



Tablet Dissolution Data Management Software

automated Media Change and pH Monitoring in Dissolution Testing

The **IDIS EE** software from Icalis Data Systems Limited automates Media Addition and Media Removal using different media during the Dissolution experiment while simultaneously monitoring and displaying pH in each vessel.

This unique design allows the analyst to configure systems to automate adding Media accurately and precisely with accuracy better than $\pm 0.5\%$ and volumes between 0.1ml min^{-1} to 400ml min^{-1} . Multiple media can be added either by **Discrete Addition** where the media is added as quickly as possible or by **Gradient Addition** where media is added slowly over a time period.

In either case the IDIS EE software performs calculations automatically based on different volumes at specific times and changes in wavelength when Media is changed.

pH can be monitored in a single Vessel or monitored in each Vessel throughout the test.

- Variable volumes and Multiple Media addition throughout the experiment.
- Media removal with priming and Tubing Dead Volume compensation.
- %Dissolved Calculations based on different Volumes.
- Multiple Media selection using the Icalis MSV300 Media Selector.
- pH data for all Samples displayed numerically and graphically in real time.
- For HPLC analysis, samples can be Collected, optionally Diluted and Injected using Icalis ASP2000 Autosampler.

Apparatus and Implementation

The apparatus for USP Methods I & II consist of a Bath, Pump, Spectrophotometer or Autosampler. Additionally, a pH Meter can be configured as part of the system.

The schematic below shows such a system for USP Methods I & II.

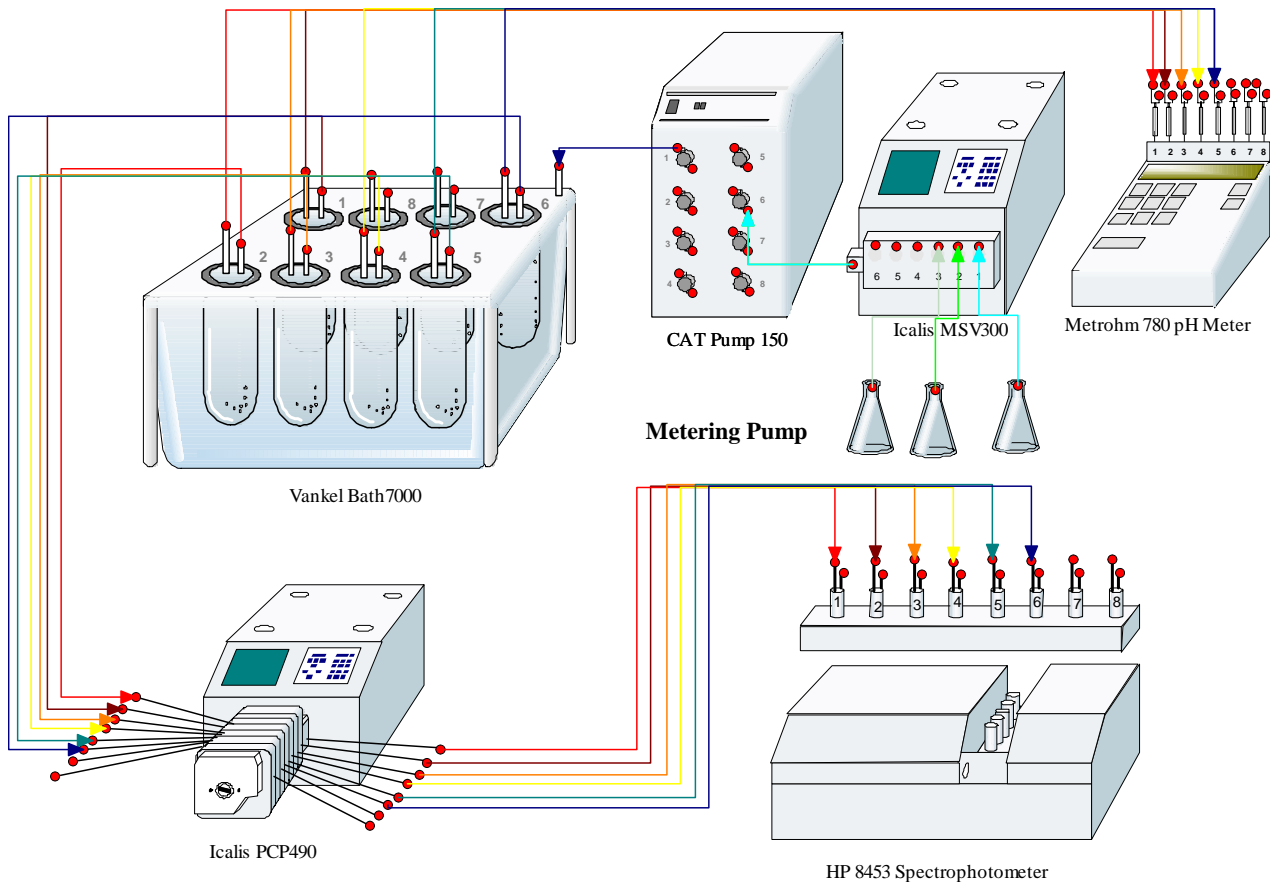


Figure 1. A Closed Loop Configuration with pH monitoring in each Vessel and automation of multiple media addition using the IDIS EE **Solution Path Technology™** instrument configuration.

