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ISO 9001:2015

RIGGTEK
Dissolution Test Systems

DissoPrep X8™/DissoPrep X15™
Dissolution Media Preparation and Delivery Station
EFFICIENT · REPRODUCIBLE · SAFE · COMPLIANT

SPECIFICATIONS *

UNIT	DissoPrep X8	DissoPrep X15
DIMENSIONS	B 30cm x H 65cm x T 60cm	B 30cm x H 65cm x T 60cm
WEIGHT	26kg net weight	28kg net weight
VOLTAGE SUPPLY AND POWER RATING	230V, 50/60Hz, 1.85kW, 115V, 50/60Hz, 1.85kW, 100V, 50/60Hz, 1.5kW	230V, 50/60Hz, 1.85kW, 115V, 50/60Hz, 1.85kW, 100V, 50/60Hz, 1.5kW
PC INTERFACES	PC Interface RS-232 (serial): COM1 and COM2; LAN Included: Browser Interface (21 CFR Part 11 compliant)	PC Interface RS-232 (serial): COM1 and COM2; LAN Included: Browser Interface (21 CFR Part 11 compliant)
PRINTER INTERFACE	Centronics (LPT parallel), USB, LAN PCL-5 and PCL-6, ASCII font	Centronics (LPT parallel), USB, LAN PCL-5 and PCL-6, ASCII font
OUTPUT CHANNEL	1 dispense output Optional: Remote Control Nozzle	1 dispense output Optional: Remote Control Nozzle
INPUT FILTER	PP Cartridge Filter 20μ	PP Cartridge Filter 20μ
INPUT CHANNELS	2 Inputs (water/premixed media line, additive line); Input pressure max. 0.1 bar)	2 Inputs (water/premixed media line, additive line); Input pressure max. 0.1 bar)
MAX. ACID CONCENTRATION	12N acid at the additive input line, 0.5% acid at the medium input/output line (~0,1N)	12N acid at the additive input line, 0.5% acid at the medium input/output line (~0,1N)
DOSING PRINCIPLE	Gravimetric	Gravimetric
CALIBRATION	Manual/Automated calibration capabilities with Protocol consolidation of the calibration instruments	Manual/Automated calibration capabilities with Protocol consolidation of the calibration instruments
STORAGE VOLUME	8,000g net, apportionable from 1 - 36 vessels, 11,000g gross	15,000g net, apportionable from 1 - 72 vessels, 16,000g gross
PREFILL VOLUME	1,500g (necessary for prefilling the tank)	1,800g (necessary for prefilling the tank)
PREHEATING	till 45 °C (setting in 0.1 °C digits) max. 25 °C temperature difference	till 45 °C (setting in 0,1 °C digits) max. 25 °C temperature difference
TEMPERATURE ACCURACY	<1.5°C at 32°C to 37°C and >5,000g, monitored	<1.5°C at 32°C to 37°C and >5,000g, monitored
MIXING UNIT	Magnetic Stirrer, functionally monitored	Magnetic Stirrer, functionally monitored
ADDITIVE MIXING	1:3 - 1:100 (33% to 1%) (setting in 0.1g digits) Max. 1,000g Additive per vessel	1:3 - 1:100 (33% to 1%) (setting in 0.1g digits) Max. 1000g Additive per vessel
MIXING ACCURACY	<0.5% of ratio 1:3 - 1:100, typ. 0.2%, monitored	<0.5% of ratio 1:3 - 1:100, typ. 0.2%, monitored
DEGASSING	Vacuum typ. <100mbar pressure absolute, monitored <5.5 ppm, typ. 3.5 - 4.5 ppm	Vacuum typ. <100mbar pressure absolute, monitored <5.5 ppm, typ. 3.5 - 4.5 ppm
THROUGHPUT	24 - 32 l/h	26 - 35 l/h
DOSING RATE	2,000mL/min	2,000mL/min
DOSING VOLUME	100g - 8,000g (setting in 1g digits)	100g - 15,000g (setting in 1g digits)
DOSING ACCURACY	<1% at 500 - 8,000g, typ. 2g, monitored	<1% at 500 - 15,000g, typ. 3g, monitored
AUTOWASH	volume and number of cycles selectable 1 cycle, 3,000g, typ. 13 - 14 min	volume and number of cycles selectable 1 cycle, 3,000g, typ. 13 - 14 min

