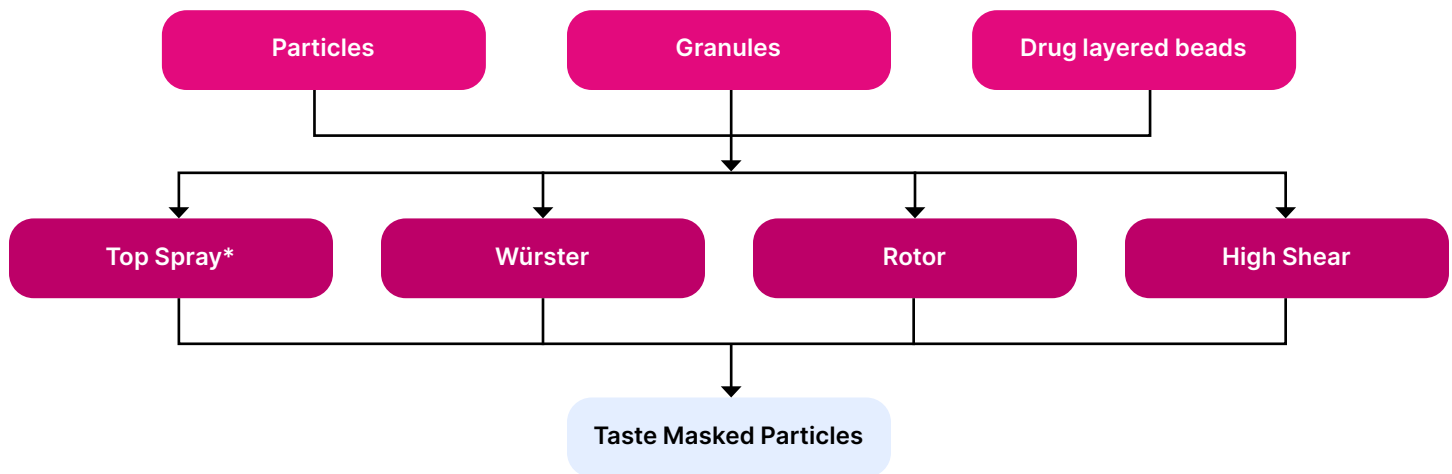


Taste Masking with Surelease[®] and Opadry[®]

Surelease, Ethylcellulose Dispersion Type B NF, provides effective taste masking by minimizing the amount of API released in the mouth.

The inclusion of Opadry along with Surelease in the coating formulation will delay the drug release in the oral cavity, yet still allow immediate release of the drug in the stomach.

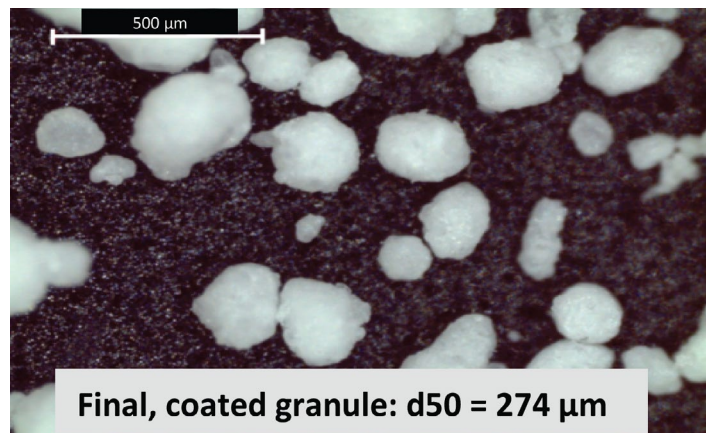
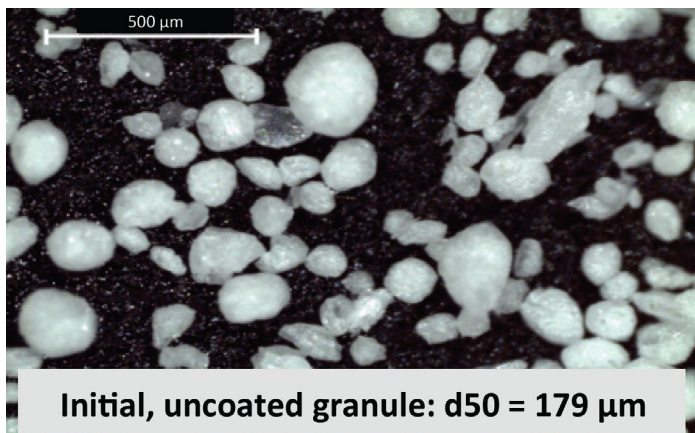


Key Considerations: Particle Size, Formulation Selection, Laboratory Scale Parameters

Substrate Properties

Desired starting particle is spherical with a size of 100-200µm

- < 100 µm, difficult to fluidize, hard to obtain uniformity
- > 300 µm in final granule size leads to a gritty mouth feel



| Formulation(s) | | |
|----------------|---------------------|---------------------|
| Replicate | Surelease E-7-19040 | Opadry YS-1-19025-A |
| 1 | 80% w/w | 20% w/w |
| 2 | 85% w/w | 15% w/w |

