

Certificate of Analysis GM501 PVP

Batchnumber	PVP-2109
Production date	22 June 2021
Expiry date	31 March 2022
Total volume (ml)	670
Batchnumber HSA	B3ALE00033

	Results	Specifications
рН	7,45	7,20-7,60
Osmolality	321*	280-320 mOsm/kg
Bacterial screen	PASSED	PASSED
Fungal screen	PASSED	PASSED
Endotoxin	< 0,05	< 1,00 EU/mL
Viscosity in cP (25°C)	285,5	> 170 cP
Mouse Embryo Assay (1-cell)	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

Vanessa Bierlich

09 July 2021

P.P.

* The slightly higher osmolality result has been accepted based on the output of the perfomed risk analysis. Therefore, this batch is released under concession. More information on this matter is available upon request.

REV 07_00 / 2019-08-14