

**Certificate of Analysis
GM501 Gradient 100%**

Batchnumber GSS-2627
Production date 16 September 2026
Expiry date 31 March 2028
Total volume (ml) 52750

Product is sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,24	7,20-7,60
Osmolality	312	300-330 mOsm/kg
Endotoxin level	< 0,15	< 0,50 EU/ml
Density	1,1221	1,1150-1,1250 g/ml
Sterility test (according to the current Ph.Eur. 2.6.1 / USP <71>)	No growth	No growth
HSSA (% motility compared with control after 4h exposure to test medium)	98	≥ 80 %
HSSA (% motility compared with control after 24h exposure to test medium)	93	≥ 75 %

Release date 02 October 2026
Released by Dr. René Richarz
Signature



REV 08_00 / 2025-01-10