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SPECIFICATIONS

PULLULAN CAPSULES

vegetable/ natural

General Information

Description	Empty, two-piece, cylindrical hard vegetable capsules, typical in taste and odour.		
Composition	Pullulan (FCC & E-1204) and water.		
Additives	Titanium dioxide (E-171), if applicable.		
Excipients	Gellan gum, xanthan gum, carrageenan, and potassium chloride.		
Processing Aids	Surfactant (sodium lauryl sulphate) and pin lubricant (vegetable oil).		
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 00	Size 0	Size 1
	70.000	100.000	125.000

Galenic Properties

	Size 00	Size 0	Size 1
Lengths (mm)			
- Cap	11.80 ± 0.40	10.90 ± 0.40	9.80 ± 0.40
- Body	20.20 ± 0.40	18.60 ± 0.40	15.50 ± 0.40
- Filled (closed)	23.40 ± 0.50	21.70 ± 0.50	19.30 ± 0.50
External Diameter (mm)			
- Cap	8.55 ± 0.05	7.66 ± 0.05	6.95 ± 0.05
- Body	8.20 ± 0.05	7.35 ± 0.05	6.65 ± 0.05



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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	0.105 ± 0.02	0.100 ± 0.02	0.100 ± 0.02
Body Volume (ml)	0.95	0.68	0.50
Weight (mg)	148 ± 9	108 ± 8	78 ± 7

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
Sulphated ash	2.0% maximum
Loss on drying	10.0% to 15.0%

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	≤ 30 min (Ph. Eur. 2.9.1.)
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