AUTOMATED LAB SYSTEMS

IDIS

*IDIS*is (IDIS Integrated Solution)

Laboratory Automation

Laboratory Automation

AUTOMATED LAB SYSTEMS

- *Unique solutions for Manual and Automated Testing for Dissolution, Content Uniformity, Dispensing, Sample Preparation, Environmental Analysis*
- *Unsurpassed performance with comprehensive data acquisition, calculations and reporting*
- *Systems using different makes of Spectrophotometer, HPLC and Tablet Dissolution Bath and ALS XYZ Sampler*
- *Multilingual dynamic language selection*
- *In depth implementation of FDA 21 cfr Part 11 for electronic records for greater compliance*
- *Stand-alone or Networked solutions*

Tablet Dissolution
Content Uniformity
Water and Environmental Analysis
Sample Preparation

AUTOMATED LAB SYSTEMS

Dissolution

Automated Lab Systems are accustomed to great things.

The first company to implement a Database for managing dissolution results, the first company to introduce Cell Grouping for product comparison and method development… now we have moved the goal post further…

- Automation using UV and HPLC on one system
- Automation of USP Methods 1 & 2, 3, 4 and 7 for Dissolution testing
- Media addition with pH titration for dissolution Testing
- Multilingual dynamic selection
- Advance data handling for profile overlay and trend analysis.

Whatever your requirements, we can meet a level of testing for both manual and automated operations for Product Development, Method Development, Quality Control and Environmental Analysis, Sample preparation and Dispensing.

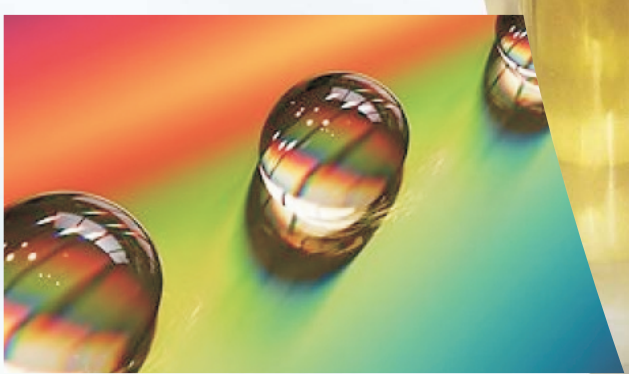
Very simple configuration for analysis of Tablet Dissolution, Content Uniformity, Sample Preparation, Environmental and Dispensing Applications.

Calculation of results in real time.

Easy automation of experiments with a higher level of integration than other systems thus delivering analytical results in faster times with reduction in labour costs for greater productivity.

Flexible solutions

- Open connectivity that links different Baths, Pumps, Valves, Spectrophotometers, HPLC and XYZ sampler from different manufacturers so you can select the instruments of choice
- A diverse range of configurations for different testing
- Delivers results on local workstations or to anywhere in the world instantly when networked so you can save time exporting and mailing and with easy access to test results.
- Work in your local language to reduce training and maximise communication.



Innovative systems that work for you...

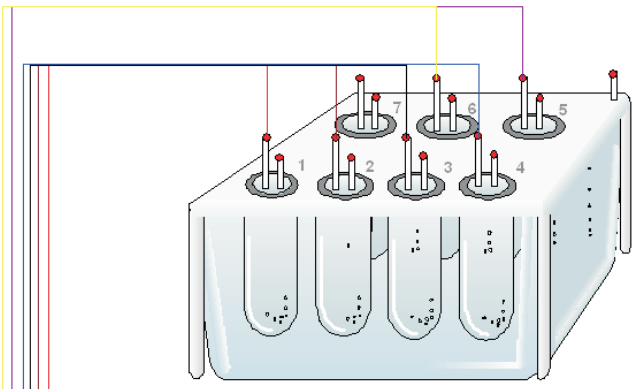
Closed Loop Tablet Dissolution Testing

Dissolution

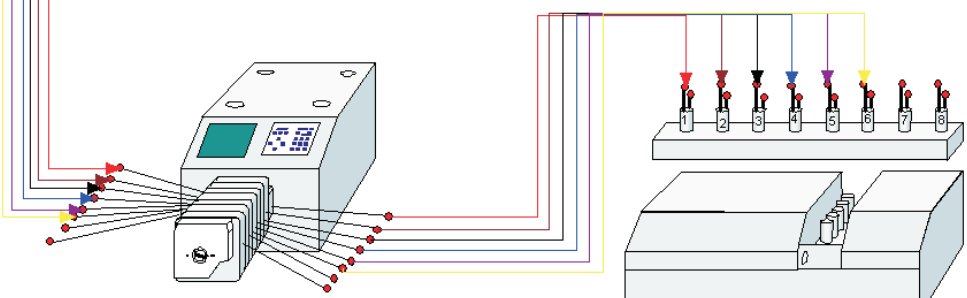
This application is used to automate testing of Tablets, Capsules and other solid dosage forms according to USP <711> Method 1 and 2 USP <711/724>, EP(European Pharmacopeia) 2.9.3/4> JP(Japanese Pharmacopeia) <6.10>.

Consists of a Dissolution Bath, Pump and Spectrophotometer and is controlled by our IDIS*is* software.

- At the time sampling interval, the sample in the Dissolution Bath is pumped into the flow cell of the spectrophotometer having an automated Cell Changer, usually 8 Positions. After Pumping, the sample in the Cell is measured individually and sequentially usually within a time of about 30 seconds. Time Intervals as low as 1 minute can be configured thus providing important information for fast dissolving tablets.
- Our application reduces labour costs as there is no manual sampling, increases testing throughput by controlling all instruments, reading the Absorbance, calculating and plotting the dissolution profile in real time.
- Bath RPM and Temperature are acquired and plotted numerically and graphically providing results of how samples are dissolving as the experiment proceeds.
- Unique open connectivity, controlling baths from ALS, Caleva, Copley, Distek, Electrolab, Erweka, Hanson, Pharmatest, Logan, Sotax and Varian (Vankel). This will allow you to select the bath of your choice.
- Intelligent software spectrophotometer drivers for from ALS, Agilent, Beckman, Biochrom, Cecil, Jena, Perkin Elmer, Shimadzu and Thermo (Unicam).
- Controls a variety of different pumps, Peristaltic, Syringe and Metering Pumps to obtain the best results.
- Control of valves for automating the sampling and measurement of multiple blanks and standards for further automation.



Bath 1

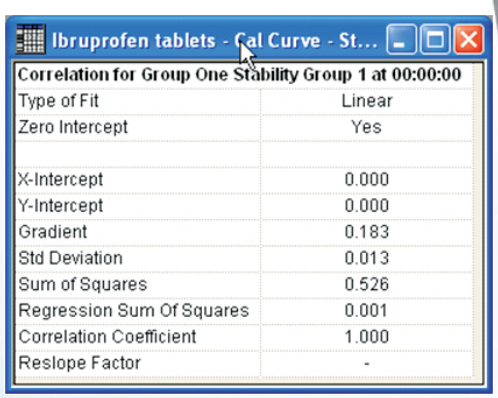


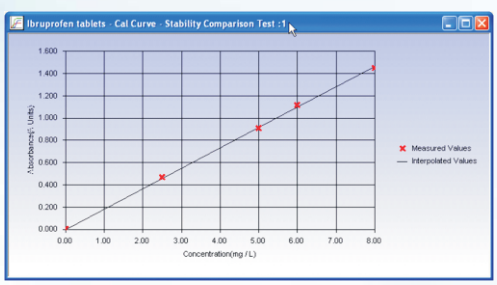
ALS Pump PCP490

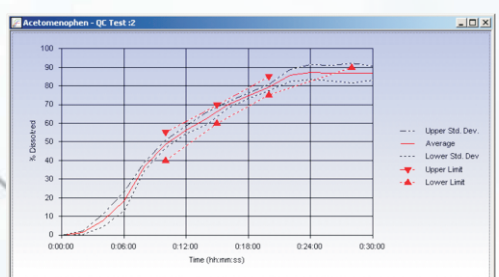
Spectrophotometer

Main Features

- Visual method representation using *Solution Path Technology*™ with definable Vessel names, colour and spectrophotometer reading position sallow identification of each sample
- Any sampling times from minutes to days allowing different tests
- Multiple Standards for System Suitability and Standard Checks with Bracketing and Calculation Standard configuration
- Cell Grouping for product comparison and method development
- pH Media Change with different volumes, wavelengths and Standard for each media for greater In-Vivo / In-Vitro correlation
- Calculations for Multicomponent Analysis using Fixed Wavelengths or Spectral Scanning and Savitsky-Golay Derivatives
- Placebo subtraction for greater accuracy by 2/3 Wavelength correction and unique application of Chemometric Target Factor Analysis
- Unique interactive cleaning sequence using different solvents and pumping times
- Multiple Bath to one spectrophotometer for return on investment.







