

Excellent Taste-Masking. Demonstrated In-Vivo Bioavailability. Easy to Formulate. Ideal for direct compression formulation.

Dissolution in pH 6.8 Phosphate Buffer – Oral pH Simulation



Figure 1. At oral pH, very low active release of Ibuprofen in the first minute demonstrates good taste-masking.

Dissolution in pH 7.2 Phosphate buffer. USP IR Requirement is not less than 80% in 60 minutes.

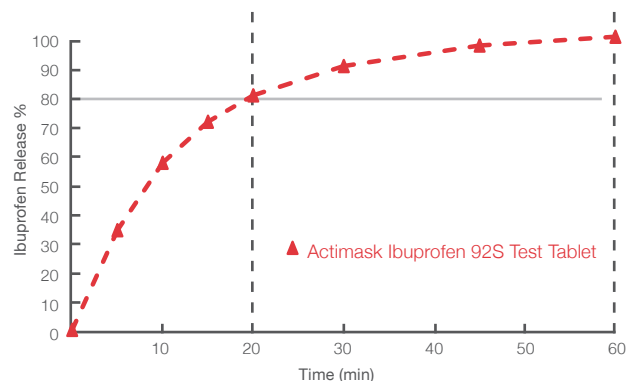


Figure 2. Tablet dissolution exceeds compendial specifications

Pilot Pharmacokinetic Data

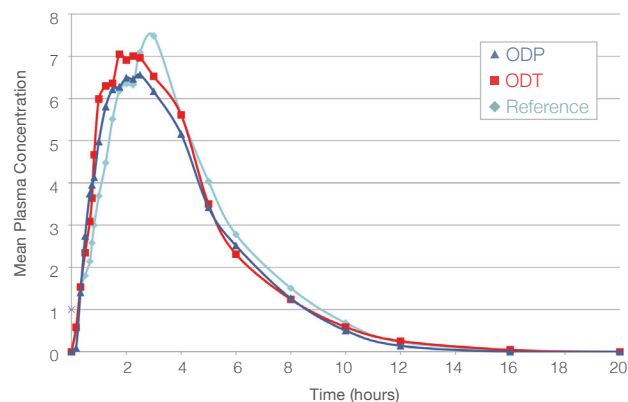


Figure 4. PK Parameters of Actimask Ibuprofen 92S formulations

Actimask Ibuprofen 92S has a hydrophilic hydrogel coating that creates an effective taste barrier without residual solvents.

The hydrophilic hydrogel coating allows the ibuprofen to slide down patients' throats while effectively preventing the burning sensation many patients experience with poorly masked or unmasked ibuprofen products. The average particle size is about 450µm and the assay averages 92%.

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

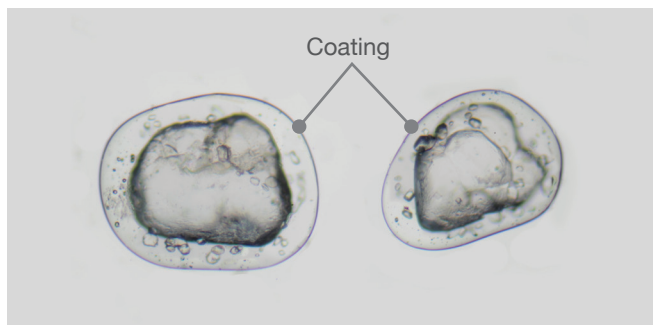


Figure 3. Actimask Coated Particles

100mg Products	AUC (0-t)	AUC (0-∞)	C _{max}
ODP with Actimask Ibuprofen 92S	32.4	34.6	8.0
ODT with Actimask Ibuprofen 92S	35.4	37.6	9.3
Junior Strength Advil® Reference	35.9	37.8	9.9

Pharmacokinetic (PK) parameters were measured in 13 adults in a three-way, crossover study of 100mg ODT and ODP formulated using Actimask Ibuprofen with Pharmaburst® and Pharmsperse®, respectively, compared with Junior Strength Advil®.

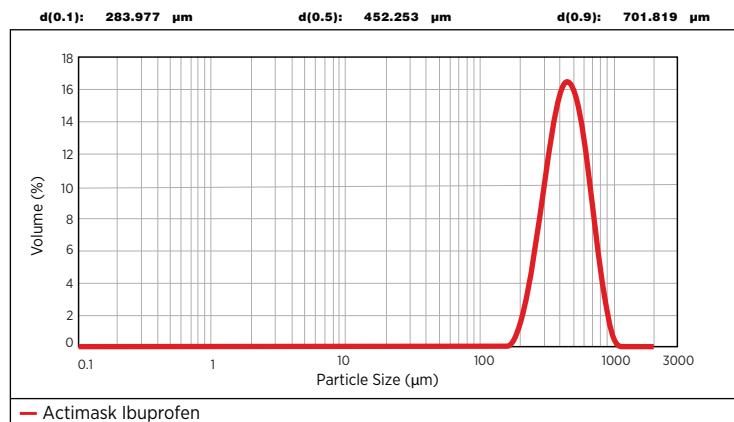
The pharmacokinetics of Actimask formulations were comparable to a reference product

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Physical Characteristics

Bulk Density _____	0.531 g/mL
Tapped Density _____	0.607 g/mL
Carr's Index _____	12.5
Angle of Repose _____	38.3
Avg. Particle Size _____	452 μm

Particle Size Distribution



Description

White to off-white granules.

Critical Properties

Assay, %	89.0 - 95.0
Ibuprofen Impurity B by UPLC, %	NMT 0.3
Ibuprofen Impurity C by UPLC, %	NMT 0.1
Ibuprofen Impurity F by UPLC, %	NMT 0.1
Ibuprofen Total Impurities, Ph. Eur. by UPLC (excluding B and F), %	NMT 0.7
Ibuprofen Total Impurities, USP by UPLC, %	NMT 1.0
Loss on Drying, %	NMT 2.0
Paricle Size on #16 mesh	NMT 1

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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