

Certificate of Analysis

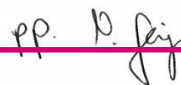
GM501 GentleVit Thaw

Batchnumber	GT-2616
Production date	06 August 2026
Expiry date	31 August 2027
Total batch size	200
Batchnumber HSA	B03J125033

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,20	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	16,1	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	16,5	14,4-21,6 g/l
GM501 GentleVit Thaw 3		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	824	805-850 mOsm/kg
Concentration HSA	16,8	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	549	535-565 mOsm/kg
Concentration HSA	18,2	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	417	405-435 mOsm/kg
Concentration HSA	19,1	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	279	270-290 mOsm/kg
Concentration HSA	19,2	16,0-24,0 g/l
Mouse Embryo Assay (1-cell)	100	≥ 80 %

Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and non-reactive for HbsAg, HBV RNA, HIV-1 RNA and syphilis. No known test method can offer assurance that products derived from human blood will not transmit infectious agents. Therefore, handle all specimens as if capable of transmitting HIV or hepatitis.

¹Sterility test (according to the current PH. Eur. 2.6.1 / USP <71>)

Release date	25 August 2026
Released by	Nicole Geiger
Signature	

REV 02_00 / 2023-09-15