

**Certificate of Analysis
GM501 Hyaluronidase**

Batchnumber	HYA-2631
Production date	24 August 2026
Expiry date	31 August 2027
Total volume (ml)	3000
	B23K049493
Batchnumber HSA	B23K064693
Batchnumber HYA	S2015H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,48	7,30-7,60
Osmolality	282	270-290 mOsm/kg
Endotoxin	< 0,13	<0,5 EU/ml
Concentration HSA	4,0	3,2-4,8 g/l
Enzyme activity	49-73	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)	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 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 09 September 2026

Released by Nicole Geiger

Signature

pp. N. Geiger

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