Product Development Sheet



Empty Hard Gelatin Capsules (Bovine and/or Porcine Origin)

HUNGARO SYSTEM'S -

Customer: HUNGARO SYSTEM'S Product Size: 1 Product Name: Type: Coni-Snap Product Code Print Type: Non Print BODY CAP Code: 43.000 Code: 43.000 NATURAL TR. NATURAL TR. Name: Name: **IMPRINTING**

Qualitative and Quantitative composition *

Composition per capsule part Body represents about 60% of the capsule weight

		Body	(43.000)	Cap (43.000)	Tota	l Capsule
Name of excipient(s)	Function	%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	45.6000	qsp100	30.4000	qsp100	76.0000
		100	45.6000	100	30.4000	100	76.0000

*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 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

Page: 1 of 2

Coni-Snap[®]

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HUNGARO SYSTEM'S -

Page: 2 of 2

CAPSUGEL[®]

Regulatory information									
Name of excipient(s)	E Nr	C.I. Nr	Function	Reference / Monograph standard EP, JP, USP/NF					
Gelatin			Structure						
Françoise Rouault - Color labora	atory Head E-m	ail: Francois	e.Rouault@Ca	osugel.com	Tel: +33 (0)3 89 20 57 18				
Kathleen Jacobs - Reg aff & ma	r sup spec E-m	ail: Kathleen	.Jacobs@caps	idel com	Tel: +32 (0)3 890 568				

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