

Certificate of Analysis GM501 GentleVit Freeze

Batchnumber	GF-2418
Production date	24 September 2024
Expiry date	30 September 2025
Total batch size	200
Batchnumber HSA	B03H100413
Product was sterilized by aseptic processing techniques	

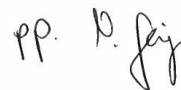
Parameter	Results	Specifications
GM501 GentleVit Pre-Vitrification		
pH	7,2	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Osmolality	281	270-290 mOsm/kg
Concentration HSA	19,2	16,0-24,0 g/l
GM501 GentleVit Freeze 1		
pH	7,21	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,4	15,6-23,4 g/l
GM501 GentleVit Freeze 2		
pH	7,22	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	18,2	15,2-22,8 g/l
GM501 GentleVit Freeze 3		
pH	7,2	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	17,0	14,4-21,6 g/l
GM501 GentleVit Freeze 4		
pH	7,24	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,1	< 0,25 EU/mL
Concentration HSA	15,3	12,8-19,2 g/l
GM501 GentleVit Freeze 5		
pH	7,3	7,20-7,40
Sterility test ¹	No growth	NO GROWTH
Endotoxin	< 0,2	< 0,25 EU/mL
Concentration HSA	9,8	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.

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

Release date
Released by
Signature

14 October 2024
Nicole Geiger



REV 02_00 / 2023-09-15