

## Certificate of Analysis GM501 Hyaluronidase

| Batchnumber       | HYA-2506         |
|-------------------|------------------|
| Production date   | 24 February 2025 |
| Expiry date       | 28 February 2026 |
| Total volume (ml) | 3900             |
| Batchnumber HSA   | B03H108433       |
| Batchnumber HYA   | S1047H40         |

Product was sterilized by aseptic processing techniques

| Parameter  | Results   | Specifications  |
|--|-----------|-----------------|
| рН   | 7,52      | 7,30-7,60       |
| Osmolality   | 281       | 270-290 mOsm/kg |
| Endotoxin  | < 0,1     | <0,5 EU/ml      |
| Concentration HSA  | 3,8       | 3,2-4,8 g/l     |
| Enzyme activity<br>Sterility test (according to the current<br>Ph.Eur.2.6.1/USP<71>) | 98-145    | 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

13 March 2025

**Nicole Geiger** 

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