

A Comparison of Dissolution Results Using O-ring vs. Clipped Basket Shafts

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Two types of basket shafts are commercially available to the analyst. One type has an O-ring inset in the disk at the end of the shaft with the basket fitting snugly around the o-ring. The other has three clips attached to the disk at the end of the shaft. The basket is attached by fitting between the clips and the disk. The latter design is described in USP 24 General Chapter on Dissolution <711> (1). The two designs are shown in *Figure 1*. The purpose of this study is to compare these two types of basket shafts using the two USP Calibrator Tablets, Prednisone and Salicylic acid, and three development products.

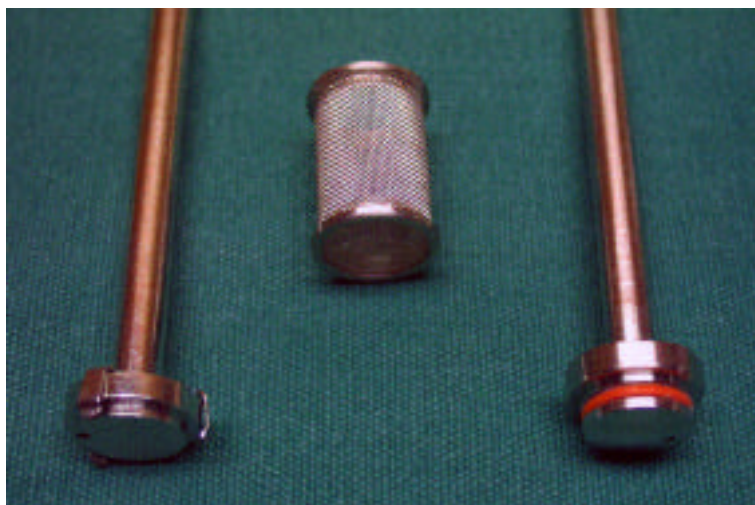


Figure 1

Method

One run was performed on the Prednisone calibrator tablet and three products. For each run the tester was equipped with three o-ring and three clipped basket shafts. For the Salicylic Acid Tablets, two runs were performed in tandem, the first with the O-ring shafts and the second with clipped shafts. For each basket shaft type there were three replicates (n=3), except Salicylic Acid which was n=6. The basket test methods used are as follows:

Compound A

Tablet—erosion type
Apparatus, speed: 1 (basket), 50 rpm
Medium, volume: 0.05 M sodium carbonate containing 0.25% sodium lauryl sulfate adjusted to pH 9.5, 900 mL
Time points—10, 20, 30, 45 minutes
UV analysis @ 265 nm

Compound B

Tablet--disintegrating
Apparatus, speed: 1 (basket), 50 rpm
Medium, volume: 0.01 N hydrochloric acid, 900 mL
Time points —10, 20, 30, 45, 60 minutes
UV analysis @ 305 nm

Compound C

Capsule
Apparatus, speed: 1 (basket), 100 rpm
Medium, volume: 0.5% sodium lauryl sulfate in 0.001 N hydrochloric acid
Time points—10, 20, 30, 45 minutes
HPLC—Symmetry C18 (5 μ) 3.9x150 mm
Column temperature 40° C
Flow rate 1 mL/min
Wavelength 220 nm
Injection volume 25 μ L
Mobile phase—50/50 acetonitrile/water with 0.1% TFA

USP Prednisone Calibrator Tablet

Disintegrating tablet
Apparatus, speed: 1 (basket), 100 rpm
Medium, volume: water, 900 mL
Time point-30 minutes
UV analysis @ 242 nm

USP Salicylic Acid Calibrator Tablet

Non-disintegrating Tablet
Apparatus, speed: 1 (basket), 100 rpm
Medium, volume: 0.05M phosphate buffer adjusted to pH 7.4, 900 mL
Time point-30 minutes
UV analysis @ 296 nm

Results

The data for the calibrator tablets in Tables 1 and 2 are a comparison at the 30-minute time point. Using the Student t-test, $p=0.0147$ for Prednisone Tablets and $p=0.0079$ for Salicylic Acid Tablets. Both are statistically different, however the USP Salicylic Acid Tablets data are so tight that the difference may not be relevant. The USP Prednisone Tablets dissolution results showed the most dramatic difference, with results being higher with the clipped basket shafts. The graphical comparisons using the development products are shown in Figures 2, 3, and 4. Each product gave very similar profiles for each basket shaft type.