Dissolution

When sample concentrations are too high to be measured directly or the samples need to be Prepared and to enhance detection…

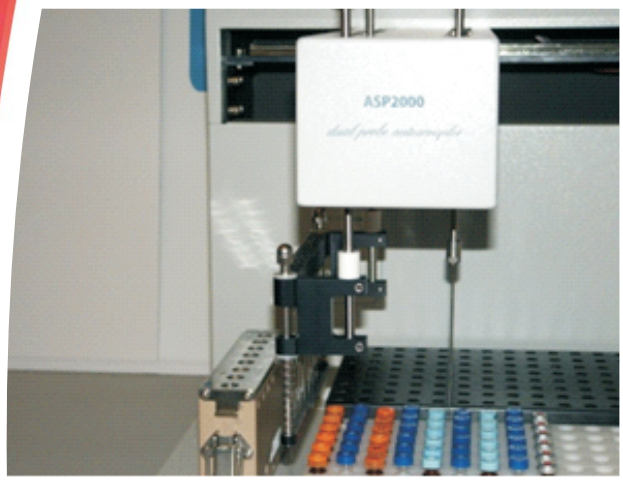
- The ASP2000 Workstation Collects Prepares and Measures the dissolution samples in real time to automate this very labour intensive task.
- Samples are filtered in the Bath and pumped to our ASP2000 XYZ Sampling probes.
- Collection in Tubes with typical volumes 5ml to 15ml but can be up to 50ml.
- Option to replace the media volume lost.

Main Features

- Visual method representation using ***Solution Path Technology***™ with definable Vessel names, colour and spectrophotometer reading positions with ASP2000
- Up to 30 intervals for collection and Dilution plus Blank and Standards
- Infinitely variable sampling intervals from as low as 2 minutes to hours
- Dilution ratio to 1 in 25 from single dilution to infinitely variable serial dilution ratios (over 1 in 1000)
- Automated Sample preparation with dilution and mixing, multiple Standards for System Suitability and Standard Checks with Bracketing and Calculation Standard configuration
- Sample Loss Replacement
- pH Media Change with different volumes, wavelengths and Standard for each media
- Calculations for Multicomponent Analysis using Fixed Wavelengths or Spectral Scanning and Derivatives
- Placebo subtraction by 2/3 Wavelength correction or unique application of Chemometric Target Factor Analysis
- Unique interactive cleaning sequence using different solvents and pumping times
- Multiple Baths can be configured

AUTOMATED LAB SYSTEMS

Dissolution



Collection into 2ml HPLC Vials or Test Tubes. The Vials can have a capped septum.

Collects Samples and injects onto the HPLC

An automated filter unit can be incorporated to provide filtration down to 0.45µ.

Intelligent communication to the HPLC to process samples

Acquires processed Peak data from HPLC for each injection in real time

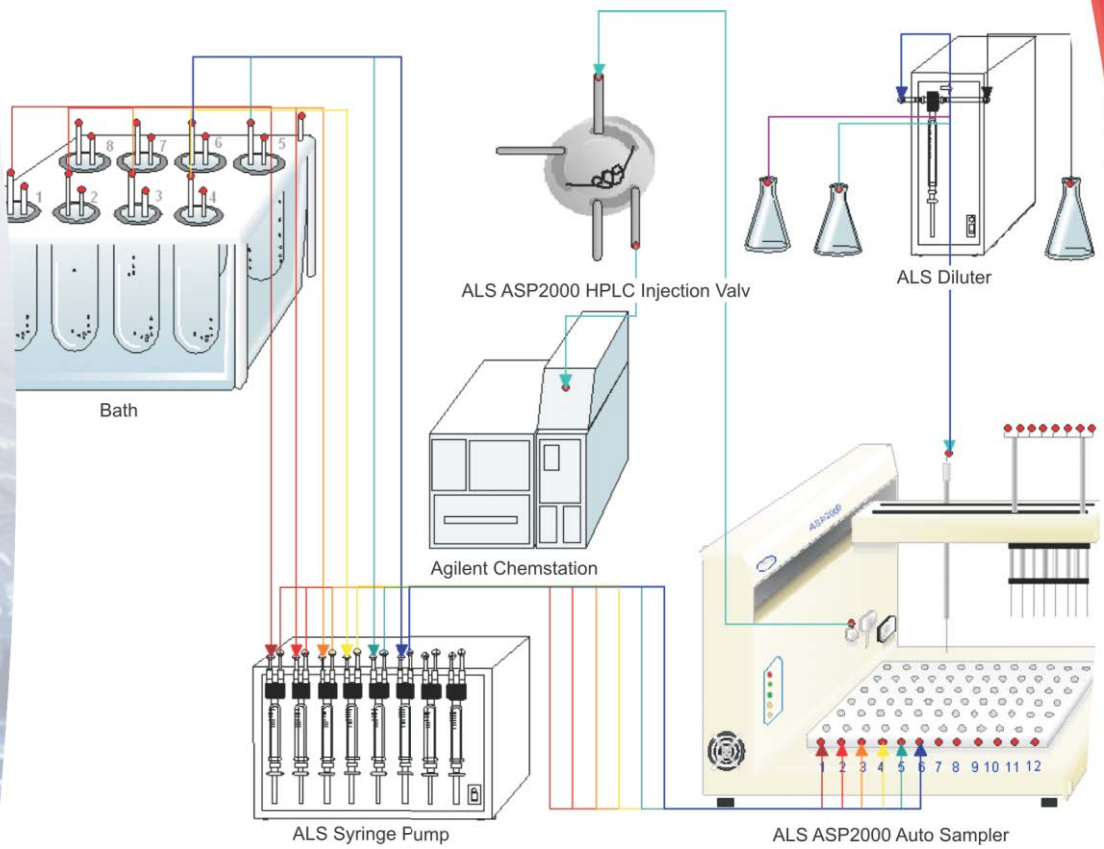
Plots the HPLC dissolution profile in real time.

Deferred Data Collection™ ensures collection is always performed at the correct time irrespective of other procedures such as dilution and injection that occur simultaneously.

Unique Intelligent two way communication to HPL CDS (Chromatography Data System) for Agilent Chemstation™ and Waters Empower™

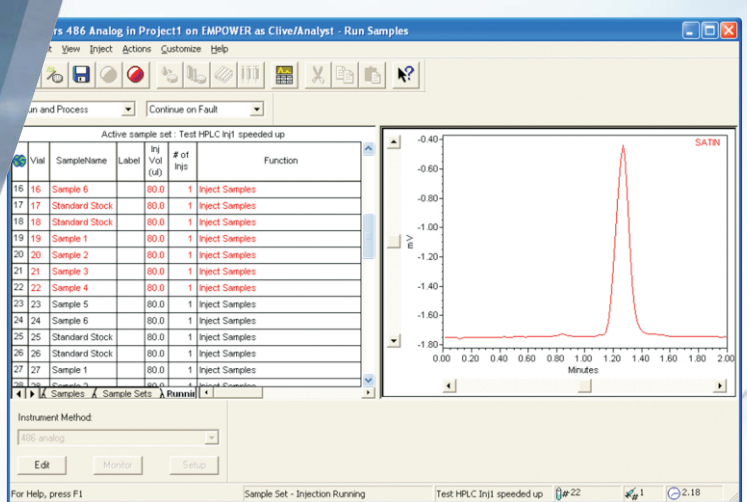
Fully Automated HPLC Analysis

Dissolution



HPLC Main Features

- Sample Set" automatically created by the **IDIS***is controlling software*
- Dilution and mixing prior to injection with options to add a reagent to stabilise the API
- Real time HPLC Dissolution profile (graphic and numeric) for %Dissolution, Area / Height Values
- Meta data such as Temperature, Speed and pH collected and plotted throughout the experiment
- Reprocessing and Sample Re-measurement
- Optional automated pH Change, monitoring and profiling for each Vessel
- An open system, for easy visualisation of operation and accessibility.



