

Customer:	Product Size:	0
Product Name:	Type:	Coni-Snap
Product Code	Print Type:	Non Print
BODY		
Code:	41.019	CAP
Name:	RICH YELLOW OP.C019	Code:
		18.037
		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	56.7360	qsp100	37.2425	qsp100	93.9785
Titanium dioxide	Opacifier	1.0000	0.5760	1.0000	0.3840	1.0000	0.9600
Yellow iron oxide	Colorant	0.5000	0.2880	1.7143	0.6583	0.9857	0.9463
Indigotine - FD&C Blue2	Colorant			0.3000	0.1152	0.1200	0.1152
		100	57.6000	100	38.4000	100	96.0000

*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

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

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