

Certificate of Analysis
GM501 Cult with Gentamicin

Batchnumber CULT-2506G
Production date 08 October 2025
Expiry date 30 April 2026
Batchnumber HSA M451A6871
Total volume (ml) 18900

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH (@37°C - 6% CO ₂)	7,31	7,20-7,45
Osmolality	281	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	9,4	8,0-12,0 g/l
Concentration gentamicin	10	5-15 mg/l
Sterility test (performed according to the current Ph.Eur.2.6.1 / USP <71>)	No growth	No growth
Mouse Embryo Assay (1-cell to expanded blastocyst within 96 hours)	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.

Release date 27 October 2025
Released by Nicole Geiger
Signature

pp. N. Geiger

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