

ACEF SPA - 001522-10

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Customer:	ACEF SPA	Product Size:	00
Product Name:	00 CS BIANCO/AZZURRO	Type:	Coni-Snap
Product Code	001522-10	Print Type:	Non Print
BODY		CAP	
Code:	44.000	Code:	04.000
Name:	WHITE OP.	Name:	LT BLUE OP
IMPRINTING			

Qualitative and Quantitative composition ***Composition per unprinted capsule part**

Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (44.000)		Cap (04.000)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	69.3840	qsp100	46.6651	qsp100	116.0491
Titanium dioxide	Opacifier	2.0000	1.4160	1.0000	0.4720	1.6000	1.8880
Indigotine - FD&C Blue2	Colorant			0.1333	0.0629	0.0533	0.0629
		100	70.8000	100	47.2000	100	118.0000

*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.
Color stability information :	Capsules containing Indigotine may be sensitive to hot temperature, moisture and light, requiring effective product packaging.

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
Indigotine - FD&C Blue2	E132	73015	Colorant	(EU) 231/2012, 21 CFR, JFSA, MHLW 126

Emmanuelle Saugues - Color lab Supervisor	E-mail: Emmanuelle.Saugues@Lonza.com	Tel: +33 (0)3 89 20 57 18
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Kaat Bracquiné - Sr.Mgr.QC & Reg.	E-mail: Kaat.Bracquine@Lonza.com	Tel: +32 (0)3 890 0645
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Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France

Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium