Assay analysis for Limit of Lovastatin Related Compound-A (USP 38 method):

SAMPLE PREPARATION:

System Suitability Solution: Dissolve accurately weighed quantities of lovastatin and lovastatin related compound-A in acetonitrile and dilute quantitatively to obtain a solution having known concentration of 2.0 µg/ml

Standard solution: Dissolve accurately weighed quantities of lovastatin in acetonitrile and dilute quantitatively to obtain the solution having a known concentration of 2.0 µg/ml.

CHROMATOGRAPHIC CONDITIONS:

Instrument: UltiMate 3000 LC
Column: Syncronis C8 (4.6*250mm, 5um, p/n 97205-254630, lot no.:12105)

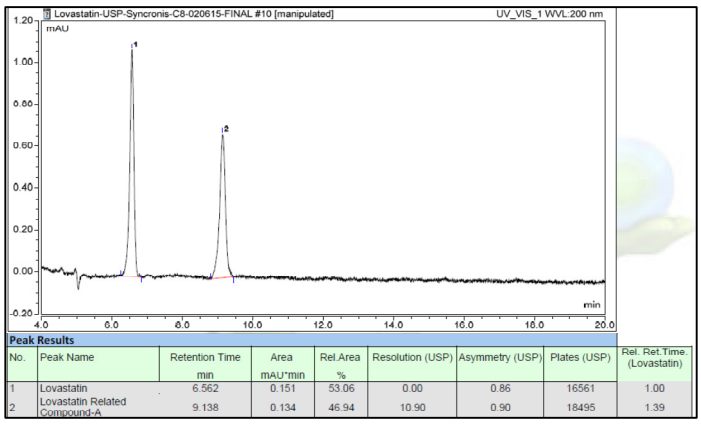
Mobile phase: Mixture of Acetonitrile and 0.01M Phosphoric Acid (13:7 v/v).
Separation Mode: Isocratic
Column temperature: 40˚C
Flow rate: 1.5 mL/min
Injection Volume: 10 µl
Detector wavelength: UV 200nm
Run Time: 20 min

System Suitability Results:

Sr. No.	Parameters	USP Criteria	Obtained Results
1	Resolution b/w Lovastatin and Lovastatin Related Compound-A	NLT 6.0	10.90
2	RRT of lovastatin related compound A with respect to Lovastatin	About 1.3	1.39
3	% RSD for replicate injection of standard solution	NMT 5.0%	0.9%

CHROMATOGRAMS:

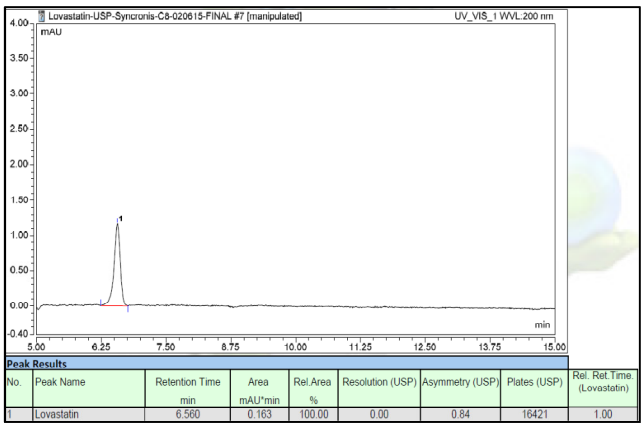
System Suitability:



Peak Results

No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (USP)	Asymmetry (USP)	Plates (USP)	Rel. Ret.Time (Lovastatin)
1	Lovastatin	6.562	0.151	53.06	0.00	0.86	16561	1.00
2	Lovastatin Related Compound-A	9.138	0.134	46.94	10.90	0.90	18495	1.39

Standard Solution:



Peak Results

No.	Peak Name	Retention Time min	Area mAU*min	Rel.Area %	Resolution (USP)	Asymmetry (USP)	Plates (USP)	Rel. Ret.Time (Lovastatin)
1	Lovastatin	6.560	0.163	100.00	0.00	0.84	16421	1.00