Sample Set / Sequence Table are created automatically by the **IDIS***is* software and sent to the CDS as shown here for Waters Empower™.

pH Media Change

For Modified and Sustained Release Products according to USP 1&2

Changes pH in the Vessel automatically as the experiment proceeds

Suitable for sustained or modified release products

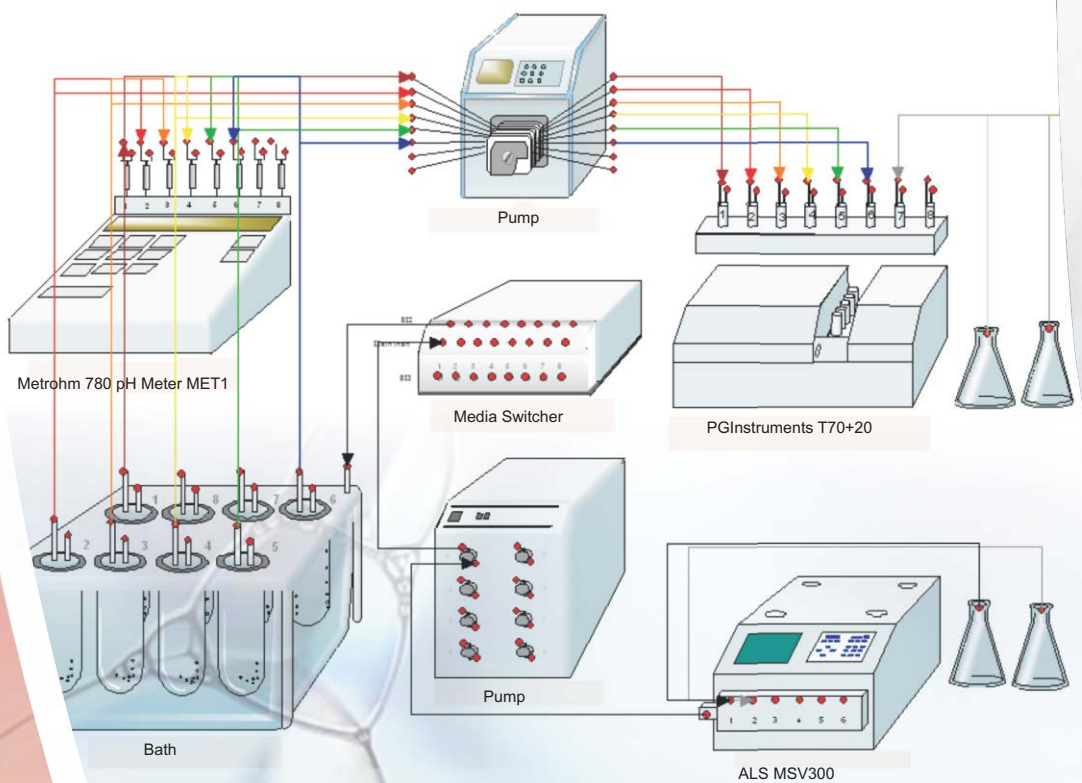
Media addition by Fixed Volume, Gradient Media Addition or a combination of both

Infinite Control of pH generates results for In-Vivo/In-Vitro correlation

Our unique application allows the pH to be monitored in each Vessel and titrates each Vessel independently to a set pH

Can be used in combination with Closed Loop UV, HPLC and Fraction Collection systems

pH and dissolution results calculated and displayed in real time.



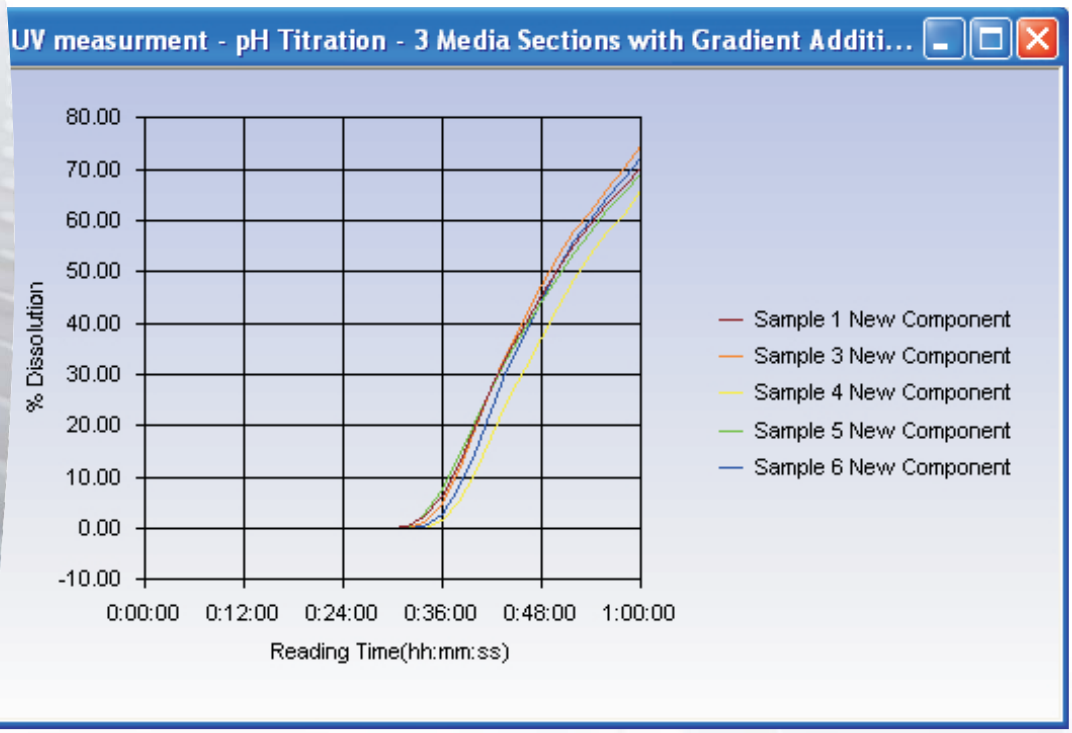
Main Features

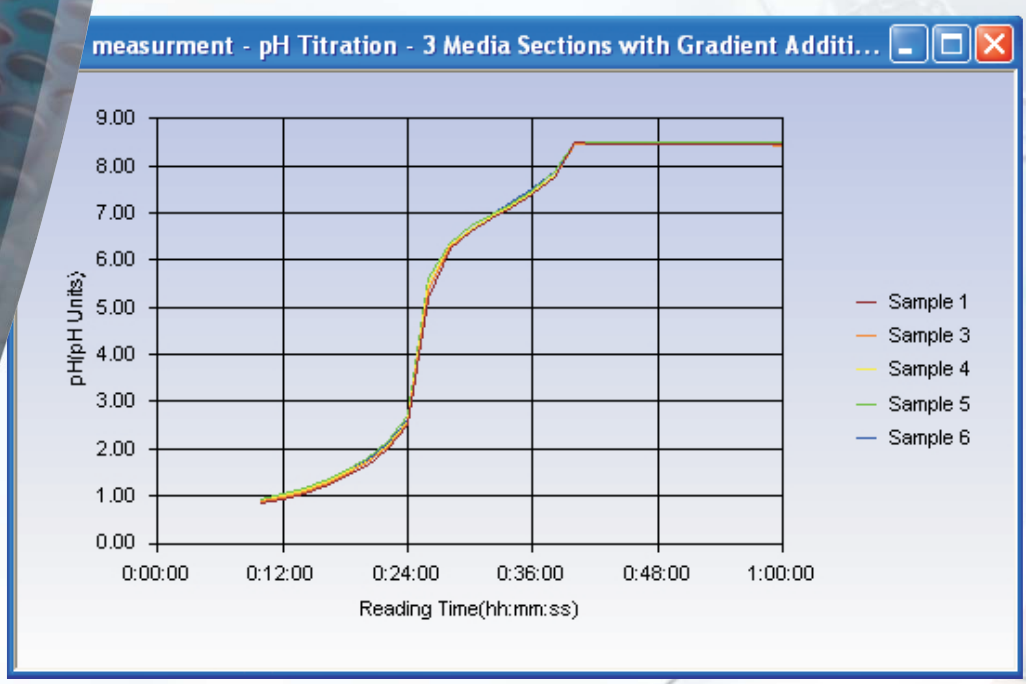
- Visual method representation using ***Solution Path Technology***™ with definable Vessel names and colour
- Media addition using Fixed Volumes, Incremental Volumes or titrate to a set pH for each Vessel.
- Option for up to 5 different Media Change
- Media Removal and priming for Change of Media
- pH Electrode in one Vessel or multiple pH Electrodes for each Vessel
- Fully automated control of all instruments by IDIS*is* software
- Calculations based on different Volumes in each Vessel
- Different Standards and Wavelength for each Media

pH Dissolution Time Plots

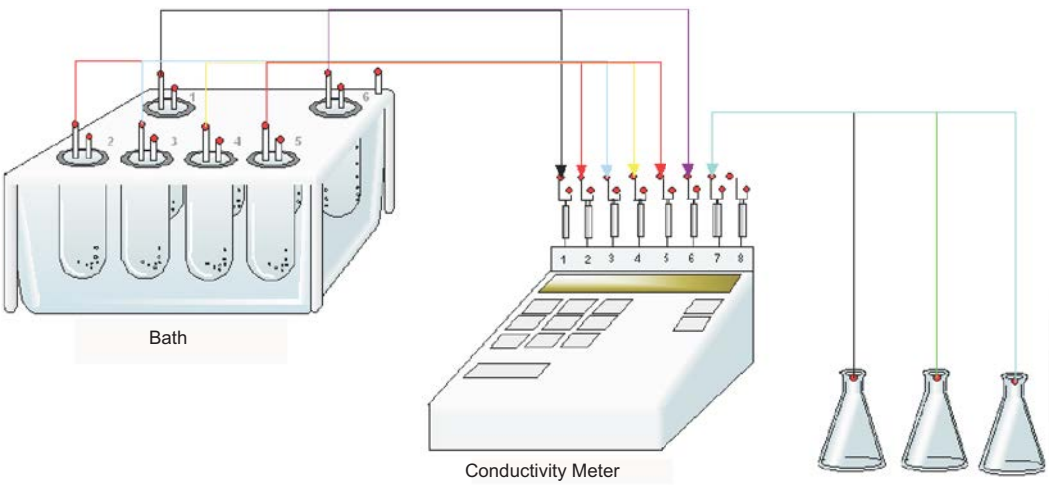
Dissolution

Results from Media Change reported for %Dissolution and pH in separate or overlayed Graphs.





