Lote: 0020517

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS

Product name	Orlistat	Batch No.	201702003
Manuf. Date	2017-02-15	Expiry Date	2019-02-14
Quantity	30Kgs	Test Standard	USP39

TEST	SPECIFICATIONS	RESULTS
Description	White to off-white fine powder or fine powder with lumps	conform
Identification	HPLC , IR conforms	conform
Specific rotation	-48.0° ~ -51.0°（on the anydrous,solvent- free basis）	-49.9°
Related substances	Total impurities ≤1.0% Related compound A ≤0.2% Related compound B ≤0.05% Related compound C ≤0.05% Related compound D≤0.2% Related compound E≤0.2% Formylleucine ≤0.2% Orlistat open ring epimer≤0.2% D-Leucine orlistat ≤0.2% Orlistat open ring amide ≤0.1% Individual unidentified impurity≤0.1%	0.41% conform ND ND ND 0.18% ND ND ND ND 0.04%
Residual solvents	n- Hexane ≤ 5000ppm Isopropyl ether ≤ 5000ppm Methanol ≤ 3000ppm Tetrahydrofuran ≤ 720ppm	948ppm ND ND ND
Residual on ignition	≤0.1%	0.06%
Heavy metals	≤20ppm	<20ppm
Water	≤0.2%	0.09%
Assay	98.0%~ 101.5%(on the anydrous,solvent- free basis	100.0%

Storage: Closed keep in cool,dry and dark place ;keep from heat and strong light
Conclusion: The product complies with the requirements of USP39

Quality Manager: 吴永彦　　Rechecker: 易清威　　Analyst: 刘谈

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重庆万利康制药有限公司 质量检验章

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