



CERTIFICATE OF ANALYSIS (COA)

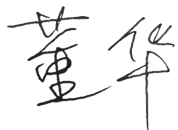
Product name	Orlistat	Batch No.	WLP-20220908
CAS No.	96829-58-2	Specification	In-house
Quantity	456.20kg	Mfg. Date	2022.09.08
Date of Analysis	2022.09.10	Expiry Date	2025.09.07

Test Items	Specification	Test Results
Appearance	White or almost white crystalline powder	White crystalline powder
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(TLC procedure 1)	NMT 0.2%	Undetectable
Orlistat Related Compound B(GC procedure 2)	NMT 0.05%	Undetectable
Impurity (HPLC proceduer 3)	Fromlylleucine (RRT 0.1):MNT 0.2%	Undetectable
	Orlistat relaed compound C(RRT 0.13):MNT 0.05%	Undetectable
	Orlistat open ring epimer(RRT 0.44):MNT 0.2%	0.041%
	D-Leucine orlistat(RRT 1.18):MNT 0.2%	Undetectable
	Individual unidentified impurity:MNT 0.1%	0.092%
Impurity (HPLC proceduer4)	Orlistat relaed compound D(RRT 1.18):MNT 0.2%	0.0012%
	Orlistat open ring epimer(RRT 1.25):MNT 0.1%	0.0011%
Orlistat Related Compound E(GC procedure 5)	NMT 0.2%	Undetectable
Residual solvents	Methanol NMT 3000ppm	Undetectable
	Ethanol NMT 5000ppm	Undetectable
	Acetonitrile NMT 410ppm	Undetectable
	Heptane NMT 5000ppm	1056ppm
Water	NMT 0.2%	0.02%
Residue on ignition	NMT 0.1%	0.04%
Heavy metals	NMT 20ppm	Conforms
Assay	98.0%~101.5%(on the anhydrous ,solvent-free basis)	99.7%
Conclusion	The test product complies with the requirements of specification.	

Analyst:



Checker:



Q. C. Director:

