

## Empty DRcaps™ Capsules

Customer:		Product Size:	1
Product Name:		Type:	Coni-Snap
Product Code		Print Type:	Non Print
<b>BODY</b>		<b>CAP</b>	
Code:	V44.700	Code:	V44.700
Pantone:	white	Pantone:	white
Name:	WHITE.OP.V700	Name:	WHITE.OP.V700
<b>IMPRINTING</b>			

### Qualitative and Quantitative composition \*

#### Composition per capsule part

Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (V44.700)		Cap (V44.700)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Hypromellose	Structure	qsp100	41.8867	qsp100	27.9245	qsp100	69.8112
Gellan gum	Gelling agent	5.0000	2.2500	5.0000	1.5000	5.0000	3.7500
Titanium dioxide	Opacifier	1.9184	0.8633	1.9184	0.5755	1.9184	1.4388
		100	45.0000	100	30.0000	100	75.0000

\*The quantities given are based on the theoretical calculations of the average specification weight of the capsules.

\*Due to the nature of raw materials, their sourcing and technology improvements, the dyestuff content data indicated are target values and actual values may vary.

### Additional information

Specifications :	The capsules described below conform to the specifications as defined in the current edition of the Capsugel "TECHNICAL REFERENCE FILE".
Packaging information :	Standard packaging consists of protective, food antistatic bags inside robust cardboard cartons.
Storage information :	Capsugel recommends that our capsules be stored in the closed containers in which they are dispatched in areas where the ambient temperature is 15°C to 25°C and the relative humidity 35% to 65%. Capsugel continues a global stability program and maintains data supporting 5 years shelflife of our capsules.
General commitment :	As the supplier of this product, Capsugel will notify of any significant changes that would affect the integrity of the product. Typically this is defined as a Level II change by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.

### Manufacturing Processes

No Addition Of Preservatives

No Ethylene Oxide Treatment

No Irradiation Treatment

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**Regulatory information**

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Name of excipient(s)	E Nr	C.I. Nr	Function	Reference / Monograph standard
Hypromellose	E464		Structure	(EU) 231/2012,, EP, JP, USP/NF
Gellan gum	E418		Gelling agent	(EU) 231/2012, JSFA, 21 CFR
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF

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**Date: Jun 06, 2017****Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France****Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium**