

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2604
Production date	29 January 2026
Expiry date	31 January 2027
Total batch size	202
Batchnumber HSA	B03J103333

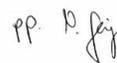
Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,27	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Concentration HSA	16,3	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,27	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,20	< 0,25 EU/mL
Concentration HSA	16,9	14,4-21,6 g/l
GM501 GentleVit Thaw 3		
pH	7,28	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,10	< 0,25 EU/mL
Osmolality	828	805-850 mOsm/kg
Concentration HSA	16,8	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,3	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,10	< 0,25 EU/mL
Osmolality	557	535-565 mOsm/kg
Concentration HSA	18,2	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,29	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,10	< 0,25 EU/mL
Osmolality	420	405-435 mOsm/kg
Concentration HSA	19,5	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,24	7,20-7,40
Sterility test ¹	NO GROWTH	No growth
Endotoxin	< 0,10	< 0,25 EU/mL
Osmolality	285	270-290 mOsm/kg
Concentration HSA	19,8	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
Released by
Signature

16. Februar 2025
Nicole Geiger



REV 02_00 / 2023-09-15

