

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2509
Production date	14 April 2025
Expiry date	30 April 2026
Total batch size	201
Batchnumber HSA	B03H121903

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	15,8	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,24	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,7	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	< 0,1	< 0,25 EU/mL
Osmolality	836	805-850 mOsm/kg
Concentration HSA	16,9	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,26	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	556	535-565 mOsm/kg
Concentration HSA	18	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	420	405-435 mOsm/kg
Concentration HSA	19,2	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,21	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	282	270-290 mOsm/kg
Concentration HSA	19,1	16,0-24,0 g/l
Mouse Embryo Assay (1-cell)	90,48	≥ 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>)

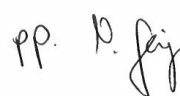
Release date

30. April 2025

Released by

Nicole Geiger

Signature



REV 02_00 / 2023-09-15