Lote: 070313

检 验 报 告 单 Certificate of Analysis

HISUN 海正药业

Orlistat 奥利司他

BATCH No.	批 号	ORB0121203	MANUFACTURING DATE	生产日期	2013.01.03
QUANTITY	数 量	200Kg	TEST DATE	检验日期	2013.01.16
RETEST DATE	复检期	2016.01	REPORT DATE	报告日期	2013.02.06

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	IR	Conforms 符合规定
鉴 别	HPLC	Conforms 符合规定
Melting Point 熔点	42~45℃	43.0~44.0℃
Specific Rotation 比旋度	-31~ -38°	-35°
Water 水 分	≤2.0%	0.1%
Residual solvents	Methanol 甲醇≤3000ppm	<59ppm
残留溶剂	n-Heptane 正庚烷≤5000ppm	928ppm
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)	98.5%
Bulk Density 堆密度	Perform and Report 检测并报告	0.26g/ml
Particle Size 颗粒度		
D10	Perform and Report 检验并报告	3um
D50	Perform and Report 检验并报告	15um
D90	Perform and Report 检验并报告	69um
Microbial Limits 微生物限度	Total Aerobic Microbial Count 总需氧菌≤1000CFU/g	10CFU/g

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 CHECKED BY 复核人 ANALYST 化验员

FINAL BATCH DISPOSITION

Approved _____ Rejected _____ By: _____

Version 1.1 SYB6
02/06/13
Hisun Pharmaceutical (Hangzhou) Co., Ltd.