

CERTIFICATE OF ANALYSIS

Product Name:	Alprostadil, Prostaglandin E1		
Batch No.	20230911	Analysis Date	September 11, 2023
Manufacturing Date	September 11, 2023	Expiry Date TO	September 10, 2025
Quantity	20 G	CAS	745-65-3
Storage	Alprostadil should be kept in a well-sealed container, protected from humidity and stored in a refrigerator (2-8°C) immediately after received.		
Analytical results			
Items	Specifications		Results
Description	White or slightly yellowish, crystalline powder		Conform
Solubility	Practically insoluble in water, freely soluble in ethanol (96 per cent), soluble in acetone, slightly soluble in ethyl acetate		Conform
Identification	According to the requirements		Conform
Optical rotation	-70°~-60°(anhydrous substance)		-64.6°
Residue on ignition	≤0.5%		0.32%
Water content	≤0.5%		0.22%
Loss on drying	≤1.0%		0.31%
Residue solvents	Ethyl acetate ≤0.5%		0.16%
	Hexane ≤0.029%		0.013%
Purity	Impurity A ≤1.5%		0.16%
	Impurity B ≤0.5%		0.12%
	Any other unknown impurities ≤0.9%		0.09%
	Total impurities ≤1.5%		0.45%
Assay	95%~102.5%		99.50%
Conclusion	This product conforms to EP standard.		

Inspector: Carlifor Wu

Verifier: Jack He

