

**Certificate of Analysis
GM501 Gradient 90%**

Batchnumber	GRAD90-2525
Production date	02 October 2025
Expiry date	30 April 2027
Total volume (ml)	23150

Parameter	Results	Specifications
pH	7,32	7,20-7,60
Osmolality	339	320-350 mOsm/kg
Density	1,1108	1,1050-1,1150 g/ml
Endotoxin level	< 0,2	< 0,50 EU/ml
Sterility test (according to the current Ph. Eur. 2.6.1 / USP <71>)	No growth	No growth
HSSA (Human sperm survival assay) (4 hours exposure)	100	≥ 80 %
HSSA (Human sperm survival assay) (24 hours exposure)	99	≥ 75 %

Release date	20 October 2025
Released by	Joana Sturm
Signature	



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