

Enteric Coating Study Using Cap

Prepared  
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A study was conducted on cellulose acetate phthalate (CAP) as an effective barrier against acid though soluble under basic conditions.

The resin was mixed as follows:

4 parts CAP	}	5% Solids
1 part DEP (di-ethyl phthalate)		
95 parts acetone		

This resin was applied to potassium chloride (KCL) tablets, which were made on our tablet press. The tablets are approximately 290 mg, 8 mm in diameter, 2 mm in thickness, and do not crack when bounced on the floor.

The run, identified as 730730-1, went very smoothly. Samples were taken at every 5% between 1.5% and 10.0%. The pumping rate and the percent solids used were determined by the requirement of about 20 minutes for a good coating. Since I was interested in the 1.5% coating level, I had to coat slow enough to have that level in roughly 20 minutes. I began coating at about 25 ml/min, increased this rate to 50 ml/min, which I maintained throughout the remainder of the run. The airflow was approximately 125 cfm, indicating that the pumping rate could have been much higher. The run took 94.7 minutes total. This time included the time taken for obtaining a sample at each level.

The disintegration tests on these tablets were done under the following conditions:

Simulated Intestinal Fluid

Sodium Secondary Phosphate		
Na <sub>2</sub> HPO <sub>4</sub> • H <sub>2</sub> O		26.8 gr
Dilute hydrochloric acid		
(10%)		6.0 ml
Water q . s	Total	1000 ml
pH = 7.5		

Simulated Gastric Fluid

NaCl		2.0 gr
Dilute hydrochloric acid		
(10%)		24.0 ml
Water q . s	Total	1000 ml
pH = 1.2		

Distilled water was used in all preparations.

All tests were conducted using a tablet disintegration tester; Type A, 500 ml of solution in a 1000 ml beaker.

The first study was in simulated intestinal fluid, the second in simulated gastric fluid, pH 1.2, and the third was done in simulated gastric fluid, pH between 0 and 1.

The results are shown on the attached table.

All of the tests were run to disintegration or 2 hours, whichever came first. In the acid test on the 1.5% coated tablets, the tablets did seem to be moist; however, no dissolving of the KCl could readily be discerned.

From the data obtained in this study, it seems that between a 2% and 5% coating would be the most suitable for tablet coating.

Disintegration Tests of KCl Tablets Coated with CAP

%	Tablet	pH 7.5 Intestinal Fluid	pH 1.2 Gastric	pH 0 to 1 Gastric
1.5	1 <sup>st</sup>		45'0" <sup>(1)</sup>	-----
	2 <sup>nd</sup>		-----	-----
	3 <sup>rd</sup>		-----	-----
2.0	1 <sup>st</sup>	4'25"		
	2 <sup>nd</sup>	4'30"		
	3 <sup>rd</sup>	4'40"		
2.5	1 <sup>st</sup>			-----
	2 <sup>nd</sup>			-----
	3 <sup>rd</sup>			-----
3.0	1 <sup>st</sup>		-----	
	2 <sup>nd</sup>		-----	
	3 <sup>rd</sup>		-----	
5.0	1 <sup>st</sup>	6'25"		
	2 <sup>nd</sup>	6'45"		
	3 <sup>rd</sup>	7'12"		
10.0	1 <sup>st</sup>	11'40"	-----	-----
	2 <sup>nd</sup>	11'40"	-----	-----
	3 <sup>rd</sup>	13'40"	-----	-----
Control	1 <sup>st</sup>	3'40"	2'50"	2'25"
	2 <sup>nd</sup>	3'50"	3'0"	2'45"
	3 <sup>rd</sup>	3'50"	3'0"	2'55"

(1) This tablet was partially capped and had a cave-like hole in it. It was at this point that the tablet failed.

NOTE: ‘ represents minutes, “ represents seconds