Comparison of Stainless Steel and PVDF Paddles Using Dissolution Performance Verification Standard—Tablets

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Figure 1. The Vision® G2 Elite 8 dissolution tester

Dissolution Test

A dissolution test is used to evaluate the rate at which and the amount of a compound that dissolves to form a solution under carefully controlled conditions. The dissolution test in a USP drug product monograph helps evaluate the performance of a drug product (article) and indicates when the drug product performs in a substandard fashion. Although passing the test does not definitively demonstrate bioavailability of the sample or bioequivalence to other products, failure is a cause for concern. Typically, for oral drug products, USP monographs call for the use of dissolution testing with apparatus described in General Chapter <711> Dissolution.[1]

USP Apparatus 1 (basket) and 2 (paddle) are widely used to perform dissolution tests of oral solid drug products. The Apparatus Suitability section in <711> describes the procedure and requirements for the qualification of dissolution apparatus.[2] Analytical instrument qualification/calibration is also required by FDA current Good Manufacturing Practices (cGMPs) and by ISO/IEC 17025, an international standard specifying general requirements for the competence of testing and calibration laboratories.[3,4]

Objective

The objective of this study is to evaluate the difference in the percentage of Prednisone dissolved by using Apparatus II (Paddles) made of stainless steel (PN 74-105-202) or polyvinylidene difluoride (PVDF) (PN 74-105-201). Additionally, a dissolution test was also performed using Apparatus I (Baskets) USP 40 mesh to qualify the instrument. Prednisone is widely accepted for use as a standard for apparatus qualification, hence it is deemed to be the best product for this type of study. For instrument qualification, other procedures such as Enhanced Mechanical Calibration (EMC) are also available as mentioned per the FDA guidance document.[3] Another procedure for apparatus qualification is also mentioned in ASTM E2503-13(2020).[4] Prior to performing the dissolution test, the instrument was qualified for EMC.

Test procedure and Results

As mentioned in the USP, the dissolution test is performed using the current Dissolution Performance Verification Standard - Tablets, lot number F161Y0, use by date: 14 November 2024.[5] Each tablet contains Prednisone 10 mg. A two-stage approach was considered during this test. Either of two types of Apparatus II paddles, made with either stainless steel or PVDF, were used as the stirring device. Additionally, Apparatus I stainless steel baskets of USP 40-mesh were also used to test for the dissolution. In all tests, dissolution media were prepared as described by the USP procedure for the Performance Verification Test. Samplers were collected and filtered per procedure. A standard solution was prepared using a Prednisone Reference Standard, current lot number R083A0. The UV absorptions of samples and standards were measured concomitantly at 242 nm using 10 mm quartz cells on a Shimadzu Spectrophotometer, model UV 1800. The raw data were recorded per internal procedures. The results were calculated by tools provided by the USP and are presented in Table 1. The entire procedure was repeated on second day; those results are reported in Table 2.

Table 1- Day 1 Result of Dissolution Performance Verification Standard—tablets.

Vessel/Tablet Number	Apparatus II		Apparatus I
	S.S. Paddles*	PVDF Paddles	USP baskets, 40 Mesh
1	52.8	53.2	86.5
1	52.8	53.2	86.5
2	51.6	50.0	86.5
3	51.7	52.4	84.7
4	51.6	56.2	86.9
5	54.1	50.7	86.7
6	55.5	53.3	84.1
Mean	52.9	52.6	85.9
Geometric Mean	52.8	52.6	85.9
% CV	2.8	3.8	1.2

Table 1, Day 2 Result of Dissolution Performance Verification Standard—tablets.

Vessel/Tablet Number	Apparatus II		Apparatus I
	S.S. Paddles*	PVDF Paddles	USP baskets, 40 Mesh
1	51.5	55.9	80.3
2	52.3	54.2	85.6
3	54.6	53.4	84.1
4	55.5	50.9	82.2
5	52.2	52.1	85.9
6	49.9	51.9	87.1
Mean	52.7	53.1	84.2
Geometric Mean	52.6	53.0	84.2
% CV	3.6	3.1	2.8

*Stainless steel paddles

Conclusion

All results as obtained above met the acceptance criteria of the USP for apparatus qualification. Based on that study data, it is evident that there is no significant difference between PVDF or stainless steel in drug product release. Both types of paddles produce similar results. PVDF is compatible with most chemicals used in drug product dissolution testing. Furthermore, PVDF is much more corrosion resistant than stainless steel; however, both are offered by Teledyne LABS, and users can choose either based on their own preference.

References

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2. United Sates Pharmacopeia, (USP) General Chapter <711> Dissolution, USP NF 2023
3. The Use of Mechanical Calibration of Dissolution Apparatus 1 and 2 – Current Good Manufacturing Practice (CGMP) U.S. Department of Health and Human Service Food and Drug Administration Center for Drug Evaluation and Research (CDER) January 2010 Current Good Manufacturing Practices (CGMP)
4. ASTM E2503-13(2020) Standard Practice for Qualification of Basket and Paddle Dissolution Apparatus
5. Dissolution Performance Verification Standard – Prednisone RS DEPTDOC-00276-01A