

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2326
Production date	26 September 2023
Expiry date	30 September 2024
Total volume (ml)	3600
Batchnumber HSA	В03Н003853
Batchnumber HYA	S1047H40

Parameter	Results	Specifications
рН	7,47	7,30-7,60
Osmolality	279	270-290 mOsm/kg
Endotoxin	< 0,1	<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>)	75-110	40-160 IU/ml
	No growth	No growth
Mouse Embryo Assay (1-cell)	80,95	≥ 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 23 October 2023

Released by Nicole Geiger

Signature

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