

检验报告单

Certificate of Analysis



Orlistat 奥利司他

BATCH No. 批号	ORB0140408	MANUFACTURING DATE 生产日期	2014.05.12
QUANTITY 数量	200kg	TEST DATE 检验日期	2014.05.26
RETEST DATE 复检期	2017.05.11	REPORT DATE 报告日期	2014.06.16

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 鉴别	IR	Conforms 符合规定
Melting Point 熔点	HPLC	Conforms 符合规定
Specific Rotation 比旋度	42~45°C	43.0~44.5°C
Water 水分	-31~ -38°	-35°
Residual solvents 残留溶剂	≤2.0%	0.1%
Individual Impurity 单个杂质	Methanol 甲醇≤3000ppm	<59ppm
Total Impurities 总杂质	n-Heptane 正庚烷≤5000ppm	1934ppm
Assay(HPLC) 含量	≤1.0%	0.4%
Bulk Density 堆密度	≤2.0%	1.1%
Particle Size 颗粒度	≥98.0%(on anhydrous basis)	98.6%
D10	Perform and Report 检测并报告	0.25g/ml
D50	Perform and Report 检测并报告	4um
D90	Perform and Report 检测并报告	19um
Microbial Limits 微生物限度	Perform and Report 检测并报告	96um
	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°C, away from light.

QC MANAGER QC 经理 陈红 CHECKED BY 复核人 李春芳 ANALYST 化验员 徐子力

FINAL BATCH DISPOSITION

Approved 专用章

Rejected

By: 李春芳

Version 1.1 SYB6

02/06/13

Hisun Pharmaceutical (Hangzhou) Co., Ltd.