植恩生物
ZEIN BIOTECHNOLOGY

Zein Biotechnology Co.,Ltd.

Certificate Of Analysis

Product Name		Orlistat Working Standard		
Batch Number		DT12B-230201		
Refer to		In-house Standard	Issued Date	2024.02.29
Quantity		100mg	Expiry Date	2025.02.15
Test Items		**Specifications**		**Results**
Appearance		White to off-white fine powder or fine powder with lumps		Conforms
Specific optical rotation, 589 nm, 20°C, c = 3% (m/v) in ethanol (anhydrous and solvent-free)		-48.0° to -51.0°		-49.9°
Identification	**HPLC**	The retention time of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the assay.		Conforms
	IR	Corresponds to Reference Spectrum		Conforms
Organic impurities（HPLC + GC + TLC）				
Total of all (organic impurities)		Not more than 1.0%		0.23%
Orlistat related compound A (TLC)		Not more than 0.2%		Conforms
Orlistat related compound B (GC)		Not more than 0.05%		Not detected
Orlistat related compound C (HPLC)		Not more than 0.05%		Not detected
Orlistat related compound D (HPLC)		Not more than 0.2%		Not detected
Orlistat related compound E (HPLC)		Not more than 0.2%		0.04%
Formylleucine (HPLC)		Not more than 0.2%		Not detected
Orlistat open ring epimer(HPLC)		Not more than 0.2%		Not detected
Orlistat open ring amide(HPLC)		Not more than 0.1%		Not detected
D-Leucine orlistat(HPLC)		Not more than 0.2%		0.007%
Any individual unspecified impurity(HPLC)		Not more than 0.1%		0.05%
Residual Solvents（GC）				
n-Heptane		Not more than 5000ppm		341ppm
Isopropyl ether		Not more than 5000ppm		Not detected
Methanol		Not more than 3000ppm		Not detected
Tetrahydrofuran		Not more than 720ppm		Not detected
Benzene		Not more than 2ppm		Not detected
Residue on Ignition		Not more than 0.1%		0.03%
Assay (HPLC) (anhydrous and solvent-free)		98.0% to 101.5%		99.7%
Water		Not more than 0.2%		0.02%
Conclusion		Conforms		

Prepared by: 2024.02.29 **Reviewed by:** 2024.02.29 **Approver by:** 2024.02.29

Zein Biotechnology Co.,Ltd
Address: No.22 Hua Nan Road, Changshou Economic Zone,Chongqing, China
Tel:023-80885015