Chongqing Zein Pharmaceutical CO.,Ltd

Certificate Of Analysis

Product Name	Orlistat	Batch size	80.07kg
Batch Number	T12-C0051908001	Manufacture Date	2019.08.01
Packaging	10kg/tin	Issued Date	2019.08.14
Quantity	20kg	Expiration date	2021.07
Address: Guankou, Fengcheng Town Changshou District, Chongqing, China		Tel.: 86-23-68639832	

Test Items	Specifications	Results
Appearance	White to off-white fine powder or fine powder with lumps.	Conforms
Specific Rotation	-48.0°~-51.0°(on the anhydrous ,solvent-free basis)	-49.8°
Identification	A HPLC The retention time of the major peak of the sample solution corresponds to that of the standard solution. B IR The IR spectrum of sample is consistent to the reference standard .	Conforms
Related Substances		
Total impurity	Not more than 1.0%	0.11%
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%	0.003%
Related Compound D	Not more than 0.2%	ND
Related Compound E	Not more than 0.2%	0.02%
Formylleucine	Not more than 0.2%	ND
Orlistat open ring epimer	Not more than 0.2%	ND
D-Leucine orlistat	Not more than 0.2%	ND
Orlistat open ring amide	Not more than 0.1%	ND
Individual unidentified impurity	Not more than 0.1%	0.03%
Residual Solvents		
n-Heptane	Not more than 5000ppm	466ppm
Isopropyl ether	Not more than 5000ppm	ND
Methanol	Not more than 3000ppm	ND
Tetrahydrofuran	Not more than 720ppm	ND
Residual on Ignition	Not more than 0.1%	0.03%
Assay	98.0%~101.5%(on the anhydrous ,solvent-free basis)	99.8%
Water	Not more than 0.2%	0.06%

Approved 合格

Conclusion: Conforms with USP42

Analyst: 陈婧 **Checker:** 邓 **Approver:**

Fecha Entrada: 31-10-2019
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ORLISTAT GRANEL
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Lote: 0089125