

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2501
Production date	06 January 2025
Expiry date	31 January 2026
Total volume (ml)	4300
Batchnumber HSA	B03H100413
Batchnumber HYA	S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,45	7,30-7,60
Osmolality	282	270-290 mOsm/kg
Endotoxin	< 0,1	<0,5 EU/ml
Concentration HSA	3,8	3,2-4,8 g/l
Enzyme activity Sterility test (according to the current Ph.Eur.2.6.1/USP<71>)	90-132	40-160 IU/ml
	No growth	No growth
Mouse Embryo Assay (1-cell)	95	≥ 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

21 January 2025

Joana Sturm

REV 09_00 /2023-09-15