Dissolution Automation: Basic Questionnaire.

In order to quote the most suitable automated Dissolution System we would like you to answer this questionnaire:

1. Do you want to work :

a) **On line** (on line is defined by a *closed loop* system with a spectrometer and multi-cell cuvette changer)

c) **Off line** (off line is defined as working with a PTFC 2/12 fraction collector either with a peristaltic, syringe pump or piston pump - Sampling only)

d) **Off line including Sample Dilution** (is defined as working with a DSR Sampling Robot or ASP 2000 Auto Sampler for direct online Dilution and/or dispensing into sealed Vials)

e) **Both or Hybrid System** (is defined as an on line and off line: possible using PTFC 2 Fraction Collector and a Photometer with multi-cell changer)

f) **HPLC** injection (requires auto sampler ASP2000 and injection system - communicates with HPLC for sample injection - data evaluation done by HPLC System software

g) **HPLC** fully control system (requires auto sampler and injection system - communicates with HPLC system for sample injection and data transfer from integrator to WinDiss32 software. Reporting supplied by WinDiss32-V3 Dissolution program)

h) **In-Situ** using Fiber Optics (does not need any pump or tubing - can measure each 15 seconds all 8 vessels, uses PDA Diode Array UV/VIS Photometer wavelength range either 200-6000 nm or 200-1000 nm)

Answer: **a** ( ) **b** ( ) **c** ( ) **d** ( ) **e** ( ) **g** ( ) **h** ( )

2. UV/VIS spectrophotometer

If you want to work “on line - closed loop”, then which spectrometer do you wish to use? We recommend the use of a Diode Array Photometer such as the SA500 (full system responsibility from one supplier only)

Answer: …… (Spectrometer brand and type).
Cell changer exists ? **Yes** ( ) **No** ( )
if yes how many channels ? **6** ( ) **7** ( ) **8** ( ) **16** ( )

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2a. Flow cells

If you need **flow cells** for the spectrometer changer, do you have a preference?

a) STARNA Optiglas, or
b) Hellma QS
c) which path length do you require ?
0.1mm ( ) 0.5 mm ( ) 1.0 mm ( ) 5.0 mm ( ) 10 mm ( ) 20 mm ( ) or other_____

Answer: a ( ) **b** ( )

3. HPLC injection:

If you want to inject samples on-line into a HPLC system, then which system do you wish to use?

Answer:

Isocratic Pump Type: ……

Detector Type: ……

Software Suite and Version:……..

(pls. tell us brand and type - manufacturing year).

4. Sampling Method

In terms of sampling, we have either ***in situ*** (sample probe remains always inside the media) or an **Automatic manifold (EPE)** which enters the solution with sampling probes only when the actual sampling is required. Do you have a preference? (This can affect the model type offered)

a) ***In situ*** - (always in media sample probes) available for PT-DT7/70, DT8, PTWS100, or
b) **Auto Sampling System - EPE** (only available for PTWS300/310, PTWS600/610, PTWS 1200/1210)

Answer: a ( ) **b** ( )

5. Filtration

We have a choice of **primary filters** which are either 10 micron or 5 micron; which type is best suited?

a) 10 micron, or
b) 5 micron.
c) other, like 0.45 micron

Answer: a ( ) **b** ( ) **c** ( )

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Do you need any further filtering down to say 0.45 microns as your product changes colour of the dissolution media ?

Answer: Yes ( ) **No** ( )

6. Dilution

You may do Dilution at present when sampling manually and measuring the concentration in a UV/VIS spectrophotometer using a 10 mm cuvette. Using a closed loop (on-line) dissolution system Dilution can be avoided using various flow-cell sizes offering different path-length. The range includes flow-cell path length from 0.1 mm, 0.2 mm, 0.5 mm - 1mm, 2mm, 5mm and 10 mm. Using a 1 mm flow cell instead of the 10mm cuvette you are using in your manual method offers a dilution factor of 1:10. Which one will you require ?

