

ophtha futur[®] sil



High patient and product safety

Multi-step proven and tested ultra-purification process

Safe, biocompatible, sterile, endotoxin-free products

36 months shelf life

ophthafutur[®] sil

technical data-sheet

Product Name	ophthafutur [®] sil 5000	ophthafutur [®] sil 2000	ophthafutur [®] sil 1000
Active compound	silicone oil	silicone oil	silicone oil

Physical and Chemical Parameters

Viscosity (25 °C)	5,000 mPas	2,000 mPas	1,000 mPas
Density (25 °C)	0.97 g/cm ³	0.97 g/cm ³	0.97 g/cm ³
Refractive Index n _D 25	1.404	1.404	1.404

Chemical Control

Polydispersity (GPC)			
Specified Range	1.0 – 2.3	1.0 – 2.3	1.0 – 2.3
Typical Range	1.6 – 1.7	1.6 – 1.7	1.6 – 1.7
Content of Volatile Oligosiloxanes (HS-GC/MS)			
HMCTS/D3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
OMCTS/D4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D5	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
DMCPS/D6	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MM/L2	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MDM/L3	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
MD2M/L4	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
Σ	≤ 25 ppm	≤ 25 ppm	≤ 25 ppm

Microbial control

Product Sterility ensured by	Heat Sterilization	Heat Sterilization	Heat Sterilization
Outer Surface Sterility ensured by	Steam Sterilization	Steam Sterilization	Steam Sterilization
Bacterial Endotoxins ¹	≤ 0.2 EU/ml	≤ 0.2 EU/ml	≤ 0.2 EU/ml

¹ LAL test acc. to EP 2.6.14/USP <85>

Biocompatibility acc. to DIN EN ISO 10993

Cytotoxicity ²	Non cytotoxic	Non cytotoxic	Non cytotoxic
Sensitization ³	Non sensitizing	Non sensitizing	Non sensitizing
Irritation ⁴	Non irritating	Non irritating	Non irritating

² Growth inhibition test of serum extract acc. to DIN EN ISO 10993-5:2009

³ Murine Local Lymph Node Assay (LLNA) acc. to DIN EN ISO 10993-10:2010

⁴ Acute eye-irritation on rabbits acc. to DIN EN ISO 10993-10:2010 Appendix B

Presentation

	Filling Volume	Container	Sterile Barrier	Shelf Life
ophthafutur [®] sil5000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur [®] sil2000	10 ml	Glass Syringe	Pouch	36 months
ophthafutur [®] sil1000	10 ml	Glass Syringe	Pouch	36 months