Closed Loop Analysis of Kcl Salt Tablet



Potassium is vital in the human body and oral potassium chloride is the common means to replenish it, although it can also be diluted and given intravenously. It can be used as a salt substitute for food, but medically, it is used in the treatment of hypokalemia and associated conditions and as an electrolyte replenisher.

Conventional method for the determination of Potassium in Potassium Chloride Salt tablets according to the Pharmacopoeia uses Flame Photometry or Atomic Absorption Spectroscopy.

By their nature, both detection methods are not convenient for automation and at most require the use of Fraction Collection then measuring the samples after the Dissolution test is completed. ALS have automated this analysis that allows direct measurement in the Dissolution Bath and results Calculated and plotted as the dissolution test proceeds.

Analysis is now possible online in real time.

Main Features

- Easy automation
- Visual method representation using ***Solution Path Technology***™ with definable Vessel names and colour
- Electrode in each Vessel, no pumping required
- Unique ALS Electrode Multiplexer uses only one meter
- Monitors Conductivity at each Interval for all Vessels
- Calculates and Plots Dissolution profile in real time

Dissolution

Uses ASP2000 Workstation equipped with an 8 Needle probe

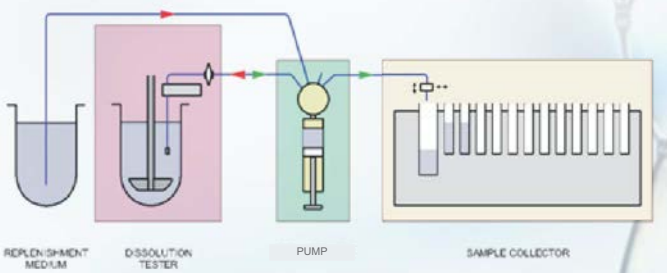
Collects all Samples simultaneously into a variety of different racks and microtitre plates

Time Intervals as low as 2 minutes.

Return of media in the line to the Bath after sampling for greater accuracy especially for sustained release products

Collection varies from a single time point to approximately 30 intervals for up to 8 samples.

Combined Racks for 12 Vessel Baths



Main Features

- 8 Needle Probe collects all samples simultaneously for up to 30 intervals
- Collection for UV or HPLC analysis (into sealed septum vials) for USP methods 1& 2, 3or 4using Baths from ALS, Cleva, Copley, Distek, Electrolab, Erweka, Hanson, Pharmatest, Sotax and Varian etc.
- Special “Flow Thorough” collection allows low volumes to be collected for USP 4 and 7 for Stent.
- Washes probe between collection cycles to reduce carryover
- Variety of different racks for samples from 1ml to 50mls
- Optional sample preparation, Dilution and Mixing
- Optional Sample Loss Replacement
- Combined Closed Loop and Fraction Collection

Dissolution

USP 3 and 7 Dissolution Testing

Automates dissolution testing for USP <711> Methods 3 and 7

Online UV or HPLC Dissolution Testing

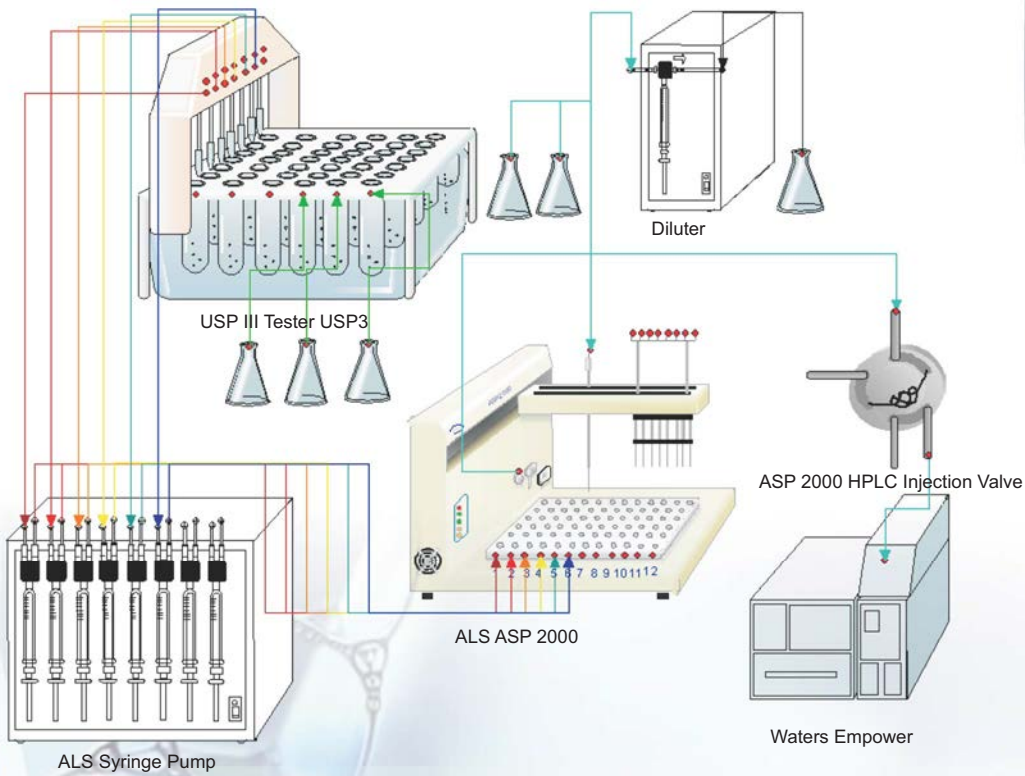
Control all Bath functions including sampling multiple time points at each row and Dip rate etc.

Single or multi-component analysis with unlimited sampling Intervals.

Concatenates Absorbance values from each interval to provide Weight Content and % Dissolution

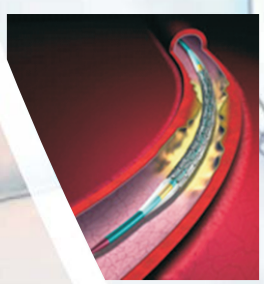
Displays calculated results in real time along with Temperature numerically and graphically as the experiment proceeds.

As tube sizes are relatively small, 250ml for USP 3 and as low as 10ml for USP 7, sample dilution with ASP2000 Workstation then measurement can be configured.



Main Features

- Closed Loop using different makes of spectrophotometer from ALS, Agilent, Beckman Biochrom, Cecil, Jena, Perkin Elmer, Shimadzu and Thermo (Unicam)
- Collection, Dilution and UV Measurement using ASP2000 Workstation
- Collection, Dilution and HPLC Offline Measurement using ASP2000 Workstation
- Automates USP 3 and 7 Baths from Varian (Agilent) and Caleva (Erweka)
- Controls Peristaltic, Syringe and Metering Pumps from ALS, Varian, Sotax.
- HPLC from Agilent Chemstation™ 1100/1200 or Waters Empower.



Stent Analysis

Stent is a short tube of stainless steel mesh, inserted in part of the artery that has been coated with a pharmacologic agent (a drug) that is known to interfere with the process of restenosis (reblocking of the arteries).

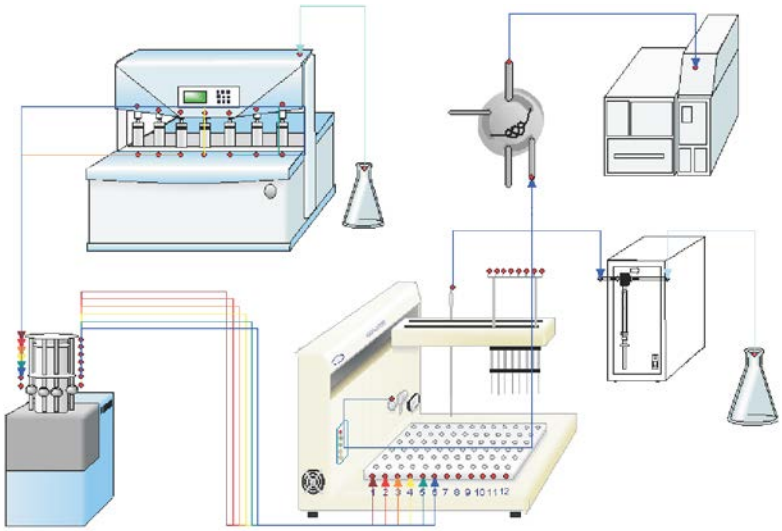
The drug level released is at low levels so invariable analytical testing involves dissolution performed using small volumes and the use of HPLC detection.

