植恩生物
ZEIN BIOTECHNOLOGY

23/06/2022

METAPHARMACEUTICAL

N DE LOTE: 0110622

Zein Biotechnology Co.,Ltd.
Certificate Of Analysis

Product Name		Orlistat	Batch Number	T12B-A010-220201
Grade		API	Refer to	USP-NF 2022
Batch size		202.28kg	Quantity	50kg
Manufacture Date		2022.02.18	Packaging	25kg/drum
Retest Date		2024.02.17	Test Date	2022.02.21
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°		-49.3°
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%		0.35%
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%		0.02%
Other unidentified impurities(HPLC)		Not more than 0.1%		0.06%
Residual Solvents（GC）				
n-Heptane		Not more than 5000ppm		407ppm
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%		99.2%
Water		Not more than 0.2%		0.01%
Conclusion		Conforms with USP-NF 2022		

Prepared by: 2022.04.06 **Reviewed by:** 2022.04.06 **Approver by:** 2022.04.06

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