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

Certificate of Analysis

Orlistat

(Bulk Material)

Batch No:	202102003	**Quantity:**	150kg
M.F. Date:	Feb. 06, 2021	**Test Date:**	Feb. 07, 2021
Expiry Date:	Feb. 05, 2023	**Standard**	USP-43
Storage: Preserve in well-closed containers between 2°C and 8°C			

Item	Results	Specifications
Identification HPLC IR	HPLC retention time Conforms with the reference Conforms	HPLC retention time Conforms with the reference Conforms
Specific Optical Rotation	-49.2°	-48.0° to -51.0°
Water content	0.1%	NMT 0.2%
Related substances I a. Orlistat related compound A	 Not detected	 NMT 0.2%
Related substances II a. Orlistat related compound B	 0.01%	 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	 Not detected Not detected 0.03% 0.05% 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	 0.13% 0.03%	 NMT 0.2% NMT 0.1%
Related substances V a. Orlistat related compound E	 0.05%	 NMT 0.2%
Total impurities(I to V)	0.72%	NMT 1.0%
Residual solvents	Methanol: 0.1% EtOAc: Not detected n-Heptane: Less than 0.1%	Methanol: NMT 0.3% EtOAc: NMT 0.5% n-Heptane: NMT 0.5%
Residue on ignition	Less than 0.1%	NMT 0.1%
Heavy Metals as Pb	Less than 20ppm	NMT 20ppm
Assay by HPLC (Orlistat)	99.3%	NLT 98.0% to 101.5% (on anhydrous,solvent-free basis)
Conclusion:	The results conform with the USP-43 specification	
QC Chemist		
QA Chemist		

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

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