

检验报告单

Certificate of Analysis



Orlistat 奥利司他

BATCH No. 批号	ORB0160509	MANUFACTURING DATE 生产日期	2016.06.28
QUANTITY 数量	30kg	TEST DATE 检验日期	2016.06.30
RETEST DATE 复检期	2019.06.27	REPORT DATE 报告日期	2016.11.10

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
Identification 鉴别	IR HPLC	Conforms 符合规定 Conforms 符合规定
Melting Point 熔点	42~45°C	43.5-44.5°
Specific Rotation 比旋度	-48~-51°	-50°
Water 水分	≤2.0%	0.1%
Residue on ignition 炽灼残渣	≤0.1%	0.03%
Heavy Metals 重金属	≤10ppm	<10ppm
Residual solvents 残留溶剂	Methanol 甲醇≤3000ppm n-Heptane 正庚烷≤5000ppm	<59ppm 2316ppm
Individual Impurity 单个杂质	≤1.0%	0.32%
Total Impurities 总杂质	≤2.0%	0.88%
Assay(HPLC) 含量	≥98.0%(on anhydrous basis)	98.4%

CONCLUSION: The results conform with enterprise standard.

结论：本品符合企业标准。

QC MANAGER QC 经理 李永 2016.11.10 CHECKED BY 复核人 何春 2016.11.10 ANALYST 化验员 程思怡 2016.11.10

FINAL BATCH DISPOSITION

Approved

Rejected

By: 刘杰 2016.11.10

Xialian Village, Xukou Town, Fuyang District,
Hangzhou City, Zhejiang Province, People's
Republic of China
Telephone: 0086-571-63280809

Version 1.2 GM
11/10/16
Hisun Pharmaceutical (Hangzhou) Co., Ltd.