



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			

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