

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2515
Production date	26 May 2025
Expiry date	31 May 2026
Total volume (ml)	3900
Batchnumber HSA	B03H121903
Batchnumber HYA	S2015H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,45	7,30-7,60
Osmolality	284	270-290 mOsm/kg
Endotoxin	< 0,459	<0,5 EU/ml
Concentration HSA	3,9	3,2-4,8 g/l
Enzyme activity	66-97	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)	90,48	≥ 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 13 June 2025

Released by Nicole Geiger

Signature

PP. D. Jeig