



Certificate of analysis

Product name: Orlistat

Cas number: 96829-58-2

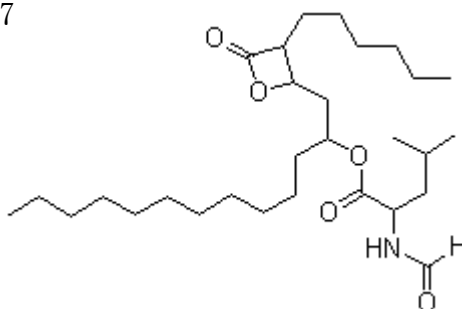
Molecular Formula: $C_{29}H_{53}NO_5$

Molecular Weight: 495.73

Date of analysis and: Aug. 20, 2017

Batch Number: 20170820

Expiry Date: Aug. 19, 2019



Chemical structure:

Items	Specifications	Results
Appearance	White or almost white crystalline powder	Conforms
Melting Point	42°C~46°C	43.0°C~44.0°C
Identification	The result of HPLC is consistent to the reference one. The result of IR is consistent to the reference one.	Conforms
Specific Rotation	-48° ~ -51° (CH ₃ CH ₂ OH, C=1)	-50.0°
Related substances	single impurity ≤ 0.5% Total impurities ≤ 2.0%	0.26% 1.40%
Residual solvents	Methanol ≤ 3000ppm Ethanol ≤ 5000ppm Acetonitrile ≤ 410ppm Heptane ≤ 5000ppm	N.D N.D N.D 500PPM
Water	≤ 0.5%	0.01%
Residual on Ignition	≤ 0.1%	0.03%
Heavy Metal	≤ 20ppm	Conforms
Assay	98.0%~101.5% (calculated on the anhydrous, solvent-free basis)	98.6%

Conclusion: It complies with the Enterprise Standard.

Analyst: Zhao

Checker: Liu

Q.C Director: Fang F