

Certificate of Analysis

GM501 Gradient 45%

Batchnumber	GRAD45-2518
Production date	29 July 2025
Expiry date	31 January 2027
Total volume (ml)	12300

Parameter	Results	Specifications
pH	7,35	7,20-7,60
Osmolality	324	310-340 mOsm/kg
Endotoxin level	< 0,15	< 0,50 EU/mL
Density	1,0552	1,0500-1,0700 g/ml
Sterility test (according to the current Ph. Eur. 2.6.1 / <71>)	No growth	No growth
HSSA (Human sperm survival assay) (4 hours exposure)	96	≥ 80 %
HSSA (Human sperm survival assay) (24 hours exposure)	97	≥ 75 %

Release date	14 August 2025
Released by	Joana Sturm
Signature	

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