lot: 0080113

检验报告单 Certificate of Analysis

HISUN 海正药业

Orlistat 奥利司他

BATCH No. 批 号	ORB0120915	MANUFACTURING DATE 生产日期	2012.10.21
QUANTITY 数 量	110Kg	TEST DATE 检验日期	2012.10.31
RETEST DATE 复检期	2015.10	REPORT DATE 报告日期	2012.11.27

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	1451ppm
Individual Impurity 单个杂质	≤1.0%	0.5%
Total Impurities 总杂质	≤2.0%	1.5%
Assay(HPLC) 含 量	≥98.0%(on anhydrous basis)	98.6%
Bulk Density 堆密度	Perform and Report 检测并报告	0.23g/ml
Particle Size		
D10	Perform and Report	3um
D50	Perform and Report	14um
D90	Perform and Report	56um
Microbial Limits	Total Aerobic Microbial Count ≤1000CFU/g	<10CFU/g

CONCLUSION: The results conform with client standard.
结 论：本 品 符 合 客 户 标 准。

QC MANAGER QC 经理 CHECKED BY 复核人 ANALYST 化验员 刘林

FINAL BATCH DISPOSITION

✓ Approved ____ Rejecte By: ____

Version 1.0 SYB6
11/09/12
Hisun Pharmaceutical (Hangzhou) Co., Ltd.