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CERTIFICATE OF ANALYSIS

Product Name: Alprostadil
Batch No.: 140801
Manufacturing Date: Aug., 2014
Expiring Date : Aug., 2016
Storage: Preserve in tight containers, at a temperature of 2° to 8°

Tests and Methods	Specifications	Results
Appearance	White or 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).	-66.2°
Water	N.M.T. 0.5%	0.32%
residue on ignition	N.M.T. 0.5%	0.08%
Purity 1) Related Substances	Impurity A: N.M.T. 1.5% Impurity B: N.M.T. 0.5% Any other impurity: N.M.T. 0.9% N.M.T one Impurity more than 0.5%	Not detected Not detected Not detected
2) Residual solvents	Total Impurities: N.M.T. 1.5% Ethyl acetate: N.M.T. 0.5% n-Heptane: N.M.T. 0.5% Acetone: N.M.T. 0.5% n-Hexane: N.M.T. 0.029%	0.19% 0.34% 0.0079% 0.0190% Not detected Not detected
Assay	95.0~102.5% (anhydrous and solvent free basis)	99.8%
Conclusion: conforms to the requirements of EP7.0		