Evaluating the Effects of Tablet Characteristics on Enteric Tablet Coating in the Novel Supercell™ Coater

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1. Abstract

In the pharmaceutical industry tablets are typically coated to improve handling, appearance, and stability. It is difficult to apply enteric or modified release coatings using current tablet coating techniques including pan coating (side-vented pan coater, SVPC) and fluid bed (Wurster) coating. Instead, microspheres or small beads are more commonly coated using Wurster Coaters or Precision Coaters™, and these coated beads are filled into capsules in order to accomplish the desired drug release profile. This technique requires extensive additional labor and equipment, as opposed to a single coating process to coat an entire dosage form.

Other techniques such as electrostatic tablet coating typically require changes in the tablet formulation to accommodate the coating process. A novel coating technique was developed to coat tablets with a high degree of accuracy. This coating technique, called Supercell™ coating, has already been demonstrated to accurately apply low doses of Active Pharmaceutical Ingredients (APIs) to tablets (<3% RSD at 200 micrograms), uniform color coatings at 10 micrometers theoretical coating thickness, and extremely low total coating weight gains to inert objects (<3% RSD at 125 micrograms total average coating weight) [1,2,3]. In this study the integrity of tablets coated with an enteric coating is evaluated using disintegration in an acid bath.

It is common practice in the pharmaceutical industry to apply enteric and modified release coatings to tablets based on coating weight gain as a percentage of the raw tablet weight. In other coatings industries it is more common to apply protective coatings in terms of coating thicknesses. Both approaches are compared with respect to tablet coating in this study.

2. Materials and Methods

Seven different tablets were coated with ACRYL-EZE™, a fully-formulated enteric coating system based on methacrylic acid co-polymer type C, supplied by Colorcon, Inc (West Point, PA, USA). The ACRYL-EZE™ was mixed in deionized water at 20% total solids content using a low-shear paddle mixer as recommended by the manufacturer [4,7]. The coating formulation is presented in Table 1. Tablets were coated to the percent weight gain where 10 tablets selected randomly from the batch passed a 2 hour disintegration test in a 0.1 N Hydrochloric Acid bath. Two similar tablets, one scored, one unscored, were coated in three different batch sizes (30, 60, and 90 grams). All other tablets were coated in 60 gram batches. The tablets are shown in Figure 1.

Table 1: Coating Formulation

Component	**Amount**
	(wt. %)
ACRYL-EZE™ (white) ID #93018359, Batch #TS026494 (Colorcon Inc., West Point, PA, USA)	20
Deionized water	80

Figure 1: Tablets A-G (Top: Raw Tablets, Bottom: Tablets Coated to Minimum Protective Coating)

Tablet weight is an average of 10 raw tablets weighed on a Sartorius MC5 balance with an accuracy of +/- 6 micrograms. Tablet dimensions were based on an average of 10 tablets as measured with Mitutoyo Digimatic CD-6# s calipers with an accuracy of +/- 0.03 mm. Surface area and volume were calculated with the measured dimensions [5]. Tablet hardness is an average of 10 tablets measured on a Dr. Schleuniger 8M hardness tester. Tablet friability was measured using weight loss of 6.5 grams of de-dusted tablets run in an Electrolab EF-2 (USP) friabilator for 4 minutes at 25 +/- 1 RPM. In the case of tablets weighing more than 650 mg, 10 tablets were used (Tablet D). A summary of tablet properties is presented in Table 2:

Table 2: Tablet Properties

Tablet	Shape	Major Diameter	Scored	Weight	Surface Area	Hardness	Friability
		(mm)		(mg)	(mm^2)	(kPa)	(%)
A	Round	11.97	No	566	336	13.5	1.4
B	Round	11.97	Yes	560	296	13.1	1.5
C	Oblong	17.61	No	574	339	39.4	0.2
D	Oval	17.56	No	775	340	14.7	0.2
E	Round	6.21	No	106	101	9.2	0.8
F	Round	6.35	Yes	90	97	5.6	0.6
G	Round	5.95	No	91	96	5.5	0.8

Tablets were coated in the Supercell™ coater manufactured by Niro Pharma Systems (Figure 2). The inlet temperature, spray rate, and atomization pressure were kept constant for all batches. Due to differences in the physical characteristics of the tablets and batch sizes, the airflow rates were adjusted to provide proper tablet movement.

Figure 2: Supercell™ Coater with Top Cover Open

Tablets were automatically weighed and loaded into the coating chamber through airlock pinch valves. Coating solution was delivered using precision syringe pumps. The tablets were coated and then discharged using a rapid vacuum extraction system. The complete batch process parameters are presented in Appendix 1.

The following characteristics were evaluated for their effect on enteric coating integrity:

Tablet weight: Tablet weights in this study ranged from 91 to 774 mg.

Batch size: Scored and unscored 12 mm round tablets were coated in 30, 60, and 90 gram batch sizes (Tablets A and B).

Score lines: Tablets A and B are both approximately 12 mm round tablets (unscored and scored), and Tablets E, F, and G are approximately 6.0 mm round tablets (scored and unscored). Pharmaceutical companies typically apply more coating to tablets with debossing or scoring [6].

Tablet shape: Tablet A is unscored and round, Tablet C is unscored and oblong, both are similar weights.

Tablet friability: Tablet friability in this study ranges from 0.2 to 1.4%. A friability of 0.8% is typically considered the limit for tablet manufacturing in the pharmaceutical industry [5].

Tablet hardness: Tablet hardness in this study ranges from 5.5 to 39.4 kPa.

