APPLICATION NOTE

USP Dissolution Performance Validation Test Used for Apparatus 2 Performance Qualification of a Semi-automated, Real-time, Fiber Optic UV-Vis Dissolution System

The United States Pharmacopeia (USP) describes the Dissolution Performance Validation Test (DPVT) for the performance qualification (PQ) of manual dissolution baths. The USP DPVT is performed using the Dissolution Performance Validation Standard (DPVS) prednisone tablets available from USP.

The acceptance criteria for DPVT experiments are set for manual collection and analysis of samples, and when automated dissolution systems are used, the results often fail, leaving the responsibility to approve the use of the automated dissolution system to the end user's quality department.

Here we show that, unlike many automated dissolution setups, Pion's integrated **DissoSpec**™ QC Dissolution Monitoring System passes the USP DPVT criteria for USP 2, providing data that will support quality departments on their decision to release the system for use.

MATERIALS AND METHODS

Pion's **DissoSpec** system was qualified according to the DPVT methods described in USP chapter <711> USP Guideline on Procedures for Mechanical Calibration and Performance Verification Test for Apparatus 1 and Apparatus 2, rev 01, using the USP Dissolution Performance Verification Standard (USP catalog number 1222818). The **DissoSpec** system includes an 8-position manual dissolution bath integrated with a Rainbow® Dynamic Dissolution Monitor System, a multi-channel fiber optic UV-Vis spectrophotometer, and **DissoPRO**™ software. The system includes *in situ* sample reading probes that comply with the sampling zone recommendation as per USP <711>. The tests were run using the 6-position test method.

RESULTS AND DISCUSSION

Two experiments were performed in two different laboratories by different analysts and on separate dates using the same system. Direct % dissolved results were obtained using 242nm wavelength calculation as recommended by the USP guidance document, and linear baseline correction of 400 to 450nm were used for the collection spectra.

USP DPVT method describes a method with two-stage testing, where if passing criteria are not met for n=6 replicates (Stage 1), an additional 6 replicates are required (Stage 2). In both experiments, **DissoSpec** provided passing results after Stage 2.

Pion

Apparatus 2 -- 2-stage test for equipment with 6 positions

Acceptance criteria for USP Prednisone Tablets RS
Dissolution Performance Verification Standard - Prednisone 1222818, R182R0

	Stage 1	Stage 2
GeoMean, lower	47	45
GeoMean, upper	54	57
%CV, upper	4.1	5.4

Stage 1 (Run 1) data	
Vessel 1	56
Vessel 2	56
Vessel 3	54
Vessel 4	60
Vessel 5	55
Vessel 6	55

Stage 2 (Run 2) data	
Vessel 1	59
Vessel 2	55
Vessel 3	58
Vessel 4	53
Vessel 5	53
Vessel 6	58

Test Results					
1st Stage GeoMean	56	Does not meet	Combined GeoMean	56	Meets
1st Stage %CV	3.7	Meets	Combined %CV	4.3	Meets

PASSES

Apparatus 2 -- 2-stage test for equipment with 6 positions

Acceptance criteria for USP Prednisone Tablets RS
Dissolution Performance Verification Standard - Prednisone 1222818, R182R0

	Stage 1	Stage 2
GeoMean, lower	47	45
GeoMean, upper	54	57
%CV, upper	4.1	5.4

Stage 1 (Run 1) data	
Vessel 1	58
Vessel 2	55
Vessel 3	50
Vessel 4	55
Vessel 5	54
Vessel 6	52

Stage 2 (Run 2) data	
Vessel 1	56
Vessel 2	56
Vessel 3	60
Vessel 4	58
Vessel 5	57
Vessel 6	56

Test Results					
1st Stage GeoMean	54	Meets	Combined GeoMean	56	Meets
1st Stage %CV	5.1	Does not meet	Combined %CV	4.1	Meets

PASSES

Figure 1. DPVT test results for the 1st (1a) and 2nd (1b) experiments using the DissoSpec system and USP <711> method for testing a 2-stage, 6-position dissolution bath. Data were analyzed using the USP PVT calculation tool.

