

Certificate of Analysis GM501 PVP

Batchnumber	PVP-2508	
Production date	10 March 2025	
Expiry date	31 December 2025	
Total volume (ml)	640	
Batchnumber HSA	B03H108433	

Product was sterilized by aseptic processing techniques

Parameter	Results	Specifications
рН	7,39	7,20-7,60
Osmolality	313	280-320 mOsm/kg
Viscosity (at 25°C)	257,9	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	3,4	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)	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

Released by

Signature

26 March 2025

Nicole Geiger

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