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Empty Gelatin Capsules Specifications

The following tables are a summary of specifications related to Empty Gelatin Capsules, as indicated by:

Table I. Overall Product Specification

PHYSICAL/CHEMICAL		Specification
Disintegration time	(min)	10
Heavy metals	(10 ⁻⁶)	<50
Arsenic	(10 ⁻⁶)	<2
Ash	(%)	NA
	For transparent capsules	<2
	For combined capsules	3
	For opaque capsules	5
Loss on drying	(%)	12.5-16.0
Viscosity	(mm ² /s)	>60
SO ₂	(10 ⁻⁶)	<200
Parabens		0
Ethylene Oxide		0
Ethylene Chlorohydrin		0
Ethylene glycol		0
MICROBIOLOGICAL		Specification
Total count	(/1g)	<1,000
Fungal count	(/1g)	<100
Coli form	(/10g)	0
Escherichia coli	(/10g)	0
Staphylococcus	(/10g)	0
Pseudomonas	(/10g)	0
Salmonella	(/10g)	0
VISUAL DEFECTS		Specification
Major A AQL	(%)	0.01
Major B AQL	(%)	0.04
Minor C AQL	(%)	0.25



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Table II. Technical Parameter

Type of Capsule	Average Weight* mg	Length* in mm			External Diameter * in mm	
		Body	Cap	Overall Closed	Body	Cap
00EL	130 ± 10	22.20 ± 0.46	12.95 ± 0.46	25.3 ± 0.3	8.18	8.53
00	118 ± 7	20.22 ± 0.46	11.74 ± 0.46	23.3 ± 0.3	8.18	8.53
0EL	107 ± 7	20.19 ± 0.46	11.68 ± 0.46	23.1 ± 0.3	7.34	7.65
0	96 ± 6	18.44 ± 0.46	10.72 ± 0.46	21.7 ± 0.3	7.34	7.64
1	76 ± 5	16.61 ± 0.46	9.78 ± 0.46	19.4 ± 0.3	6.63	6.91
2	61 ± 4	15.27 ± 0.46	8.94 ± 0.46	18.0 ± 0.3	6.07	6.35
3	48 ± 3	13.59 ± 0.46	8.08 ± 0.46	15.9 ± 0.3	5.57	5.82
4	38 ± 3	12.19 ± 0.46	7.21 ± 0.46	14.3 ± 0.3	5.05	5.32
5	28 ± 2	9.30 ± 0.46	6.20 ± 0.46	11.1 ± 0.3	4.68	4.91
Supro A	114 ± 9	15.10 ± 0.46	14.50 ± 0.46	18.0 ± 0.3	8.18	8.53
Supro B	82 ± 7	11.20 ± 0.46	10.80 ± 0.46	14.2 ± 0.3	8.18	8.53

- *Average weight based on a moisture content of 14% to 14.5% and calculated based on 100 capsules. The upper and lower limits are given at the 99.9% confidence level.
- ** These data give an indication of the external diameter and length. It should never be considered as accept/reject criteria. These data can be used for specifying packaging material dimensions.



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Table III. Suggested Filling Weight (reference number)

The average capsule volume and capsule filled weight capacity (in mg) for typical powder fill densities are as follows:

CAPACITY	Capsule Volume in (ml)	0.6g/ml	0.8g/ml	1.0g/ml	1.2/ml
00EL	1.02	612	816	1,020	1,224
00	0.91	546	728	910	1,092
0EL	0.78	468	624	780	936
0	0.68	408	544	680	816
1	0.50	300	400	500	600
2	0.37	222	296	370	444
3	0.30	180	240	300	360
4	0.21	126	168	210	252
5	0.10	78	104	130	156
Supro A	0.68	408	544	680	816
Supro B	0.50	300	400	500	600

The above data are to be considered as approximation since filling product variables and filling machines type can significantly affect the capsule weight capacity.

Table IV. Packing In Push-Through Packs

The following minimum dimensions of the cavities in the die-rolls on the push-through packaging machines are recommended.

It must be noted that the following values correspond to a film thickness of 0.1mm.

Legend:

h = depth of cavity of blister die-roll

L* = length of cavity of blister die-roll measured at h/2 along the axis of the capsule

D* = width of cavity of blister die-roll measured at h/2 along the perpendicular axis of the capsule

unit: (mm)

	h	L*	d*
00	9.1	24.8	9.8
0EL	8.2	25.3	8.9
0	8.1	22.6	8.8
1	7.4	20.4	8.1
2	6.9	18.9	7.6
3	6.3	16.9	7.0
4	5.8	15.3	6.5