



# GUSTAV PARMENTIER GmbH

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## SPECIFICATIONS

### HPMC CAPSULES

vegetable

#### General Information

<b>Description</b>	Empty, two-piece, cylindrical hard vegetable capsules, typical in taste and odour.
<b>Composition</b>	Hydroxypropyl methyl cellulose (HPMC, E-464 & USP) and water.
<b>Excipients</b>	Carrageenan (E-407 & USP)
<b>Storage</b>	Store between 15 °C and 25 °C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.
<b>Shelf Life</b>	5 years from date of manufacture, when stored as above.

	Size 00	Size 0	Size 1
<b>Capsules/ Box</b>	70.000	100.000	125.000

#### Galenic Properties

	Size 00	Size 0	Size 1
<b>Body Volume (ml)</b>	0.96	0.66	0.50
<b>Weight (mg)</b>	125 ± 11	99 ± 10	74 ± 7
<b>Lengths (mm)</b>			
- Cap	11.70 ± 0.40	11.10 ± 0.40	9.95 ± 0.45
- Body	20.20 ± 0.40	18.50 ± 0.40	16.50 ± 0.40
- Empty (pre-closed)	25.50 ± 0.35	23.70 ± 0.35	21.30 ± 0.35
<b>External Diameter (mm)</b>			
- Cap	8.67 ± 0.06	7.75 ± 0.06	6.76 ± 0.06
- Body	8.32 ± 0.06	7.42 ± 0.06	6.42 ± 0.06



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## Galenic Properties

	Size 00	Size 0	Size 1
Single Wall Thickness (mm)			
- Cap	0.105 ± 0.02	0.100 ± 0.02	0.095 ± 0.02
- Body	0.110 ± 0.02	0.105 ± 0.02	0.100 ± 0.02

## AQL-defect rate

Critical	0.01% maximum
Major	0.10% maximum
Minor	0.40% maximum

## Analytical Parameters

### Chemical

Arsenic (As)	3.0 ppm maximum
Lead (Pb)	1.0 ppm maximum
Cadmium (Cd)	1.0 ppm maximum
Mercury (Hg)	0.1 ppm maximum
Sulphated ash, transp./ opaque	3.0%/ 8.0% maximum
Loss on drying	8.0% maximum (105°C, 4 hours or constant weight)

### Microbiology

Total viable count	≤ 500 cfu/g
Yeasts and moulds	≤ 100 cfu/g (Ph.Eur. 2.4.12./13 or equivalent)
E. coli	Negative in 1 g
Pseudomonas aeruginosa	Negative in 1 g
Staphylococcus aureus	Negative in 1 g
Salmonella	Negative in 10 g

### Galenic

Disintegration time	≤ 15 min (EP)
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