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Certificate of Analysis

Product Name	Orlistat		
Cas No.	96829-58-2	Batch QTY	500kgs
Production Date	2019-03-05	Batch No.	QA20190305
Expiry Date	2021-03-04	Report Date	2019-03-12
Original			
ITEMS	SPECIFICATIONS		RESULTS
Appearance	White or almost white crystalline Powder		Complies
Odor & Tasted	Characteristic		Complies
Solubility	very soluble in methanol and ethanol, freely soluble in chloroform, practically insoluble in water.		Complies
Assay(% on anhydrous basis) the	≥ 99.0		99.13
Identification	HPLC: the retention time of principal peak should comply with its RS.		Complies
	IR spectrum should, comply with that of its RS.		Complies
Melting point (°C)	42~46		43~45°C
Specific rotation(°)	-48~-51		-50°
Water(%)	≤0.5		0.07
Residue on ignition(%)	≤0.1		0.06
Particle size(%)	100% through 80 mesh sieves		Complies
Heavy Metals			
Heavy Metal (ppm)	≤20		Complies
Residual solvents(ppm)	Methanol ≤ 3 000		Complies
	Ethanol ≤5000		Complies
	Acetonitrile ≤ 410		Complies
	Heptane NMT 5000		Complies
Conclusion	Conform to the standard.		
Packing	25kg/drum		
Storage and Handling	Store in a cool and dry place, keep away from direct strong and heat.		
Shelf life	Two years if sealed and store away from direct sun light.		

QC: Li Ting

