

**Certificate of Analysis
GM501 Gradient 90%**

Batchnumber GRAD90-2425
 Production date 28 October 2024
 Expiry date 30 April 2026
 Total volume (ml) 20150

Parameter	Results	Specifications
pH	7,3	7,20-7,60
Osmolality	335	320-350 mOsm/kg
Density	1,1087	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)	91	≥ 80 %
HSSA (Human sperm survival assay) (4 hours exposure)	95	≥ 75 %

Release date 12 November 2024
 Released by Joana Sturm
 Signature



REV 09_00 / 2024-09-11