The system depicted is a Closed Loop configuration. In this example, at the defined interval, a media selector gives the option to select which Media will be pumped via a metering pump to the dissolution vessels. At the specified sampling interval, samples are moved from the bath to the spectrophotometer via the sampling pump, samples and pH are measured and results are calculated and displayed in real time

Graphs can be displayed simultaneously for all data types (pH, Absorbance, %Dissolved etc) during and after the analysis is completed.

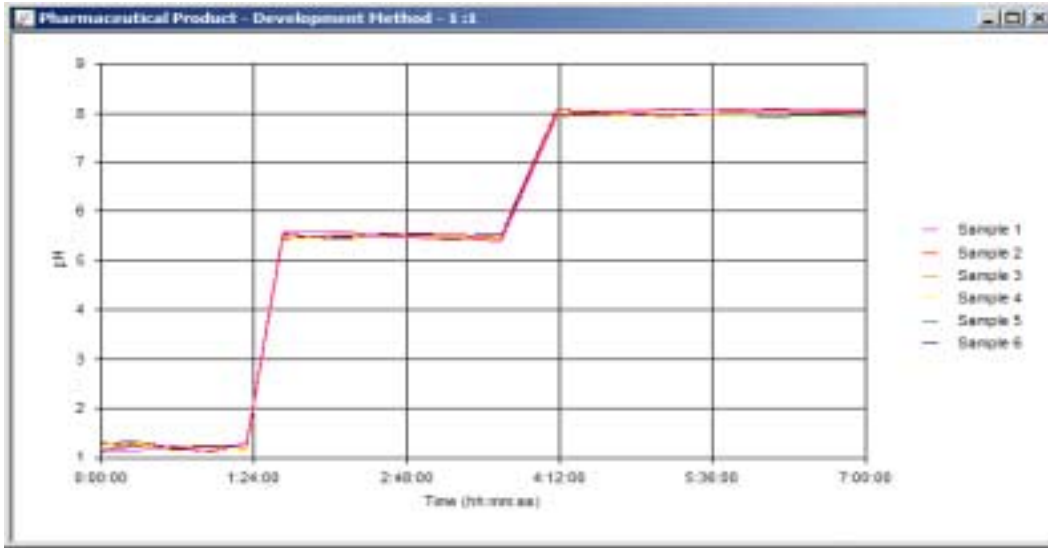


Figure 2. The Graph showing a pH profile obtained from monitoring the pH in a method with 3 Media Change.

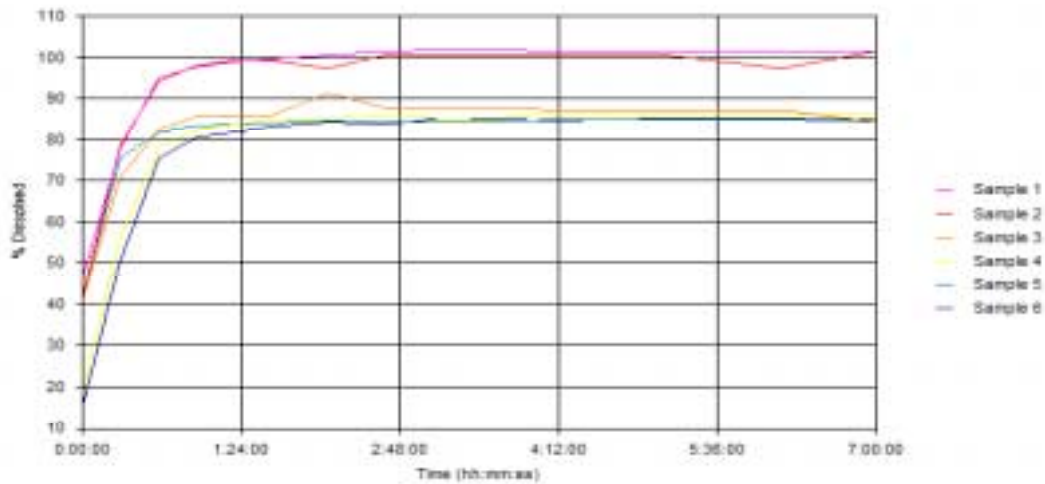


Figure 3. Corresponding % Dissolve Data Graph.