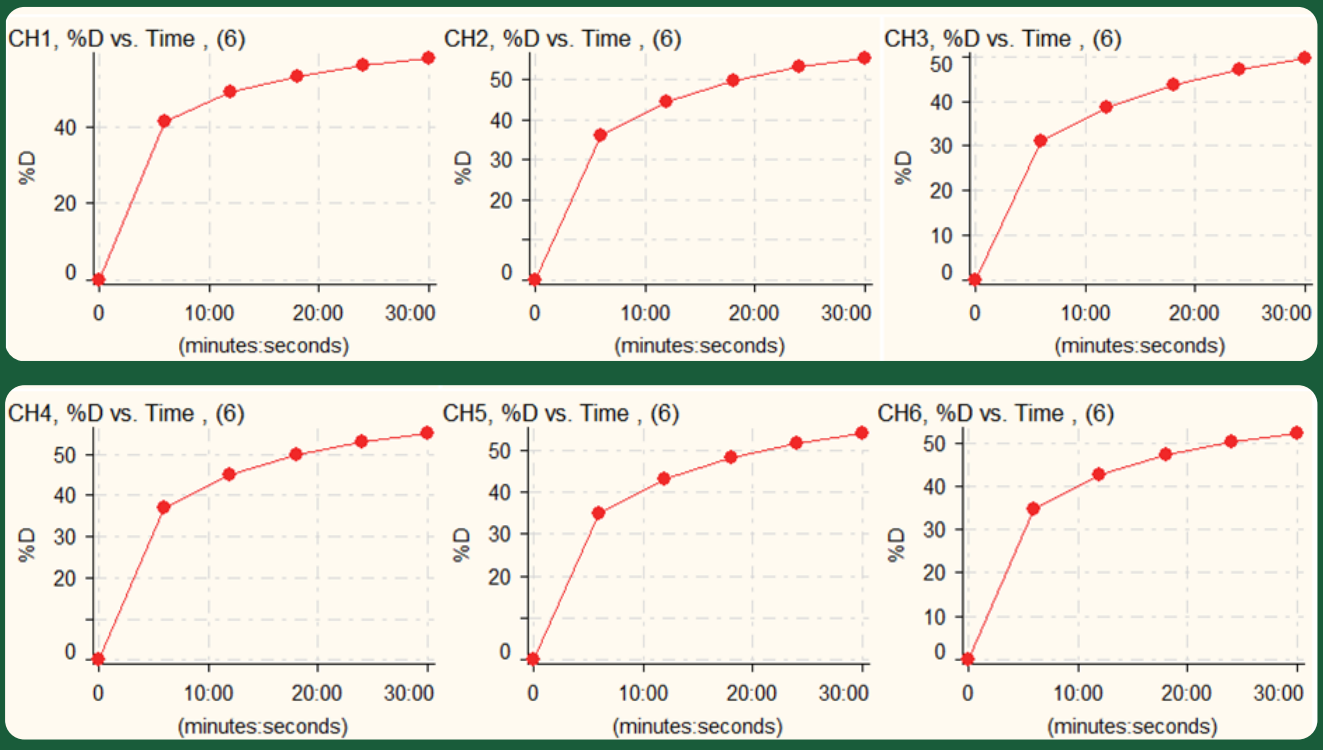

Figure 2. Screenshots show a section of Pion's **DissoPRO** software report for the USP DPVS for each of the six vessels in the **DissoSpec** dissolution system.

CONCLUSIONS

This work demonstrates that the **DissoSpec** system passes PQ testing using the DPVT USP apparatus 2 test method, meeting the same criteria required for manual sampling experiments.

DPVT experiments typically uncover issues such as instrument deviations, incorrect operation by analysts, or analytical errors. This application note shows passing results with minimum analyst bias. While the system eliminates sampling errors, care must still be taken to ensure proper cleaning of the bath components and accuracy in degassing, media volume delivery, and standards preparation.

Figure 2 showcases one of the advantages of UV-Vis on-line fiber optics use, with dissolution profiles that include more sampling points than the traditional single-reading DPVT manual method.

About the Pion **DissoSpec** System

DissoSpec addresses several common issues from QC Dissolution experiments including:

- No carry-over on surfaces exposed to test solutions
- No risk of sample absorption to autosampling lines
- No absorption or extraction interference from sample filters
- No delay between sample collection and analysis, avoiding errors due to sample degradation

DissoSpec enables QC departments to use the USP DPVT test to support the approval and release of automated dissolution systems.

Pion's **DissoSpec** QC Dissolution Monitoring System integrates *in situ,* fiber optic UV-Vis probes for measuring concentrations directly in the dissolution baths in real-time.

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