Product Specification Sheet



Empty Hard Gelatin Capsules

Page: 1 of 2

Customer: ACEF SPA Product Size: 0

Product Name: 0 CS TRASPARENTE Type: Coni-Snap

Product Code 001522-12 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	57.6000	qsp100	38.4000	qsp100	96.0000
		100	57.6000	100	38.4000	100	96.0000

Regulatory references

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

Gelatin** Structure EP, JP, USP/NF

Date: Apr 17, 2013

Kathleen Jacobs - Regulatory Affairs & Market Support Specialist

CAPSUGEL - EMEA

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Signature:

^{*}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)

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Page: 2 of 2

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

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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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