

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2504
Production date	11 February 2025
Expiry date	28 February 2025
Total batch size	201
Batchnumber HSA	B03H108433

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	17,7	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	17,8	14,4-21,6 g/l
GM501 GentleVit Thaw 3		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	823	805-850 mOsm/kg
Concentration HSA	18,3	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	< 0,1	< 0,25 EU/mL
Osmolality	549	535-565 mOsm/kg
Concentration HSA	19	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,2	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	19,5	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,2	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,13	< 0,25 EU/mL
Osmolality	282	270-290 mOsm/kg
Concentration HSA	20,3	16,0-24,0 g/l
Mouse Embryo Assay (1-cell)	95,24	≥ 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

27. Februar 2025
Joana Sturm



REV 02_00 / 2023-09-15