Conclusions

There was no difference between the two basket shaft types for the three development products and USP Salicylic Acid Tablets. However, the USP Prednisone Calibrator Tablets did show a significantly different dissolution rate. The difference showed a higher dissolution rate using the clipped basket shaft design. The clipped basket shaft is the official USP design, however there are some drawbacks to this design. The clips protrude and disturb the fluid flow in the vessel. The clips can weaken over time and cause the basket to be attached too loosely to the shaft—increasing the chance for wobble. When using robotic dissolution testers, a robotic arm can remove the O-ring type basket more efficiently.

Since the O-ring style is not an official design, the analyst should show that it does not give results different from the clipped shafts when testing their products. As part of valida-

Table 1. Comparison of Dissolution Results for USP Prednisone Calibrator Tablets, Percent Dissolved in 30 Minutes

Basket attachment type	O-ring	Clips
% Dissolved	78	82
	79	81
	77	84
Mean	78	82
SD	1	2

Table 2. Comparison of Dissolution Results for USP Salicylic Acid Calibrator Tablets, Percent Dissolved in 30 Minutes

Basket attachment type	O-ring	Clips
% Dissolved	25	27
	26	26
	26	27
	26	27
	25	27
	26	29
Mean	26	27
SD	1	1

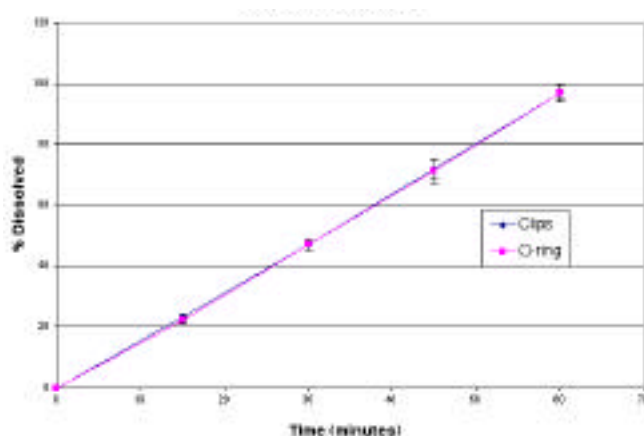


Figure 2. Compound A: Tablet - Erosion Type

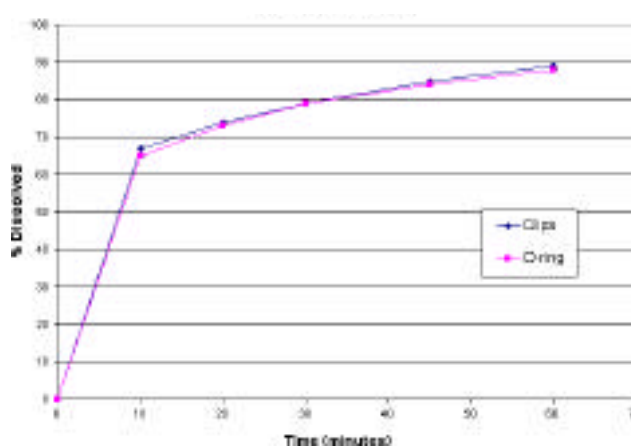


Figure 3. Compound B: Tablet Disintegrating Type

O-ring vs. Clipped Basket ... continued

tion, the two basket shaft types should be compared and equivalence shown. If the types do not give comparable results, there could be problems with technology transfer. In addition, if a regulatory agency performs the dissolution test on a product using the USP procedure, the results obtained could be different.

References

(1) USP 24/NF 19, National Publishing Company, Philadelphia,(1999), page 1942.

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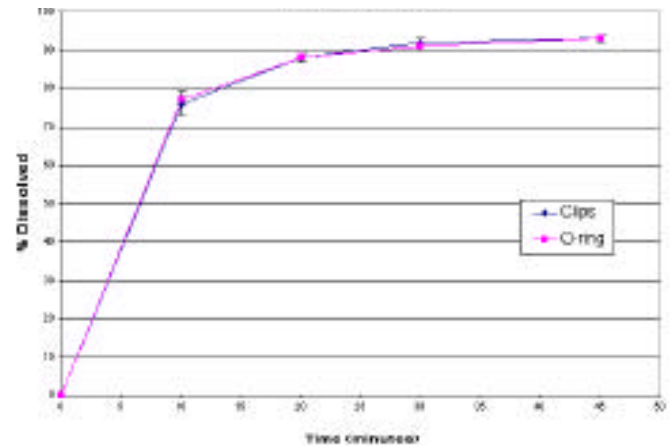


Figure 4: Compound C: Capsule