



# Certificate of analysis

Productname: Alprostadil (Prostaglandin E1)

Cas number: 745-65-3

Molecular Formula: C<sub>20</sub>H<sub>34</sub>O<sub>5</sub>

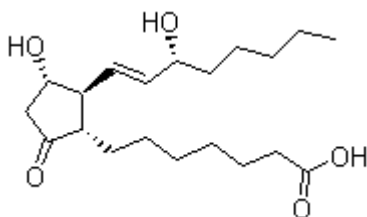
Molecular Weight: 354.48

Date of production: Oct. 01, 2017

Batch NO: 20171001

Exp Date: Sep. 31, 2019

Chemical structure:



Items	Specification	Results
Appearance	White to off-white crystalline powder	white crystalline powder
Identification	HPLC retention time of sample complies with that of known sample	Complies
Water	Not more than 0.5%	0.18%
Residue on Ignition	Not more than 0.5%	0.15%
Limit of prostaglandin A1, prostaglandin B1, and 13,14-dihydroprostaglandin E1	1) Prostaglandin A1 should not be more than 1.5% 2) prostaglandin B1 not more than 0.1% 3) Sum of prostaglandin B1 and 13,14-dihydroprostaglandin E1 should not be more than 0.5%	0.12% N.D. 0.21%
Limit of foreign prostaglandins	1) Single foreign prostaglandin not more than 0.9% 2) Total foreign prostaglandins not more than 2.0%	N.D. N.D.
Limit of chromium	Not more than 20 ppm	Complies
Limit of rhodium	Not more than 20 ppm	Complies
Assay	95.0%~105.0%	99.0%
Residual solvents	Ethyl acetate should be not more than 4000 ppm Hexane should be not more than 200 ppm	2334ppm N.D.

**Conclusion: It complies with the USP35 Standard**

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F