3. Supercell™ Tablet Coating Process

The coating apparatus (Figures 3 and 4) is described in US patent 6,209,479 and EP patent 1 140 366 and eqv. [8,9]. It consists of a processing chamber that sits on top of an air distribution plate (Rotonozzle). The Rotonozzle contains gas jets designed to accelerate tablets through the coating zone in a ballistic flight path [10]. Additionally, the gas jets impart momentum to the tablets asymmetrically such that the tablet is rapidly rotating as it passes through the coating zone. The spray zone is created by a low-momentum two-fluid nozzle located beneath the Rotonozzle to atomize the stream of coating solution into fine droplets.

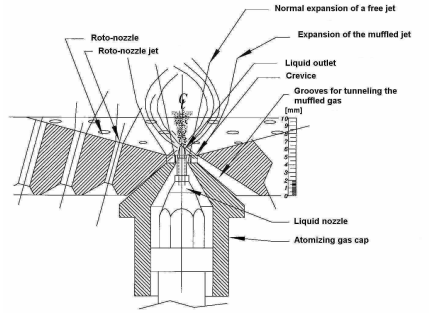

Figure 2: Cutaway of Rotonozzle & Liquid Nozzle

Tangentially located slots around the two-fluid nozzle mix the high-pressure atomizing gas with low-pressure process gas, muffling the energy from the two-fluid nozzle. The objects are loaded into the processing chamber and are coated co-currently with the drying gas.

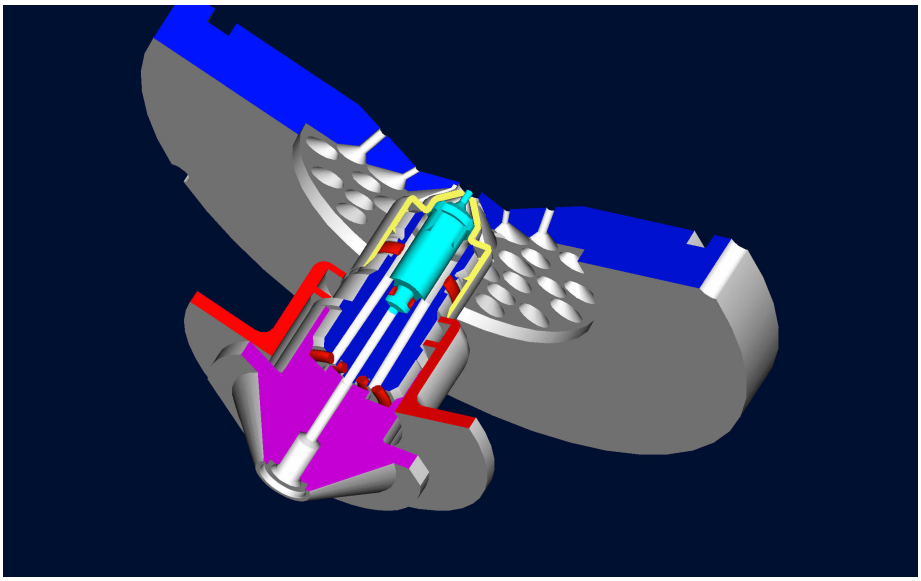

Figure 3: Three-Dimensional Cutaway of Rotonozzle and Spray Nozzle

4. Results

The least amount of coating required for enteric protection was achieved on Tablet G, which required only 6% weight gain (47.5 microns) to pass the 2 hour disintegration test. The disintegration results for all 73 batches are presented in Appendix 2. The protective thickness is based on the tablet surface area and a theoretical 100% yield of coating material applied uniformly to each tablet. Actual coating yield in a tablet coating process is difficult to quantify and is discussed in Section 4.2. A condensed version of the results with only the batches that passed disintegration is presented in Table 3:

Table 3: Disintegration Results

Tablet	Batch Size	Protective Weight Gain	Protective Thickness
	(g)	(%)	(micron)
A	90	10	140.3
B	90	10	157.7
B	60	8	126.2
A	60	8	112.2
A	30	9	126.3
B	30	9	141.9
C	60	9	127.1
D	60	10	190.0
E	60	8	69.4
F	60	7	53.9
G	60	6	47.5

4.1. Effect of Tablet Weight

Previous test work has indicated that the weight of the object being coated in the Supercell™ process is proportional to the amount of coating the object receives [3]. However, in that study, the objects were all of a similar size, shape, and surface area, but varied only a small amount in weight. Slightly heavier objects within a batch had lower fly-heights and made more passes through the coating zone, receiving a proportionally greater amount of coating than lighter objects. In the current study, however, the size, shape, and weight of the objects varies greatly. Significantly larger objects are not accelerated by the Rotonozzle gas jets as fast as small ones, and therefore significantly larger objects make fewer passes through the coating zone in a batch and receive more coating per pass. The results for the protective coating vs. tablet weight are shown in Table 4 and Figure 4:

Table 4: Disintegration Results for Seven Tablet Weights (60 g Batches)

Tablet	Tablet Weight	Protective Weight Gain	Protective Thickness
	(mg)	(%)	(micron)
B	560	8	126.2
A	566	8	112.2
C	574	9	127.1
D	775	10	190.0
E	106	8	69.4
F	90	7	53.9
G	91	6	47.5

