

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2418
Production date	22 May 2024
Expiry date	31 May 2025
Total volume (ml)	3000 B03H025323,
Batchnumber HSA	B03H003853
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
рН	7,52	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,103	<0,5 EU/ml
Concentration HSA	4,2	3,2-4,8 g/l
Enzyme activity	83-123	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)	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 06 June 2024

Released by Nicole Geiger

Signature

PP. P. feig