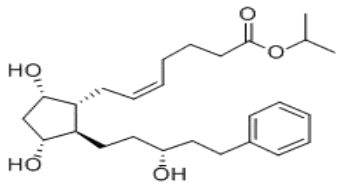
上海京河医药科技有限公司
Shanghai Genriver Pharmaceutical Co., Ltd.

CERTIFICATE OF ANALYSIS

Product Name		Latanoprost	Batch No.	180901
Structure				
Molecular Formula		$C_{26}H_{40}O_5$	CAS No.	130209-82-4
Manufacturing Date		2018.09.08	Retest Date	2020.09.07
Storage		Preserve at 2℃~8 ℃ in airtight and light resistant containers		
Quality Specification		USP		
Tests		Specifications		Results
Appearance		Colorless to pale yellow viscous oily liquid		Conforms
Solubility		Very soluble in Acetonitrile, freely soluble in Ethyl acetate and in Ethanol, practically insoluble in water		Conforms
Identification	HPLC	The retention time of the major peak in the chromatogram of Assay preparation corresponds to that of the Standard preparation as obtained in the assay.		Conforms
	IR	The IR Spectrum of the same should be consistent with that of the reference standard.		Conforms
Optical rotation		+31.0° ~ +38.0° (10mg/ml of Latanoprost in acetonitrile)		+33.8°
Residue on ignition		NMT 0.5%		0.05%
Water		N.M.T.2.0%		0.08%
Residual	Ethanol	N.M.T. 0.5%		0.20%

solvents	n-Hexane	N.M.T. 0.029%	Not detected
Related Substances	Isopropyl diphenylpho-sphorylpentanoate	N.M.T. 0.1%	Not detected
	Latanoprost related compound B	N.M.T. 0.5%	Not detected
	Latanoprost related compound A	N.M.T. 3.5%	Not detected
	Any unspecified impurity	N.M.T. 0.1%	0.091%
	Total impurities	N.M.T.0.5%	0.15%
Latanoprost related compound E		N.M.T. 0.2%	Not detected
Assay		94.0~102.0% (calculated on the anhydrous and solvent-free basis)	99.5%
Conclusion		**Conform to** USP	

Date of Report: 2018-09-09

Date of Audit: 2018-09-09 Approved by QA: Jun Yang