



"Off-Line" Dissolution System comprising Dissolution Tester DIS 6000 and DissoFract Sampling System

AUTOMATION - THE DISSOFRACT

INTRODUCTION

The DissoFract is an "off-line" dissolution sampling system specifically designed to automatically remove samples from either six or eight dissolution vessels at predetermined time intervals and deposit them in test tubes or HPLC vials for subsequent analysis (see No.1. on Page 44).

The system employs a series of six or eight 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)

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 media replacement obsolete and dissolution calculations simple. Cross contamination is <1% at two minute sampling intervals.

The short interval time is particularly important when testing quick release formulations in so much that it allows sampling at intervals hitherto unachievable by more conventional methods.

The user interface is simple, functional and easy to use.

The unit is supplied as standard with two collection racks, one to accept 2 mL HPLC vials and the other 8 mL test tubes.

Each rack accommodates 10 rows of 8 lines and an additional row with test tubes for waste.

In order to eliminate any cross contamination, the standard sampling procedure is always *flush-sample-purge*.

The DissoFract has three main menus:

1. Start menu (the START button)
2. Method menu (the SET UP button)
3. Functions menu (the ENTER button)

1. START MENU

The Start menu is activated by pressing the START button.

This allows you to select and run a previously stored method.

The system first checks to ensure that the correct rack has been loaded into the collector to meet the method requirements.

It then checks to ensure that the sample lines are clear and initiates a purge if this is not the case.

The message now appears "start dissolution". The sampling process is initiated by pressing the START button.

During sampling, the number of the next step, the elapsed time and the remaining time to the next step are indicated on the display.

At the end of the sampling process, a message appears on the display to indicate that the method has been completed and the sampling protocol automatically stored and printed.

AUTOMATION - THE DISSOFRACT

2. METHOD MENU

The Method Menu is activated by pressing the SET UP button.

The Method entry comprises two parts - an initial part relating to the system parameters to be employed and a second part relating to the actual sampling procedure to be followed.

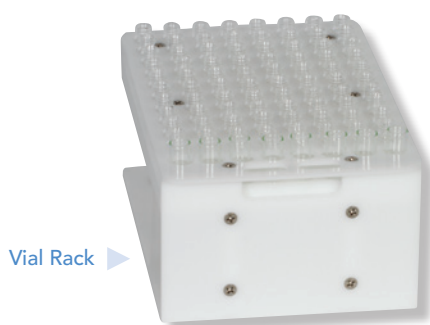
The **System Parameters** comprise as follows:

- *Rack Type*: Vials or Test Tubes
- *Lines*: No. of sample lines/vessels
- *Collection Flow Rate*: 1-15 mL/min
- *Flush Volume*: 1-8 mL
- *Purge Flow Rate*: 1-15 mL/min
- *Stagger Interval*: The required interval between lines when employing staggered starts (0-99 sec)
- *Double Sampling*: Samples into two rows at each step
- *UV/HPLC Transfer* (Option)
- *UV/HPLC Transfer Volume* (Option)
- *Rack Cooling/Heating Temperature*: (5-37 degrees C). Only available with Peltier option

Once the System Parameters have been entered correctly, the ENTER button is pressed in order to set up the **Sampling Procedure** required:

- *Step*: Selects the Step Number.
- *Time - Seconds*: Time in seconds
- *Time - Minutes*: Time in minutes
- *Time - Hours*: Time in Hours
Note: Maximum is 99:59:59
- *Collection Volume*:
Vials - 0.1 - 1.8 mL in 0.1 digits
Tubes - 0.5 - 8.0 mL in 0.5 digits

Press the START button.



3. FUNCTIONS MENU

The Functions Menu is activated by pressing the ENTER button.

This provides access to no less than eight separate sub-menus:

3.1 Print Menu

Used to print (a) Test (b) Performance and (c) Calibration Protocols as well as Method Data.

3.2 Purge

Empty all lines back to the vessels/backflush.

3.3 Flush

Perform a manual flush to flush out the system.

3.4 Single Sample

Perform a single sample.

3.5 Autowash

Regular cleaning procedure designed to keep the system in good working order.



▲ DissoFract open to illustrate sample needles and collection rack

3.6 Drying

Used in conjunction with the Peltier Rack Cooling/Heating option to reduce condensate following cooling.

3.7 Calibration Menu

Complete guidance on the IQ/OQ/PQ procedures required to validate and document your system.

3.8 System Menu

Allows you to set up your system parameters in order to meet your own individual needs. The DissoFract measures 30 x 58 x 35 cm (w x d x h) and weighs 23 kg.

◀ DissoFract Sampling System

Cat. No. Description

1325	Set of 6 Resident Probes with Omnifit fitting
1326	DissoFract 6-Line Sampling System
1327	Additional Lines incl. Resident Probe - max. 8 (each)
1513	Pack (of 50) 45 Micron Filters for special probes
1328	HPLC Vial Rack (spare)
1511	Test Tube Rack (spare)
1330	Printer (including USB cable)
1319	Validation Logbook
1512	Validation Tools