



SHANDONG NEW TIME PHARMACEUTICAL CO., LTD.

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Certificate of Analysis

No:4Y21030038

Product name	Orlistat	
Batch No.	602210202	Batch size
Manufacturing Date	Feb.17, 2021	Retest Date
Test	Specification	Result
Appearance	White to off-white fine powder or fine powder with lumps	White powder
Solubility	Very soluble in methanol, in ethanol and in chloroform; practically insoluble in water.	Conforms
Identification	A. IR: consistent with the spectrum obtained with that of its RS.	Conforms
	B. 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
Specific rotation	-48.0° ~ -51.0°	-50.0°
Water	NMT 0.2%	0.006%
Residue on ignition	NMT 0.1 %	0.05%
Limit of Orlistat related compound A	NMT 0.2 %	undetected
Limit of Orlistat related compound B	NMT 0.05 %	undetected
Organic impurities	Formylleucine: NMT 0.2 %	undetected
	Orlistat related compound C: NMT 0.05 %	undetected
	Orlistat open ring epimer: NMT 0.2 %	undetected
	d-Leucine orlistat: NMT 0.2 %	undetected
	Individual unidentified impurity: NMT 0.1 %	0.090%
Limit of Orlistat related compound D and Orlistat open ring amide	Orlistat related compound D: NMT 0.2 %	undetected
	Orlistat open ring amide: NMT 0.1 %	undetected
Limit of Orlistat related compound E	NMT 0.2 %	0.041%
Total impurities	NMT 1.0 %	0.31%
Residual solvents	Heptane: NMT 5000 ppm	607ppm
	Acetonitrile: NMT 410 ppm	Undetectable
	Methanol: NMT 3000 ppm	Undetectable
	Ethanol: NMT 5000 ppm	Undetectable
Assay	98.0% ~ 101.5% (on the anhydrous, solvent-free basis)	100.4%
Microbial Limit	Total Aerobic Limit: <1000cfu/g	<10cfu/g
	TYMC(Total combined yeasts and molds count): < 100cfu/g	<10cfu/g
	Escherichia Coli: Absent	Undetectable/g
Conclusion	Conforms to the requirements of current USP standard.	
Storage condition	Stored at the temperature of 2-8° C.	

QC Manager:

Reporter: