

**Certificate of Analysis  
GM501 GentleVit Freeze**

Batchnumber	GF-2407 / GT-2407A
Production date	09 April 2024
Expiry date	30 April 2024
Total batch size	200
Batchnumber HSA	B03H003853

Parameter	Results	Specifications
<b>GM501 GentleVit Pre-Vitrification</b>		
pH	7,27	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
Concentration HSA	20,3	16,0-24,0 g/l
<b>GM501 GentleVit Freeze 1</b>		
pH	7,26	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,9	15,6-23,4 g/l
<b>GM501 GentleVit Freeze 2</b>		
pH	7,27	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,1	15,2-22,8 g/l
<b>GM501 GentleVit Freeze 3</b>		
pH	7,27	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,4	14,4-21,6 g/l
<b>GM501 GentleVit Freeze 4</b>		
pH	7,35	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	15,4	12,8-19,2 g/l
<b>GM501 GentleVit Freeze 5</b>		
pH	7,26	7,20-7,40
Sterility test <sup>1</sup>	NO GROWTH	NO GROWTH
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	10,6	8,6-12,9 g/l
Mouse Embryo Assay (1-cell)	95,24	≥ 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.

<sup>1</sup>Sterility test (according to the current PH. Eur. 2.6.1 / USP <71>)

Release date	24 April 2024
Released by	Nicole Geiger
Signature	

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