

Certificate of Analysis
GM501 PVP

Batchnumber PVP-2518
Production date 18 June 2025
Expiry date 31 March 2026
Total volume (ml) 860
Batchnumber HSA B03H121903

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
pH	7,5	7,20-7,60
Osmolality	304	280-320 mOsm/kg
Viscosity (at 25°C)	214,8	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	4,1	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)	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 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 09 July 2025
Released by Joana Sturm
Signature 

REV 08_00 / 2023-09-15