

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2439
Production date	29 November 2024
Expiry date	30 November 2025
Total volume (ml)	4000
Batchnumber HSA	B03H100413
Batchnumber HYA	S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,45	7,30-7,60
Osmolality	281	270-290 mOsm/kg
Endotoxin	< 0,102	<0,5 EU/ml
Concentration HSA	3,6	3,2-4,8 g/l
Enzyme activity	79-117	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)	95,24	≥ 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	17 December 2024
Released by	Nicole Geiger
Signature	