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ISO 9001:2015

RIGGTEK
Dissolution Test Systems

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SPECIFICATIONS *

DIMENSIONS	B 30cm x H 55cm x D 58cm
WEIGHT	23kg tare weight (28 kg packing included)
VOLTAGE SUPPLY AND POWER RATING	90 - 250 V 50/60 Hz, 250 W
ENVIRONMENTAL CONDITIONS	15 - 40°C, less 95% humidity
INTERFACES	USB, LAN, RS-232, RS-485, Contact Closure (WAGO)
INTERNAL METHOD STORAGE	> 100.000 methods
TEST TUBE AND VIAL CAPACITY	HPLC vials 2mL (max. OD 12mm, max H 35mm),
	test tubes 10mL (max. OD 14mm, max H 100mm)
RACKS	Test Tube Racks and Vial Racks with 10 rows and 8 lines,
	Optional: 12 rows and 8 lines
	1 additional row for Waste with Test Tubes, material: POM
RACK CHANGE	possible during running method
PUMP STROKE	180µL
PUMP FLOW RATE	1 - 20 mL/min (limited by used ID of tubings:
	1.0 or 1.2 mm version available, 15 & 20 mL optional)
VOLUMETRIC PRECISION	≤ 0.25 mL, typical 0.1mL, limited by used filters and media
SAMPLE VOLUME	0.5 - 8 mL (10 mL optional)
CROSS CONTAMINATION	<1 % at 2 min sampling interval
SAMPLE INTERVAL TIME	2min - 999h (limited on selected flow rates and volumes)
	timepoint accuracy 0.5%
REMOTE CONTROL SOFTWARE	no installation required, control via Browser Interface
TUBINGS VOLUME	without pumps, internal tubings, sampling needles and filters,
	the volumes are:
	Low Flow Tubing Kit with 1.0 mm ID: 1.57mL
	High Flow Tubing Kit with 1.2 mm ID: 2.26mL
	(all volumes without Transfer Module)
INTERNAL VOLUME	pumps, needles and internal tubings volumes are: 0.5mL
TUBING TYPE	PTFE, 1/16" OD with bend protection
TRANSFER OPTION	Option to transfer samples to UV or HPLC with an internal
	Transfer Module (triggering from UV or HPLC possible)
	Option to replace media in the vessel
PATENT-NO.	US 8,899,101 / DE 16.102011 008024 / JP 5662189

* specification subject to change without notice

SAMPILIO X8™

Dissolution Autosampler

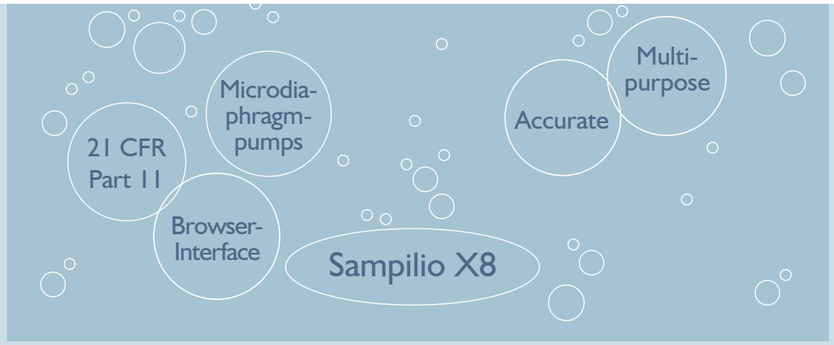
EFFICIENT · ACCURATE · RELIABLE · MULTIPURPOSE

SAMPILIO X8

Dissolution Autosampler

EFFICIENT · ACCURATE · RELIABLE · MULTIPURPOSE

USP
EP
FDA, GLP/GMP



INTRODUCTION

Normally a sample collector comprises a peristaltic or syringe pump to provide the motive force to transport the sample from the dissolution tester to the collector, a PC and interface box to control the system during operation.

The principle of operation is simple - medium from each of the dissolution vessels is circulated via an 6- or 8-line peristaltic pump through 6 or 8 switching valves prior to being returned to the dissolution vessel.

At user-defined intervals the valves operate, diverting a preset volume of sample into the sample collection lines, whereupon the samples are dispensed into either test tubes or open HPLC vials (or injected directly into sealed septum vials by means of an electrically operated vial piercing head provided for that purpose).

The pump is then reversed to clear the sampling lines prior to the next sampling interval, whereupon the operation is repeated. The whole operation is controlled and monitored by an embedded system. The exact status of the test at any given time can be determined from the firmware.

In ase of test tubes, the samples must be handled manually, for example by presenting them to the „sipper“ accessory of a suitable spectrophotometer.

HPLC vials containing samples can be removed at any time and placed directly into an HPLC Autosampler.

This version is particularly useful where analytical techniques other than UV/Vis or HPLC are employed or where the samples require a degree of manipulation, for example, to be diluted or mixed with a reagent prior to analysis.

PRINCIPLE OF OPERATION

The „Sampilio X8“ is a new generation of „Off-Line“ Dissolution Sampling System specifically designed with a patented series of 6, 7 or 8 dedicated bidirectional small volume diaphragm pumps (one per line/vessel) to facilitate the flush-sample-purge functions.

As well as being extremely accurate (Volumetric Precision <0.25 mL, typically 0.1 mL), the bidirectional pumps have a number of advantages over the more conventional peristaltic or syringe pumps employed in such systems, namely:

- First In/First Out (FIFO) principle
- Low dead volume
- Eliminates need for media replacement
- Low cross contamination
- Short sampling interval times (2 min)
- Long life for years with no abrasion
- Wide range of applications, incl. use of organic solvents

The First In/First Out (FIFO) principle employed in the system is the same as that found in manual testing.

The low dead volumes employed in the system ensure that flush, sample and purge times are kept to a minimum whilst flush media recycling makes filter changer and media replacement obsolete and dissolution calculations simple. Cross contamination is <1% at 2 minute sampling intervals. The short interval time is particularly important when testing quick release formulations because it allows sampling at intervals which were unachievable by more conventional methods so far. The user interface is simple, functional and easy to use.

The standard unit is supplied with two collection racks, one to carry 2 mL HPLC vials and the other for 10 mL test tubes.

Each rack accommodates 10 rows of 8 lines and an additional row with test tubes for waste. With additional racks (optional) it is possible to increase up to 100 samples each line.

In order to eliminate any cross contamination, the standard sampling procedure is always flush-sample-purge, so that not sampled media is completely recycled.

The unique patented delivery system with individual bidirectional pumps offers a wide range of applications like staggered sampling, replace vessel media or transfer to UV, HPLC (option).

Methods, reports and administration can be done via PC with the Browser Interface.