



CERTIFICATE OF ANALYSIS

Product name: Alprostadil (PGE₁)

Chemical name: 7-[(1R,2R,3R)-3-Hydroxy-2-[(1E,3S)-3-hydroxyoct-1-enyl]-5-oxocyclopentyl]heptanoic acid

CAS No.: 745-65-3

Manufacture date: 2024/05/10

Retest date: 2027/05/09

Batch No.: E021 245AA01

Anal. Rec. No.: I40247

Test item	Specification	Result
Appearance	White or slightly yellowish, crystalline powder	White crystalline powder
Identification	Specific Optical Rotation: -70.0~ -60.0° (anhydrous)	-65.5°
	I.R. Spectrum: Compare the IR spectrum between sample and standard.	Conform
	HPLC chromatogram:	Conform
	Examine the chromatograms obtained in the assay	
Related substances	System A (RRT < 1.2): (1) Any other single impurity (D, E, F) ≤ 0.50% (2) Any other unknown impurity ≤ 0.10% (3) Total any other impurities ≤ 0.90%	Not Detected Not Detected Not Detected
	System B (RRT > 1.2): (1) Impurity A (PGA ₁) ≤ 1.50% (2) Impurity B (PGB ₁) ≤ 0.50% (3) Any other single impurity (K, I) ≤ 0.50% (4) Any other unknown impurity ≤ 0.10% (5) Total any other impurities ≤ 0.90%	Not Detected Not Detected Not Detected Not Detected Not Detected
	System A+ System B Total impurities ≤ 1.50%	Not Detected
	Water	0.04 %
	Assay	99.4 %
	Residual solvents	1061 ppm
	Ethyl acetate ≤ 4000 ppm	Not Detected
	Ethanol ≤ 5000 ppm	Not Detected
	n-Hexane ≤ 290 ppm	Not Detected

Approved by: *[Signature]*

Prepared by: *[Signature]*

INDUSTRIAL

Headquarters:

5-6 Floor, Chung Ting Building No. 77, Section 2, Tun Hua South Road, Taipei, Taiwan
Tel: +886-2-2706-6006 Fax: +886-2-2326-3596
E-mail: sales-pharma@ecic.com.tw
www.ecic.com

Pharmaceutical Plant (Kuanyin II Plant):

12, Industrial Third Rd., Kuanyin District, Taoyuan City, Taiwan
Tel: +886-3-283-8088 Fax: +886-2-2326-3545

META
PHARMACEUTICAL

CERTIFICATE OF ANALYSIS

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Chemical name: 7-[(1R,2R,3R)-3-Hydroxy-2-[(1E,3S)-3-hydroxyoct-1-enyl]-5-oxocyclopentyl]heptanoic acid

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Test item	Specification	Result
Elemental Impurities	As ≤ 1.5 µg/g	Not Detected
	Cd ≤ 0.2 µg/g	Not Detected
	Pb ≤ 0.5 µg/g	0.24 µg/g
	Hg ≤ 0.3 µg/g	Not Detected
	Co ≤ 0.5 µg/g	Not Detected
	Ni ≤ 2 µg/g	0.09 µg/g
	V ≤ 1 µg/g	0.03 µg/g
	Sb ≤ 9 µg/g	Not Detected
	Li ≤ 25 µg/g	Not Detected
	Cu ≤ 30 µg/g	Not Detected
	Sn ≤ 60 µg/g	Not Detected
	Cr ≤ 20 µg/g	Not Detected
	Rh ≤ 20 µg/g	Not Detected
Bacterial Endotoxin	≤ 8 EU/mg	< 0.244 EU/mg
Microbial test	(1) Total aerobic microbial count (TAMC) ≤ 10 ² cfu/g	< 10 cfu/g
	(2) Total combined yeasts and molds count (TYMC) ≤ 10 cfu/g	< 10 cfu/g
	(3) Bile-tolerant <i>G. bacteria</i> : Negative	Negative
	(4) <i>Escherichia coli</i> : Negative	Negative
	(5) <i>Staphylococcus aureus</i> : Negative	Negative
	(6) <i>Salmonella</i> : Negative	Negative
	(7) <i>Pseudomonas aeruginosa</i> : Negative	Negative

Result: The above product is in conformity with the specification.

Note: (1) The specifications of this compound are in compliance with current European Pharmacopoeia edition. (2) Non-sterile. (3) CEP No.: R1-CEP 2012-204-Rev 01.

Storage conditions: This compound should be kept in a well-sealed container, protected from humidity and stored in a refrigerator (2 ~ 8 °C) immediately after received.

Approved by: *Xing*

DISTRIBUIDO POR

METAPHARMACEUTICAL

Prepared by: *Wen-Ling*

INDUSTRIAL SL 24/05/23

Headquarters:

5-6 Floor, Chung Ting Building No. 77, Section 2, Tun Hui South Road, Taipei, Taiwan
Tel: +886-2-2706-6006 Fax: +886-2-2326-3596
E-mail: sales-pharma@ecic.com.tw
www.ecic.com

Pharmaceutical Plant (Kuanyin II Plant):

12, Industrial Third Road, Kuanyin District, Taoyuan City, Taiwan
Tel: +886-3-439-8088 Fax: +886-2-2326-3545

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