Our automated system can take volumes as low as 100µl

Injects samples into HPLC in real time to reduce labour costs and deliver faster results by calculating and plotting the results in real time.

USP 4 Dissolution Testing

Dissolution



Automates dissolution testing for USP <711> Methods 4 Flow Through Cell

Online UV or unique automated HPLC Dissolution Testing

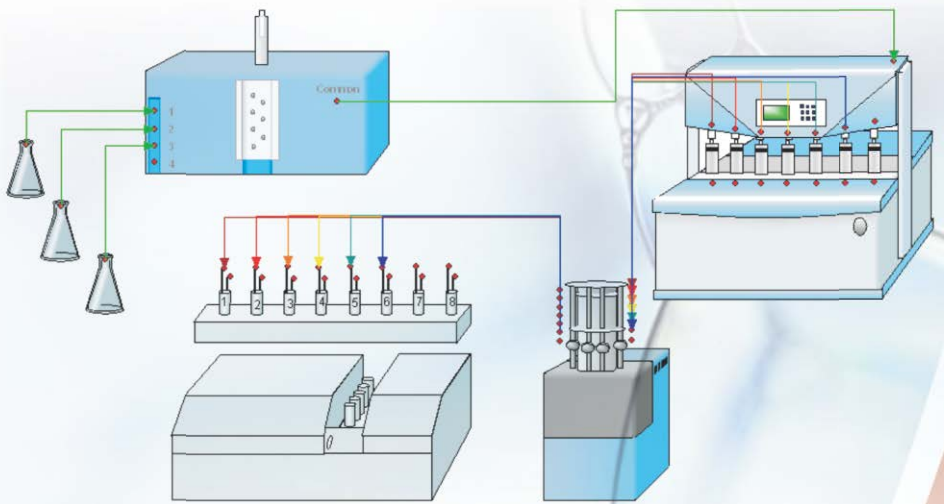
Control all Bath functions including Media Splitting and Media Changing

Single or multi-component analysis with unlimited sampling Intervals

Integrates Absorbance values from Flow Through configurations to provide Weight Content and %Dissolution

Displays calculated results in real time along with Temperature numerically and graphically as the experiment proceeds.

Changes the pH with change of standard for each media



Main Features

- Close or Open Loop using Spectrophotometers from ALS, Agilent, Beckman, Biochrom Cecil, Jena, Perkin Elmer, Shimadzu and Thermo (Unicam)
- Collection, Dilution and UV Measurement using ASP2000 Workstation
- Collection, Dilution and HPLC Offline Measurement using ASP2000 Workstation
- Online HPLC with Agilent Chemstation™ 1100/1200 or Waters Empower™
- Automated Media Change
- Integration of data in real time for Open Loop calculations
- Unique ASP2000 Dual Sampling Rack for sample size reduction

Manual Data Reading

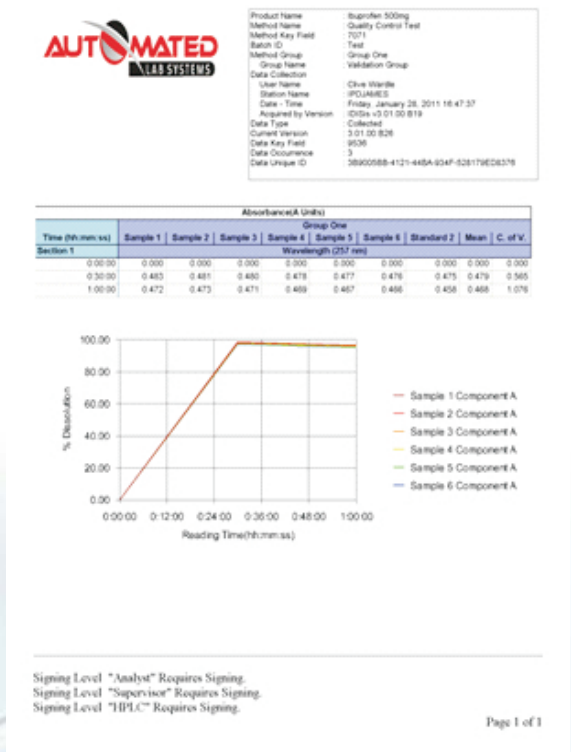
This system can be used to read and produce results from Absorbance or HPLC data that are stored in files, input from the keyboard or connection to spectrophotometers

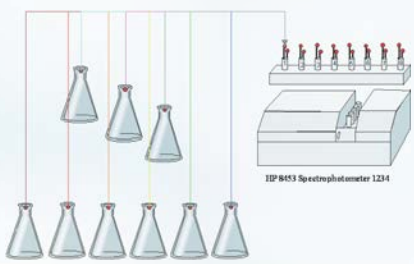
Reads data manually using different procedures

Calculates, produces reports and catalogues the record so that results are easily found at a later date.

Calculated results (no need for external spreadsheet) catalogued and printed to customised reports

This unique feature can be used for Dissolution, Content Uniformity, Assay, Water Environmental Analysis etc. data readings

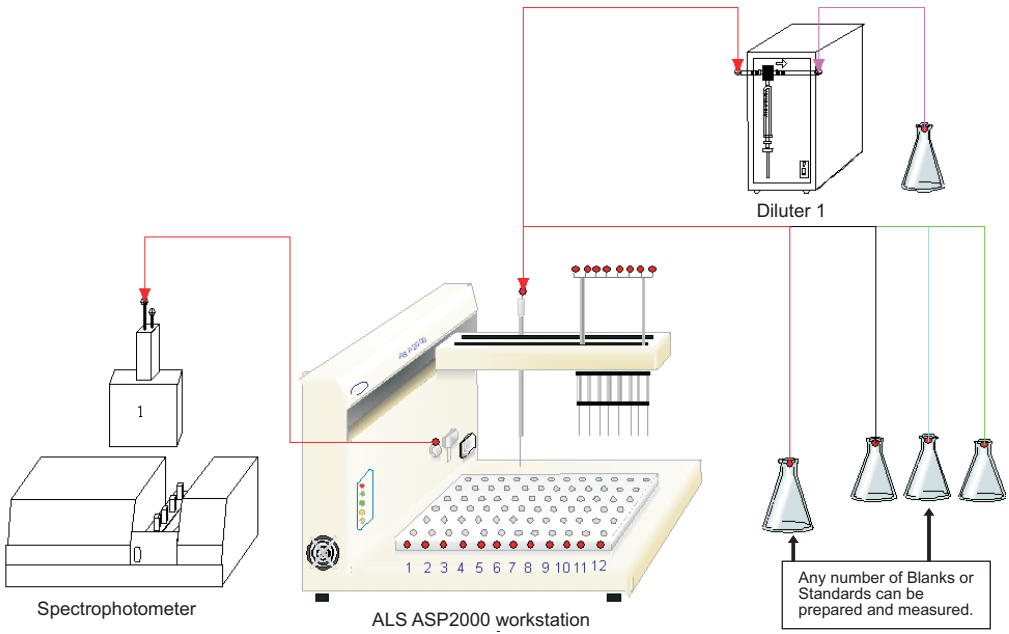




Content Uniformity

Content Uniformity / Assay
for Solid and Liquid Finished products

Semi-automation of Uniformity Of Dosage according to USP <905>



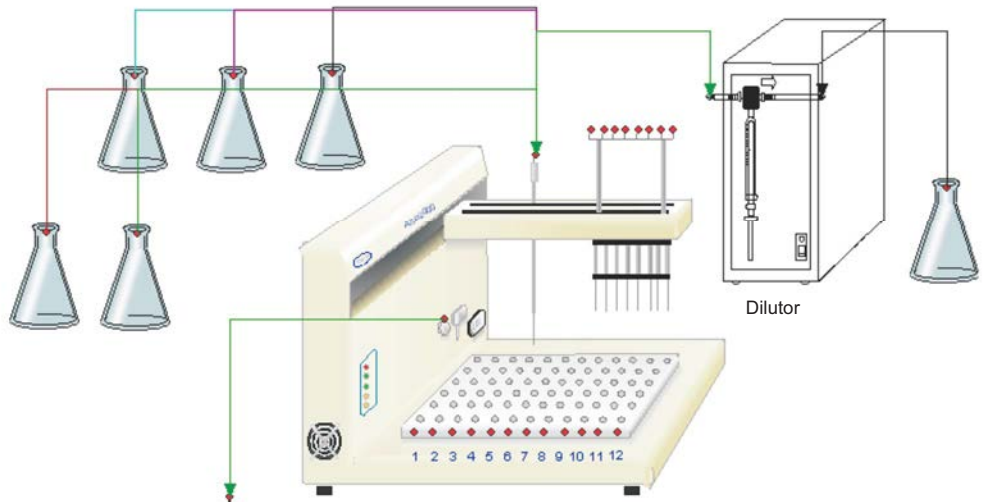
Uniformity of Content and Assay is a pharmaceutical analysis technique for the quality control of hard shell gelatin capsules or tablets. The test for Content Uniformity is required for Coated Tablets, Transdermal systems, Suspensions, Inhalations, Solids and Suppositories etc.

