

Empty Hard Gelatin Capsules (Bovine and/or Porcine Origin)

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Customer:		Product Size:	000
Product Name:		Type:	Snap-Fit
Product Code		Print Type:	Non Print
BODY		CAP	
Code:	44.000	Code:	44.000
Name:	WHITE OP.	Name:	WHITE OP.
IMPRINTING			

Qualitative and Quantitative composition *

Composition per capsule part Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (44.000)		Cap (44.000)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	95.8440	qsp100	63.8960	qsp100	159.7400
Titanium dioxide	Opacifier	2.0000	1.9560	2.0000	1.3040	2.0000	3.2600
		100	97.8000	100	65.2000	100	163.0000

*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.

**Containing on average 14.5% water (loss on drying)

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

Name of excipient(s)	E Nr	C.I. Nr	Function	Reference / Monograph standard
Gelatin			Structure	EP, JP, USP/NF
Titanium dioxide	E171	77891	Opacifier	(EU) 231/2012, 21 CFR, EP, JP, USP/NF

Françoise Rouault - Color laboratory Head	E-mail: Francoise.Rouault@Capsugel.com	Tel: +33 (0)3 89 20 57 18
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Kaat Bracquiné - Sr.Mgr.QC & Reg.	E-mail: Kaat.Bracquine@Capsugel.com	Tel: +32 (0)3 890 0645
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Date: May 06, 2016**Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France****Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium**