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SPECIFICATIONS

GELATINE CAPSULES

from bovine gelatine

General Information

Description	Empty, two-piece, cylindrical hard gelatine capsules, typical in taste and odour.			
Composition	Gelatine (bovine) and water.			
Additives	Titanium dioxide (E-171), if applicable.			
Processing Aids	Sodium lauryl sulphate (surfactant), acetic acid (acidifier) and vegetable oil (lubricant).			
Storage	Store between 10 °C and 25 °C and relative humidity (RH) between 35% and 65%, in tightly closed packing, protected from direct light.			
Shelf Life	4 years from date of manufacture, when stored as above.			
Capsules/ Box	Size 000	Size 00	Size 0	Size 1
	50.000	70.000	100.000	125.000

Galenic Properties

	Size 000	Size 00	Size 0	Size 1
Lengths (mm)				
- Cap	13.1 ± 0.4	11.8 ± 0.4	10.9 ± 0.4	9.8 ± 0.4
- Body	22.0 ± 0.4	20.2 ± 0.4	18.6 ± 0.4	16.5 ± 0.4
- Filled (closed)	25.7 ± 0.5	23.4 ± 0.5	21.7 ± 0.5	19.3 ± 0.5
External Diameter (mm)				
- Cap	9.85 ± 0.05	8.55 ± 0.05	7.66 ± 0.05	6.95 ± 0.05
- Body	9.49 ± 0.05	8.20 ± 0.05	7.35 ± 0.05	6.65 ± 0.04
Single Wall Thickness (mm)				
- Cap	0.115 ± 0.02	0.105 ± 0.02	0.100 ± 0.02	0.100 ± 0.02
- Body	0.110 ± 0.02	0.105 ± 0.02	0.100 ± 0.02	0.095 ± 0.02



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Galenic Properties

	Size 000	Size 00	Size 0	Size 1
Body Volume (ml)	1.35	0.93	0.68	0.50
Weight (mg)	177 ± 8	128 ± 7	98 ± 6	75 ± 6

AQL-defect rate

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

Analytical Parameters

Chemical

Arsenic (As)	1.0 ppm maximum
Lead (Pb)	1.0 ppm maximum
Cadmium (Cd)	1.0 ppm maximum
Mercury (Hg)	0.1 ppm maximum
Chromium (Cr)	2.0 ppm maximum
Heavy metals (as Pb)	40.0 ppm maximum
Sulphated ash, transp./ opaque	2.0%/ 5.0% maximum
Loss on drying	12.5 to 17.0%

Microbiology

Total viable count	≤ 1000 cfu/g
Yeasts and moulds	≤ 100 cfu/g
Enterobacteria	≤ 100 cfu/g
E. coli	Negative in 1 g
Salmonella	Negative in 10 g

Galenic

Disintegration time	≤ 15 min (Ph. Eur. 2.9.1.)
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