none ( ) **1:10** ( ) **1:20** ( ) **1:50** ( ) **1:100** ( )

Do you need to dilute the sample from the very first sampling or later ?

need to dilute all the time ( ) **need to dilute after ….. hrs.** ( )

7. Online Dilution

Besides the use a various path length cells its possible to Dilute the sample online if the DSR or ASP 2000 System is attached to the Dissolution Bath.

a) The DSR Sampling Robot can be connected directly to a PTA Dissolution Bath Type DT8, PTWS 310, a PTWS 600/610, or a PTWS 1200/1210. There is no need to use a PC or software, sampling information is programmed via the keypad of the Dissolution Bath. Its also possible to attach the DSR to any other make of Dissolution Bath and program all sampling information using the DSR keypad. Only online injection into a Spectrophotometer is possible.

http://www.pharma-test.de/en/products/p20_6.htm

b) The ASP2000 Auto Sampling System can be connected to any Dissolution Bath. The entire System will be controlled by the WinDiss32 Software. Samples can be diluted and injected online into a connected Spectrophotometer or even a HPLC System

http://www.pharma-test.de/en/products/p30_10.htm

Which system will you prefer ?

Answer: System a) ( ) **System b)** ( )

8. Absorbance problems

Do any of your active materials react with or are absorbed by polypropylene?

Answer: Yes ( ) **No.** ( ) (Filter material is PP)

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9. Which tubing material do you need ?

We supply **tubing for sample loops** PTFE. Do you need any other material, like FEP?

a) PTFE is fine
b) Need other: _____

Answer: a ( ) **b** ( )

10. Sample transportation (pumps)

For sample transportation, we can offer either a peristaltic pump or a piston pump. Within a closed loop system no media will be lost. The peristaltic pump is fine for *closed loop* (i.e., on line systems), but a piston pump is recommended for off line (Fraction collector) systems and auto samplers. This is because of the sure degradation with time of the peristaltic pump tubes which are under a lot of pressure during their working life. Fractions need to be accurately taken as they remove liquid from the dissolution vessels. Do you need :

a) peristaltic
b) piston pump.

Answer: a ( ) **b** ( )

11. Sampling only = off-line operation (PTFC 2 Fraction Collector)

If you are working off line, would you like simultaneous refilling of the fraction which has been removed from the dissolution vessel (applies to peristaltic pumps only). Do you need refilling?

http://www.pharma-test.de/en/products/p20_8.htm

a) Yes
b) No.

Answer: Yes ( ) **No** ( )

12. sampling and injection (Auto Sampler DSR and ASP 2000)

Would you require refilling of the fraction which has been removed from the dissolution vessel ?

Answer: Yes ( ) **No** ( )

Do you need to dilute the sample previous to injection ?

Answer: Yes ( ) **No** ( )

Which Dilution do you need: **1:10** ( ) **1:20** ( ) **1:50** ( ) **1:100** ( )

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13. Media Change while dissolution testing

Do you need to have **medium exchange** (applies to USP Apparatus 1 or 2 using Sinkers)?

a) Yes
b) No.

Answer: Yes ( ) **No** ( )

14. Dissolution Volume

Do you need to work with **larger dissolution volumes**? We are able to offer a variety of larger vessels, not only the standard 1 liter version. Do you need:

http://www.pharma-test.de/en/products/po10.htm

a) 1 liter
b) 2 liter
c) 4 to 5 liter versions

Answer: a ( ) **b** ( ) **c** ( )

15. Media Degassing and Filling

The use of degassed dissolution media is preferable, are you using a degassing system, which one ?

Remark:
- Helium has relatively high running costs
- Ultra Sonic is often insufficient as the volume you need to degas for a dissolution run is at least 6 ltr.
- Heating, vacuum and filtration is very time consuming

http://www.pharma-test.de/en/products/p10_11.htm

a) Helium
b) Ultra Sonic
c) Heating, vacuum and filtration (FDA recommended)
d) None

Answer: a ( ) **b** ( ) **c** ( ) **d** ( )

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