

**Certificate of Analysis
GM501 PVP**

Batchnumber PVP-2505
 Production date 05 February 2025
 Expiry date 30 November 2025
 Total volume (ml) 620
 Batchnumber HSA B03H108433

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,35	7,20-7,60
Osmolality	301	280-320 mOsm/kg
Viscosity (at 25°C)	253.1	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	3,7	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)	95,24	≥ 80 %
HSSA (% motility compared with control after 60 minutes exposure to test medium)	95	≥ 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 20 February 2025
 Released by Joana Sturm

Signature



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