

Certificate of Analysis GM501 Hyaluronidase

Batchnumber HSA

HYA-2534

Production date 27 October 2025

Expiry date 31 October 2026

Total volume (ml) 4050

Bo3J094493

Batchnumber HYA S2015H40-17072025

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,48	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,06	<0,5 EU/ml
Concentration HSA	3,9	3,2-4,8 g/l
Enzyme activity	71-105	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 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 November 2025

Released by Nicole Geiger

Signature

REV 09_00 /2023-09-15