



Certificate of analysis

Product name: Carboprost tromethamine

Cas number: 58551-69-2

Molecular Formula: C₂₁H₃₆O₅·C₄H₁₁NO₃

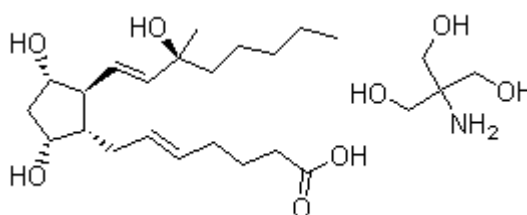
Molecular Weight: 489.64

Date of production: Sep. 18, 2017

Expiry Date: Sep. 17, 2019

Batch NO: 20170918

Chemical structure:



Items	Specifications	Results
Description	White or almost white powder	white powder
Identification	IR HPLC	Conform
Loss on Drying	≤1.0%	0.32%
Optical rotation	+18.0°~+24.0°	+22.6°
Residue Solvent	Methanol ≤ 0.3% Tert-Butyl methyl ether ≤ 0.5% Ethyl acetate ≤ 0.5% Tetrahydrofuran ≤ 0.072% n-Hexane ≤ 0.029% Acetonitrile ≤ 0.041% Toluene ≤ 0.089%	N.D N.D N.D N.D N.D N.D N.D
Related substances	15-epicarboprost (Impurity B): ≤ 2.0 % trans carboprost (Impurity A): ≤ 3.0 % Any other individual impurity ≤ 0.10% Total impurities ≤ 4.0 %	0.07% 0.29% 0.04% 0.43%
Assay (Calculated on anhydrous)	Between 94.0%~102.0%	98.1%

Conclusion: It complies with the USP39 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F