

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2420
Production date	21 October 2024
Expiry date	31 October 2025
Total batch size	200
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,3	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	17,5	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	< 0,1	< 0,25 EU/mL
Osmolality	827	805-850 mOsm/kg
Concentration HSA	17,2	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	550	535-565 mOsm/kg
Concentration HSA	18,1	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,33	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	421	405-435 mOsm/kg
Concentration HSA	19,4	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	284	270-290 mOsm/kg
Concentration HSA	19,9	16,0-24,0 g/l
Mouse Embryo Assay (1-cell)	100	≥ 80 %

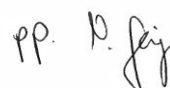
Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and non-reactive for HbsAg, HBV RNA, HIV-1 RNA and syphilis. No known test method can offer assurance that products derived from human blood will not transmit infectious agents.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

5. November 2024

Nicole Geiger



REV 02_00 / 2023-09-15