

## Chongqing Zein Pharmaceutical Co.,Ltd

### Certificate Of Analysis

Report No.: T12B-2005006

Product Name	Orlistat	Batch Number	T12B-A010-200503
Grade	API	Refer to	YJ-TS-T12B-C1-01
Batch size	202.41kg	Manufacture Date	2020.05.03
Packaging	25kg/drum	Retest Date	2022.05.02
Quantity	50kg	Test Date	2020.05.06
Test Items	Specifications		Results
Appearance	White to off-white fine powder or fine powder with lumps		Conforms
Specific Rotation	-48.0°~-51.0°		-50.3°
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%		0.37%
Related Compound A	Not more than 0.2%		Conforms
Related Compound B	Not more than 0.05%		ND
Related Compound C	Not more than 0.05%		0.0009%
Related Compound D	Not more than 0.2%		ND
Related Compound E	Not more than 0.2%		0.03%
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%		ND
Individual unidentified impurity	Not more than 0.1%		0.07%
Residual Solvents			
n-Heptane	Not more than 5000ppm		273ppm
Isopropyl ether	Not more than 5000ppm		6ppm
Methanol	Not more than 3000ppm		ND
Tetrahydrofuran	Not more than 720ppm		ND
Formamide	Not more than 220ppm		ND
Benzene	Not more than 2ppm		ND
Residual on Ignition	Not more than 0.1%		0.06%
Assay	98.0%~101.5%		100.4%
Water	Not more than 0.2%		0.01%
Conclusion	Conforms with USP42		

Analyst: 刘静 2020.07.10

Checker: 2020.07.10

Approver: 2020.07.10

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