

Certificate of Analysis GM501 Hyaluronidase

Batchnumber HSA HYA-2509
HYA-2509
Production date 11 March 2025
Expiry date 31 March 2026
Total volume (ml) 3800
Batchnumber HSA B03H108433

Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,47	7,30-7,60
Osmolality	281	270-290 mOsm/kg
Endotoxin	< 0,09	<0,5 EU/ml
Concentration HSA	3,9	3,2-4,8 g/l
Enzyme activity	75-111	40-160 IU/ml
Sterility test (according to the current Ph.Eur.2.6.1 /USP<71>)	No growth	No growth
Mouse Embryo Assay (1-cell)	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 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 31 March 2025

Released by Nicole Geiger

Signature

PP. P. Jeig