# **Product Specification Sheet**



### **Empty Hard Gelatin Capsules**

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Customer: ACEF SPA Product Size: 00

Product Name: 00 CS TRASPARENTE Type: Coni-Snap

Product Code 001522-58 Print Type: Non Print

**BODY** CAP

Code: 43.000 Code: 43.000

Name: NATURAL TR. Name: NATURAL TR.

**IMPRINTING** 

# **Qualitative and Quantitative composition \***

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

		Body (43.000)		Cap (43.000)		Total Capsule	
Name of excipient(s)	Function	%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	70.8000	qsp100	47.2000	qsp100	118.0000
		100	70.8000	100	47.2000	100	118.0000

#### **Regulatory references**

Name of excipient(s) E Nr C.I. Nr Function Reference / Monograph standard

Gelatin\*\* Structure EP, JP, USP/NF

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Date: Apr 17, 2013 Signature:

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

<sup>\*</sup>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.

<sup>\*\*</sup>Containing on average 14.5% water (loss on drying)

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#### **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  $15^{\circ}$ C to  $25^{\circ}$ C and the relative humidity 35% to 65%. Capsugel continues a global

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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.

### **Manufacturing Processes**

No Addition Of Preservatives No Ethylene Oxide Treatment No Irradiation Treatment

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