

检验报告单

Certificate of Analysis



Orlistat 奥利司他

Lot: 0080712

BATCH No. 批号 ORB111212 MANUFACTURING DATE 生产日期 2012.01.18
 QUANTITY 数量 65Kg TEST DATE 检验日期 2012.01.21
 RETEST DATE 复检期 2015.01 REPORT DATE 报告日期 2012.02.28

Item 项目	Standard 标准	Result 结果
Description 性状	White or almost white crystalline powder. 白色或类白色结晶性粉末	Almost white crystalline powder 类白色结晶性粉末
Solubility 溶解性	Practically insoluble in water, freely soluble in chloroform. Very soluble in methanol and ethanol. 几乎不溶于水, 易溶于氯仿, 极易溶于甲醇和乙醇。	Practically insoluble in water, freely soluble in chloroform. Very soluble in methanol and ethanol. 几乎不溶于水, 易溶于氯仿, 极易溶于甲醇和乙醇
Identification 鉴别	IR HPLC	Conforms 符合规定 Conforms 符合规定
Melting Point 熔点	42~45°C	42.5~44.0°C
Specific Rotation 比旋度	-31~ -38°	-35°
Water 水分	≤2.0%	0.1%
Residual solvents 残留溶剂	Methanol 甲醇 ≤3000ppm n-Heptane 正庚烷 ≤5000ppm	<59ppm 1330ppm
Individual Impurity 单个杂质	≤1.0%	0.5%
Total Impurities 总杂质	≤2.0%	1.3%
Assay(HPLC) 含量	≥98.0%(on anhydrous basis)	98.6%
Bulk Density 堆密度	Perform and Report 检测并报告	0.28g/ml

CONCLUSION: The results conform with client standard.

结论: 本品符合客户标准。

Storage conditions: Stored in temperature between 2~8°C, away from light.

QC MANAGER QC 经理 张明 CHECKED BY 复核人 邵志敏 ANALYST 化验员 黄光能

FINAL BATCH DISPOSITION

Approved

Rejected

By: 李心彬