* specification subject to change without notice

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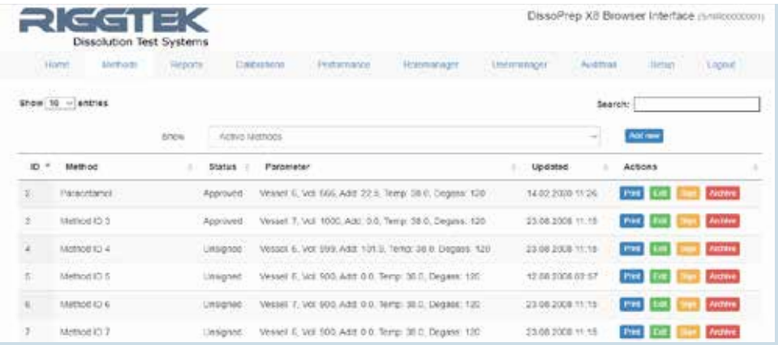
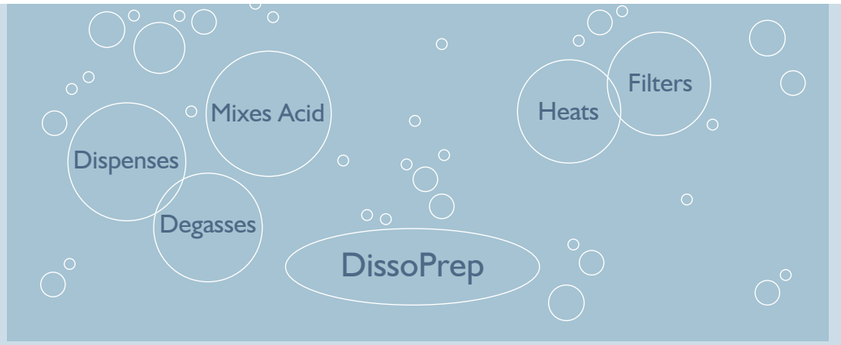
USP
EP
FDA, GLP/GMP





DEAERATION – THE PRINCIPLES

The effects of air bubbles and other dissolved gases in the media used to conduct dissolution tests can be significant. A Design of Experiment (DOE) study reported by USP in 2007 (Joseph Eaton et al. „Perturbation Study of Dissolution Apparatus Variables – A Design of Experiment Approach“, Dissolution Technologies February 2007 Volume 14 Issue 1) found that of the 9 variables and 36 two-factor variables studied, three variables stood out as being statistically significant as far as average percent dissolved was concerned: level of deaeration, vessel type and rotation speed, with the level of deaeration contributing to 52.3% of the total reported effects. The major influence of gas or air in dissolution work seems to be physical. Air bubbles may collect on the dosage form, the basket containing the dosage form or the sampling probe or the filters used to draw off samples for analysis. Their presence in spectrophotometer flow cells or on fibre optic probes may lead to incorrect absorbance readings. They may also accumulate on the membranes employed in the vertical diffusion cells used in transdermal and percutaneous absorption tests.

THE REGULATIONS

The Pharmacopoeias recognise that „dissolved gases in the dissolution medium may affect dissolution test results and recommends that gases be removed before the test is performed“. They advocate the following procedure as one method of deaeration: „Heat the medium, while stirring gently, to about 41°C, immediately filter under vacuum using a filter having a porosity of 0.45 microns or less, with vigorous stirring and continue stirring under vacuum for about 5 minutes“. This „filtering, warming and stirring under vacuum“ approach is echoed by the FDA (Terry W. Moore. „A Fast, Efficient Procedure for Degassing Dissolution Medium“ Dissolution Technologies. May 1996). The Pharmacopeias also state „Place the stated volume of the Dissolution Medium (+/- 1%) in the vessel of the specified apparatus given in the individual monograph, assemble the apparatus, equilibrate the Dissolution Medium to 37 +/- 0.5°C, and remove the thermometer“.

The temperature of the medium is critical to volumetric precision. The volume of the dissolution medium at the stated temperature of 25°C is different for that at 37°C, at which point the volume would be greater because the medium expands as the temperature rises.
It is for this reason that USP suggests that a more accurate and temperature independent measure of the media volume is gravimetric i.e., by weight.

