

**Certificate of Analysis
GM501 Gradient 100%**

Batchnumber GSS-2532
Production date 02 October 2025
Expiry date 30 April 2027
Total volume (ml) 80000

Product is sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,3	7,20-7,60
Osmolality	323	300-330 mOsm/kg
Endotoxin level	< 0,25	< 0,50 EU/ml
Density	1,1196	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)	100	≥ 80 %
HSSA (% motility compared with control after 24h exposure to test medium)	96	≥ 75 %

Release date Joana Sturm

Released by 20 October 2025

Signature



REV 08_00 / 2025-01-10