

Zein Biotechnology Co.,Ltd

Certificate Of Analysis

Product Name	Orlistat	Batch Number	T12B-A010-210503
Grade	API	Refer to	YJ-TS-T12B-C1-02
Batch size	202.32kg	Quantity	50kg
Manufacture Date	2021.04.30	Packaging	25kg/drum
Retest Date	2023.04.29	Test Date	2021.05.17
Test Items	Specifications		Results
Appearance	White to off-white fine powder or fine powder with lumps		Conforms
Specific Rotation	-48.0° ~ -51.0°		-49.6°
Identification	A HPLC The retention time of the major peak of the sample solution corresponds to that of the standard solution.		Conforms
	B IR The IR spectrum of sample is consistent to the reference standard .		Conforms
Related Substances			
Total impurity	Not more than 1.0%		0.61%
Related Compound A	Not more than 0.2%		<0.2%
Related Compound B	Not more than 0.05%		ND
Related Compound C	Not more than 0.05%		ND
Related Compound D	Not more than 0.2%		ND
Related Compound E	Not more than 0.2%		0.05%
Formylleucine	Not more than 0.2%		ND
Orlistat open ring epimer	Not more than 0.2%		ND
Orlistat open ring amide	Not more than 0.1%		ND
D-Leucine orlistat	Not more than 0.2%		0.03%
Individual unidentified impurity	Not more than 0.1%		0.05%
Residual Solvents			
n-Heptane	Not more than 5000ppm		393ppm
Isopropyl ether	Not more than 5000ppm		7ppm
Methanol	Not more than 3000ppm		ND
Tetrahydrofuran	Not more than 720ppm		ND
Benzene	Not more than 2ppm		0.1ppm
Residual on Ignition	Not more than 0.1%		0.04%
Assay	98.0%~101.5%		99.3%
Water	Not more than 0.2%		0.02%
Conclusion	Conforms with USP43		

 Prepared by:  2021.05.17

 Reviewed by:  2021.05.17

 Approver by:  2021.05.17

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