



西安菲斯弗生物科技有限公司
Xi'an Faithful Biological Technology Co., Ltd.

Certificate of Analysis-Pitavastatin calcium

CAS: 147526-32-7

Batch Number: FTF0240126 Batch Quantity: 60kg

Manufacture Date: Jan.24th,2024 Analysis Date: Jan.25th,2024 Certificate Date: Jan.26th,2024

Storage Store in cool & dry place. Store in well-closed containers.
Shelf life 3 years when properly stored.

ITEM	SPECIFICATION	RESULTS
Appearance Specific optical rotation	White to light yellow powder +21°--+25	White powder +23.5
Identification	Calcium salts identification UV IR	Complies Complies Complies
Related substances (HPLC) Unknown individual impurity Enantiomer of pitavastatin Diastereomer of pitavastatin Lactone of pitavastatin Total impurities	NMT 0.1% NMT 0.1% NMT 0.1% NMT 0.1% NMT 1.0%	0.06% N/D N/D N/D 0.6%
LOD(%w/w,60°C,vacu- um)	NMT 6.0%	2.0%
Heavy metals	NMT 20 ppm	Conform
Assay	99.0%	99.53%
Conclusion:	Conform with enterprise specification	

QC MANAGER: 刘娟

INSPECTOR: 黄子烨

