

Certificate of Analysis GM501 Hyaluronidase

Batchnumber	HYA-2440
Production date	10 December 2024
Expiry date	31 December 2025
Total volume (ml)	4000
Batchnumber HSA	B03H100413
Batchnumber HYA	S1047H40

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,46	7,30-7,60
Osmolality	280	270-290 mOsm/kg
Endotoxin	< 0,1	<0,5 EU/ml
Concentration HSA	3,7	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

Released by

Signature

02 January 2025

Nicole Geiger

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REV 09_00 /2023-09-15