

SHANDONG OCTAGON CHEMICALS LIMITED

CERTIFICATE OF ANALYSIS

Product name	Olanzapine (Cas 132539-06-1)		
Batch No.	20190401	Mfg. date	2019.04.26
Rep. Date	2019.05.30	Exp. date	2021.04.25
Packaging	25kg/Drum	Batch Quantity	20.5KG
Test Items	Standards: USP42		Results
Appearance	Yellow crystal or crystalline powder		Yellow powder
Identification	Should conform		conforms
Residual on ignition	≤0.10%		0.01%
Water(KF)	≤1.0%		0.05%
Impurities(HPLC)	Impurity A≤0.10% Impurity B≤0.15% Chloromethyl olanzapinium chloride≤0.15% Each single impurity≤0.10% Total impurity≤0.4%		ND ND ND 0.06% 0.05%
Residual solvents(GC)	Ethanol≤5000ppm Dimethyl sulfoxide≤5000ppm Toluene≤890ppm		192ppm ND ND
Assay	98.0%~102.0%(on dried basis)		100.1%
Conclusion	It meets the requirements of USP42 Standards		
Storage	Store in a well-closed container at ambient temperature		
Prepared by: LI	Reviewed by: WEI	Released by:Zhang	