检验报告单 Certificate of Analysis

HISUN 海正药业

Lot: 0011019

ORLISTAT

BATCH NUMBER	ORC0190702	MANUFACTURE DATE	2019.08.05
QUANTITY	50kg	TEST DATE	2019.08.20
RETEST DATE	2022.08.04	REPORT DATE	2019.09.10

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	-50.3°
Water Content	Not More Than 0.2%	0.08%
Heavy Metals	Not More Than 20ppm	<20ppm
Residue on Ignition	Not More Than 0.1%	0.01%
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%	0.07%
Individual Unidentified Impurity	Not More Than 0.1%	0.05%
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%	0.49%
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	1996ppm

CONCLUSION: The results conform with USP standard.

Analyst: 2019.09.10 Checker: 2019.09.10 Supervisor: 2019.09.10

FINAL BATCH DISPOSITION

Approved Rejected By: 2019.09.10

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