检验报告单 Certificate of Analysis

HISUN 海正药业

LOT: 20170418

ORLISTAT

BATCH NUMBER	ORC0170401	MANUFACTURE DATE	2017.05.19
QUANTITY	25kg	TEST DATE	2017.05.23
RETEST DATE	2020.05.18	REPORT DATE	2018.03.22

TEST	ACCEPTANCE CRITERIA	RESULT
Appearance	White or off-white fine powder or fine powder with lumps.	Off-white fine powder
Identification A	The infrared spectrum exhibits maxima only at the same wavelengths as that of a similar preparation of the *Reference standard*.	Conforms
Identification B	The major peak in the chromatogram obtained with the *Test solution* is similar in retention time and size to the major peak in the chromatogram obtained with *Reference solution*.	Conforms
Specific Optical Rotation	-48.0° to -51.0°, calculated on the anhydrous basis	-50.2°
Water Content	Not More Than 0.2%	0.05%
Heavy Metals	Not More Than 20ppm	<20ppm
Residue on Ignition	Not More Than 0.1%	0.02%
Related Substances		
Orlistat Related Compound A	Not More Than 0.2%	<0.06%
Orlistat Related Compound B	Not More Than 0.05%	<0.01%
Formylleucine	Not More Than 0.2%	<0.04%
Orlistat Related Compound C	Not More Than 0.05%	<0.01%
Orlistat Open Ring Epimer	Not More Than 0.2%	<0.04%
Impurity 5	Not More Than 0.15%	0.08%
D-Leucine Orlistat	Not More Than 0.2%	<0.04%
Individual Unidentified Impurity	Not More Than 0.1%	0.05%
Orlistat Related Compound D	Not More Than 0.2%	<0.04
Orlistat open ring amide	Not More Than 0.1%	<0.04%
Orlistat Related Compound E	Not More Than 0.2%	0.20%
Total Impurities	Not More Than 1.0%	0.42%
Assay	98.0% to 101.5%, on the anhydrous, solvent-free basis	99.6%
Residual Solvents		
Methanol	Not More Than 3000ppm	<59ppm
n-Heptane	Not More Than 5000ppm	993ppm

CONCLUSION: The results conform with USP standard.

Analyst: 2018.03.22 Checker: 2018.03.22 Supervisor: 2018.03.22

FINAL BATCH DISPOSITION

Approved Rejected By: 2018.03.23

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