

Hallochem Group

HALLOCHEM

Chongqing Waycome Pharmaceutical Co.,Ltd.

CERTIFICATE OF ANALYSIS -revised

Product name	Orlistat	Batch No.	201608006
Manuf. Date	2016-08-14	Expiry Date	2019-08-13
Quantity	10Kgs	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 anhydrous,solvent- free basis)	-50.5°
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%	0.28% conform ND ND ND 0.06% ND ND ND ND 0.04%
Residual solvents	n- Hexane ≤ 5000ppm Isopropyl ether ≤ 5000ppm Methanol ≤ 3000ppm Tetrahydrofuran ≤ 720ppm	690ppm 20ppm ND ND
Residual on ignition	≤0.1%	0.05%
Heavy metals	≤20ppm	<20ppm
Water	≤0.2%	0.04%
Assay	98.0%~ 101.5%(on the anhydrous,solvent- free basis	99.8%

Conclusion: The product complies with the requirements of USP39

Quality Manager:

Rechecker:

Analyst:

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