

ACEF SPA - 001522-09

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Customer:	ACEF SPA	Product Size:	00
Product Name:	00 CS BIANCO/ROSSO	Type:	Coni-Snap
Product Code	001522-09	Print Type:	Non Print
BODY		CAP	
Code:	44.000	Code:	32.364
Name:	WHITE OP.	Name:	SCARLET OP.C364
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 (32.364)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	69.3840	qsp100	46.5911	qsp100	115.9751
Titanium dioxide	Opacifier	2.0000	1.4160	0.5000	0.2360	1.4000	1.6520
Yellow iron oxide	Colorant			0.4500	0.2124	0.1800	0.2124
Red Iron Oxide	Colorant			0.2000	0.0944	0.0800	0.0944
Azorubine - Carmoisine	Colorant			0.1400	0.0661	0.0560	0.0661
		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 Azorubine may be sensitive to light at various rates requiring effective product packaging.

Manufacturing Processes

No Addition Of Preservatives
 No Ethylene Oxide Treatment
 No Irradiation Treatment

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
Yellow iron oxide	E172	77492	Colorant	(EU) 231/2012, 21 CFR, JPE, USP/NF
Red Iron Oxide	E172	77491	Colorant	(EU) 231/2012, 21 CFR, JPE, USP/NF
Azorubine - Carmoisine	E122	14720	Colorant	(EU) 231/2012

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