



Certificate of analysis

Product name: Eplerenone

Cas number: 107724-20-9

Molecular Formula: C₂₄H₃₀O₆

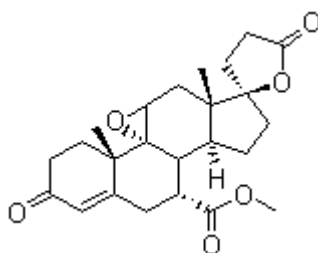
Molecular Weight: 414.49

Date of production: Oct. 21, 2017

Batch NO: 20171021

Exp Date: Oct. 20, 2019

Chemical structure:



ANALYSIS TEST	SPECIFICATIONS	RESULTS
Appearance	White or almost white slightly yellow ,crystalline powder	almost white crystalline powder
Solubility	Slightly soluble in water and 96% ethanol, freely soluble in methylene chloride	Conforms
Identification	IR :The infrared absorption spectrum of test sample should conform to that of reference standard	Conforms
Sulphate ash	≤0.1%	0.04%
Water	≤0.5%	0.2%
optical rotation	-16° ~-14°	-15°
Related substance	Impurity A ≤0.3%	<0.02%
	ImImpurity B ≤0.3%	0.02%
	unspecified impurities ≤0.10%	0.038%
	Total impurities ≤0.6%	0.1%
Residual solvent	Ethanol ≤5000ppm	25ppm
	Methanol ≤3000ppm	ND
	Dichloromethane ≤600ppm	50ppm
	Acetone ≤5000ppm	ND
Assay	97.5%~102%	100.7%

Conclusion: It complies with the EP8.4 Standard.

Analyst: Zhao

Checker: Liu

Q.C Director. Fang F