Lote: 0160419

检验报告单

Certificate of Analysis

HISUN 海正药业

ORLISTAT

BATCH NUMBER	ORC0180902	MANUFACTURE DATE	2018.10.07
QUANTITY	41kg	TEST DATE	2018.11.01
RETEST DATE	2021.10.06	REPORT DATE	2019.01.14

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	-49.4°
Water Content	Not More Than 0.2%	0.09%
Heavy Metals	Not More Than 20ppm	<20ppm
Residue on Ignition	Not More Than 0.1%	0.03%
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%	0.09%
D-Leucine Orlistat	Not More Than 0.2%	<0.04%
Individual Unidentified Impurity	Not More Than 0.1%	<0.04%
Orlistat Related Compound D	Not More Than 0.2%	0.05%
Orlistat open ring amide	Not More Than 0.1%	<0.04%
Orlistat Related Compound E	Not More Than 0.2%	0.09%
Total Impurities	Not More Than 1.0%	0.34%
Assay	98.0% to 101.5%, on the anhydrous, solvent-free basis	99.8%
Residual Solvents		
Methanol	Not More Than 3000ppm	<59ppm
n-Heptane	Not More Than 5000ppm	2025ppm

CONCLUSION: The results conform with USP standard.

Analyst: 2019.01.14 Checker: 2019.01.14 Supervisor: 2019.01.14

FINAL BATCH DISPOSITION

✓ Approved _____ Rejected

By: 2019.01.14

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