

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2517
Production date	17.06.2025
Expiry date	30.06.2026
Total volume (ml)	6000
Batchnumber HSA	B03J094493
Batchnumber HYA	S2015H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,42	7,30-7,60
Osmolality	282	270-290 mOsm/kg
Endotoxin	< 0,05	<0,5 EU/ml
Concentration HSA	3,9	3,2-4,8 g/l
Enzyme activity Sterility test (according to the current Ph.Eur.2.6.1 /USP<71>)	50-74	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

07 July 2025

Nicole Geiger

PP. D. frig

REV 09_00 /2023-09-15