Product Specification Sheet

CAPSUGEL®

Empty Hard Gelatin Capsules

Customer:	ACEF SPA	Product Size:	0
Product Name:	0 CS BIANCO	Type:	Coni-Snap
Product Code	001522-19	Print Type:	Non Print

BODY

Code:	44.000
Name:	WHITE OP.

CAP

Code:	44.000
Name:	WHITE OP.

IMPRINTING

Qualitative and Quantitative composition *

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

		Body (44.000)		Cap (44.000)		Total Capsule	
Name of excipient(s)	**Function**	**%**	**mg/body**	**%**	**mg/cap**	**%**	**mg/capsule**
Gelatin**	Structure	qsp100	56.4480	qsp100	37.6320	qsp100	94.0800
Titanium dioxide	Opacifier	2.0000	1.1520	2.0000	0.7680	2.0000	1.9200
		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
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.

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

Kathleen Jacobs - Regulatory Affairs & Market Support Specialist
CAPSUGEL - EMEA
Rijksweg 11 - 2880 Bornem - Belgium
Rue Timken 10 - F68027 Colmar - France
Tel: +32 (0)3 8900568

Date: Apr 17, 2013

Signature:

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 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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