

Certificate of Analysis GM501 Cult with Gentamicin

Batchnumber CULT-2406G

Production date 02 September 2024

Expiry date 31 March 2025

Batchnumber HSA K331A687L

Total volume (ml) 15000

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,287	7,20-7,45
Osmolality	280	270-290 mOsm/kg
Endotoxin level	< 0,05	< 0,25 EU/ml
Concentration HSA	10	8,0-12,0 g/l
Concentration gentamicin	12	5-15 mg/l
Sterility test (performed according to the current Ph.I USP <71>)	Eur.2.6.1 / No growth	No growth
Mouse Embryo Assay (1-cell to expanded blastocy hours)	st within 96 95	≥ 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 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 18 September 2024

Released by Nicole Geiger

Signature

PP. P. fig