

Certificate of Analysis GM501 Hyaluronidase

Batchnumber HYA-2436

Production date 05 November 2024

Expiry date 30 November 2025

Total volume (ml) 4000

Batchnumber HSA B03H100413

Batchnumber HYA S1047H40

Product was sterilized by aseptic processing techniques

| Parameter | Results | Specifications |
|---|-----------|-----------------|
| рН | 7,48 | 7,30-7,60 |
| Osmolality | 280 | 270-290 mOsm/kg |
| Endotoxin | < 0,117 | <0,5 EU/ml |
| Concentration HSA | 3,8 | 3,2-4,8 g/l |
| Enzyme activity | 86-127 | 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) | 95,24 | ≥ 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 20 November 2024

Released by Nicole Geiger

Signature

PP. P. Jey