

Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2514
Production date	10 July 2025
Expiry date	31 July 2026
Total batch size	200
Batchnumber HSA	B03H121903
Product was sterilized by aseptic processing techniques	

Parameter	Results	Specifications
GM501 GentleVit Pre-Vitrification		
pH	7,24	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	282	270-290 mOsm/kg
Concentration HSA	20,6	16,0-24,0 g/l
GM501 GentleVit Freeze 1		
pH	7,23	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		
	7,23	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,8	15,2-22,8 g/l
GM501 GentleVit Freeze 3		
pH	7,31	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,5	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	16,6	12,8-19,2 g/l
GM501 GentleVit Freeze 5		
pH	7,29	7,20-7,40
Sterility test ¹	NO GROWTH	NO GROWTH
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10,7	8,6-12,9 g/l
Mouse Embryo Assay (1-cell)	86	≥ 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

28 July 2025
Nicole Geiger

pp. P. Geiger

REV 02_00 / 2023-09-15