

Excellent Taste-Masking. Rapid Compendial Dissolution. Easy to Formulate. Ideal for direct compression formulation.

Dissolution in 900 mL of pH 6.8 Phosphate Buffer – Oral pH Simulation

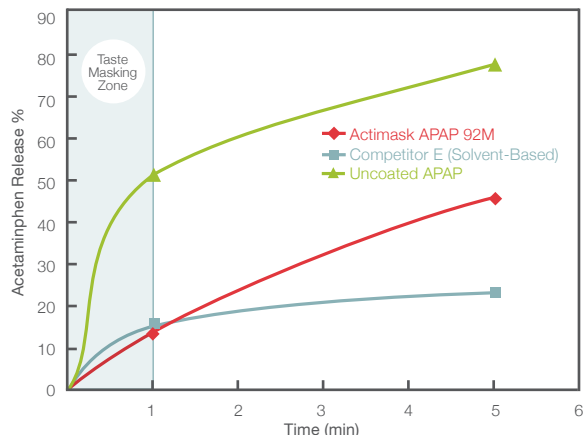


Figure 1. At Oral pH, low active release in the first minute leads to excellent taste-barrier.

Actimask Acetaminophen 92M has a hydrophilic hydrogel coating that creates an effective taste barrier without residual solvents. It easily slides down the patient's throat and releases within the GI tract. The dissolution profile matches that of uncoated acetaminophen. The average particle size is about 400µm and the assay averages 92%.

Dissolution in 900mL pH 5.8 Phosphate Buffer – USP Compendial Media for IR Tablets

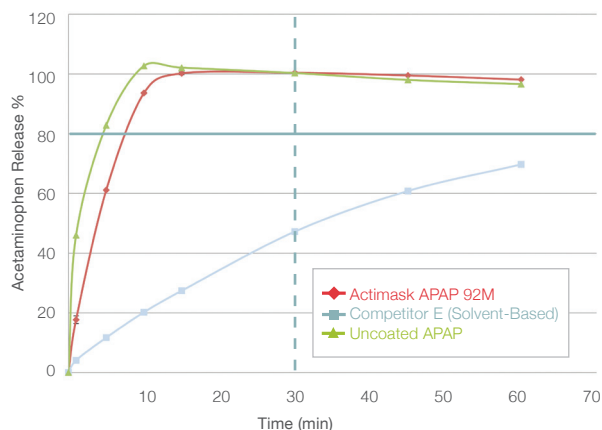


Figure 2. IR Requirement is 80% or more dissolved in 30 minutes.

Dissolution in 1000mL pH 1 HCl – Gastric Environment

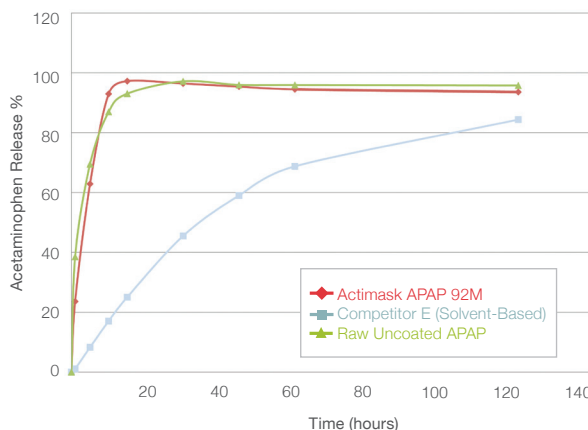


Figure 3. In Gastric pH, the dissolution profile of Actimask Acetaminophen 92M matches uncoated APAP.

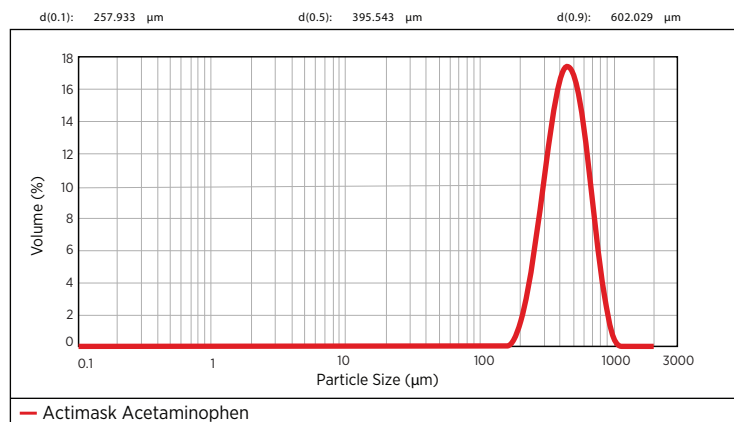


The hydrophilic coating provides superior organoleptic properties and a high assay helps reduce tablet weight.

Physical Characteristics

Bulk Density	0.643 g/mL
Tapped Density	0.739 g/mL
Carr's Index	13.0
Angle of Repose	38.4
Avg. Particle Size	395µm

Particle Size Distribution



Description

White granules.

Critical Properties

Assay, %	89.0 - 95.0
4-chloroacetanilide, ppm	NMT 10
4-aminophenol, ppm	NMT 50
4-nitrophenol, %	NMT 0.05
Loss on Drying, %	NMT 2.0
1 Minute Dissolution Assay, %	NMT 30
30 Minute Dissolution Assay, %	NMT 80
Particle Size	
% on #20 mesh	NMT 1
% thru #70 mesh	NMT 10
Micro Standard	
Total Aerobic Plate Count, cfu/g	NMT 100
Total Yeast and Mold, cfu/g	NMT 100

Product manufactured with pharmaceutical ingredients meeting USP/NF, EP or FCC Compendia.

Standard Packaging 50kg fiber drum. **Shipping/Storage** Ambient warehouse conditions.

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