperature, which is constantly monitored and displayed. By this process the following is achieved: improvement of the degassing process, as an increase in temperature decreases the maximum level of solubility of gasses and also saves a lot of time as the media is preheated before being dispensed into the vessels of the dissolution testing equipment.

Wide Dispensing Range

User selectable volume settings allows to dispense volumes between 250 and 8000 ml. Typically it takes approx. 30 s to dispense 1000 ml.

Detailed Documentation

All important steps of the media preparation are being documented and can be either printed on an external printer or sent to a PC.

Safety for the laboratory personnel

The extra risk at regular work with concentrated acid is being reduced to a minimum, as the only required activity is to occasionally replace the storage container. This greatly improves safety for the laboratory personnel.

Cost and Time Saving

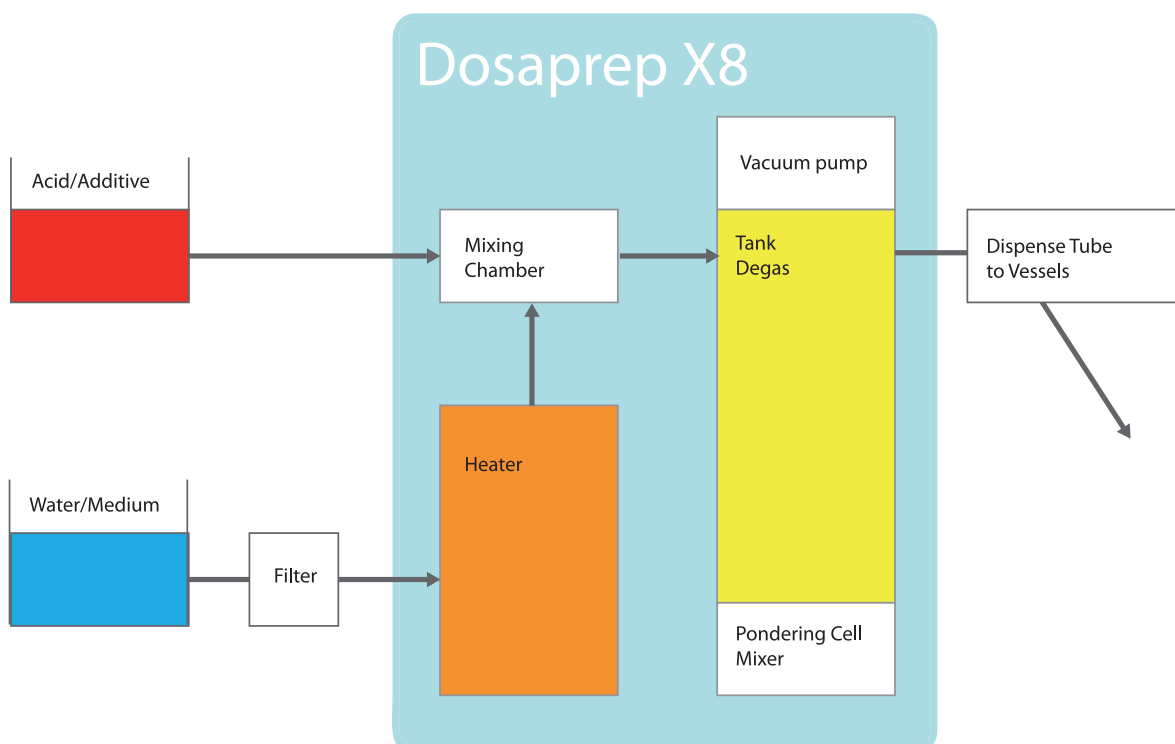
Rather than a tedious and manual media preparation all important steps are carried out fully automatically. Just push the "Start" button, and the instrument will take all necessary steps to prepare the media as required. The media can be dispensed directly into the vessel, any further handling is unnecessary. Therefore it is easy to make a dissolution test while new media is being prepared. This saves time for the laboratory personnel.

Preparation of 8 ltrs media is approx. 15 min.

Extensive Standard Accessories

Everything to start immediately is included: all tubings for the inlet including filter cartridge, tubing to dispense directly into the vessels including special frit and a dispense holder. The documentation includes operator`s manual, validation protocol, installation protocol and technical manual.

Schematic



Dosaprep X8

Instrument for automatic media preparation
 230 V, order no. 71-0010
 115 V, order no. 71-0020
 100 V, order no. 71-0030

Useful Accessories

Remote Control Outlet
 order no. 71-1030

Balance for automatic calibration (no foto)
 order no. 71-1060

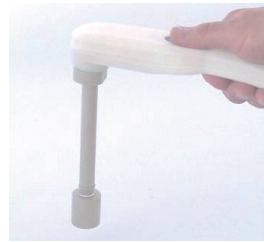
Vessel Carrier for up to 8 vessels
 order no. 71-1020

Water Connector, reduces water pressure from regular line water
 order no. 71-1010

Printer 40Z including Interface cable (no foto)
 order no. 71-1050

Storage Tank for up to 60 l of ready prepared medium
 order no. 71-1080

PC Software for external control, method storage, data storage
 order no. 71-1040



Remote Control Outlet



Vessel Carrier



Storage Tank for up to 60 l



Water Connector

Specifications

Dispense volume	250 – 8000 ml
Useable Storage Tank Volume	9000 ml
Heating	increase of max. 20 ° above room temperature
Temperature Accuracy	+/- 2 °
Liquid Input A (Media)	Water or ready-made media, maximum 1% acid concentration
Filter for Line A	Cartridge filter 20 µm
Liquid Input B (Additive)	additive like acid or buffer; acid concentration up to 36% hypochloric acid
Dispensing accuracy	better than +/- 5 g
Mixer	magnetic stirrer, electronically driven
Printer output	Centronics
PC control	RS232
Remote control input	For remote control outlet
Dimensions and weight	L x W x H: 61 x 30 x 65 cm, instrument including accessories 28 kg
Power Supply	230 V 2400 W, 50/60 Hz, or: 115 V 50/60 Hz, or: 100 V 1800 W, 50/60 Hz

Distributor

