171000029

检验报告单 Certificate of Analysis

HISUN

LOVASTATIN USP

BATCH NUMBER	3020 E170305	MANUFACTURE DATE	2017.04.16
BATCH SIZE	621.3kg	TEST DATE	2017.05.06
QUANTITY	445kg	RETEST DATE	2019.04.16

TEST	SPECIFICATION	RESULT
Appearance	White to off-white crystalline powder.	White crystalline powder
Solubility	Soluble in acetone, sparingly soluble in alcohol, in ethyl acetate, and in acetonitrile, insoluble in water.	Conforms
Identification A	IR spectrum of the sample corresponds to that of the reference standard.	Conforms
Identification B	UV spectrum corresponds to the reference standard.	Conforms
Specific Rotation	Between +324° and +338°	+328°
Loss on Drying	Not More Than 0.3%	0.0%
Residue on Ignition	Not More Than 0.2%	0.0%
Heavy Metals	Not More Than 0.002%	≤0.002%
Related Compound A	Not More Than 0.5%	0.1%
Chromatographic Purity		
Individual Impurity	Not More Than 0.2%	0.1%
Total Impurities	Not More Than 1.0%	0.4%
Assay	98.5% to 101.0% of $C_{24}H_{36}O_5$ (Calculated on the dried basis)	99.9%
Particle Size		
D(10)	Perform and Report	9µm
D(50)	Perform and Report	34µm
D(90)	Less Than 100µm	83µm
D(100)	Less Than 500µm	176µm
Bulk Density	Perform and Report	0.44g/ml
Tapped Density	Perform and Report	0.71g/ml
Residual Solvents		
Ethanol	Not More Than 5000ppm	240ppm
Ethyl Acetate	Not More Than 5000ppm	≤50ppm
Acetone	Not More Than 5000ppm	≤50ppm

Conclusion: The results conform to USP specification plus additional customer requirements, which are not used for registration purpose.

Analyst: [signature] Checker: [signature] Supervisor: [signature]

FINAL BATCH DISPOSITION

✓ Approved

Rejected

By: [signature] 2017.08.23

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