



**Actimask<sup>®</sup>**  
**Taste Masked Actives**  
Acetaminophen and Ibuprofen



## Actimask® Taste Masked Actives

### The Need for Taste Masking

Many Active Pharmaceutical Ingredients (APIs) are quite bitter and, as such, would not be good candidates for use in orally dispersible dosage forms unless they are effectively taste masked. If a patient refuses to take a medication due to an objectionable taste or aroma, compliance with drug therapy suffers, leading to potential adverse health outcomes. While this is an issue for all age groups, the primary concern focuses on the pediatric and geriatric populations.



### Taste Masking Techniques

- Incorporation of flavors and sweeteners into the formulation
- Attaching an API to an ion exchange resin
- Film coating of tablets or multi-particulates with functional polymer coatings
- Encapsulating active drug particles in gelatin through a coacervation process

## Actimask® Technology

Taste-Masked Actives

### Actimask APAP 92M

### Actimask Ibuprofen

Smooth Mouthfeel,  
Easy to Swallow

Better, Without the Bitter!

Aqueous Hydrophilic  
Gelatin Coating

Low Active Release  
in First Minute

Exceeding Compendial Target

Perfect for direct compression applications!

High Assay, Helping to Reduce Tablet Weight

### Actimask® Technology

SPI Pharma offers taste masked acetaminophen and ibuprofen, two popular analgesic/antipyretic drugs, by encapsulating the active particles within a gelatin coating using a coacervation process. The process is completely aqueous, therefore, there is no concern regarding the level of residual solvents as with many other taste masked products.

### Actimask Acetaminophen

Actimask taste masked acetaminophen is an ideal choice for the formulation of chewable or orally dispersible dosage forms. The aqueous hydrophilic coating delivers an excellent taste barrier as shown in Figure 1. In addition, the uniform hydrogel coating provides a smooth surface that has an excellent mouth feel, enhanced palatability, and is easy to swallow.

The gelatin coating provides effective taste masking by delaying the release of the API in the first couple of minutes while the product is still in the oral cavity. This does not affect the product's ability to meet compendial dissolution specifications for immediate release acetaminophen as noted in Figure 2.

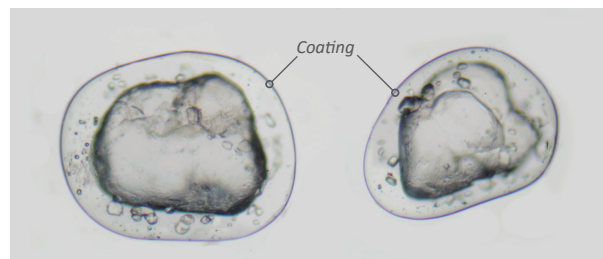


Figure 1

### Actimask Ibuprofen

It is well known that uncoated ibuprofen causes an intense burning sensation when exposed to the oral cavity and throat. The hydrophilic, Actimask coating effectively taste masks the active and reduces to extremely low levels the burning sensation that many patients experience with poorly masked or unmasked ibuprofen products.

As with the Actimask Acetaminophen, dissolution is delayed just enough to effectively taste mask the API while the product is still contained in the oral cavity with absolutely no effect on the overall dissolution.

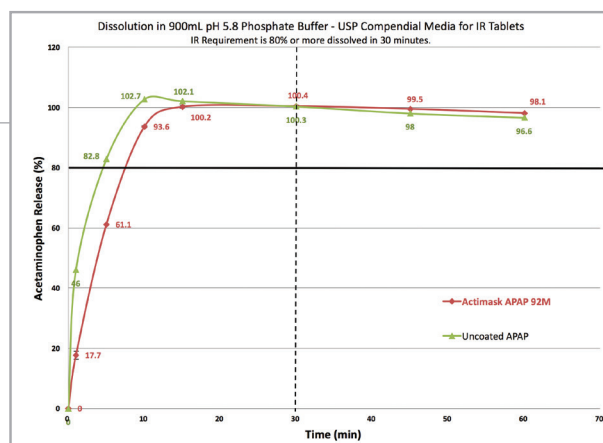


Figure 2

### Pilot Pharmacokinetic Data

Pharmacokinetic (PK) parameters were measured in 13 adults in a three-way, crossover study of 100mg ODT and ODP products, formulated using Actimask Ibuprofen with Pharmaburst® and Pharmasperse® respectively, compared to a reference product. See Figure 3.

The pharmacokinetics of Actimask formulations were comparable to a reference product. Additional information is available upon request.

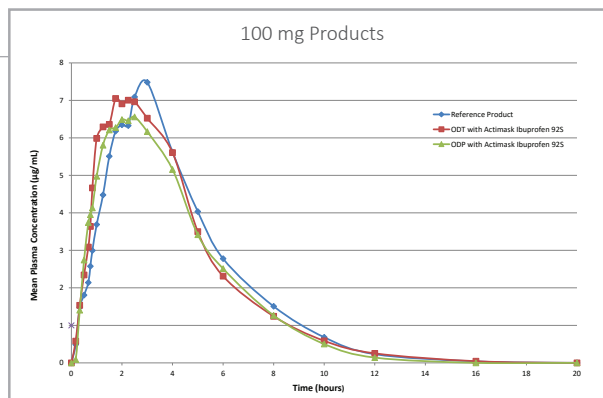


Figure 3

### The SPI Formulation Advantage

Both Actimask Acetaminophen and Actimask Ibuprofen are designed to be utilized in dry blend processes for direct compression of orally disintegrating and chewable tablets, or for blending of orally dispersible powders.

The use of off-the shelf, co-processed drug delivery platforms and excipients can facilitate formulation efforts and possibly increase a product's speed to market. SPI Pharma's Pharmaburst 500 for orally disintegrating tablets, Compressol® SM and Advantol® 300 for chewable tablets, and Pharmasperse 416 for orally dispersible powders are popular formulation choices.



## Actimask® Taste Masked Actives

### Typical Properties

Attribute	Actimask Acetaminophen	Actimask Ibuprofen
Description	White to off-white granules	White to off-white granules
Average Assay (%)	94%	92%
Dissolution (%)	≥ 95% in 30 minutes (Q = 80% in 30 minutes)	≥ 87% in 60 minutes (Q = 80% in 60 minutes)
Mean Particle Size in microns (d50)	Approximately 380μ	Approximately 370μ
Bulk density (g/ml)	Approximately 0.65	Approximately 0.55
Tapped Density (g/ml)	Approximately 0.75	Approximately 0.60
Carr's Index	Approximately 13	Approximately 10

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