

Customer:	Product Size:	4
Product Name:	Type:	Coni-Snap
Product Code	Print Type:	Non Print
BODY	CAP	
Code: 44.000	Code:	37.068
Name: WHITE OP.	Name:	FLESH OP.C068
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 (37.068)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	22.3440	qsp100	14.7774	qsp100	37.1214
Titanium dioxide	Opacifier	2.0000	0.4560	2.1200	0.3222	2.0480	0.7782
Red Iron Oxide	Colorant			0.5100	0.0775	0.2040	0.0775
Yellow iron oxide	Colorant			0.1500	0.0228	0.0600	0.0228
		100	22.8000	100	15.2000	100	38.0000

*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.

Manufacturing Processes

No Addition Of Preservatives
No Ethylene Oxide Treatment
No Irradiation Treatment

Empty Hard Gelatin Capsules (Pure Bovine Origin)

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

If printed, the composition and regulatory references of the ink are available on the ink constituent sheet, allowing evaluation of suitability for the intended use.

Capsugel has made every effort to ensure suitability of the capsule composition. However, capsule constituents, such as colorants, may be restricted in terms of their application. We recommend that you give careful consideration to your final composition and ensure compliance with the regulations of the market and countries in which the product will be launched. A crosscheck by your regulatory people as well as appropriate authorities in these countries is advised.

Below table provides the regulatory status of the empty unprinted capsules (44.000/37.068) based on the colorants present.

	Food Supplement
E.U	Allowed, under following restrictions: <u>Titanium dioxide:</u> In Europe, TiO ₂ is an approved food additive and can be used quantum satis (as per Regulation (EC) N° 1333/2008), except in France as of January, 1st 2020 (Arrêté of 17 April 2019 – NOR: ECOC1911549A)

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