

Zein Biotechnology Co.,Ltd.

Certificate Of Analysis

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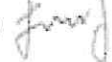
11/02/2022



Product Name		Orlistat	Batch Number	T12B-A010-210706
Grade		USP API	Refer to	USP-NF 2022
Batch size		202.71kg	Quantity	50kg
Manufacture Date		2021.07.16	Packaging	25kg/drum
Retest Date		2023.07.15	Test Date	2021.12.01
Test Items		Specifications	Results	
Appearance		White to off-white fine powder or fine powder with lumps		Off white powder
Specific optical rotation, 589 nm, 20°C, c = 3% (m/v) in ethanol (anhydrous and solvent-free)		-48.0° to -51.0°		-49.8°
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%		0.41%
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%		0.05%
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%		0.03%
Other unidentified impurities(HPLC)		Not more than 0.1%		0.06%
Residual Solvents (GC)				
n-Heptane		Not more than 5000ppm		232ppm
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		0.1ppm
Residue on Ignition		Not more than 0.1%		0.06%
Assay (HPLC) (anhydrous and solvent-free)		98.0% to 101.5%		99.5%
Water		Not more than 0.2%		0.02%
Conclusion		Conforms with USP-NF 2022		

 Prepared by:  2022.01.20

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 Approver by:  2022.01.20

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