



检验报告单

CERTIFICATE OF ANALYSIS

Product Name	Bimatoprost(比马前列素)		
According to	In-house standard	Batch No	170820
CAS No.	155206-00-1	Manufacturing Date	Aug. 2017
Quantity	160g	Retest Date	Aug. 2019
Test Items	Specification		Test Results
Appearance	White or almost white crystalline powder		Complies
Identification	IR absorbance Spectrum: Both the test sample and the reference standard exhibit the same intensity of absorption at the same wave number(wavelengths).(potasium bromide disk method)		Identical
Optical rotation	[α] _D 20: +30.0° ~ +36.0° (C=1.0, CH ₃ CN)		+34.5°
Water(K.F.)	NMT1.0%		0.30%
Melting range (熔点)	60.0-70.0°C		64.7°C
Heavy metals(干燥失重)	NMT20ppm		Complies
Sulphated ash (灰分)	NMT 0.2%		0.01%
Related substances	15-Epi-Bimatoprost: NMT 0.15% 5,6-trans-Bimatoprost: NMT 0.15% Any other single impurity: NMT 0.10% Total other impurities: NMT 1.0%		Not detected Not detected Not detected Not detected
Residual solvents	Methanol:NMT 1000ppm Dichloromethane:NMT 600ppm Tert-Butylmethy ether:NMT 5000ppm Acetone:NMT 1000ppm Ethanol: NMT 5000ppm Toluene: NMT 890ppm Ethyl acetate: NMT 5000ppm		Not detected Not detected 6ppm Not detected Not detected Not detected Not detected
Purity (含量)	97.0~102.0%(anhydrous and solvent free basis)		99.8%

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