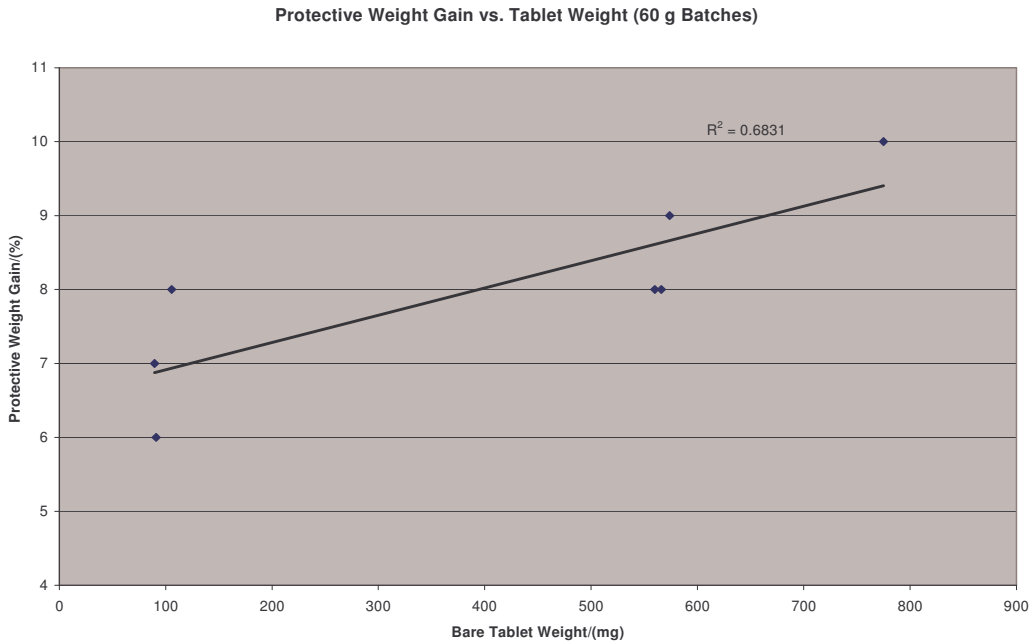

Figure 3: Protective Weight Gain (%) vs. Bare Tablet Weight (mg)

Table 4 and Figure 4 indicate there is a correlation between the minimum protective coating weight gain and the bare tablet weight. The heaviest tablet (Tablet D) required the most amount of coating (10% weight gain) to withstand the acid bath, and the lightest two tablets (Tablets F and G) required the least amount (7 and 6% weight gain). However, as shown in Figure 4, the correlation between minimum protective coating thickness and the bare tablet weight is much stronger than that of coating weight gain (0.9208 R^2 vs. 0.6831 R^2).

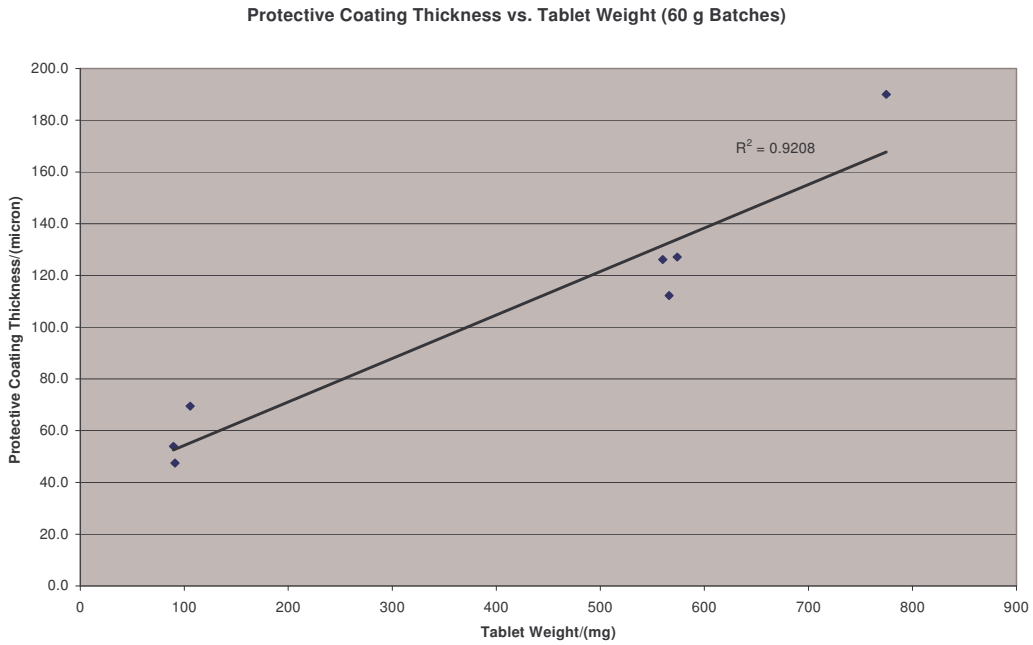

Figure 4: Protective Coating Thickness (micron) vs. Bare Tablet Weight (mg)

For a given tablet weight the thickness of enteric coating required can be predicted with good accuracy. Coating thickness is shown to be a better indicator of enteric protection than coating weight gain in the Supercell™ coating process.

4.2. Effect of Batch Size

Typical batch sizes for tablets in the Supercell™ coating process are 30 to 90 grams. When coating tablets in this process, larger batch sizes (with a larger total surface area) typically have a higher yield of coating efficiency, while smaller batches have a higher degree of uniformity [1,2]. The disintegration results for the batch sizes are presented in Table 5:

Table 5: Disintegration Results for 30, 60, and 90 Gram Batch Sizes

Tablet	Batch Size	Protective Weight Gain	Protective Thickness
	(g)	(%)	(micron)
A	90	10	140.3
B	90	10	157.7
B	60	8	126.2
A	60	8	112.2
A	30	9	126.3
B	30	9	141.9

Batch size is demonstrated to be a factor in the amount of coating required for enteric protection in the Supercell™ coating process. In this study, with 12 mm tablets, the optimum batch size was 60 grams. It is believed that in the 90 gram batches the tablets do not make as many passes through the coating zone as in the smaller ones, and therefore the coating is not as uniform. However, in smaller batch sizes, the tablets present less of a surface to receive the coating, and therefore the overall coating yield is lower, and more coating must be applied to offset the coating loss.

