

Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2615
Production date	06 August 2026
Expiry date	31 August 2027
Total batch size	198
Batchnumber HSA	B03J125033
Product was sterilized by aseptic processing techniques	

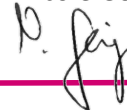
Parameter	Results	Specifications
GM501 GentleVit Pre-Vitrification		
pH	7,23	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	279	270-290 mOsm/kg
Concentration HSA	19,2	16,0-24,0 g/l
GM501 GentleVit Freeze 1		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	18,5	15,6-23,4 g/l
GM501 GentleVit Freeze 2		
pH	7,27	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	18,1	15,2-22,8 g/l
GM501 GentleVit Freeze 3		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	17,2	14,4-21,6 g/l
GM501 GentleVit Freeze 4		
pH	7,25	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	15,5	12,8-19,2 g/l
GM501 GentleVit Freeze 5		
pH	7,22	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	9,9	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
Released by
Signature

25 August 2026
Nicole Geiger

pp. 

REV 02_00 / 2023-09-15