Atorvastatin Calcium Trihydrate
10 mg Tablets

Structure:
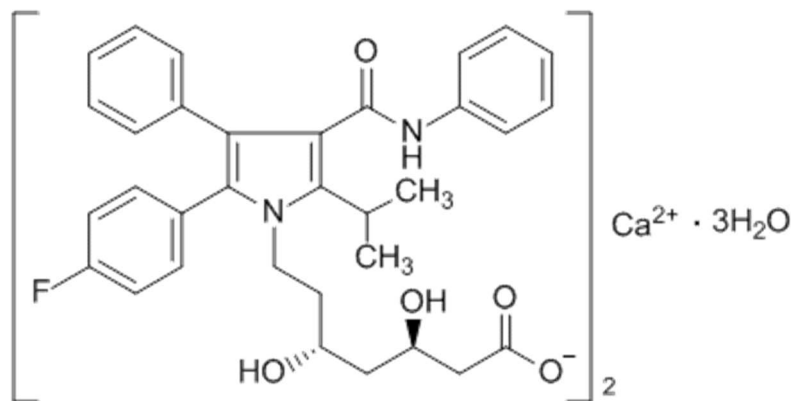
Molecular Formula and Mass: $C_{66}H_{68}F_2N_4O_{10}Ca\cdot3H_2O$ - 1209.407

Category: Statin

Sample:

Grind one tablet and dissolve in 25.0 mL of methanol. Shake for at least 15 min and filter. Final concentration of sample solutions = 10.0 mg/25.0 mL and = 0.400 mg/mL, which is the required concentration representing 100%.

Standards:

High Standard:

The high limit is 115%; therefore the concentration of the high standard = 0.400 mg/mL × 1.15 = 0.460 mg/mL. Weigh approximately 23.0 mg of standard. If you weighed 23.1 mg of standard, dissolve it in: 23.1 mg ÷ 0.460 mg/mL = 50.2 mL of methanol. This makes the high standard solution concentration equal to 0.460 mg/mL.

Low Standard:

The low limit is 85%; therefore the concentration of the low standard = (0.400 mg/mL × 0.85 = 0.340 mg/mL. Dilute 3.00 mL of high standard to 4.00 mL by adding 1.00 mL of methanol. This gives a concentration of 0.460 mg/mL × 3.00 mL ÷ 4.00 mL = 0.345 mg/mL.

Spotting:

Spot on the 5 × 10 cm silica gel TLC aluminum plate with 3.00 μL aliquots as follows:

Left spot	low standard (85%) = 1.04 μg	
Center Spot	100% sample = 1.20 μg	
Right Spot	high standard (115%) = 1.38 μg	

Development:

Mix 30.0 mL of ethyl acetate, 8.00 mL of methanol, and 2.00 mL concentrated ammonia. Develop the plate in a small glass chamber with approximately 20.0 mL of this solution until the solvent front reaches within 1 cm of the top of the TLC plate.

(Rf = 0.17)

Detection:

UV:

Dry the plate and observe under ultraviolet light at 254 nm. Observe the intensities and the sizes of the spots.

R_f value

1.0

0.8

0.6

0.4

0.2

0.0

Mobile phase front

Atorvastatin Ca spot
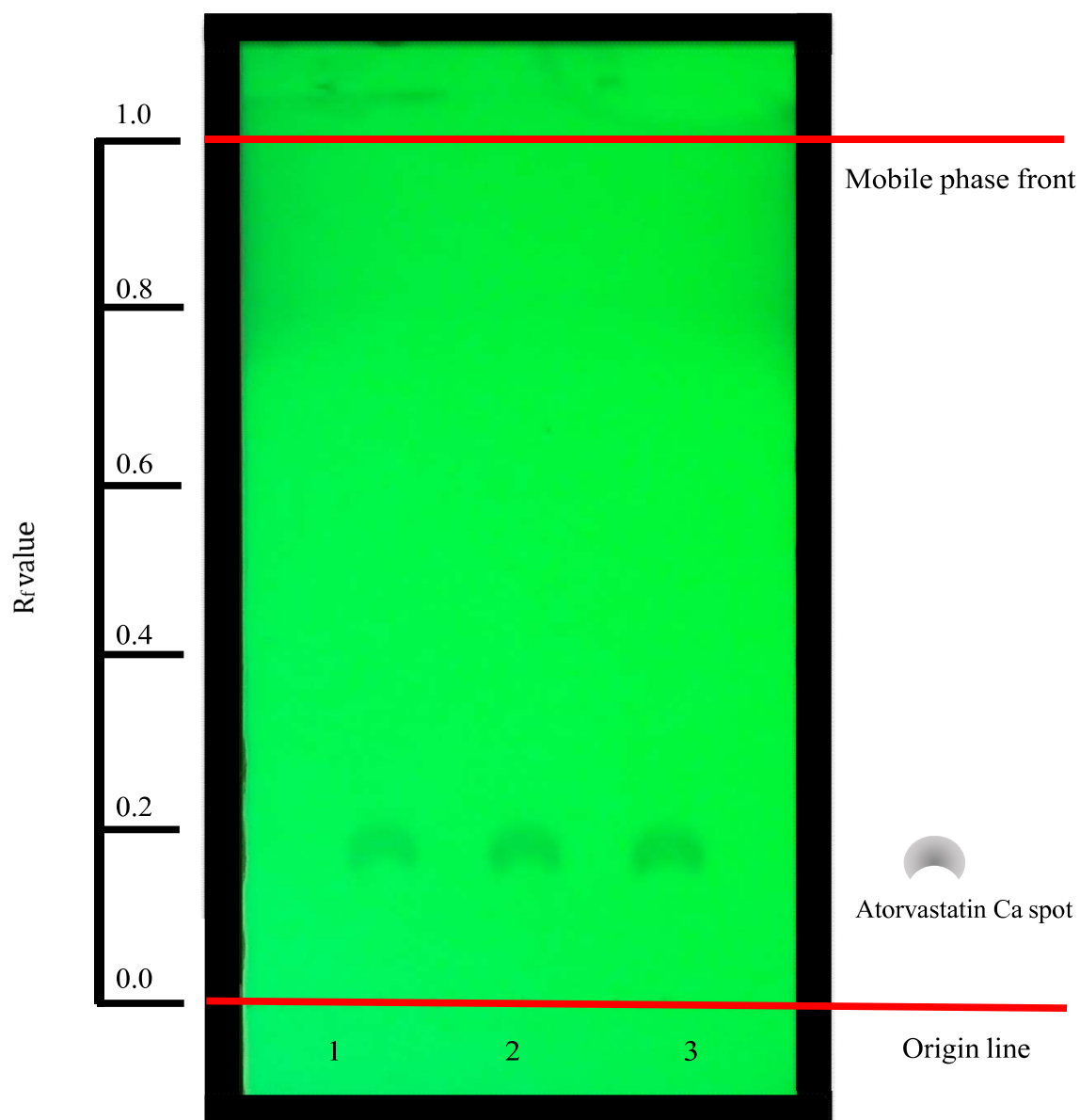
Origin line

1   2   3

Plate observed under ultraviolet light at 254 nm

Lane 1: Low standard (85%) = 1.04 μg

Lane 2: 100% sample = 1.20 μg

Lane 3: High standard (115%) = 1.38 μg