

Customer:	ACEF SPA	Product Size:	0
Product Name:	DRCAPS 0 BIANCO	Type:	Coni-Snap
Product Code	001522-80	Print Type:	Non Print
<b>BODY</b>		<b>CAP</b>	
Code:	V44.700	Code:	V44.700
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	53.0565	qsp100	35.3710	qsp100	88.4275
Gellan gum	Gelling agent	5.0000	2.8500	5.0000	1.9000	5.0000	4.7500
Titanium dioxide	Opacifier	1.9184	1.0935	1.9184	0.7290	1.9184	1.8225
		100	57.0000	100	38.0000	100	95.0000

**Regulatory references**

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	2008/84/EC, JSFA, 21 CFR
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF

\*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.



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**Additional information**

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Specifications :	The capsules described below conform to the specifications as defined in the current edition of the Capsugel "TECHNICAL REFERENCE FILE", except for the 'disintegration time' the specification is 'greater than 30 min'
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 Level II and III changes by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.

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**Manufacturing Processes**

No Addition Of Preservatives  
No Ethylene Oxide Treatment  
No Irradiation Treatment

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