



瑾 岚 医 药 技 术 开 发 有 限 公 司
JINLAN PHARM-DRUGS TECHNOLOGY CO., LIMITED
Hangzhou ROYALL Import & Export Co.,Ltd.

Certificate of Analysis

Product name	Alprostadil	Batch No.:	140701
Manufacturing date	Jul.,14	Expiration date	Jul.,2016
Storage	Preserve in tight containers ,at a temperature of 2°C-8°C		

Items	Specification	Results
Appearance	White to slightly yellowish crystalline powder	Conforms
Identification		
1.HPLC	The retention time of the major peak in the chromatogram of Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay	Identical
2.IR absorbance Spectrum	Both the test sample and the reference standard exhibit the same intensity of absorption at the same wave number.(wavelengths). (potassium bromide disk method)	Identical
Optical rotation	-60° to -70° (anhydrous substance)	-69.4°
Water	Not more than 0.5%	0.19%
Residue on Ignition	Not more than 0.5%	0.21%
Purity		
1. Related substances	Imputiry A: N.M.T. 1.5%	Not detected
	Imputiry B: N.M.T. 0.5%	Not detected
	Any other impurity: N.M.T. 0.9%	0.26%
	N.M.T. one impurity:N.M.T.0.5%	Not detected
	Total impurity:N.M.T.1.5%	0.51%
2.Residual solvents	Ethyl acetate:N.M.T.0.5%	0.0484%
	n-Heptane:N.M.T.0.5%	0.0056%
	Acetone:N.M.T.0.5%	Not detected
	n-Hexane:N.M.T.0.029%	Not detected
Assay	95.0%~102.5%(anhydrous and solvent free basis)	99.8%
Conclusion:	Complies with EP7.0	

Tested by: Penny

Checked by: Alice

Approved by: Michelle

Add: 1113 Modern Star, #337 Shaoxing Road, Hangzhou, China
 Tel: 0086-571-85829052-812 Fax: 0086-571-85829153
 Email: sales04@royalpharms.com Http://www.royalpharms.com

