

Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2413
Production date	25 June 2024
Expiry date	30 June 2025
Total batch size	200
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
GM501 GentleVit Thaw 1		
pH	7,28	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,8	13,9-20,9 g/l
GM501 GentleVit Thaw 2		
pH	7,28	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	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	831	805-850 mOsm/kg
Concentration HSA	17,4	14,9-22,3 g/l
GM501 GentleVit Thaw 4		
pH	7,31	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	553	535-565 mOsm/kg
Concentration HSA	18,5	15,4-23,1 g/l
GM501 GentleVit Thaw 5		
pH	7,26	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	415	405-435 mOsm/kg
Concentration HSA	19,1	15,7-23,6 g/l
GM501 GentleVit Thaw 6		
pH	7,29	7,20-7,40
Sterility test ¹	No growth	No growth
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	279	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

15. Juli 2024
Joana Sturm



REV 02_00 / 2023-09-15