LOGAN INSTRUMENTS CORP.

Application Note

ADSP - Automated Dissolution Solubility Permeation

Introduction

In today's fast-paced race to bring novel and generic medicines to market, it's important that your equipment be an ally, not an obstacle you must overcome to extract results. Logan Instrument Corporation has been working closely with our customers for decades to innovate and refine systems that enable researchers to accelerate the generation of meaningful analytical data.

This collaboration has resulted in Logan's ADSP system. **Automated, Dissolution, Solubility, Permeation**. ADSP is a modular, integrated range of equipment that significantly streamlines the process of evaluating API solubility, tablet dissolution and compares absorption rates through the gut. The individual apparatus can be used for studies of each of these pharmacokinetic (PK) parameters or used together to evaluate your API through solubility, dissolution and permeation in total.

- **One range of equipment to measure dissolution and solubility. Multiple capabilities, one learning curve.**
- **Extend the understanding of your API with in vitro GIT absorption.**
- **All components supported and serviced by Logan.**
- **Meets all current USP, BP guidelines.**
- **Dedicated software integrates and simplifies operation.**
- **Optional filter system to eliminate undissolved particles.**
- **Online UV detection and data analytical capabilities.**

The quality and features of every Logan component set them above alternative systems. Working together they provide unparalleled capability and performance.

The system comprises a (UDT), 8, or 12 vessel, USP 1 & 2 dissolution system, with a controller, parallel syringe pumping unit (DSC-800) and discrete sample collector (SCR-DL). The controller and sample collector can be used to feed directly into an in-line parallel flow, 8 position, UV spectrophotometer. Samples can also be collected in discrete vials or test tubes for off-line analysis by UV or HPLC.

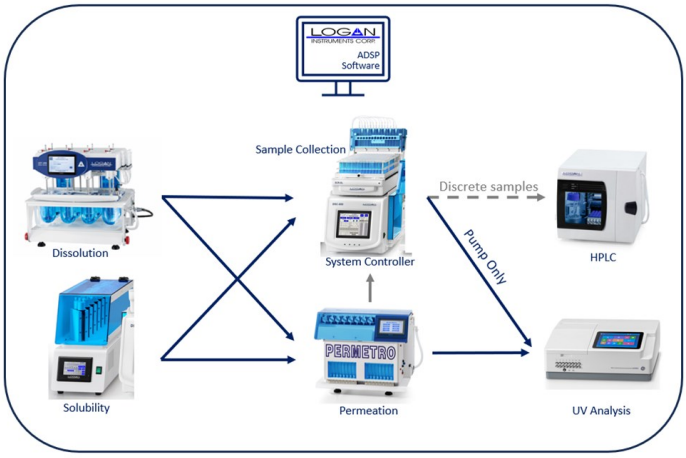
This starter system can then be expanded by adding the STL-100 to directly measure the solubility of your API, independent of excipient and finished tablet form. The APIs can be examined at six different pH and/or temperatures simultaneously. Each solvent and temperature can be changed by the user in six different sample tubes. Optional filtration can be added eliminate undissolved particles. Accessories are available to consolidate the API powder to extend the solubility time.

The STL-100 is controlled by the same DSC-800 and samples collected by the SCR-DL, or sent directly to the UV-1900 for spectrophotometric analysis.

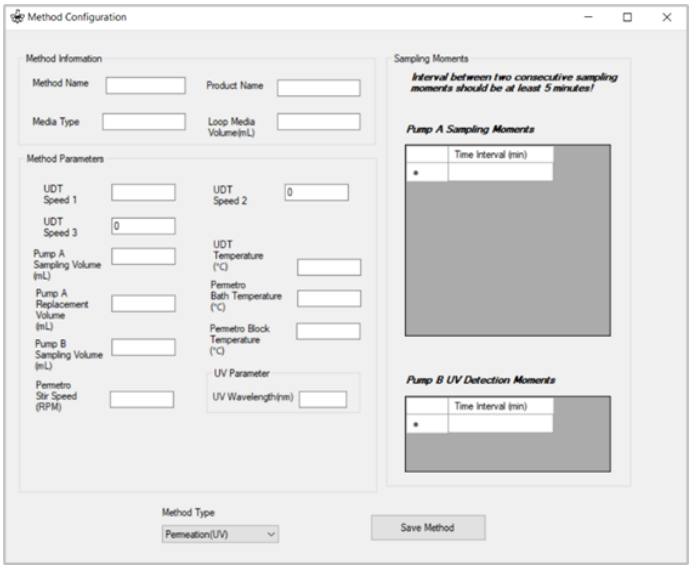
Whether measuring tablet dissolution or API solubility, these samples can be directed to Logan's PERMETRO system. PERMETRO is a novel Logan system that uses a unique dual cell design, holding an API solution on one side and a receptor solution on the other, separated by a permeable membrane. The receptor solution is constantly transferred to your choice of measurement device. In this way PERMETRO can simulate the gut environment, to compare permeation of different dosage forms. For example, evaluation of different formulations of novel drug or comparison of generic to reference doses.

