

Certificate of Analysis
GM501 PVP

Batchnumber PVP-2625

Production date 15 September 2026

Expiry date 30 June 2027

Total volume (ml) 860

Batchnumber HSA B03J125033

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,32	7,20-7,60
Osmolality	299	280-320 mOsm/kg
Viscosity (at 25°C)	242,3	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	3,6	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)	100	≥ 80 %
HSSA (% motility compared with control after 60 minutes exposure to test medium)	93	≥ 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 October 2026

Released by Dr. René Richarz

Signature



REV 08_00 / 2023-09-15