

## **Certificate of Analysis GM501 Hyaluronidase**

Batchnumber	HYA-2513
Production date	21 May 2025
Expiry date	31 May 2026
Total volume (ml)	7050
Batchnumber HSA	B03H121903
Batchnumber HYA	S2015H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,43	7,30-7,60
Osmolality	282	270-290 mOsm/kg
Endotoxin	< 0,05	<0,5 EU/ml
Concentration HSA	3,8	3,2-4,8 g/l
Enzyme activity	40-59	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.

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Released by Joana Sturm

Signature

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