PERMETRO can help highlight the most promising formulation candidates, reducing the number of test compounds that require full scale in vivo bioequivalence studies. This represents a significant saving in time and money.

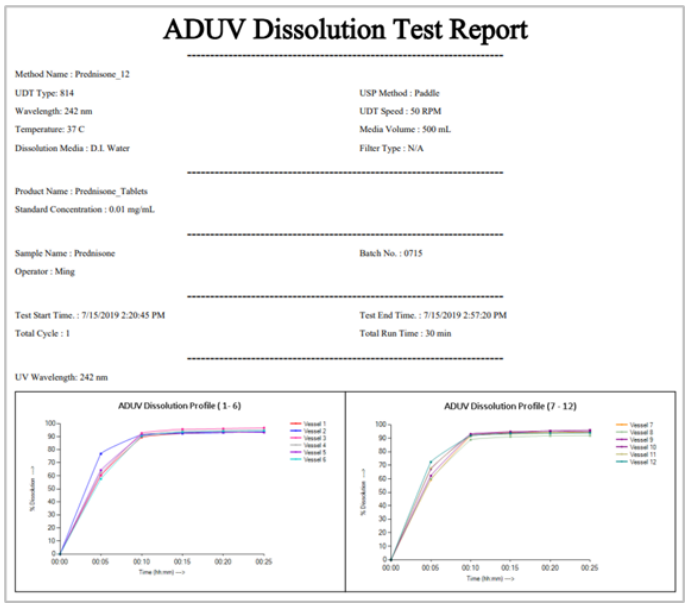
A key component of the integrated system is the ADSP software. This comprehensive, but flexible, program links the unit operations together. The PC based software controls whichever hardware components are in use for a particular study. Simply select which study is being run and the ADSP software will guide you through the set-up. A practically unlimited number of methods can be stored, and of course the software is CFR 21 Part 11 capable, with security levels managing access to method protocol conditions.



Every combination of components can be controlled by one screen. In this example the ADSP system is being used to run a permeation study from the TDS using the PERMETRO system to measure in vitro gut absorption. This one screen controls the tablet dissolution parameters, sampling from the vessels, permeation conditions and the UV analysis.



When the sample processing is complete the ADSP software will automatically generate a full report.



ADUV Dissolution Test Report

Method Name : Prednisone_12
UDT Type: 814
Wavelength: 242 nm
Temperature: 37 C
Dissolution Media : D.I. Water
USP Method : Paddle
UDT Speed : 50 RPM
Media Volume : 500 mL
Filter Type : N/A

Product Name : Prednisone_Tablets
Standard Concentration : 0.01 mg/mL

Sample Name : Prednisone
Operator : Ming
Batch No. : 0715

Test Start Time. : 7/15/2019 2:20:45 PM
Total Cycle : 1
Test End Time. : 7/15/2019 2:57:20 PM
Total Run Time : 30 min

UV Wavelength: 242 nm

ADUV Dissolution Profile (1- 6)

ADUV Dissolution Profile (7 - 12)

Bringing together these different aspects of drug evaluation can be challenging. Logan Instrument Corporation has shown that it doesn't have to be. ADSP takes care of the mechanics of dissolution, solubility and permeation so you can focus on optimizing the formulation.

For more information on ADSP and full specifications on the individual components please contact us at info@loganinstruments.com or visit our website loganinstruments.com.

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