

Jinlan pharm-drugs technology CO.LTD Hangzhou Royall Import&Export CO.LTD

CERTIFICATE OF ANALYSIS

Product: Pitavastatin Calcium

CAS NO.: 147526-32-7

Manufacturing Date: 2018.09.16

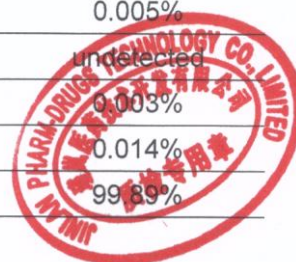
Batch NO.: 18RY0916001

Expiry Date: 2 Years

Quantity: 75KG

Report Date: 2018.09.20

Tests	Specifications	Results
Appearance	Off-white colored powder	Off-white powder
Polymorph	Similar to Reference Standard	Complies
Specific Rotation	+20.0° ~ +26.0°	+20.3°
Test for calcium	Shall respond to test for calcium	Complies
Calcium content	Between 4.0% and 5.0% (on anhydrous basis)	4.19%
Identification	Similar to Reference Standard	Complies
Related Substances (HPLC)	Desfluoro	Not more than 0.15% 0.05%
	Anti isomer	Not more than 0.15% ND
	z-isomer	Not more than 0.15% ND
	Lactone	Not more than 0.15% 0.01%
	Tertiary butyl ester	Not more than 0.15% ND
	Individual other impurity	Not more than 0.1% 0.03%
	Total impurities	Not more than 1.0% 0.11%
Water	Between 7.0% and 13.0%	11.8%
Heavy Metals	Not more than 10ppm	Complies
Solubility	Hexane	Practically insoluble Complies
	acetic acid	Soluble Complies
	Ethanol	very sparingly soluble Complies
	NaOH 0.1N	Practically insoluble Complies
	Hcl 0.1N	sparingly soluble Complies
	methanol	sparingly soluble Complies
	distilled water	very sparingly soluble Complies
	Chloroform	very sparingly soluble Complies
Related Substances (GC)	Acetone ≤ 0.5%	0.005%
	t-butyl alcohol ≤ 0.5%	undetected
	Acetonitrile ≤ 0.041%	0.003%
	Diethyl ether ≤ 0.5%	0.014%
Purity	Not more than 1.0%	99.89%



Analyst: *Esther*

Checker: *Cherry*

Supervisor: *Ramy*