Coating yield in a tablet coating process is difficult to determine [14,15]. Tablet weight gain cannot be used due to changing levels of moisture in the tablet and coating. All current tablet coating processes pass hot air around the tablets to speed up the drying rate of the coating. In doing this, some of the moisture inside the tablets may be removed as well, or moisture from the coating solution may be absorbed by the tablets. Additionally, coatings retain some solvent when they are dry, and the amount of solvent left may differ depending on the drying rate. Another method of measuring coating yield is to run many batches sequentially and weigh the total amount of tablets processed, the total amount of solids sprayed, and the total amount of dust collected in the exhaust air stream using a high efficiency cyclone and filter combination. However, this method is also not very accurate, as the tablets lose mass in the coating process due to attrition, and it is difficult to determine how much of the dust is oversprayed coating and how much is material from the tablets themselves.

Coated tablets were weighed at the end of each batch but an accurate yield could not be determined from this (Appendix 2). Larger, harder tablets showed some consistency of weight gain, but in order to determine an accurate yield uniform and inert objects must be coated with enough coating to be measured accurately with a microbalance.

Coating thickness is also difficult to measure. The surface of a tablet is uneven when viewed under a microscope, and the surface of the coating will therefore also be uneven. In addition, in order to view the two surfaces the tablet must be cryogenically frozen and cut in

half; this cleaving process obscures the surfaces somewhat, further reducing the accuracy of measure. It is therefore difficult to obtain an accurate measure of yield by measuring the coating thickness.

Coating thicknesses and weight gains are not presented in this study. All thicknesses and weight gains presented are theoretical and not measured.

4.3. Effect of Score Lines

When coating tablets in a conventional SVPC process, pharmaceutical companies typically apply more coating to tablets with score lines or debossing [6]. The disintegration results for both scored and unscored tablets are shown in Table 6:

Table 6: Disintegration Results for Scored and Unscored Tablets

Tablet	**Scored**	**Batch Size**	**Protective Weight Gain**	**Protective Thickness**
		(g)	(%)	(micron)
A	No	90	10	140.3
B	Yes	90	10	157.7
B	Yes	60	8	126.2
A	No	60	8	112.2
A	No	30	9	126.3
B	Yes	30	9	141.9
E	No	60	8	69.4
F	Yes	60	7	53.9
G	No	60	6	47.5

Tablets of similar weight, shape, and batch size required the same level of protection regardless of whether they were scored or not. The presence of score lines is shown to not affect the amount of coating required for enteric protection. A microscope image of Tablet B raw and coated to the minimum protective level is shown in Figure 5:

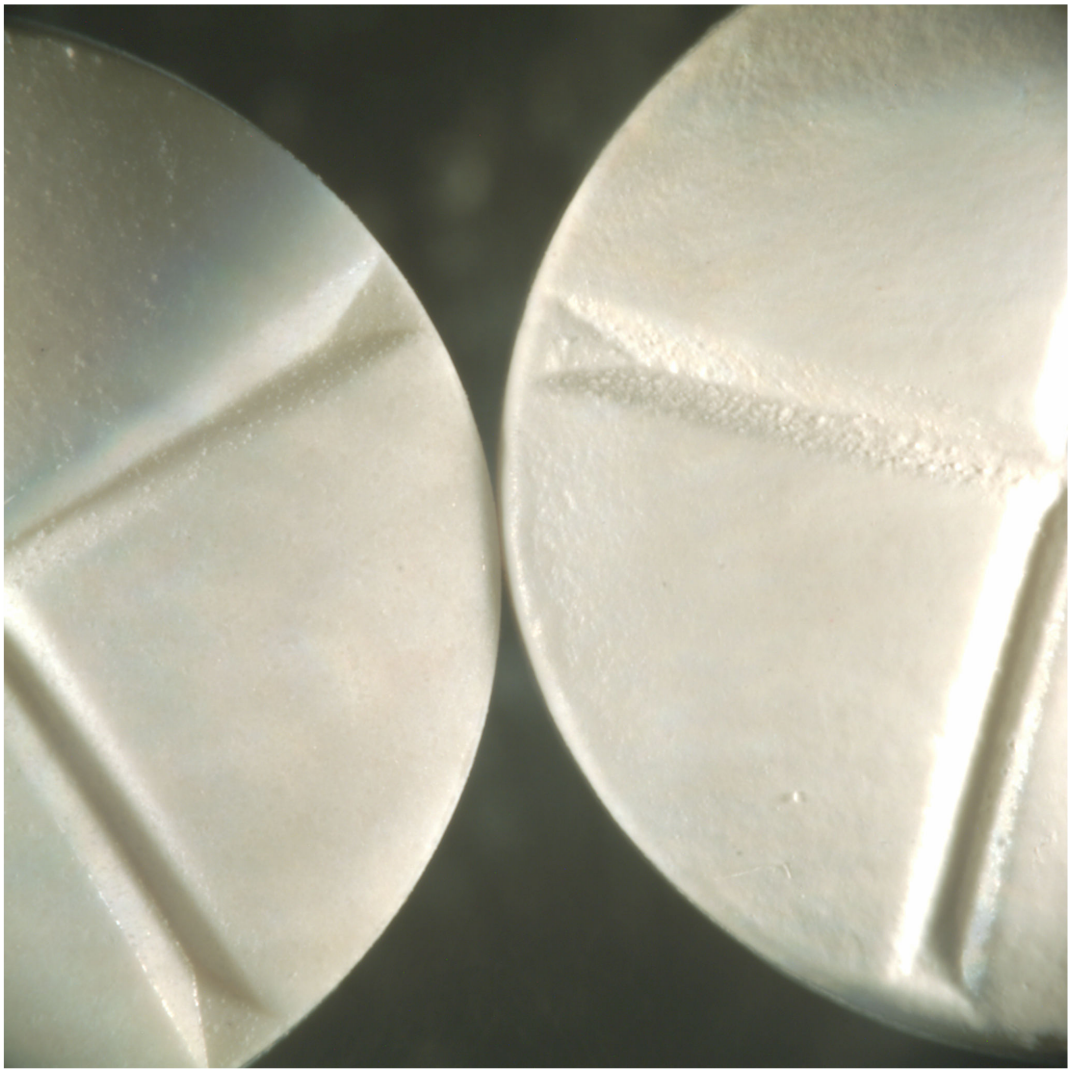

Figure 5: Tablet B Raw (Left) and with Minimum Protective Coating (8%, Right)

