

9GLENs® Medical - Product Safety Issues

Products	9G-Visc	9G-Gel
Specification		
Active ingredient	Sodium hyaluronate (HA)	Hydroxymethylpropyl-methylcellulose (HPMC)
Origin	Bacterial fermentation – no animal	
Concentrations	1.0 %, 1.4 %, 1.6 %, 1.8 %, 3.0 %	2.0 %, 2.4 %
Storage conditions	Room temperature	
Biocompatibility	<p>XTT Cytotoxicity Test: ISO 10993-5:2009 Does not possess any cytotoxic potential</p> <p>Local Lymph Node Assay (LLNA) in Mice: ISO 10993-10:2010 Not a skin sensitizer</p> <p>Intracutaneous Reactivity Test in Rabbits: ISO 10993-10:2010 Well intracutaneous toleration, no visible dermal reactions</p>	
Test agents	9G-Visc 3.0 %	9G-Gel 2.4 %
Purity	<p>Sterility test: USP <71> No preserving agents, no antimicrobial activity</p> <p>LAL – Test according to European Pharmacopeia, Chapter 2.6.14 Method C Endotoxin concentration below 0.05 and 0.5 IU/ml</p>	
Shelf life	3.5 years	5 years
Tested for selected batches up to	<p>4.75 years (57 months): Proved stability of main performance parameters</p> <p>Sterility test: USP <71> No growth of aerobic bacteria, yeasts or moulds, no growth of fastidious aerobic and anaerobic bacteria</p>	
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