

**Certificate of Analysis  
GM501 Hyaluronidase**

Batchnumber HYA-2433  
 Production date 04 October 2024  
 Expiry date 31 October 2025  
 Total volume (ml) 3600  
 Batchnumber HSA B03H100413  
 Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

<b>Parameter</b>	<b>Results</b>	<b>Specifications</b>
pH	7,43	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,0917	<0,5 EU/ml
Concentration HSA	3,8	3,2-4,8 g/l
Enzyme activity	77-114	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 21 October 2024  
 Released by Joana Sturm

Signature



REV 09\_00 /2023-09-15