4.4. Effect of Tablet Shape

It is difficult to directly compare coating results for tablets of different shapes, since that for a single tablet formulation one or more of the following parameters must necessarily also change with the tablet shape: surface area, volume, weight, density, hardness, friability. It was decided to compare two tablets of similar weight and surface area, since the coating thickness should be related to the surface area of the tablets, and previous studies have indicated that the tablet weight is proportional to the amount of coating received [3]. Tablets A and C are approximately the same surface area and weight; Tablet A is round and Tablet C is oblong. The disintegration results for these two tablet shapes are shown in Table 7:

Table 7: Disintegration Results for Two Tablet Shapes (60 g Batches)

Tablet	**Shape**	**Weight**	**Surface Area**		**Protective Weight Gain**	**Protective Thickness**
		(mg)	(mm^2)		(%)	(micron)
A	Round	566	336		8	112.2
C	Oblong	574	339		9	127.1

From Table 7, Tablet A (round) required slightly less coating than Tablet C (oblong). However, since tests were only performed on tablets coated in 1% weight gain intervals, it is not possible to know within that interval how close the two actually were. Therefore, the effect of tablet shape is quantified as 1.0% weight gain +/- 1.0% for round and oblong tablets of approximately the same weight and surface area. In conventional pan coating, tablet shape "can significantly influence intra-tablet uniformity" [13].

4.5. Effect of Tablet Friability

Coating integrity is more difficult to achieve if the coating process is chipping or damaging the tablets. These areas of damage will have a thinner coating than the undamaged areas and will cause the tablet to fail disintegration. It is therefore important to monitor tablet friability to determine if more friable tablets require more coating to pass the disintegration test. The disintegration results for tablet friability are presented in Table 8 and Figure 7:

Table 8: Disintegration Results for Tablet Friability (60 gram batches)

Tablet	**Friability**	**Protective Weight Gain**	**Protective Thickness**
	(%)	(%)	(micron)
A	1.4	8	126.2
B	1.5	8	112.2
C	0.2	9	127.1
D	0.2	10	190.0
E	0.8	8	69.4
F	0.6	7	53.9
G	0.8	6	47.5

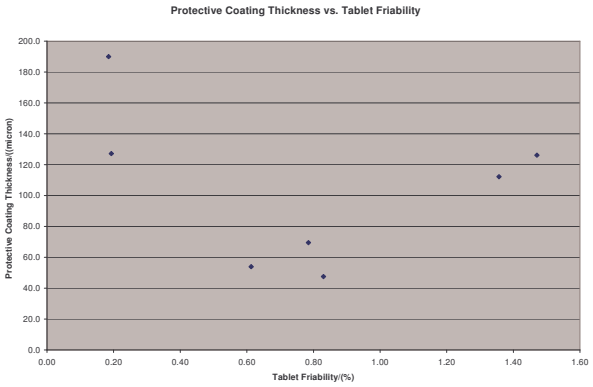

Figure 7: Protective Coating Thickness (micron) vs. Tablet Friability (%)

From Figure 7, there is no discernable correlation between tablet friability and coating integrity. The two least friable tablets (C and D) required the most coating, and tablets that would be considered too friable for conventional tablet coating processes (A and B) were successfully coated in the Supercell^{TM} process.

4.6. Effect of Tablet Hardness

Tablets that are not very hard may break during a coating process. This is most common in Wurster-type coating, where tablets must be harder than necessary for traditional pan coating to withstand the coating process. The disintegration results for tablet hardness are presented in Table 9 and Figure 8:

Table 9: Disintegration Results for Tablet Hardness (60 gram batches)

Tablet	Hardness	Protective Weight Gain	Protective Thickness
	(kPa)	(%)	(micron)
A	13.5	8	126.2
B	13.1	8	112.2
C	39.4	9	127.1
D	14.7	10	190.0
E	9.2	8	69.4
F	5.6	7	53.9
G	5.5	6	47.5

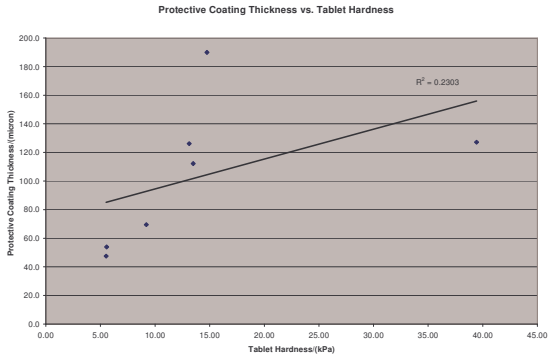

Figure 8: Protective Coating Thickness (micron) vs. Tablet Hardness (kPa)

From Figure 8, there is no clear effect of tablet hardness on the Supercell™ coating process. No tablets were broken during the coating process in this study.

5. Experimental Comparison to Conventional Tablet Coating Techniques

73 batches were performed in a total of 5.1 hours in the Supercell™ using 4.4 kg of tablets. Using conventional laboratory-sized side-vented pan coating equipment (300 gram batch size), this same experiment would require 3.0 days of coating time and 29.1 kg of tablets [4,7,10]. In addition, the pan coater requires cleaning in between all or most batches, whereas the Supercell™ did not require any cleaning. Transferring the process to larger pan coating equipment would require additional development, whereas the Supercell™ process is modular and requires no scale-up. All of the Supercell™ wetted parts fit in a sink or automatic dishwasher, and the machine can be broken down and reassembled in less than 30 minutes.

