



大邦（湖南）生物制药有限公司
ARGUS PHARMACEUTICALS, LTD.

N DE LOTE:

0140525

13/05/2025

Certificate of Analysis

Orlistat (Bulk Material)

Batch No:	202504002	Quantity:	181.05kg
M.F. Date:	Apr. 02, 2025	Test Date:	Apr.04, 2025
Expiry Date:	Apr. 01, 2028	Standard	USP-42
Storage: Preserve in well-closed containers between 2°C and 8°C			
Item	Results	Specifications	
Description	White crystalline powder	White to off-white crystalline powder	
Solubility	Conforms	Very soluble in methanol and ethanol, freely soluble in chloroform,practically insoluble in water.	
Identification HPLC IR	HPLC retention time Conforms with the reference Conforms	HPLC retention time Conforms with the reference Conforms	
Specific Optical Rotation	-50.3°	-48.0° to -51.0°	
Water content	0.03%	NMT 0.2%	
Related substances I a. Orlistat related compound A	Not detected	NMT 0.2%	
Related substances II a. Orlistat related compound B	0.005%	NMT 0.05%	
Related substances III a. Formylleucine b. Orlistat related compound C c. Orlistat open ring epimer d. D-Leucine orlistat e. Individual unidentified impurity	0.006% 0.01% 0.05% Not detected 0.06%	NMT 0.2% NMT 0.05% NMT 0.2% NMT 0.2% NMT 0.1%	
Related substances IV a. Orlistat related compound D b. Orlistat open ring amide	0.03% 0.01%	NMT 0.2% NMT 0.1%	
Related substances V a. Orlistat related compound E	0.10%	NMT 0.2%	
Total impurities(I to V)	0.27%	NMT 1.0%	
Residual solvents	Methanol: Not detected EtOAc: Not detected n-Heptane: 200ppm	Methanol: NMT 3000PPM EtOAc: NMT 5000ppm n-Heptane: NMT 5000ppm	
Residue on ignition	0.02%	NMT 0.1%	
Heavy Metals as Pb	Less than 20ppm	NMT 20ppm	
Assay by HPLC (Orlistat)	99.9%	NLT 98.0% to 101.5% (on anhydrous,solvent-free basis)	
Microbial Limit Bacteria Mould Escherichia coli	<10cfu/g <10cfu/g Not detected	NMT1000cfu/g NMT 100cfu/g Not detected	
Conclusion:	The results conform with the USP-42 specification		
QC Chemist	Zhu Dai Xia		
QA Chemist	Peng Liang		

This document is approved and is electronically released without personal signature.

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