

Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2416
Production date	07 August 2024
Expiry date	31 August 2025
Total batch size	200
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
GM501 GentleVit Pre-Vitrification		
pH	7,2	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	280	270-290 mOsm/kg
Concentration HSA	20,3	16,0-24,0 g/l
GM501 GentleVit Freeze 1		
pH	7,25	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,7	15,6-23,4 g/l
GM501 GentleVit Freeze 2		
pH	7,2	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,1	15,2-22,8 g/l
GM501 GentleVit Freeze 3		
pH	7,22	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,2	14,4-21,6 g/l
GM501 GentleVit Freeze 4		
pH	7,26	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,2	12,8-19,2 g/l
GM501 GentleVit Freeze 5		
pH	7,37	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10,5	8,6-12,9 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	26 August 2024
Released by	Vanessa Bierlich
Signature	

REV 02_00 / 2023-09-15