6. Conclusions

Coating thickness is shown to be a better predictor of enteric protection than coating weight gain in the Supercell™ process. Raw tablet weight provides an accurate prediction of the amount of coating required for enteric protection. Batch size is a factor in the amount of coating required; in this study, for friable 12mm tablets the optimum batch size was 60 grams in comparison to 30 and 90 gram batch sizes. Tablet score lines, shape, friability, and hardness are not significant factors in determining the amount of coating required for enteric protection.

In comparison to traditional tablet coating techniques, the Supercell™ requires over an order of magnitude less time and materials to perform the same number of batches, and in addition, no further scale-up is ever required to move to manufacturing. The Supercell™ also requires less cleaning than conventional processes, and since it is semi-continuous, it is possible to couple the Supercell™ directly to a tablet press for continuous tablet coating and feeding directly to a filling line for real-time release. In order to determine an accurate overall coating yield, inert placebo objects similar to tablets should be coated and measured for weight gain.

7. References

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Appendix 1: Supercell™ Batch Process Parameters

Batch ID	Tablet	Count (n)	Batch Weight (g)	Spray Rate (mL/min)	Inlet Temp. C	Airflow Rate (m^3/hr)	Inlet Pressure (mmWC)	Atomizing Pressure (bar)	Solution Vol. (ml)	Coat Thickness (micron)	Tab. Wt. Gain (%)
Part 1											
05071401	A	159	89.994	4.0	70	24.7	1800	2.5	12.5	42.1	3
05071402	A	159	89.994	4.0	70	24.7	1800	2.5	16.7	56.1	4
05071403	A	159	89.994	4.0	70	24.7	1800	2.5	20.8	70.1	5
05071404	A	159	89.994	4.0	70	24.7	1800	2.5	25.0	84.2	6
05071405	A	159	89.994	4.0	70	24.7	1800	2.5	29.2	98.2	7
05072501	A	159	89.994	4.0	70	24.7	1800	2.5	33.3	112.2	8
05072502	A	159	89.994	4.0	70	24.7	1800	2.5	37.5	126.3	9
05072503	A	159	89.994	4.0	70	24.7	1800	2.5	41.7	140.3	10
Part 2											
05071406	B	161	90.16	4.0	70	24.7	1800	2.5	12.5	47.3	3
05071407	B	161	90.16	4.0	70	24.7	1800	2.5	16.7	63.1	4
05071408	B	161	90.16	4.0	70	24.7	1800	2.5	20.9	78.9	5
05071409	B	161	90.16	4.0	70	24.7	1800	2.5	25.0	94.6	6
05071410	B	161	90.16	4.0	70	24.7	1800	2.5	29.2	110.4	7
05072504	B	161	90.16	4.0	70	24.7	1800	2.5	33.4	126.2	8
05072505	B	161	90.16	4.0	70	24.7	1800	2.5	37.6	141.9	9
05072506	B	161	90.16	4.0	70	24.7	1800	2.5	41.7	157.7	10
Part 3											
05071501	B	107	59.92	4.0	70	23	1300	2.5	8.3	47.3	3
05071502	B	107	59.92	4.0	70	23	1300	2.5	11.1	63.1	4
05071503	B	107	59.92	4.0	70	23	1300	2.5	13.9	78.9	5
05071504	B	107	59.92	4.0	70	23	1300	2.5	16.6	94.6	6
05071505	B	107	59.92	4.0	70	23	1300	2.5	19.4	110.4	7
05072507	B	107	59.92	4.0	70	23	1300	2.5	22.2	126.2	8
Part 4											
05071506	A	106	59.996	4.0	70	23	1300	2.5	8.3	42.1	3
05071507	A	106	59.996	4.0	70	23	1300	2.5	11.1	56.1	4
05071508	A	106	59.996	4.0	70	23	1300	2.5	13.9	70.1	5
05071509	A	106	59.996	4.0	70	23	1300	2.5	16.7	84.2	6
05071510	A	106	59.996	4.0	70	23	1300	2.5	19.4	98.2	7
05072508	A	106	59.996	4.0	70	23	1300	2.5	22.2	112.2	8
Part 5											
05071511	A	53	29.998	4.0	70	20.4	800	2.5	4.2	42.1	3
05071512	A	53	29.998	4.0	70	20.4	800	2.5	5.6	56.1	4
05071513	A	53	29.998	4.0	70	20.4	800	2.5	6.9	70.1	5
05071514	A	53	29.998	4.0	70	20.4	800	2.5	8.3	84.2	6
05071515	A	53	29.998	4.0	70	20.4	800	2.5	9.7	98.2	7
05072509	A	53	29.998	4.0	70	20.4	800	2.5	11.1	112.2	8
05072510	A	53	29.998	4.0	70	20.4	800	2.5	12.5	126.3	9
Part 6											
05071516	B	54	30.24	4.0	70	20.4	800	2.5	4.2	47.3	3
05071517	B	54	30.24	4.0	70	20.4	800	2.5	5.6	63.1	4
05071518	B	54	30.24	4.0	70	20.4	800	2.5	7.0	78.9	5
05071519	B	54	30.24	4.0	70	20.4	800	2.5	8.4	94.6	6
05071520	B	54	30.24	4.0	70	20.4	800	2.5	9.8	110.4	7
05072511	B	54	30.24	4.0	70	20.4	800	2.5	11.2	126.2	8
05072512	B	54	30.24	4.0	70	20.4	800	2.5	12.6	141.9	9
Part 7											
05071801	C	105	60.27	4.0	70	24.1	1300	2.5	8.4	42.4	3
05071802	C	105	60.27	4.0	70	24.1	1300	2.5	11.2	56.5	4
05071803	C	105	60.27	4.0	70	24.1	1300	2.5	14.0	70.6	5
05071804	C	105	60.27	4.0	70	24.1	1300	2.5	16.7	84.8	6
05071805	C	105	60.27	4.0	70	24.1	1300	2.5	19.5	98.9	7
05072513	C	105	60.27	4.0	70	24.1	1300	2.5	22.3	113.0	8
05072514	C	105	60.27	4.0	70	24.1	1300	2.5	25.1	127.1	9
Part 8											
05071806	D	77	59.675	4.0	70	25.3	1450	2.5	8.3	57.0	3
05071807	D	77	59.675	4.0	70	25.3	1450	2.5	11.1	76.0	4
05071808	D	77	59.675	4.0	70	25.3	1450	2.5	13.8	95.0	5
05071809	D	77	59.675	4.0	70	25.3	1450	2.5	16.6	114.0	6
05071810	D	77	59.675	4.0	70	25.3	1450	2.5	19.3	133.0	7
05072515	D	77	59.675	4.0	70	25.3	1450	2.5	22.1	152.0	8
05072516	D	77	59.675	4.0	70	25.3	1450	2.5	24.9	171.0	9
05072517	D	77	59.675	4.0	70	25.3	1450	2.5	27.6	190.0	10
Part 9											
05071901	E	568	59.98478	4.0	70	23	1300	2.5	8.3	26.0	3
05071902	E	568	59.98478	4.0	70	23	1300	2.5	11.1	34.7	4
05071903	E	568	59.98478	4.0	70	23	1300	2.5	13.9	43.4	5
05071904	E	568	59.98478	4.0	70	23	1300	2.5	16.7	52.1	6
05071905	E	568	59.98478	4.0	70	23	1300	2.5	19.4	60.8	7
05072518	E	568	59.98478	4.0	70	23	1300	2.5	22.2	69.4	8
Part 10											
05071906	F	670	60.02731	4.0	70	23	1300	2.5	8.3	23.1	3
05071907	F	670	60.02731	4.0	70	23	1300	2.5	11.1	30.8	4
05071908	F	670	60.02731	4.0	70	23	1300	2.5	13.9	38.5	5
05071909	F	670	60.02731	4.0	70	23	1300	2.5	16.7	46.2	6
05071910	F	670	60.02731	4.0	70	23	1300	2.5	19.5	53.9	7
Part 11											
05071911	G	659	59.969	4.0	70	23	1300	2.5	8.3	23.7	3
05071912	G	659	59.969	4.0	70	23	1300	2.5	11.1	31.7	4
05071913	G	659	59.969	4.0	70	23	1300	2.5	13.9	39.6	5
05071914	G	659	59.969	4.0	70	23	1300	2.5	16.7	47.5	6
05071915	G	659	59.969	4.0	70	23	1300	2.5	19.4	55.4	7

