

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

HUNGARO SYSTEM'S - 001289-22

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Customer:	HUNGARO SYSTEM'S	Product Size:	0
Product Name:	HGC SIZE 0 WHITE/WHITE N	Type:	Coni-Snap
Product Code	001289-22	Print Type:	Non Print
BODY		CAP	
Code:	44.000	Code:	44.000
Name:	WHITE OP.	Name:	WHITE OP.
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 (44.000)		Total Capsule	
		%	mg/body	%	mg/cap	%	mg/capsule
Gelatin**	Structure	qsp100	56.4480	qsp100	37.6320	qsp100	94.0800
Titanium dioxide	Opacifier	2.0000	1.1520	2.0000	0.7680	2.0000	1.9200
		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 :	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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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

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