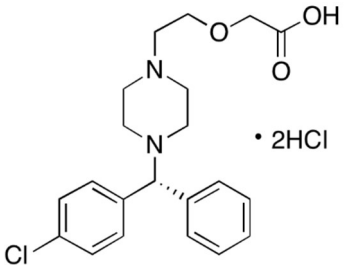
Levocetirizine 2HCl
5 mg Tablet

Structure:



Molecular Formula and Mass: $C_{21}H_{27}Cl_3N_2O_3$ – 461.808
Category: Antihistamine
Sample:

Grind one tablet and dissolve in 5.00 mL of methanol. Shake for at least 10 min and filter. Final concentration of sample solutions = 1.00 mg/mL, which is the required concentration representing 100%.

Standards:

High Standard:

The high limit is 115%; therefore the concentration of the high standard = 1.00 mg/mL × 115% = 1.15 mg/mL. Weigh approximately 11.5 mg of standard and dissolve it in 10.0 mL of methanol. If you weighed 11.6 mg of standard, dissolve it in: 11.6 mg ÷ 1.15 mg/mL = 10.1 mL of methanol. This makes the high standard solution concentration equal to 1.15 mg/mL, which is 115%.

Low Standard:

The low limit is 85%; therefore the concentration of the low standard = 1.00 mg/mL × 85.0% = 0.850 mg/mL. Dilute 1.70 mL of high standard to 2.30 mL by adding 0.60 mL of methanol. This gives a concentration of 1.15 mg/mL × 1.70 mL ÷ 2.30 mL = 0.850 mg/mL, which is 85.0%.

Spotting:

Spot on the 5 × 10 cm silica gel TLC aluminum plate with 5.00 µL aliquots as follows:

Left spot	low standard (85%) = 4.25 µg
Center Spot	100% sample = 5.00 µg
Right Spot	high standard (115%) = 5.75 µg

Due to weak absorption at 254 nm and resulting poor limit of detection for this drug and the inability to dissolve the 5 mg tablet in a lower volume of solvent to prepare higher concentration solutions, the applied volumes were raised to 5.00 µL instead of the usual 3.00 µL for Compendium methods in order to apply the needed weights for visualization.

Development:

Mix 7.50 mL of toluene, 21.0 mL of ethyl acetate, 7.50 mL of methanol, and 3.00 mL of 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.

(R_f = 0.20)

Detection:

UV:

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

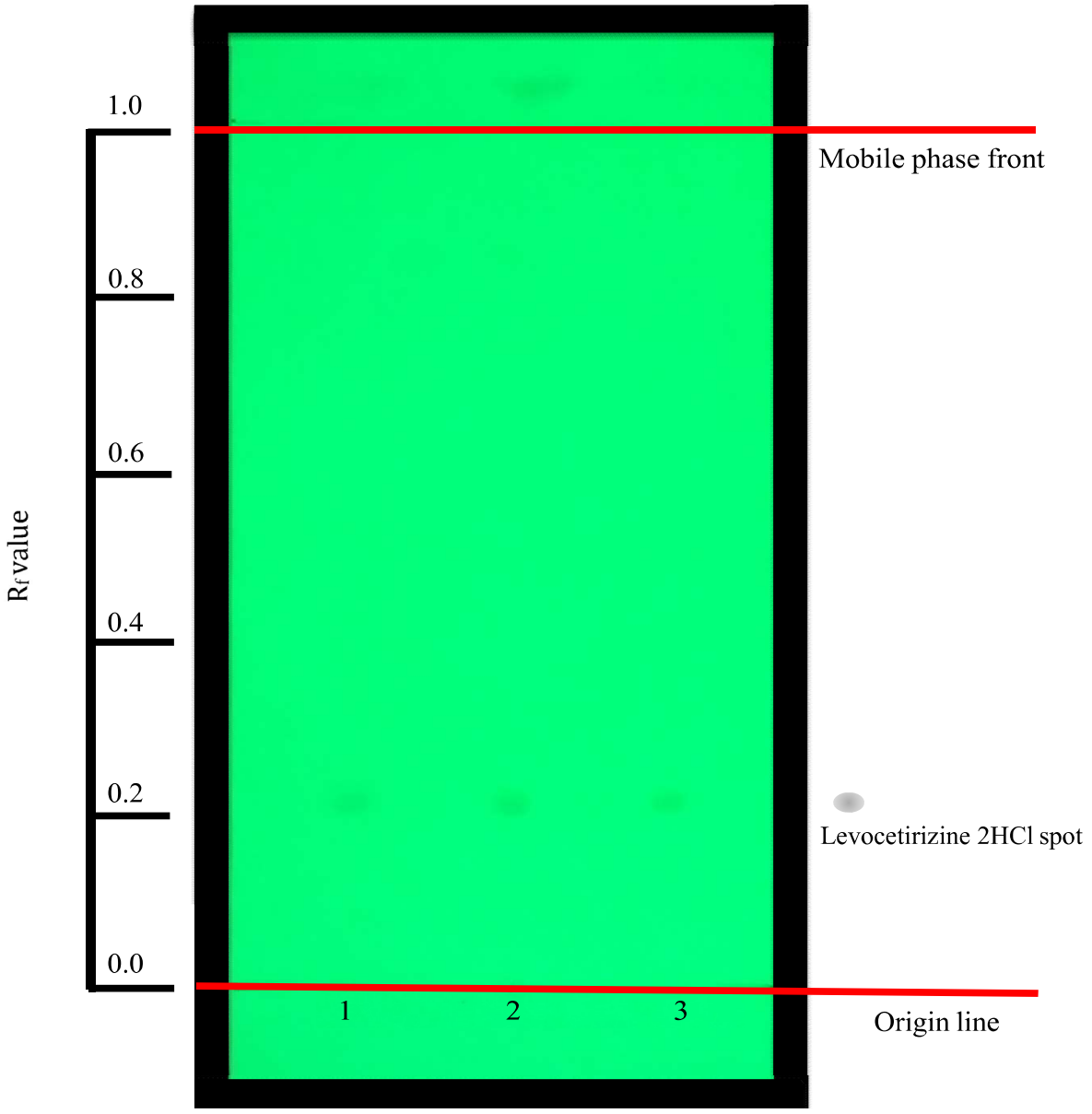


Plate observed under ultraviolet light at 254 nm.

Lane 1: Low standard (85%) = 4.25 µg

Lane 2: 100% sample = 5.00 µg

Lane 3: High standard (115%) = 5.75 µg

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