

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2504
Production date	10 February 2025
Expiry date	28 February 2026
Total volume (ml)	3900
Batchnumber HSA	B03H108433
Batchnumber HYA	S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,47	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,1	<0,5 EU/ml
Concentration HSA	3,7	3,2-4,8 g/l
Enzyme activity Sterility test (according to the current Ph.Eur.2.6.1/USP<71>)	70-103	40-160 IU/ml
	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 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

Released by

Signature

26 February 2025

Joana Sturm

J.Sturm

REV 09_00 /2023-09-15