



Certificate of Analysis

Items	Specifications	Results
Appearance	White to off-white powder	White powder
Solubility	Freely solution in methanol and in ethanol, soluble in 2-propanol	Conforms
Identification	HPLC: the retention time of the test sample corresponds to that of the reference standard IR: the infrared absorption spectrum of the test sample is concordant with the spectrum of reference standard	Conforms Conforms
Water content by KF	NMT 0.5%	0.06%
Specific optical rotation	+7.0°~+10.5°(c=2 in MeOH)	+10.21°
Residue on ignition	NMT 0.2%	0.10%
Heavy metals	NMT 20 ppm	Conforms
Sulphated ash	NMT 0.105	0.03%
Organic volatile impurities	Ethylacetate: NMT 0.5% Heptane: NMT 0.5% Tetrahydrofuran: NMT 0.072%	0.40% 0.16% ND
Related substances (by HPLC, area%)	Impurity E (RRT=0.36):NMT 0.3% Impurity O(RRT=1.11):NMT 0.3% Impurity T (RRT=2.87):NMT 0.2% Any other individual impurity: NMT 0.1% Total impurities: NMT1.0%	0.08% ND ND Conforms 0.16%
Assay (by HPLC)	98.0%~102.0%	99.0%