It is performed using 10 or 20 Tablets. The solid dosage are dissolved in a solvent then filtered. The filtrate is loaded onto our ASP2000 Workstation where the samples can be further diluted, treated and measured on UV or HPLC. Can be used for UV or HPLC Chromatography Data System detection.

Main Features

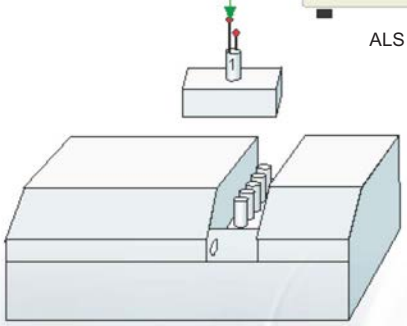
- Different Dilution ratios, infinitely variable from 1 in 25 to over 1 in 1000
- Reagent Addition to Stabilise the API or enhance sample detection
- Up to 240 positions for Samples, Blank and Standards
- Preparation of Multiple Standards from a stock solution for System Suitability and Standard Checks with Bracketing and Calculation Standard configuration
- Calculations for Multicomponent Analysis using Fixed Wavelengths or Spectral Scanning and Derivatives
- Display of results Numerically or in Bar Graph format

The ASP2000 Workstation can be combined with a UV to determine various metals such as Iron, Copper, Cobalt etc. and organic contaminants such as Trinitro-Compounds.

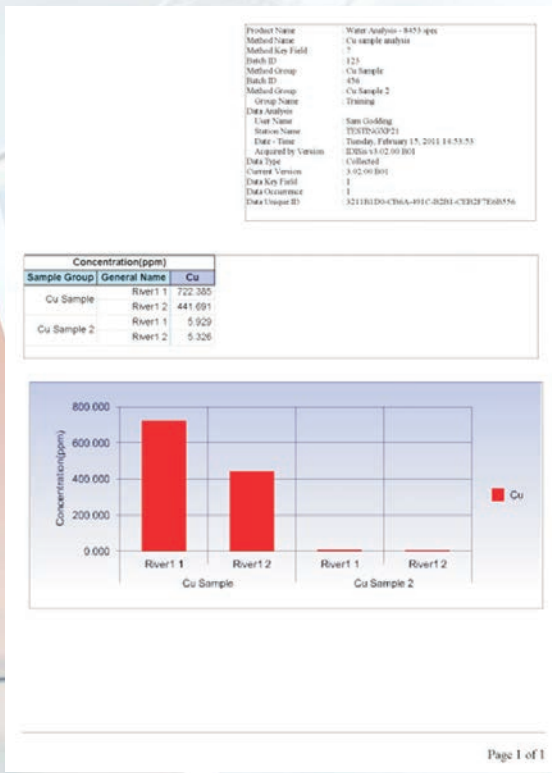


Dilutor

ALS ASP2000 Autosampler



Spectrophotometer



Concentration(ppm)		
Sample Group	General Name	Cu
Cu Sample	River1 1	722.385
	River1 2	441.691
Cu Sample 2	River1 1	5.929
	River1 2	5.326

Page 1 of 1

Main Features

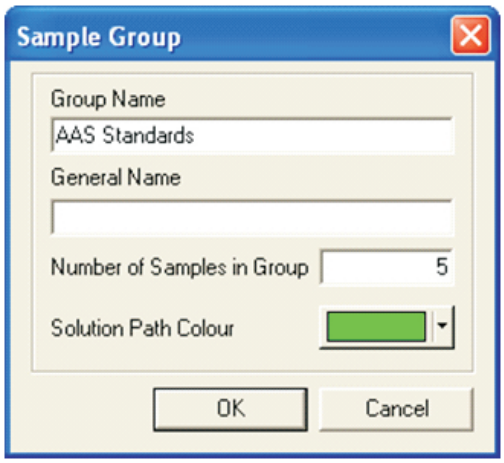
- Different Dilution ratios, infinitely variable from 1 in 25 to over 1 in 1000
- Pretreatment and mixing to enhance detection
- Up to 240 positions for Samples, Blank and Standards
- Preparation of Multiple Standards from a stock solution
- Calculations for Fixed Wavelengths or Spectral Scanning to determine multiple contaminants
- Placebo subtraction by 2/3 Wavelength correction or unique application of Chemometric Target Factor Analysis for accurate results
- Production of clear customisable reports for meetings and mailings.

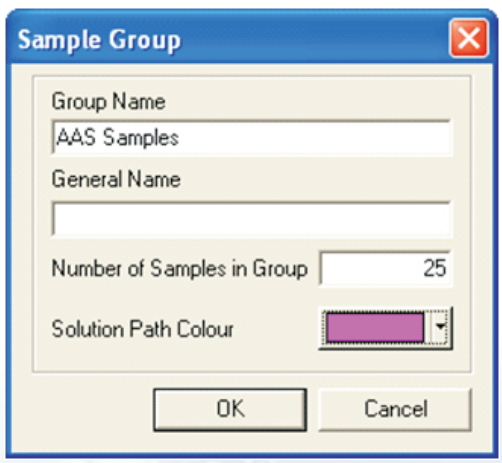
Dilution, Mixing, Reagents Addition

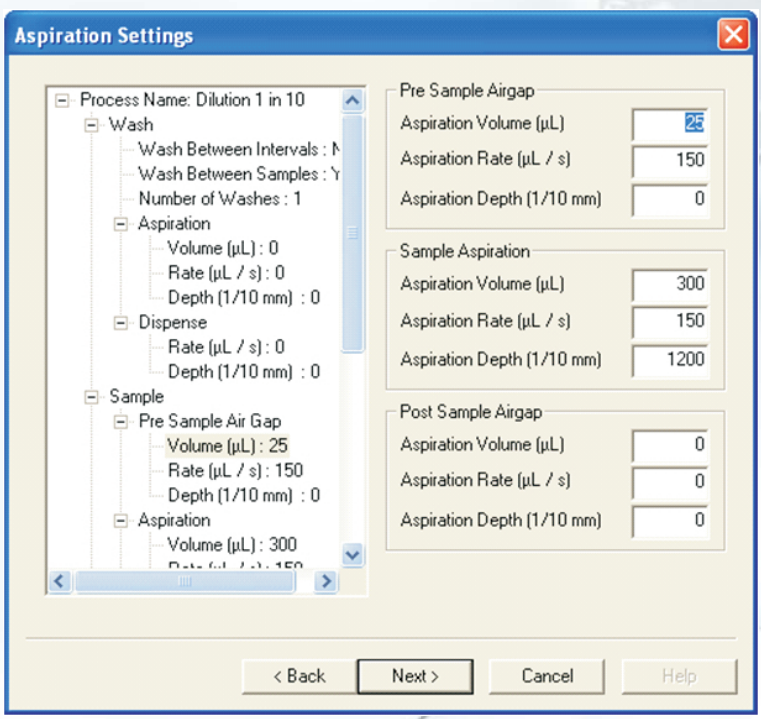
Sample Preparation

Main Features

- Different Dilution ratios, infinitely variable from 1 in 25 to over 1 in 1000.
- Addition and mixing of reagents to enhance sample detection or to Stabilise the sample
- Up to about 240 positions for Samples, Blank and Standards
- Preparation of Multiple Standards from stock solution
- Infinitely variable parameters for optimized preparation







Extended Calculations

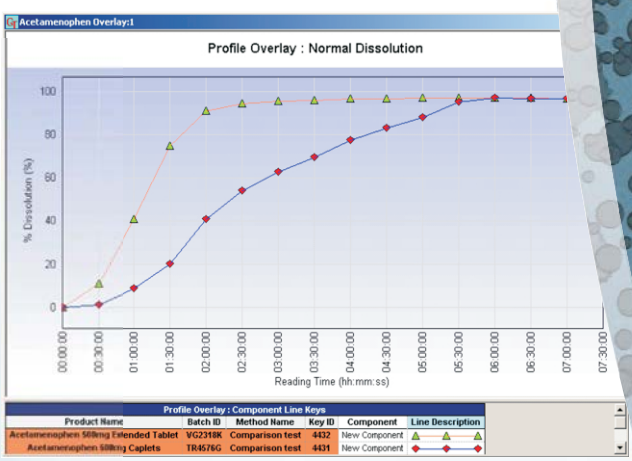
Extended Calculations for F1/F2 USP Q Value Retest and Stability Trend

The Extended Calculations allow data to be represented differently without onerous exporting and recalculation in spreadsheets. This feature saves considerable time, reduces errors and allows the data to be easily reported in different formats.

F1 (similarity Factor) and F2 (Difference Factor) are used in Quality Control for comparing batch to batch variation, Overlaying is used in Quality and R&D while Higuchi and Weibull plots are used in R&D and product development.

