

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2536
Production date	19 November 2025
Expiry date	30 November 2026
Total volume (ml)	3650
Batchnumber HSA	B03J094493
Batchnumber HYA	S2015H40
Product was sterilized by aseptic processing techniques	

Parameter	Results	Specifications
pH	7,51	7,30-7,60
Osmolality	277	270-290 mOsm/kg
Endotoxin	< 0,05	<0,5 EU/ml
Concentration HSA	3,7	3,2-4,8 g/l
Enzyme activity	74-109	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	04 December 2025
Released by	Joana Sturm
Signature	

REV 09_00 /2023-09-15