Appendix 2: Disintegration Test Results

Batch ID	Tablet ID	Tablet Shape	Surface Area (mm^2)	Weight (mg)	Hardness (kPa)	Friability (%)	Count (n)	Batch Weight (g)	Coating Thickness (micron)	Weight Gain (%)	Average Weight (mg)	Average Weight Gain (mg)	Disintegration Test (# pass))
	Part 1												
05071401	A	Round	336.23	566	13.49	1.36	159	90	42.1	3	571.06	5.06	0
05071402	A	Round	336.23	566	13.49	1.36	159	90	56.1	4	571.65	0.59	0
05071403	A	Round	336.23	566	13.49	1.36	159	90	70.1	5	585.04	13.40	0
05071404	A	Round	336.23	566	13.49	1.36	159	90	84.2	6	588.15	3.10	0
05071405	A	Round	336.23	566	13.49	1.36	159	90	98.2	7	592.48	4.34	0
05072501	A	Round	336.23	566	13.49	1.36	159	90	112.2	8	594.29	1.80	3
05072502	A	Round	336.23	566	13.49	1.36	159	90	126.3	9	599.20	4.92	5
05072503	A	Round	336.23	566	13.49	1.36	159	90	140.3	10	603.11	3.91	10
	Part 2												
05071406	B	Round	295.89	560	13.13	1.47	161	90	47.3	3	573.55	13.55	0
05071407	B	Round	295.89	560	13.13	1.47	161	90	63.1	4	579.74	6.19	0
05071408	B	Round	295.89	560	13.13	1.47	161	90	78.9	5	581.21	1.47	0
05071409	B	Round	295.89	560	13.13	1.47	161	90	94.6	6	586.57	5.36	0
05071410	B	Round	295.89	560	13.13	1.47	161	90	110.4	7	581.71	-4.86	0
05072504	B	Round	295.89	560	13.13	1.47	161	90	126.2	8	589.44	7.73	2
05072505	B	Round	295.89	560	13.13	1.47	161	90	141.9	9	593.19	3.75	5
05072506	B	Round	295.89	560	13.13	1.47	161	90	157.7	10	594.89	1.70	10
	Part 3												
05071501	B	Round	295.89	560	13.13	1.47	107	60	47.3	3	569.95	9.95	0
05071502	B	Round	295.89	560	13.13	1.47	107	60	63.1	4	575.55	5.60	0
05071503	B	Round	295.89	560	13.13	1.47	107	60	78.9	5	579.19	3.64	0
05071504	B	Round	295.89	560	13.13	1.47	107	60	94.6	6	582.16	2.97	0
05071505	B	Round	295.89	560	13.13	1.47	107	60	110.4	7	588.51	6.36	7
05072507	B	Round	295.89	560	13.13	1.47	107	60	126.2	8	593.51	4.99	10
	Part 4												
05071506	A	Round	336.23	566	13.49	1.36	106	60	42.1	3	567.14	1.14	0
05071507	A	Round	336.23	566	13.49	1.36	106	60	56.1	4	579.70	12.56	0
05071508	A	Round	336.23	566	13.49	1.36	106	60	70.1	5	579.69	-0.02	1
05071509	A	Round	336.23	566	13.49	1.36	106	60	84.2	6	584.26	4.57	2
05071510	A	Round	336.23	566	13.49	1.36	106	60	98.2	7	588.75	4.49	5
05072508	A	Round	336.23	566	13.49	1.36	106	60	112.2	8	594.43	5.68	10
	Part 5												
05071511	A	Round	336.23	566	13.49	1.36	53	30	42.1	3	569.42	3.42	0
05071512	A	Round	336.23	566	13.49	1.36	53	30	56.1	4	575.96	6.55	0
05071513	A	Round	336.23	566	13.49	1.36	53	30	70.1	5	570.95	-5.01	0
05071514	A	Round	336.23	566	13.49	1.36	53	30	84.2	6	576.34	5.39	0
05071515	A	Round	336.23	566	13.49	1.36	53	30	98.2	7	580.95	4.61	3
05072509	A	Round	336.23	566	13.49	1.36	53	30	112.2	8	584.20	3.25	6
05072510	A	Round	336.23	566	13.49	1.36	53	30	126.3	9	586.60	2.40	10