Main Features

- Dynamically allows any number of records to be selected to obtain the F1, F2 and Overlays for comparing batch to batch variation
- Unique feature allows a Query to be created and saved to trend data for a specific Batch, Stability or Production ID's.
- Selectable colours, line types enables customised data presentation
- Other data types for Higuchi and Weibull plots.
- Automated rescheduling for USP Q Values checks and recalculation of S, L, level values etc., shown below.



Specification 1 Level S1 Results Group One - Acetaminophen		
Test Value (hh:mm:ss)	00:30:00	01:00:00
Lower Bound Value (%)	40.00	90.00
Upper Bound Value (%)	-	-
Data Record	Run 1	Run 1
Sample 1	46.80	98.00
Sample 2	49.10	99.40
Sample 3	47.50	99.70
Sample 4	42.50	100.60
Sample 5	48.70	98.70
Sample 6	44.40	99.40
Average	46.50	99.30
Status	Fail	Pass

Specification 1 Level S2 Results Group One - Acetaminophen				
Test Value (hh:mm:ss)	00:30:00		01:00:00	
Lower Bound Value (%)	40.00		90.00	
Upper Bound Value (%)	-		-	
Data Record	Run 1	Run 2	Run 1	Run 2
Sample 1	46.80	47.40	98.00	99.60
Sample 2	49.10	48.20	99.40	97.80
Sample 3	47.50	46.90	99.70	98.90
Sample 4	48.70	49.40	100.60	98.80
Sample 5	42.50	46.80	98.70	99.70
Sample 6	44.40	47.40	99.40	97.90
Average		47.09		99.04
Status	Pass		Pass	

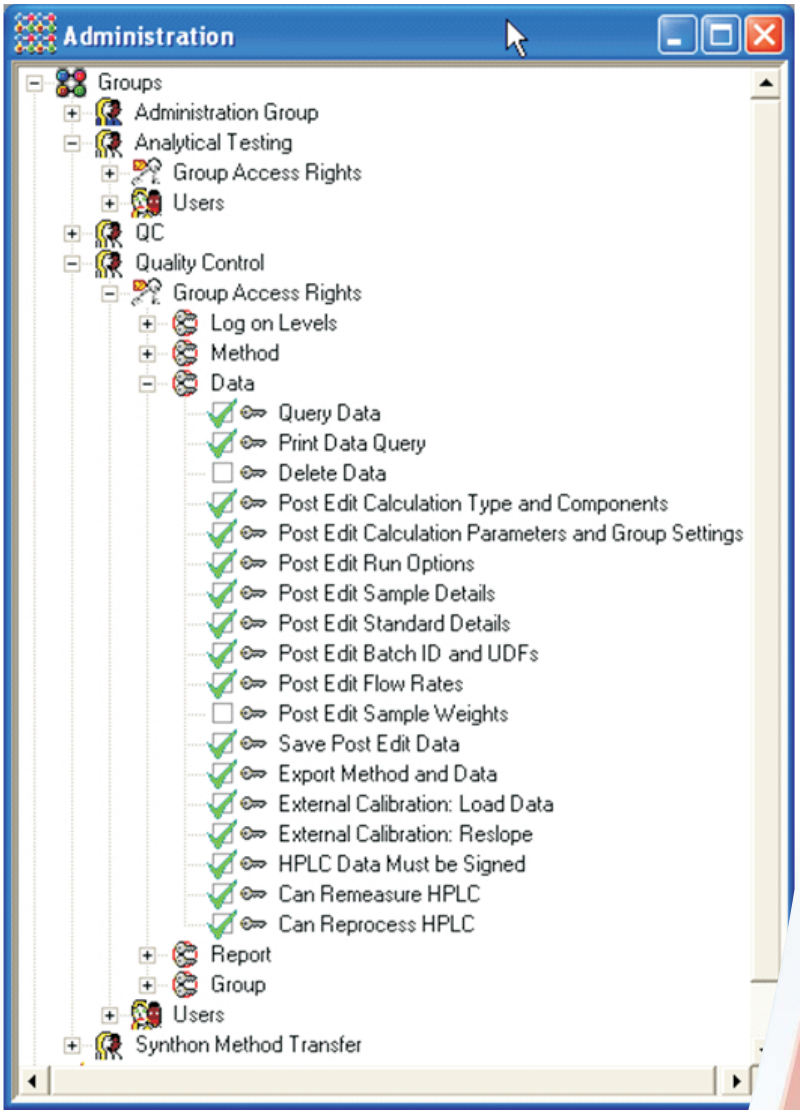
S level Compliance Table showing automatic calculations for S2 level retest

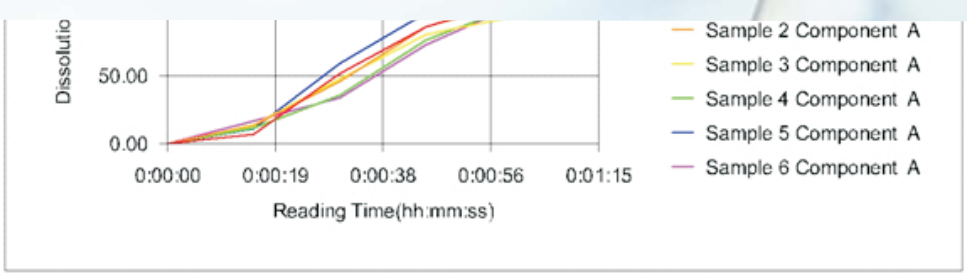
FDA 21 CFR Part 11 GAMP... GAMP4

Pharmacopoeia Compliance

AUTOMATED LAB SYSTEMS

- Analysis and data management performed with strict compliance to FDA 21 CFR Part 11
- Compliance level can be disabled for application areas where it is not required
- Unparalleled compliance for Electronic Records and Electronic signature
- Administration management allows configuration of Users, Groups and Access rights with simplicity
- Unique features include Log off Times by level, Password Expiry Editable prompts, User Queryable Audit Trail and Signature Tracking.





Analyst : Tested By Keith Wilkinson 21/01/2006 18:04:33 Analyst Sign Off
Signing Level "Supervisor" Requires Signing.

Page '

Report Editor

Dynamic Report Editor

The Dynamic Report Editor allows easy configuration of different reports to user requirements

Produce customised reports by simply dragging and dropping objects, no complicated programming macros are required

Company logo can be added for total customisation.

Any number of pages with automatic page numbering.

Non-Editable Graphics Printer allows records to be generated electronically that can be circulated, emailed etc.

For Pharmacopoeia compliance, current signature status (signature tracking) are shown on each page as would appear for manual signatures

User Defined Calculation Spreadsheet provides additional calculation functionality for specific user requirements

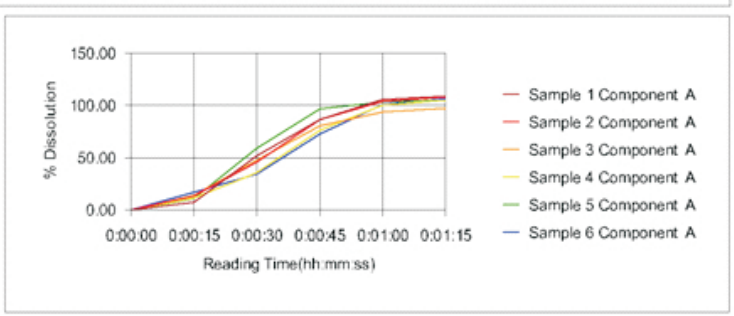
Product Name	: Acetomenophen 500mg tbalets
Method Name	: Stability Test
Method Key Field	: 1394
Batch ID	: TR4543SD
Method Group	: Group One
Group Name	: Test Section 8
Data Collection	
User Name	: Keith Wilkinson
Station Name	: TESTINGXP09
Date - Time	: Saturday, January 21, 2006 17:55:43
Acquired by Version	: IDIS EE v2.20.00 B30
Data Type	: Collected
Current Version	: 3.01.00 B21
Data Key Field	: 1837
Data Occurrence	: 1
Data Unique ID	: 95F27496-5146-42CD-ABBC-50972E5EA92
User Defined Fields	
Stability test at 45	: 1UDF1
Pproduction number	: 2UDF2

Absorbance(A Units)

Time (hh:mm:ss)	Group One							
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Mean	C. of V.
Section 1	Wavelength (285 nm)							
0:00:00	0.000	0.000	0.000	0.000	0.000	0.000	0.000	0.000
0:00:15	0.016	0.031	0.032	0.027	0.025	0.039	0.028	27.308
0:00:30	0.120	0.106	0.110	0.082	0.137	0.079	0.106	21.065
0:00:45	0.200	0.200	0.186	0.177	0.224	0.169	0.193	10.222
0:01:00	0.245	0.241	0.217	0.233	0.240	0.234	0.235	4.213
0:01:15	0.252	0.251	0.225	0.244	0.244	0.247	0.244	4.030

