



# Certificate of analysis

Productname: obeticholic acid

Cas number: 459789-99-2

Molecular Formula: C<sub>24</sub>H<sub>36</sub>N<sub>4</sub>O<sub>6</sub>S<sub>2</sub>

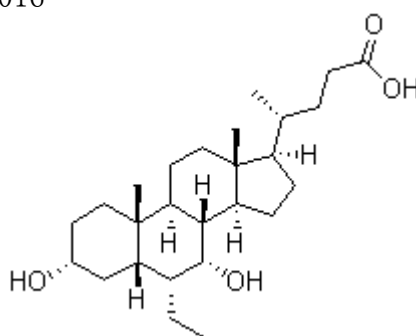
Molecular Weight: 540.70

Date of production:Dec. 18, 2016

Batch NO:20161218

Exp Date:Dec. 17, 2018

Chemical structure:



ITEMS	SPECIFICATIONS	RESULTS
Description	White to light yellow powder	Complies
Identification	NMR HPLC	Complies
Related substances	CDCA ≤0.5% UDCA ≤0.5% Any other individual impurity ≤0.3% Total impurities ≤1.0%	0.09% 0.07% 0.16% 0.58%
Loss on drying	≤3.0%	1.3%
Residue on ignition	≤0.20%	0.06%
Heavy metal	≤20PPM	Complies
Redidual solvents	Tetrahydrofuran ≤720ppm Methanol ≤3000ppm Ethyl acetate ≤5000ppm Ethanol ≤5000ppm	N.D 150ppm 300ppm 164ppm
Assay	98.5%-102.0%	99.4%

**Conclusion: It complies with the Enterprise Standard.**

Analyst:Zhao

Checker:Liu

Q.C Director. Fang F