Surelease®
Ethylcellulose Dispersion Type B NF

Colorcon®

Surelease® Encapsulated Caffeine for Gummies

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Challenge

In recent years, gummies have become increasingly popular as an innovative dosage form for dietary supplements[1], especially among younger consumers, those seeking a more enjoyable sensory experience, and individuals with dysphagia, for whom traditional formats like tablets or capsules are lessdesirable[2,3]. Yet, the unpleasant flavors of some active ingredients can diminish the sensory appeal of gummies[4]. Caffeine, commonly added for its stimulating effects and promoted as a coffee alternative or a pre-workout aid, is one such ingredient, because its bitterness can lead to an undesirabletaste[5].

In this study we explored using Surelease®, Ethylcellulose Dispersion Type BNF, to encapsulate caffeine for taste-masking while testing its stability during the pectin-based gummy cooking process. We also compared gummies containing wax-encapsulated and non-encapsulated caffeine against the gummies with Surelease encapsulated caffeine.

Method

Caffeine anhydrous fine powder (Aarti Pharmalabs) was processed, with a 5% flow aid added to enhance flowability. This blend was granulated using clear Opadry® coating at 12% weight gain and 10.5% w/w solids in a VFC-Lab 3 Flo-Coater (Vector Corp) with a 4-liter top-spray bowl, as outlined in Table 1 (Granulation). The resulting granules were encapsulated with Surelease E-7-19040, Ethyl cellulose Dispersion Type B NF, up to 85%weight gain, with samples also collected at 65% and 75%, as shown in Table1 (Encapsulation), using optimized fluid-bed conditions for producing smaller, less gritty particles more suitable for gummies.

Surelease encapsulated caffeine samples were analyzed by microscopy and particle size (Malvern Mastersizer 3000), then formulated into pectin-based gummies (Melt-to-Make™)6, each containing 40mg caffeine and colored with Opatint® (0.5% of recipe, natural brown). For comparison, gummies containing non-encapsulated and wax-encapsulated caffeine were also prepared. All were tested for content uniformity and dissolution (purified water, 900 mL, apparatus 2, 50 rpm, 60 min) to evaluate release characteristics.

Table 1: Top-Spray Granulation and Encapsulation Parameters

Parameter	Granulation / Opadry®	Encapsulation / Surelease®
Batch size (g)	1500	1455
Weight gain (%)	12	65, 75, 85
Dispersion solids (%w/w)	10.5	15
Spray rate (g/min)	-14	-12
Bed temperature (°C)	32-35	42-45
Inlet air temperature (°C)	71-71	78-82
Air flow (cfm)	30-32	35
Number of spray guns	1	1
Gun-to-bed distance (inch)	Lower position /-5	Upper position /-6
Nozzle size (mm)	1.2	1.0
Atomization air (psi)	40	4.0

Results

After granulation with clear Opadry coating, caffeine was efficiently fluidized for encapsulation with Surelease. Microscopy (Figure 1) and particle size analysis showed well-controlled encapsulation and resulted in particle sizes around 500–600 µm (D90v), as shown on Table 2. Note that the off-colored spots observed in some of the granulated and encapsulated microscopy are the flow aid, which are naturally brown in appearance.

Lab-scale pectin-based gummies made with Surelease-encapsulated caffeine exhibited uniform, discrete particles (Figure 2-A), while those with non-encapsulated or wax-encapsulated caffeine were discolored and opaque (Figure 2-B, C).

Dissolution testing revealed gummies containing Surelease-encapsulated caffeine exhibited slower release compared to the other forms, indicating improved barrier protection. Higher coating weight increased barrier efficacy, but differences were minimal between 75% and 85%weight gains. All Surelease-encapsulated gummies released over 80% of their active ingredient, consistent with immediate-release characteristics (Figure 3). Note: It is considered that the amount of weight gain needed would be more likely dependent on the specific substrate characteristics and processing conditions.