USER REQUIREMENTS

In addition to conformity to the compendial and regulatory requirements, there are a number of user requirements which must be taken into account:

- Simple, safe and easy-to-use operation
- Proven time savings in comparison with manual methods
- Compact (space saving)
- Accurate and reproducible
- Capable of validation
- Documentation

The „DissoPrep“ Media Preparation Station combines degassing and dispensing to provide a fresh source of prewarmed, deaerated and dosed dissolution medium thus substantially reducing down times between dissolution tests. There is no necessity to premix the dissolution medium in advance. The „DissoPrep“ automatically adds the appropriate volume of acid, buffer or surfactant to the prewarmed medium prior to mixing and dispensing.

PRINCIPLE OF OPERATION

The principle of operation is extremely simple. The „DissoPrep“ operates on the same „filtering, warming and stirring under vacuum“ approach as recommended by the Pharmacopoeias and FDA. On initiation, dissolution medium is withdrawn under vacuum from the media reservoir (not provided) through the heater which warms the medium to the desired temperature and into the polypropylene mixing chamber. An easily exchangeable filter cartridge located in-line within the fill tube filters the medium prior to use. The life of the filter is constantly monitored in terms of total elapsed volume filtered and the user is prompted to change the filter when required. The default setting is 5,000 litres.

The medium is preheated to the appropriate temperature (adjustable between 20 and 45°C in 0.1 increments) en route to the mixing chamber by means of a special continuous-flow heater, before degassing takes place. This enhances the degassing process and saves considerable time in testing.

If the „Additive“ function has been selected, then the concentrated acid, buffer or surfactant is automatically added to the mixing chamber at this point. Dilution ratios of between 1:3 and 1:100 can be accommodated. An in-built magnetic stirrer ensures a homogenous mix within the mixing chamber (Accuracy: <0.5%, typically <0.2%).
The efficiency of the degassing process is dependent on:

- the vacuum applied, in this case, <250 mbar (typically <100 mbar) pressure absolute
- the time the medium is exposed to the vacuum
- the temperature of the medium
- the stirring of the medium

All of these factors assist in the deaeration process. In case of the „DissoPrep“, the interaction of heating, mixing and degassing generates a typical effective deaeration level of 3 to 4.5 ppm dissolved oxygen (measured after filling into the vessel).

The mixing chamber has a maximum total capacity of 11 litres (DPX8) or 16 litres (DPX15). This allows for 8 litres (DPX8) or 15 litres (DPX15) of fresh medium sufficient to fill all the vessels of one or two dissolution bathes, plus additional litres to accommodate the dead volume created by the tubes, etc., and also provide a flush sequence at the start of the dispense cycle.
Note: The importance of fresh medium cannot be overestimated. An investigation into the overnight reaeration of unused previously deaerated media found that the concentrations of dissolved oxygen almost doubled during the period concerned (Owen S. Degenhardt et al. „Comparison of the Effectiveness of Various Deaeration Techniques“. Dissolution Technologies. February 2004). The prewarmed and deaerated medium is dispensed directly into the dissolution vessels by means of a hand-held dispense nozzle (Dispense rate: 2L/min and Accuracy <1%).

Thus, a single „DissoPrep“ could possibly service all of your Dissolution and Disintegration Testing needs.

THE „DISSOPREP“

It typically takes 15 minutes from start to prepare 8 litres of medium and about 30 seconds per vessel to dispense. This means that a single „DissoPrep“ will handle several dissolution testers concurrently. Accuracy is paramount in any drug release study. One of the unique features of the „DissoPrep“ is that both fill and dispense volumes employed are determined gravimetrically, i.e. by weight using the in-built load cell provided for this purpose. Different media have different volumes dependent on their temperature and pressure conditions – only weight remains constant under such changing conditions. The use of a load cell means that all the processes involved can be documented and output to an external printer or PC. The „DissoPrep“ provides a full report detailing, weights, mixing ratios, vacuum and temperature after each „Dispense“ Cycle. Separate functions are available for Emptying, Autowashing and Calibration. A „Calibration“ report is also provided from the „Dissoprep“. Dissolution methods, reports and administration can be done via PC by the „Browser Interface“, without any software installation, optional with 21 CFR Part 11 compliance and data integrity rules.
The „DissoPrep“ is extremely compact, it measures 30 x 59 x 66 cm (w x d x h) and weighs 26 kilos (DPX8) or 28 kilos (DPX15).