检 验 报 告 单 Certificate of Analysis

HISUN 海正药业

Orlistat 奥利司他

BATCH No. 批 号	ORB111008	MANUFACTURING DATE 生产日期	2011.11.07
QUANTITY 数 量	130Kg	TEST DATE 检验日期	2011.11.10
RETEST DATE 复检期	2014.11	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	Conforms 符合规定
	HPLC	Conforms 符合规定
Melting Point 熔点	42~45℃	43.0~44.0℃
Specific Rotation 比旋度	-31~ -38°	-36°
Water 水 分	≤2.0%	0.0%
Residual solvents 残留溶剂	Methanol 甲醇≤3000ppm	<59ppm
	n-Heptane 正庚烷≤5000ppm	2010ppm
Individual Impurity 单个杂质	≤1.0%	0.6%
Total Impurities 总杂质	≤2.0%	1.5%
Assay(HPLC) 含 量	≥98.0%(on anhydrous basis)	98.5%
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℃, away from light.

QC MANAGER QC 经理 [signature] CHECKED BY 复核人 [signature] ANALYST 化验员 [signature]

FINAL BATCH DISPOSITION

✓ Approved ____ Rejected

By: [signature]

Version 1.0 SYB4
02/11/11
Hisun Pharmaceutical (Hangzhou)Co., Ltd.