Figure 1. Microscopy

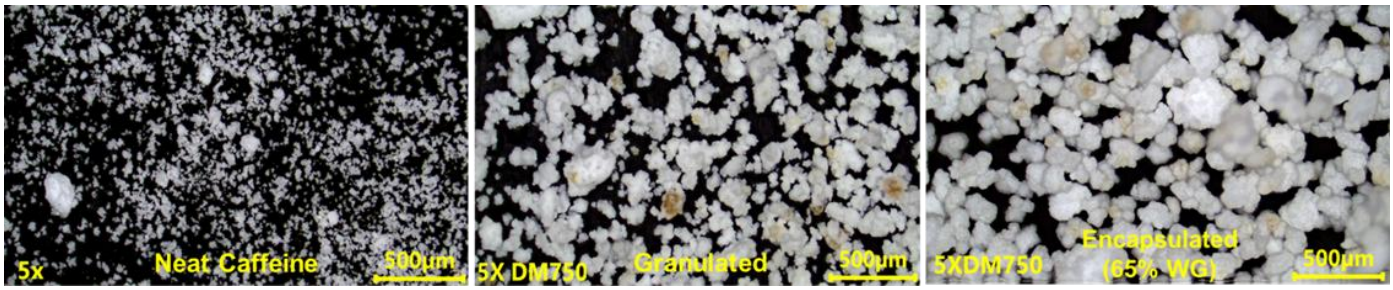
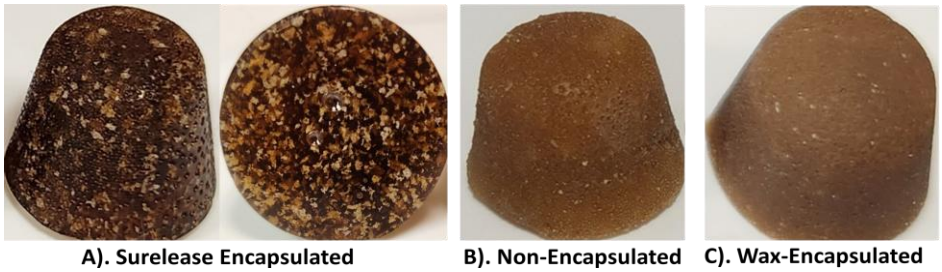


Table 2. Particle Size Analysis

Particle Size Distribution per Volume (µm)	Neat Caffeine	Granulation / Opadry	Encapsulation - Surelease		
			65% WG	75% WG	85% WG
D(10)	3	98	151	181	204
D(50)	27	204	263	315	348
D(90)	197	404	451	540	581

Figure 2: Gummies

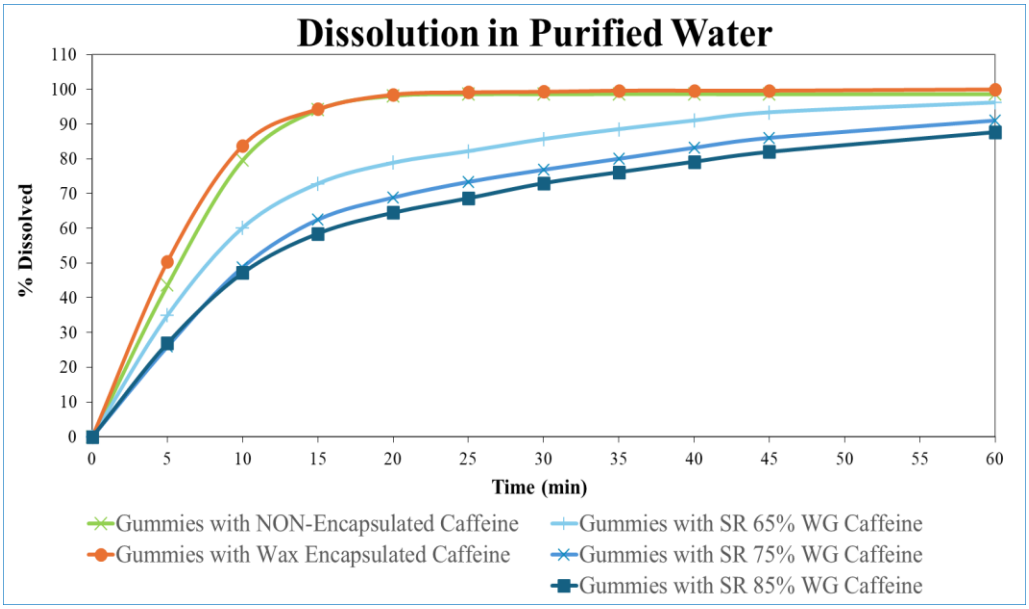


A). Surelease Encapsulated B). Non-Encapsulated C). Wax-Encapsulated

Table 3: Content Uniformity (mg/g)

	Non-Encapsulated Caffeine Gummies	Wax-encapsulated Caffeine Gummies	Surelease Encapsulated Caffeine Gummies		
			65% WG	75% WG	85% WG
AVG (mg/g)	12.94	13.64	13.25	13.14	12.47
%RSD	1.1%	0.3%	0.6%	1.5%	1.7%

Figure 3. Dissolution of Gummies with Encapsulated Caffeine



Conclusion

Fine particle caffeine was encapsulated using Surelease®, Ethylcellulose Dispersion Type B NF, via top-spray fluidization for use within gummies. This process produced small particle sizes which resulted in uniform distribution within pectin-based gummies. Surelease encapsulation provided better protection to caffeine than non- and wax-encapsulated forms, as shown by a slight delay in release and less discoloration of the gummies. Increased coating weight enhanced barrier efficacy, though gains seem to diminish after 75%. The optimal coating weight likely depends on specific substrate characteristics and processing conditions.

In conclusion, the findings of this study demonstrated Surelease as an effective encapsulating agent for caffeine for gummy applications, providing a protective barrier as compared to wax-encapsulated alternatives.

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6. Trademark Reference: Melt-to-Make™ is a trademark of Melt-to-Make™, which does not sponsor, authorize, or endorse this document.

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