

Certificate of Analysis
GM501 Cult with Gentamicin

Batchnumber CULT-2503G

Production date 02 May 2025

Expiry date 30 November 2025

Batchnumber HSA K439A6671

Total volume (ml) 18.100

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH (@37°C - 6% CO ₂)	7,29	7,20-7,45
Osmolality	281	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	9,6	8,0-12,0 g/l
Concentration gentamicin	12	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)	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.

Release date 20 May 2025

Released by Nicole Geiger

Signature

pp. N. Geiger

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