

Certificate of Analysis GM501 PVP

Batchnumber	PVP-2318
Production date	25 September 2023
Expiry date	30 June 2024
Total volume (ml)	660
Batchnumber HSA	B03H025323

Parameter	Results	Specifications
pH	7,33	7,20-7,60
Osmolality	310	280-320 mOsm/kg
Viscosity (at 25°C)	222	> 170 cP
Endotoxin level	< 0,05	< 0,5 EU/mL
Concentration HSA	3,6	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)	85,71	≥ 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	25 October 2023
Released by	Nicole Geiger
Signature	

REV 09_00 / 2023-09-15

