

**Size 00 Clear Veg Capsule**

Production Date: 2012/06

Expiration Date: 2017/06

The capsules are produced under very carefully controlled conditions. Controls are performed continuously throughout the process and guarantee that capsules conform to the highest quality standards. The capsules conform to the specifications as defined below.

Product description			
Product Size: 00		Customer: CAPSULE DEPOT	
Lot : K1206000083		CAP	
BODY		Code: 01-0K	
Code: 01-0K		Name: NATURAL	
Name: NATURAL		CAP COMPOSITION (Target Values):	
BODY COMPOSITION (Target Values):	Percent	Hydroxypropyl Methylcellulose	Percent
Hydroxypropyl Methylcellulose	QS 100%	Hydroxypropyl Methylcellulose	QS 100%
Excipients	QS 100%	Excipients	QS 100%

Ingredient/Reference	EEC Nr	C.Inr	Function	Pharmacopoeia References
HYDROXYPROPYL METHYLCELLULOSE	E464		Structure	USP/EP

**ANALYTICAL DATA**

Characteristics	Specifications/units	Real value
Identification of Hypromellose	Positive	Meets
Identification of TiO2	Conforms to composition	N/A
Identification of dyestuffs	Conforms to composition	N/A
Sulphated ash	N.M.T. 1.5%	Meets
Arsenic	N.M.T. 0.8 ppm	Meets
Heavy Metals	N.M.T. 10 ppm	Meets
Loss on drying	4.0 to 8.0 / %	5.6
Disintegration time	Less than 16:00 / min/sec	Meets
Average weight	129.0 – 143.0 / mg	140.2
Cap's length	11.45 – 12.15 / mm	11.59 – 12.10
Body's length	19.75 – 20.45 / mm	19.80 – 20.40
Total count	N.M.T. 1000 / cfu/gram	90
E. Coli	NEGATIVE / 10 g	NEGATIVE
Salmonella	NEGATIVE / 10 g	NEGATIVE
Staphylococcus Aereus	NEGATIVE / 10 g	NEGATIVE
Pseudomonas Aeruginosa	NEGATIVE / 10 g	NEGATIVE
Yeast and Molds	N.M.T. 100 / cfu/gram	Conform

Packaging consists of protective food-grade antistatic plastic bags inside robust cardboard cartons.

NOTE: The VISUAL QUALITY is superior to the established figures in the sampling plans of the Norm ISO 2859 - 1. "Procedure of sampling to inspect for attributes", using simple sampling with level II of General Inspection and acceptable level of quality (AQL) of 0,010 for Critical defects, 0,040 for Major defects and 0,250 for Minor defects.

They also fulfill the specifications established in the Technical Information manual in force.

Our capsules are certified as Kosher and Halal, and meet all requirements of current European Pharmacopoeia (EP) and United States Pharmacopoeia (USP)

  
QUALITY ASSURANCE MANAGER

Code: DCC-032K (Valid since June 1<sup>st</sup>, 2012)