GYNEMED

Certificate of Analysis
GM501 PVP

Batchnumber	PVP-2631
Production date	28 October 2026
Expiry date	31 July 2027
Total volume (ml)	600
Batchnumber HSA	B03J125033

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,49	7,20-7,60
Osmolality	306	280-320 mOsm/kg
Viscosity (at 25°C)	201,6	> 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)	95	≥ 80 %
HSSA (% motility compared with control after 60 minutes exposure to test medium)	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 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	16 November 2026
Released by	Nicole Geiger
Signature	pp. N. Geiger

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