

Certificate of Analysis

GM501 Cult with Gentamicin

Batchnumber	CULT-2505G
Production date	18 August 2025
Expiry date	28 February 2026
Batchnumber HSA	K439A6671
Total volume (ml)	13000

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH (@37°C - 6% CO ₂)	7,28	7,20-7,45
Osmolality	282	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	9,1	8,0-12,0 g/l
Concentration gentamicin	6	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	02 September 2025
Released by	Joana Sturm
Signature	

REV 09_00 / 2024-09-17