

ProCap™ 100 HD Capsule Excipient

Ideal For High Dilutions / Lactose-Free / Excellent Static-Control

ProCap™ 100 HD is a versatile capsule fill excipient that can be used with numerous active pharmaceutical ingredients (APIs). It exhibits superior flow/spreadability and consistently uniform small particle size that is ideal for high dilution applications especially for micronized and APIs with a small average particle size (~50 µm). ProCap™ 100 HD is very resistant to clumping and humidity related issues, has excellent static-control properties for problematic static-prone APIs, and has consistent packing properties resulting in optimal content uniformity, stability, and dissolution. ProCap™ 100 HD is lactose-free, formulated from ingredients of strictly vegetable origin, and an ideal capsule excipient for patients with allergy and sensitivity concerns. **All ingredients are pharmaceutical grade excipients that meet or exceed current USP-NF monographs.**

Ideally Suited For:

- High Dilution applications
- Micronized or small particle APIs for improved content uniformity.
- Static-prone APIs
- Patients with high allergy / sensitivity requirements
- Moisture-sensitive APIs

Benefits:

- Compendial pharmaceutical grade ingredients
- Manufactured from raw materials of strictly vegetable origin
- Uniform particle size distribution average particle size (~50 µm)
- Improved Static Reduction
- Ideal spreadability
- High API compatibility
- Improved Stability: Formulated with very low hygroscopic ingredients that resist moisture lending to improved stability, especially for moisture-sensitive APIs
- Classified GRAS status ingredients
- Ideally suited for allergy sensitive patients
- Pet Friendly: formulated without xylitol

Formulated Without:

<ul style="list-style-type: none"> • Lactose • Gluten • Casein • Soy 	<ul style="list-style-type: none"> • Corn • Dyes • Sugar • Sodium Lauryl Sulfate (SLS) • Magnesium Stearate 	<ul style="list-style-type: none"> • Xylitol • Cellulose • Sorbitol • Tree Nuts • Artificial Ingredients
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Capsule Packing Statistics

Capsule Size	#5	#4	#3	#2	#1	#0	#00	#000
ProCap™ 100 HD	0.090	0.144	0.204	0.248	0.335	0.459	0.653	0.988
CapsOral®	0.087	0.138	0.186	0.237	0.321	0.444	0.626	0.947
Hypromellose 2910/4000 cps (Methylcel E4M)	0.081	0.129	0.183	0.222	0.300	0.411	0.585	0.885

*Results may vary slightly from person to person due to a variety of factors. Weights listed in grams (g) per capsule.

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Technical Data Sheet

CATEGORY	An easy to use, natural, free-flowing pharmaceutical grade capsule excipient formulated for use where high API dilution is needed and exhibits excellent static control, very low hygroscopicity that resist moisture lending to improved stability, especially for moisture-sensitive APIs. Anhydrous.
INGREDIENTS	Proprietary pharmaceutical grade (USP-NF) blended capsule excipients that contains primarily a co-processed glyceryl/oligosaccharide manufactured strictly from vegetable origin. Ingredients were selected specifically for their mean particle size, low allergy/sensitivity, compendial compliance, physical properties, low hygroscopicity, and suitability for the intended application.
ALLERGY	Per the 2004 Food Allergen Labeling and Consumer Protection Act, no allergen declarations are required for this product relating to corn, milk, egg, tree nut, fish, crustacean shellfish, wheat, peanuts, and soybeans. Gluten-free, non-GMO/vegan compliant.
TECHNICAL DATA	Description: White free-flowing powder Shelf Life: 2 years from date of manufacture when stored in its original, unopened container. Density, at 25°C approx. 0.47 g/cm ³ Melting Point 69-74°C
SAFETY DATA	All ingredients classified as “Generally Recognized As Safe” (GRAS) and inactive excipient ingredients by the US FDA. For information on the toxicology and safety of this product, please consult the material safety data sheet (MSDS).
HANDLING AND STORAGE	Comment: Keep from prolonged heat exposure. During storage at high temperatures (>35°C), this product is liable to become compacted or conglomerated. Storage Conditions: Product can be stored at ambient conditions for temperature, pressure, and humidity. Product should be kept in a tightly sealed container, under cool and dry conditions.
COMMENTS	This information reflects US requirements for ingredients and allergy declarations. SpecializedRx makes no warranties or claims to the accuracy or completeness of the above information given the variations in use and formulations.