

Certificate of Analysis GM501 Cult with Gentamicin and Phenol Red

Batchnumber	CULT-2503PRG
Production date	02 May 2025
Expiry date	30 November 2025
Batchnumber HSA	K439A6671
Total volume (ml)	5400

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH (@37°C - 6% CO ₂)	7,28	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	11	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)	yst 90	≥ 80 %

Source materials from which this product was derived was found negative when tested for antibodies against HIV-1/2 and HCV and nonreactive for HbsAg, HBV RNA, HIV-1 RNA and syphillis. 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

Released by

Signature

20 May 2025

Nicole Geiger

PP. D. feij

REV 10_00 / 2025-08-04