	Part 6												
05071516	B	Round	295.89	560	13.13	1.47	54	30	47.3	3	567.23	7.23	0
05071517	B	Round	295.89	560	13.13	1.47	54	30	63.1	4	573.56	6.32	0
05071518	B	Round	295.89	560	13.13	1.47	54	30	78.9	5	578.78	5.22	0
05071519	B	Round	295.89	560	13.13	1.47	54	30	94.6	6	579.26	0.48	0
05071520	B	Round	295.89	560	13.13	1.47	54	30	110.4	7	585.70	6.44	3
05072511	B	Round	295.89	560	13.13	1.47	54	30	126.2	8	590.05	4.35	5
05072512	B	Round	295.89	560	13.13	1.47	54	30	141.9	9	593.98	3.93	10
	Part 7												
05071801	C	Oblong	338.579	574	39.44	0.19	105	60	42.4	3	588.10	14.10	0
05071802	C	Oblong	338.579	574	39.44	0.19	105	60	56.5	4	590.30	2.20	0
05071803	C	Oblong	338.579	574	39.44	0.19	105	60	70.6	5	596.81	6.51	0
05071804	C	Oblong	338.579	574	39.44	0.19	105	60	84.8	6	598.40	1.60	0
05071805	C	Oblong	338.579	574	39.44	0.19	105	60	98.9	7	602.81	4.41	2
05072513	C	Oblong	338.579	574	39.44	0.19	105	60	113.0	8	605.35	2.54	7
05072514	C	Oblong	338.579	574	39.44	0.19	105	60	127.1	9	609.88	4.53	10
	Part 8												
05071806	D	Oval	339.965	775	14.74	0.19	77	60	57.0	3	789.48	14.48	0
05071807	D	Oval	339.965	775	14.74	0.19	77	60	76.0	4	793.95	4.48	0
05071808	D	Oval	339.965	775	14.74	0.19	77	60	95.0	5	800.32	6.36	0
05071809	D	Oval	339.965	775	14.74	0.19	77	60	114.0	6	806.74	6.42	0
05071810	D	Oval	339.965	775	14.74	0.19	77	60	133.0	7	811.30	4.57	0
05072515	D	Oval	339.965	775	14.74	0.19	77	60	152.0	8	816.54	5.24	2
05072516	D	Oval	339.965	775	14.74	0.19	77	60	171.0	9	821.05	4.51	7
05072517	D	Oval	339.965	775	14.74	0.19	77	60	190.0	10	826.36	5.31	10
	Part 9												
05071901	E	Round	101.387	105.607	9.2	0.79	568	60	26.0	3	109.31	3.71	0
05071902	E	Round	101.387	105.607	9.2	0.79	568	60	34.7	4	108.71	-0.61	0
05071903	E	Round	101.387	105.607	9.2	0.79	568	60	43.4	5	109.92	1.21	0
05071904	E	Round	101.387	105.607	9.2	0.79	568	60	52.1	6	109.80	-0.12	3
05071905	E	Round	101.387	105.607	9.2	0.79	568	60	60.8	7	111.96	2.16	8
05072518	E	Round	101.387	105.607	9.2	0.79	568	60	69.4	8	113.97	2.01	10
	Part 10												
05071906	F	Round	96.919	89.593	5.57	0.61	670	60	23.1	3	93.26	3.66	0
05071907	F	Round	96.919	89.593	5.57	0.61	670	60	30.8	4	94.89	1.63	1
05071908	F	Round	96.919	89.593	5.57	0.61	670	60	38.5	5	93.82	-1.06	3
05071909	F	Round	96.919	89.593	5.57	0.61	670	60	46.2	6	95.80	1.98	8
05071910	F	Round	96.919	89.593	5.57	0.61	670	60	53.9	7	96.58	0.77	10
	Part 11												
05071911	G	Round	95.8	91	5.51	0.83	659	60	23.7	3	93.32	2.32	0
05071912	G	Round	95.8	91	5.51	0.83	659	60	31.7	4	93.24	-0.08	4
05071913	G	Round	95.8	91	5.51	0.83	659	60	39.6	5	92.92	-0.32	8
05071914	G	Round	95.8	91	5.51	0.83	659	60	47.5	6	95.93	3.00	10
05071915	G	Round	95.8	91	5.51	0.83	659	60	55.4	7	96.13	0.21	10