

**Certificate of Analysis
GM501 Hyaluronidase**

Batchnumber HYA-2510
 Production date 14 March 2025
 Expiry date 31 March 2026
 Total volume (ml) 12963
 Batchnumber HSA B03H108433 + B03H12190
 Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

| Parameter | Results | Specifications |
|---|----------------|-----------------------|
| pH | 7,4 | 7,30-7,60 |
| Osmolality | 282 | 270-290 mOsm/kg |
| Endotoxin | < 0,1 | <0,5 EU/ml |
| Concentration HSA | 4,0 | 3,2-4,8 g/l |
| Enzyme activity | 85-124 | 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 syphilis. 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 01 April 2025
 Released by Joana Sturm
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