

## Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2409
Production date	18 April 2024
Expiry date	30 April 2025
Total batch size	200
Batchnumber HSA	B03H003853

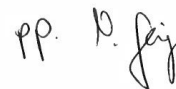
Parameter	Results	Specifications
<b>GM501 GentleVit Pre-Vitrification</b>		
pH	7,2	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	279	270-290 mOsm/kg
Concentration HSA	20,5	16,0-24,0 g/l
<b>GM501 GentleVit Freeze 1</b>		
pH	7,2	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	20,2	15,6-23,4 g/l
<b>GM501 GentleVit Freeze 2</b>		
pH	7,2	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	19,8	15,2-22,8 g/l
<b>GM501 GentleVit Freeze 3</b>		
pH	7,21	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,7	14,4-21,6 g/l
<b>GM501 GentleVit Freeze 4</b>		
pH	7,23	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	16,5	12,8-19,2 g/l
<b>GM501 GentleVit Freeze 5</b>		
pH	7,24	7,20-7,40
Sterility test <sup>1</sup>	No growth	NO GROWTH
Endotoxin	< 0,24	< 0,25 EU/mL
Concentration HSA	10,7	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.

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

Release date  
Released by  
Signature

05 June 2024  
Nicole Geiger



REV 02\_00 / 2023-09-15