

PHARMACEUTICAL GRADE GELATIN SPECIFICATIONS

S. No.	Test	Specification
1.	Description	: As per USP / NF. IP.
2.	Storability	: As per USP / NF. IP.
3.	Identification	: Must confirm to current USP / NF. & IP.
4.	Water absorption & Swelling	: Should absorb minimum 5 to 10 times of its own wt.
5.	Odor	: a) Must be free of any odors b) No Phenolic Smell
6.	Taste	: Should not have salty taste
7.	Mesh size tested on 100 g.	: a) 100% Passing through mesh 4 size 4 mm b) 99% retention on mesh no. 22 c) Fines not more than 1 %
8.	Nitrites	: Not more than 100 ppm
9.	Phenolic Preservative	: Absent
10.	Heavy Metals	: Not more than 50 ppm
11.	Copper	: Not more than 10 ppm
12.	Zinc	: Not more than 50 ppm
13.	Arsenic	: Not more than 0.8 ppm
14.	Loss on drying	: Not more than 12.5%
15.	Loss on ignition	: Not more than 1 %
16.	Viscosity of 6.66% (W/W) Solution. (at 11.5 % Moisture content in Gelatin)	: 44 to 54 mps
17.	Bloom Strength (at 11.5 % Moisture content in Gelatin)	: 245 to 255 g. (not less than 245 g.)
18.	Grease Content	: Less than 0.2%
19.	a) PH b) ISO electric point	: 5.6 to 6.0 4.8 to 5.2
20.	Reducing Substance as SO ₂	: Not more than 40 ppm
21.	Oxidizing Substance as H ₂ O ₂	: Should be absent
22.	% Viscosity Drop	: Not more than 18% as it is.
23.	% Transmittance	: Not less than 90%
24.	Microbial Analysis: a Total aerobic microbial count b Staphylococcus aureus Pseudomonas aeruginosa c Salmonella Species d E. Coli e Keeping Quality: 1. Turbidity 2. Foul Odor 3. Liquefy	: Not more than 50 cfu/g. : Should be absent : Should be absent : Should be absent in 1 g. : Absent : Absent : Should not liquefy
f	Gelatin Liquefying Organism	: Not more than 50 cfu/g.
g	Anaerobic Bacteria	: Absent
h	Thermopiles	: Absent

The Gelatin should be free of preservatives, free of BSE, TSE, SRM & Kosher Certified.

