

Certificate of Analysis GM501 PVP

Batchnumber		PVP-2513
Production date		23 April 2025
Expiry date		31 January 2026
Total volume (ml)		650
Batchnumber HSA		B03H120903
Product was sterilized by aseptic processing techniques		
Parameter	Results	Specifications
рН	7,39	7,20-7,60
Osmolality	299	280-320 mOsm/kg
Viscosity (at 25°C)	196,8	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	3,5	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) HSSA (% motility compared with control after 60	95	≥ 80 %
minutes exposure to test medium)	98	≥ 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 09 May 2025

Released by Nicole Geiger

Signature

PP. D. Jay

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