检验报告单 Certificate of Analysis

HISUN 海正药业

Orlistat 奥利司他

lot: 0030414.

BATCH No. 批 号	ORB0131209	MANUFACTURING DATE 生产日期	2014.01.19
QUANTITY 数 量	200kg	TEST DATE 检验日期	2014.01.26
RETEST DATE 复检期	2017.01.18	REPORT DATE 报告日期	2014.03.19

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。	Conforms 符合规定
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	1725ppm
Individual Impurity 单个杂质	≤1.0%	0.3%
Total Impurities 总杂质	≤2.0%	1.1%
Assay(HPLC) 含 量	≥98.0%(on anhydrous basis)	98.6%
Bulk Density 堆密度	Perform and Report 检测并报告	0.25g/ml
Particle Size 颗粒度		
D10	Perform and Report 检验并报告	4um
D50	Perform and Report 检验并报告	17um
D90	Perform and Report 检验并报告	71um
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.