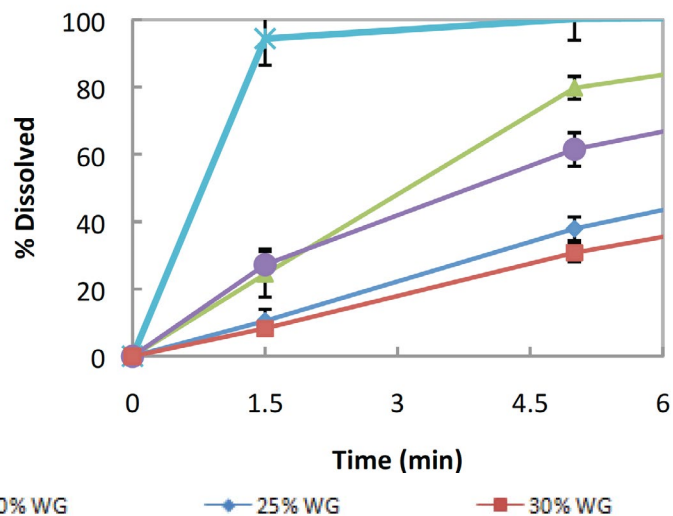
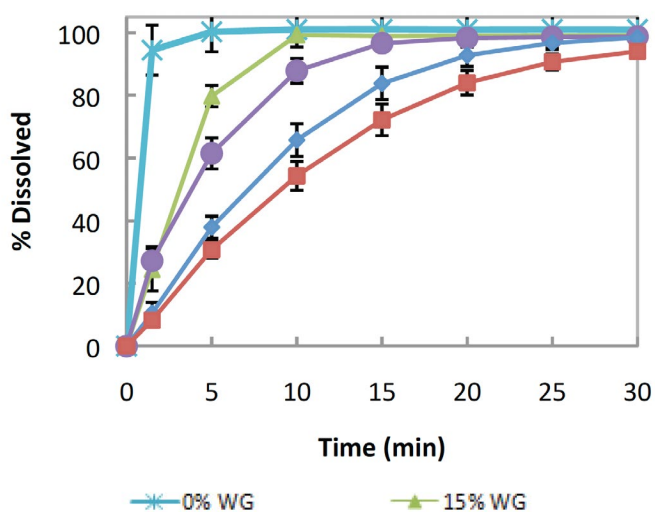
| Process 2.0 kg GPCG-3, Top-Spray configuration | |
|---|-------|
| Fluidizing Airflow (CFM) | 40-45 |
| Inlet Air Temperature (°C) | 64-67 |
| Product Temperature (°C) | 42-45 |
| Spray Rate (g/minute) | 15 |
| Atomizing Pressure (psi) | 30 |

Ref: 2013 AAPS Poster: Investigation of Taste Masking Performance of an Aqueous Ethylcellulose Dispersion (Surelease®) on Acetaminophen Granules

Drug Release Profile (APAP Granules as Model Drug, USP Dissolution Testing)

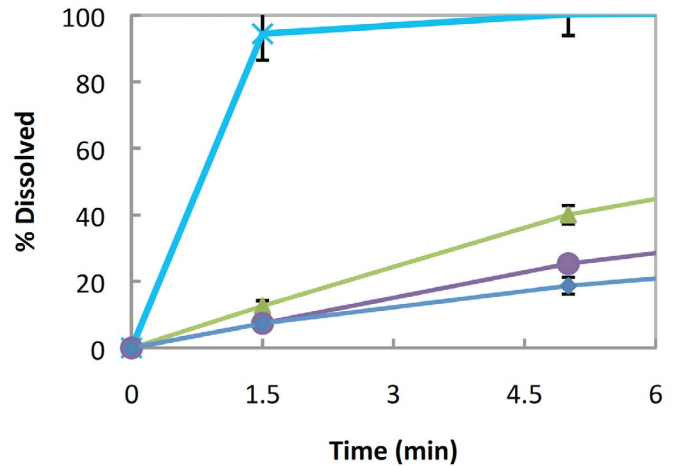
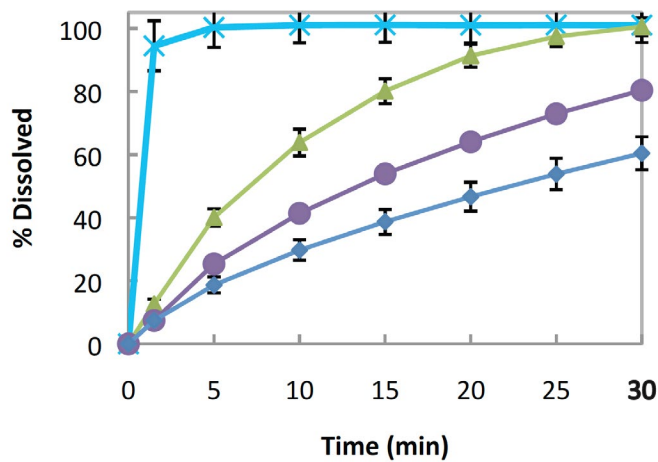
Surelease : Opadry (80:20)

25% WG creates immediate release granules with <11% release of API in 1.5 min



Surelease : Opadry (85:15)

15% WG creates immediate release granules with <13% release of API in 1.5 min



Why use Surelease for Taste Masking?

- Consistent, reproducible taste masking results
- Precedence of use (in certain markets) in taste masking products for children aged 2 and older
- Proven market success, utilized in 22 NDAs and 32 ANDAs
- Fully formulated, aqueous-based, pH-independent polymeric system
- Tailor release profiles with variations in weight gain and pore-former inclusion levels
- Non-ionic polymer system, with low potential for drug interactions

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