

山东丰金制药有限公司
Shandong Fengjin Pharmaceutical Co., Ltd

Address: No.777 of Jinniushan Road, Wuning Subdistrict Office, Muping District

Yantai, Shandong, China.

Post code: 264100, Tel: +86-0535-4611777

化工产品 仅供出口

Chemical Product for Exportation Only

Certificate of Analysis

Product name	Orlistat	Product Batch No	AL24002
COA Report No	C240202	Weight	200kg
Manufacturing Date	2024-02-20	Test Date	2024-02-22
Report Date	2024-02-26	Retest Date	2026-02
Standard	USP		

Test item	Specification	Results
Appearance	White to off-white fine powder or fine powder with lumps	White fine powder
Identification	(1) HPLC The retention time of the major peak of the sample solution corresponds to that of the standard solution.	Conforms
	(2) IR The IR spectrum of sample is consistent to the reference standard	Conforms
Specific Rotation	-48.0°~-51.0°	-49.2°
Melting point	42-46 °C	43.4°C-44.5°C
	Total impurity: Not more than 1.0%	0.31%
Related Substances	Related Compound A: Not more than 0.2%	0.02%
	Related Compound B: Not more than 0.05%	Not detected
	Related Compound C: Not more than 0.05%	0.0002%
	Related Compound D: Not more than 0.2%	Not detected
	Related Compound E: Not more than 0.2%	0.04%
	Formylleucine: Not more than 0.2%	Not detected
	Orlistat open ring epimer: Not more than 0.2%	Not detected
	Orlistat open ring amide: Not more than 0.1%	Not detected
	D-Leucine orlistat: Not more than 0.2%	Not detected
	Individual unspecified impurity: Not more than 0.1%	0.03%
Residual Solvents	n-Heptane: Not more than 5000ppm	207ppm
	Isopropyl ether: Not more than 5000ppm	Not detected
	Methanol: Not more than 3000ppm	Not detected
Residue on ignition	Tetrahydrofuran: Not more than 720ppm	Not detected
	Not more than 0.1%	0.03%
	Water	Not more than 0.2%
Assay	98.0%~101.5%	100.0%

Conclusion: Complies with USP

 Approved by: *Liukang 2024.02.26* check by: *Mingchengju 2024.02.26* Test by: *SunLina 2024.02.26*