

Certificate of Analysis GM501 PVP

Batchnumber	PVP-2426
Production date	04 October 2024
Expiry date	31 July 2025
Total volume (ml)	620
Batchnumber HSA	B03H100413

Parameter	Results	Specifications
pH	7,32	7,20-7,60
Osmolality	292	280-320 mOsm/kg
Viscosity (at 25°C)	241,1	> 170 cP
Endotoxin level	< 0,1	< 0,5 EU/mL
Concentration HSA	3,9	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)	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 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	21 October 2024
Released by	Joana Sturm
Signature	

REV 08_00 / 2023-09-15