

**Certificate of Analysis
GM501 Gradient 90%**

Batchnumber	GRAD90-2509
Production date	04 April 2025
Expiry date	31 October 2026
Total volume (ml)	17800

Parameter	Results	Specifications
pH	7,33	7,20-7,60
Osmolality	336	320-350 mOsm/kg
Density	1,1112	1,1050-1,1150 g/ml
Endotoxin level	< 0,15	< 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)	96	≥ 80 %
HSSA (Human sperm survival assay) (24 hours exposure)	100	≥ 75 %

Release date	22 April 2025
Released by	Joana Sturm
Signature	



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