

Empty Hard Gelatin Capsules (Pure Bovine Origin)

ACEF SPA - 004782-70000

Page: 1 of 2

Customer:	ACEF SPA	Product Size:	00
Product Name:	00 CS GIALLO/VERDE	Type:	Coni-Snap
Product Code	004782-70000	Print Type:	Non Print
BODY		CAP	
Code:	41.019	Code:	18.037
Name:	RICH YELLOW OP.C019	Name:	DARK GREEN OP.C037
IMPRINTING			

Qualitative and Quantitative composition *

Composition per unprinted capsule part

Body represents about 60% of the capsule weight

Name of excipient(s)	Function	Body (41.019)		Cap (18.037)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	69.7380	qsp100	45.7772	qsp100	115.5152
Titanium dioxide	Opacifier	1.0000	0.7080	1.0000	0.4720	1.0000	1.1800
Yellow iron oxide	Colorant	0.5000	0.3540	1.7143	0.8092	0.9857	1.1632
Indigotine - FD&C Blue2	Colorant			0.3000	0.1416	0.1200	0.1416
		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 :	These capsules 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%.
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 changes by the International Pharmaceutical Excipient Council's Significant Change Guide for Bulk Pharmaceutical Excipients.
Shelf life :	Capsugel continues a global stability program and maintains data supporting 5 years shelflife of our capsules.
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

ACEF SPA - 004782-70000

Page: 2 of 2

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

Emmanuelle Saugues - Color lab Supervisor E-mail: Emmanuelle.Saugues@Capsugel.com Tel: +33 (0)3 89 20 57 18

Kaat Bracquiné - Sr.Mgr.QC & Reg. E-mail: Kaat.Bracquine@Capsugel.com Tel: +32 (0)3 890 0645

Date: Jun 05, 2018**Capsugel France SAS, Rue Timken 10 - F68027 Colmar - France****Capsugel Belgium NV, Rijksweg 11 - 2880 Bornem - Belgium**