Product Specification Sheet

CAPSUGEL®

Empty Hard Gelatin Capsules

Customer:	ACEF SPA	Product Size:	0
Product Name:	0 CS AZZURRO/AZZURRO	Type:	Coni-Snap
Product Code	001522-40	Print Type:	Non Print

BODY

Code:	L910
Name:	LIGHT BLUE

CAP

Code:	L910
Name:	LIGHT BLUE

IMPRINTING

Qualitative and Quantitative composition *

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

		Body (L910)		Cap (L910)		Total Capsule	
Name of excipient(s)	**Function**	**%**	**mg/body**	**%**	**mg/cap**	**%**	**mg/capsule**
Gelatin**	Structure	qsp100	55.2910	qsp100	36.8607	qsp100	92.1517
Titanium dioxide	Opacifier	4.0000	2.3040	4.0000	1.5360	4.0000	3.8400
Indigotine - FD&C Blue2	Colorant	0.0086	0.0050	0.0086	0.0033	0.0086	0.0083
		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
Indigotine - FD&C Blue2	E132	73015	Colorant	(EU) 231/2012, 21 CFR, JFSA, MHLW 126

*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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