MODIFIED RELEASE

SURETERIC®

AQUEOUS ENTERIC COATING SYSTEM

Technical Data Sheet

Coating Application

Effect of Dissolution Media pH on the Release of Aspirin from Sureteric® Coated Tablets

Study Purpose:

To investigate the effect of enteric-coating weight gain, and dissolution media pH on the release of aspirin from delayed release tablets.

Methods:

Aspirin tablets (325 mg) were coated in a 24" Accela-Cota with a 2.0% weight gain of Opadry® Y-1-7000 (subcoat), and a 10.0% weight gain of Sureteric YAE-6-18108. Samples were taken at theoretical Sureteric weight gains of 5.0, 7.5, and 10.0%. No topcoat was applied. Tablets at each weight gain were tested using the U.S.P. Method I for Delayed Release Aspirin Tablets. The acid phase of testing was conducted using 0.1N HCL. In addition to the standard 6.8 phosphate buffer required for drug release testing of aspirin, U.S.P. phosphate buffers at pH 5.8 and 7.5 were also used for testing.

The U.S.P. criteria for delayed release aspirin requires that not more than 10.0% aspirin is released in 0.1N HCL after 2 hours. The aspirin tablets are then transferred into the buffer phase where not less than 80.0% of the aspirin must be released within 90 minutes.

Dissolution Results: Acid Phase

	Percent Aspirin Released IN 0.1N HCl		
Weight Gain	**A**	**B**	**C**
5.0	0.67	0.14	0.8
7.5	0.09	0.2	0.14
10.0	0.1	0.09	0.13

All tablet samples passed the acid phase of testing. A, B, and C designates samples which were than transferred to pH 5.8, 6.8, and 7.5 phosphate buffers.

Buffer Phase Results

As shown in figures 1, 2 and 3, tablets coated with a 5.0, 7.5, or 10.0% weight gain of Sureteric met the drug release criteria in pH 6.8 as well as pH 7.5 buffer. Tablets of various weight gains, however, exhibited slow dissolution characteristics in buffer solution, pH 5.8.

Figure 1. Drug Release from Aspirin Tablets with 5% Weight Gain

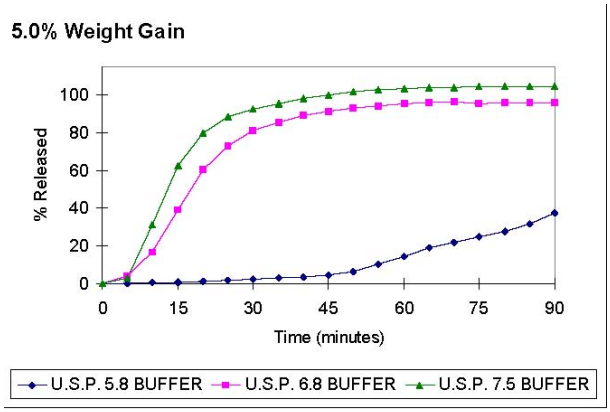


Figure 2. Drug Release from Aspirin Tablets with 7.5% Weight Gain

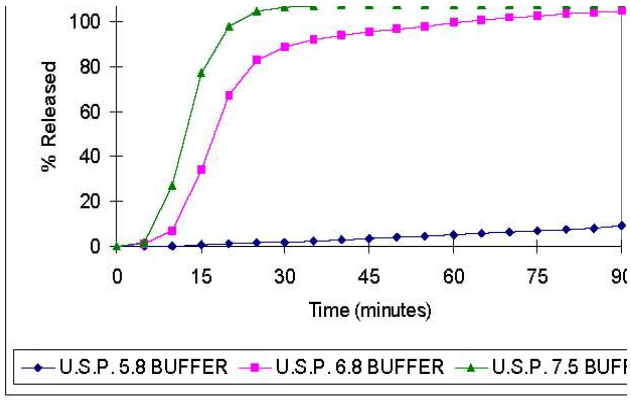
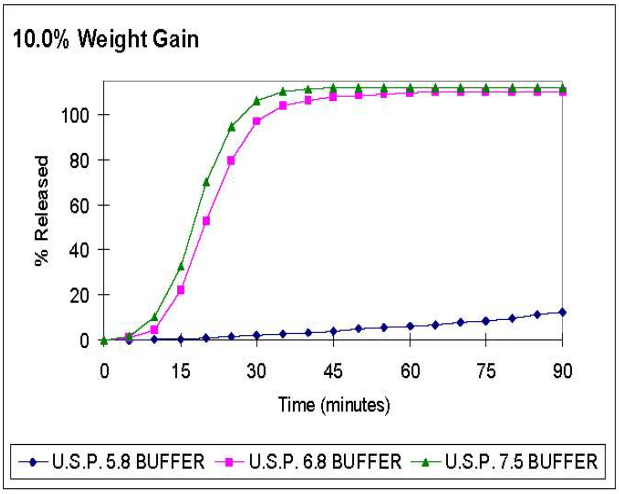


Figure 3. Drug Release from Aspirin Tablets with 10% Weight Gain



Conclusion

Aspirin tablets coated with as little as a 5.0% theoretical weight gain of Sureteric met drug release criteria for USP Delayed Release Aspirin Tablets. Increasing weight gains of Sureteric did not significantly slow the release of aspirin in 6.8 and 7.5 buffers.

Samples tested for drug release in pH 5.8 buffer failed, with the highest amount of aspirin release being 37.5% in 90 minutes for the 5.0% w.g. sample.

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Santa Ana, California	714-549-0631	714-549-4921	Singapore	65-6438-0318	65-6438-0178
Indianapolis, Indiana	317-545-6211	317-545-6218	Nishiyama, Japan	81-5-4465-2711	81-5-4465-2730
Humacao, Puerto Rico	787-852-3815	787-852-0030	Shanghai, China	86-21-5442-2222	86-21-5442-2229
			Goa, India	91-832-288-3434	91-832-288-3440
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