



CERTIFICATE OF ANALYSIS

Product Name	Orlistat	Batch No.	WT20210301
CAS No.	96829-58-2	Specification	USP
Quantity	521.9kgs	Mfg. Date	2021.03.01
Date of Analysis	2021.03.02	Expiry Date	2023.03.02

Test Items	Specification	Test Results
Description	Appearance: White or almost white crystalline powder	White crystalline powder
	IR spectrun should comply with that of its RS.	Conforms
	HPLC: the retention time of principal peak should comply with its RS	Conforms
Specific Rotation	-48° ~ -51° at 20°C	-49.9°
Identification	HPLC: the retention time of principal peak should comply with its RS	Conforms
	IR spectrum should comply with that of its RS	Conforms
Orlistat Related Compound A	NMT 0.2%	Undetectable
Orlistat Related Compound B	NMT 0.05%	Undetectable
Organic impurities	Fromlylleucine :MNT 0.2%	Undetectable
	Orlistat relaed compound C:MNT 0.05%	Undetectable
	Orlistat open ring epimer:MNT 0.2%	Undetectable
	D-Leucine orlistat:MNT 0.2%	Undetectable
	Individual unidentified impurity:MNT 0.1%	0.096%
Limit of Orlistat related compound D and Orlistat open ring amide	Orlistat relaed compound D:MNT 0.2%	Undetectable
	Orlistat open ring epimer:MNT 0.1%	0.0016%
Limit of Orlistat Related Compound E	NMT 0.2%	0.082%

Total impurities	NMT 1.0%	0.35%
Water	NMT 0.2%	0.005%
Residue on ignition	NMT 0.1%	100.4%
Residual solvents	Methanol NMT 3000ppm	Undetectable
	Ethanol NMT 5000ppm	Undetectable
	Acetonitrile NMT 410ppm	Undetectable
	Heptane NMT 5000ppm	500ppm
Assay	98.0%~101.5%(on the anhydrous,solvent-free basis	100.4%
Microbial Limit	Total Aerobic Limti:<10 ³ cfu/g	<10 ³ cfu/g
	TYMC(Total combined yeasts and molds count):10 ² cfu/g	10 ² cfu/g
	Escherichia coli Count: A bsent/g	Undetectable/g
	Staphylococcus aureus: A bsent/g	Undetectable/g
	Pseudomonas aeruginosa: A bsent/g	Undetectable/g
	Salmonella:A bsent/10g	Undetectable/10g
D10	———— ————	7.901μ m
D50	———— ————	49.89μ m
D90	———— ————	187.9μ m
Storage Condition	Stored at the temperature of 2~8°C	

Conclusion: The test product complies with the requirements of current USP Standard.

Analyst: Wu

Checker: Wang

Q.C.Director: Wang Li

