

## Certificate of Analysis GM501 GentleVit Thaw

Batchnumber	GT-2613
Production date	04 June 2026
Expiry date	30 June 2027
Total batch size	199
Batchnumber HSA	B03J125033

Parameter	Results	Specifications
<b>GM501 GentleVit Thaw 1</b>		
pH	7,30	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	15,9	13,9-20,9 g/l
<b>GM501 GentleVit Thaw 2</b>		
pH	7,31	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Concentration HSA	16,6	14,4-21,6 g/l
<b>GM501 GentleVit Thaw 3</b>		
pH	7,32	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,15	< 0,25 EU/mL
Osmolality	826	805-850 mOsm/kg
Concentration HSA	16,5	14,9-22,3 g/l
<b>GM501 GentleVit Thaw 4</b>		
pH	7,31	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,18	< 0,25 EU/mL
Osmolality	553	535-565 mOsm/kg
Concentration HSA	17,7	15,4-23,1 g/l
<b>GM501 GentleVit Thaw 5</b>		
pH	7,29	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,17	< 0,25 EU/mL
Osmolality	419	405-435 mOsm/kg
Concentration HSA	18,6	15,7-23,6 g/l
<b>GM501 GentleVit Thaw 6</b>		
pH	7,27	7,20-7,40
Sterility test <sup>1</sup>	No growth	No growth
Endotoxin	< 0,16	< 0,25 EU/mL
Osmolality	284	270-290 mOsm/kg
Concentration HSA	19,2	16,0-24,0 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

pp. *N. Geiger*

24 June 2026  
Nicole Geiger

REV 02\_00 / 2023-09-15