

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2537
Production date	24 November 2025
Expiry date	30 November 2025
Total volume (ml)	3600
Batchnumber HSA	B03J094493
Batchnumber HYA	S2015H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,49	7,30-7,60
Osmolality	279	270-290 mOsm/kg
Endotoxin	< 0,06	<0,5 EU/ml
Concentration HSA	3,6	3,2-4,8 g/l
Enzyme activity	60-89	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 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 December 2025
--------------	------------------

Released by	Joana Sturm
-------------	-------------

Signature



REV 09_00 /2023-09-15