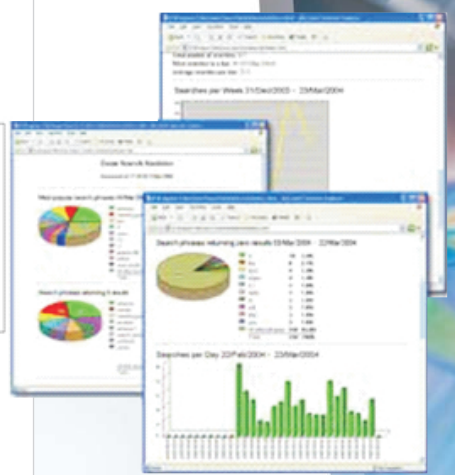
% Dissolution

Time (hh:mm:ss)	Group One							
	Sample 1	Sample 2	Sample 3	Sample 4	Sample 5	Sample 6	Mean	C. of V.
0:00:00	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
0:00:15	6.9	13.4	13.8	11.6	10.8	16.8	12.2	27.3
0:00:30	51.7	45.7	47.4	35.3	59.1	34.1	45.5	21.1
0:00:45	86.2	86.2	80.2	76.3	96.6	72.8	83.0	10.2
0:01:00	105.6	103.9	93.5	100.4	103.4	100.9	101.3	4.2
0:01:15	108.6	108.2	97.0	105.2	105.2	106.5	105.1	4.0



Analyst : Tested By Keith Wilkinson 21/01/2006 18:04:33 Analyst Sign Off
Signing Level "Supervisor" Requires Signing.

Page 1 of 1



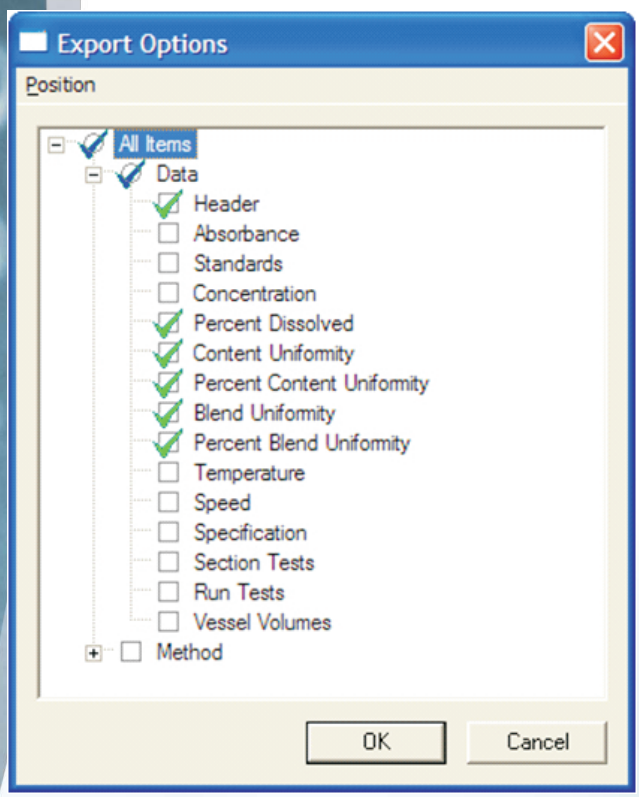
LIMS Notebook Interface

This functionality allows our data management system to transfer data to other laboratory data management systems such as LIMS or Electronic Notebooks.

Easily managed and configurable ASCII Format Data Export

Print reports to our Graphics printer or PDF for acquisition into data management packages such as Agilent OL and Waters NuGenesis

Unique seamless two-way communication with LIMS is provided by our ODBC LIMS Interface. No user intervention and totally transparent.

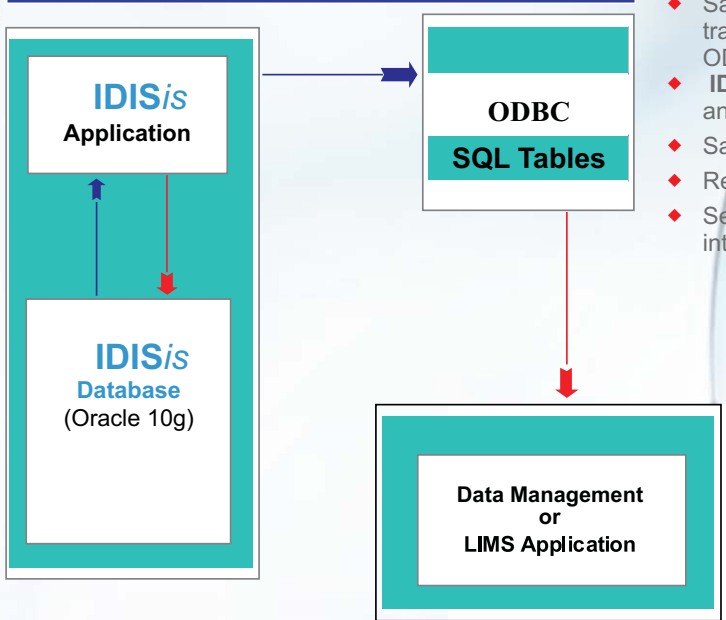


For ASCII Data Export, format of the data is selected as shown opposite. The LIMS or application will access the data according to the format options ticked.

Allows total customisation for each Company,

Features and Advantages

- Samples details for analysis are transferred to our proprietary ODBCTables
- **IDIS***is* workstations are imported with analysis requirements automatically
- Sample tracking with LIMS
- Results are sent to LIMS via ODBC.
- Seamless integration with no user intervention.



Networking

POWERED BY ORACLE

Networking and Globalisation

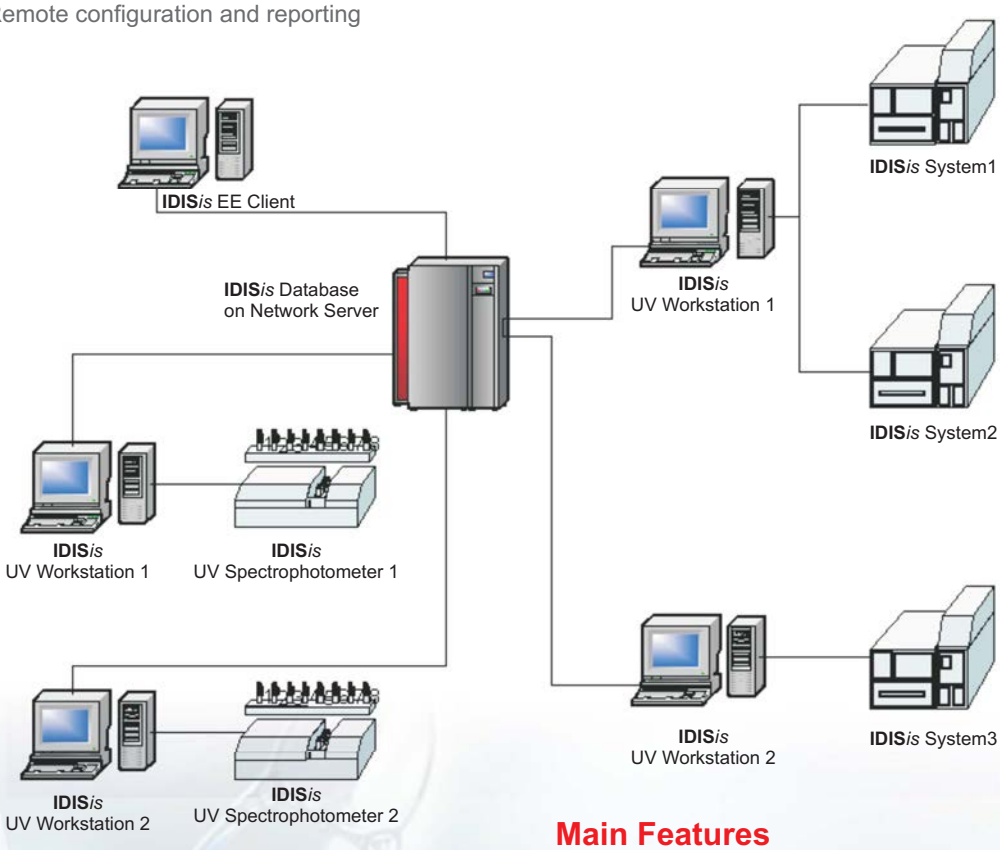
Networking of workstations produces a common data base for all workstations using Oracle™.

Considerable time saving by central administering, user, group and rights as these only need to be performed once and not on each workstation as with other systems

Results stored centrally for backing up and secure data protection

Results can be accessed from any remote workstation or client anywhere in the world

Remote configuration and reporting



Main Features

- Uses Oracle Database which is reliable, fast, efficient and scalable
- Fault Tolerant Database protects data loss in case of network break
- Users managed within **IDIS***is* structure without incurring additional license costs
- Intelligent Archiving and Restoring of records
- Dynamically selectable local language for ease of use

Chinese	English	French	German	Japanese	Spanish
中文	English	Français	Deutsche	日本語	español

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