

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2412
Production date	26 March 2024
Expiry date	31 March 2025
Total volume (ml)	3600
Batchnumber HSA	B03H025323
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
рН	7,48	7,30-7,60
Osmolality	281	270-290 mOsm/kg
Endotoxin	< 0,13	<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>)	80-118	40-160 IU/ml
	No growth	No growth
Mouse Embryo Assay (1-cell)	90,48	≥ 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

P.P. Bl

REV 09_00 /2023-09-15

17 April 2024

Vanessa Bierlich