

Empty Hard Gelatin Capsules

Customer:	ACEF SPA	Product Size:	3
Product Name:	3 CS BIANCO/ROSSO	Type:	Coni-Snap
Product Code	001522-33	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 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	28.2240	qsp100	18.9523	qsp100	47.1763
Titanium dioxide	Opacifier	2.0000	0.5760	0.5000	0.0960	1.4000	0.6720
Yellow iron oxide	Colorant			0.4500	0.0864	0.1800	0.0864
Red Iron Oxide	Colorant			0.2000	0.0384	0.0800	0.0384
Azorubine, carmoisine	Colorant			0.1400	0.0269	0.0560	0.0269
		100	28.8000	100	19.2000	100	48.0000

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
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

*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

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Date: Apr 17, 2013

Signature:

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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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