

**Certificate of Analysis
GM501 Hyaluronidase**

Batchnumber HYA-2435
 Production date 16 October 2024
 Expiry date 31 October 2025
 Total volume (ml) 4600
 Batchnumber HSA B03H100413
 Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,47	7,30-7,60
Osmolality	283	270-290 mOsm/kg
Endotoxin	< 0,08	<0,5 EU/ml
Concentration HSA	4,0	3,2-4,8 g/l
Enzyme activity	102-150	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 04 November 2024
 Released by Nicole Geiger
 Signature

