

OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Alprostadil (Cas 745-65-3)				
Batch No.	191201	Mfg. date	2019.12.03		
Rep. Date	2019.12.06	Exp. date	2021.12.02		
Packaging	1kg/tin	Test according to	EP9.2		
Test Items	Standards	Results			
Characters	White or slightly yellowish crystalline powder	conforms			
Solubility	Practically insoluble in water, freely soluble in ethanol, soluble in acetone, slightly soluble in ethyl acetate	conforms			
Identification	Specific optical rotation: -70~-60(anhydrous substance)	-63.7			
	IR: IR spectrum is accordant with that of reference standard	conforms			
	HPLC: The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to the principal peak in the chromatogram obtained with the reference solution in the Assay	conforms			
Water	≤0.5%	0.12%			
Residue on ignition	≤0.5%	0.03%			
Related substances	Impurity A≤1.5%	Not detected			
	Impurity B≤0.5%	Not detected			
	Any other impurity≤0.9%	0.12%			
	Impurity number(more than 0.5%)≤1	0			
	Total impurities≤1.5%	0.24%			
Residual solvents	Ethanol≤5000ppm	505ppm			
	Acetone≤5000ppm	Not detected			
	Dichloromethane≤600ppm	Not detected			
	n-Hexane≤290ppm	Not detected			
	Ethyl acetate≤5000ppm	699ppm			
	n-Heptane≤5000ppm	448ppm			
Assay(anhydrous basis)	95.0%-102.5%(anhydrous substance)	100.85%			
Conclusion	It meets the requirements of EP9.2 Standards				
Storage	Store in a well-closed container at ambient temperature				
Prepared by:	LI	Reviewed by:	WEI	Released by:	Zhang