

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2422
Production date	02 July 2024
Expiry date	31 July 2025
Total volume (ml)	3600
Batchnumber HSA	B03H003853 B03H100413
	333.1230.123
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
рН	7,51	7,30-7,60
Osmolality	279	270-290 mOsm/kg
Endotoxin	< 0,104	<0,5 EU/ml
Concentration HSA	3,9	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)	85,71	≥ 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 22 July 2024

Released by Nicole Geiger

Signature

PP. P. Sig