

**Certificate of Analysis
GM501 PVP**

Batchnumber PVP-2605
 Production date 03 March 2026
 Expiry date 31 December 2026
 Total volume (ml) 650
 Batchnumber HSA B03J103333

Product was sterilized by aseptic processing techniques

| Parameter | Results | Specifications |
|--|----------------|-----------------------|
| pH | 7,24 | 7,20-7,60 |
| Osmolality | 292 | 280-320 mOsm/kg |
| Viscosity (at 25°C) | 181,2 | > 170 cP |
| Endotoxin level | < 0,1 | < 0,5 EU/mL |
| Concentration HSA | 3,8 | 3,2-4,8 g/l |
| Sterility test (according to the current Ph. Eur. 2.6.1 / USP <71>) | No growth | No growth |
| Mouse Embryo Assay (% blastocysts after 96 hours, exposure time to test medium:10 minutes) | 95 | ≥ 80 % |
| HSSA (% motility compared with control after 60 minutes exposure to test medium) | 99 | ≥ 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 19 March 2026
 Released by Dr. René Richarz
 Signature 

REV 08_00 / 2023-09-15