

# Certificate of Analysis

## Tetrahydropipstatin

<b>Other Name:</b>	Orlistat	<b>Batch No:</b>	080903
<b>Quantity:</b>	50kg	<b>M.F. Date:</b>	SEP 14, 2008
<b>Test Date:</b>	SEP 24, 2008	<b>Retest Date:</b>	AUG, 2010
<b>Storage:</b> in well closed container at temperature below 20°C			

Item	Results	Specification
Description	Off-white crystalline powder	White to off-white crystalline powder
Identification HPLC IR	Conforms Conforms	HPLC retention time Conforms with the reference
Melting Point	42-44 °C	42-45 °C
Specific Optical Rotation	-34.9 °	-31.0° -35.0°
Max. individual impurity	0.3%	NMT 0.5%
Total impurity	1.6%	NMT 2.0%
Water content%(K&F)	0.06%	NMT 0.5%
Residual solvents	EtOH: Not detected EtOAc: Not detected n-Heptane: 0.1%	EtOH: NMT 0.5% EtOAc: NMT 0.5% n-Heptane: NMT 0.5%
Residue on ignition	0.04%	NMT 0.2%
Heavy Metals as Pb	Conforms	NMT 20ppm
Assay by HPLC (Orlistat)	100.0%	NLT 98.0% on anhydrous basis

<b>Conclusion:</b>	The results conform with the internal specification
<b>QC Chemist</b>	
<b>QA Chemist</b>	
<b>Approved by</b>	Manager of QA/QC