

**Certificate of Analysis
GM501 Hyaluronidase**

Batchnumber HYA-2432

Production date 23 September 2024

Expiry date 30 September 2025

Total volume (ml) 2900

Batchnumber HSA B03H100413

Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,48	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,108	<0,5 EU/ml
Concentration HSA	3,8	3,2-4,8 g/l
Enzyme activity	75-110	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 08 October 2024

Released by Nicole Geiger

Signature 

REV 09_00 /2023-09-15