Mirabegron
50 mg Tablet

Structure:
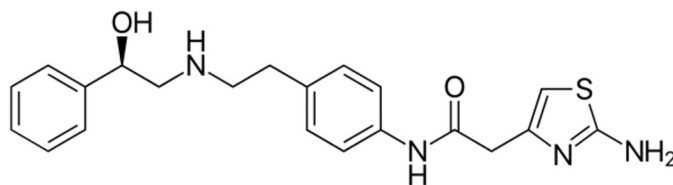
Molecular Formula and Mass: $C_{21}H_{24}N_4O_2S$; 396.506

Category: Bladder relaxant

Sample:

Grind one tablet and dissolve in 100 mL of methanol. Shake for at least 10 min and filter. Pipette 3.00 mL stock sample solution and dissolve it in 50.0 mL of methanol. Final concentration of the sample solution is 0.0300 mg/mL, which is the required concentration representing 100%.

Standards:

High Standard:

The high limit is 115%; therefore the concentration of the high standard is 0.0300 mg/mL × 115% = 0.0345 mg/mL Weigh approximately 34.5 mg of and dissolve it in 100 mL of methanol. Dilute 1.00 mL of stock high standard to 9.00 mL methanol. This makes the high standard solution concentration equal to 0.0345 mg/mL, which is 115%.

Low Standard:

The low limit is 85%; therefore the concentration of the low standard = 0.0300 mg/mL × 85% = 0.0255 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 0.0345 mg/mL × 1.70 mL ÷ 2.30 mL = 0.0255 mg/mL, which is 85%.

Spotting:

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

Left spot	low standard (85%) = 0.0765 μg
Center Spot	100% sample = 0.0900 μg
Right Spot	high standard (115%) = 0.104 μg

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.

($R_f = 0.50$)

Detection:

UV:

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

1.0 — Mobile phase front

0.8

0.6

R_f value

0.4 — Mirabegron spot

0.2

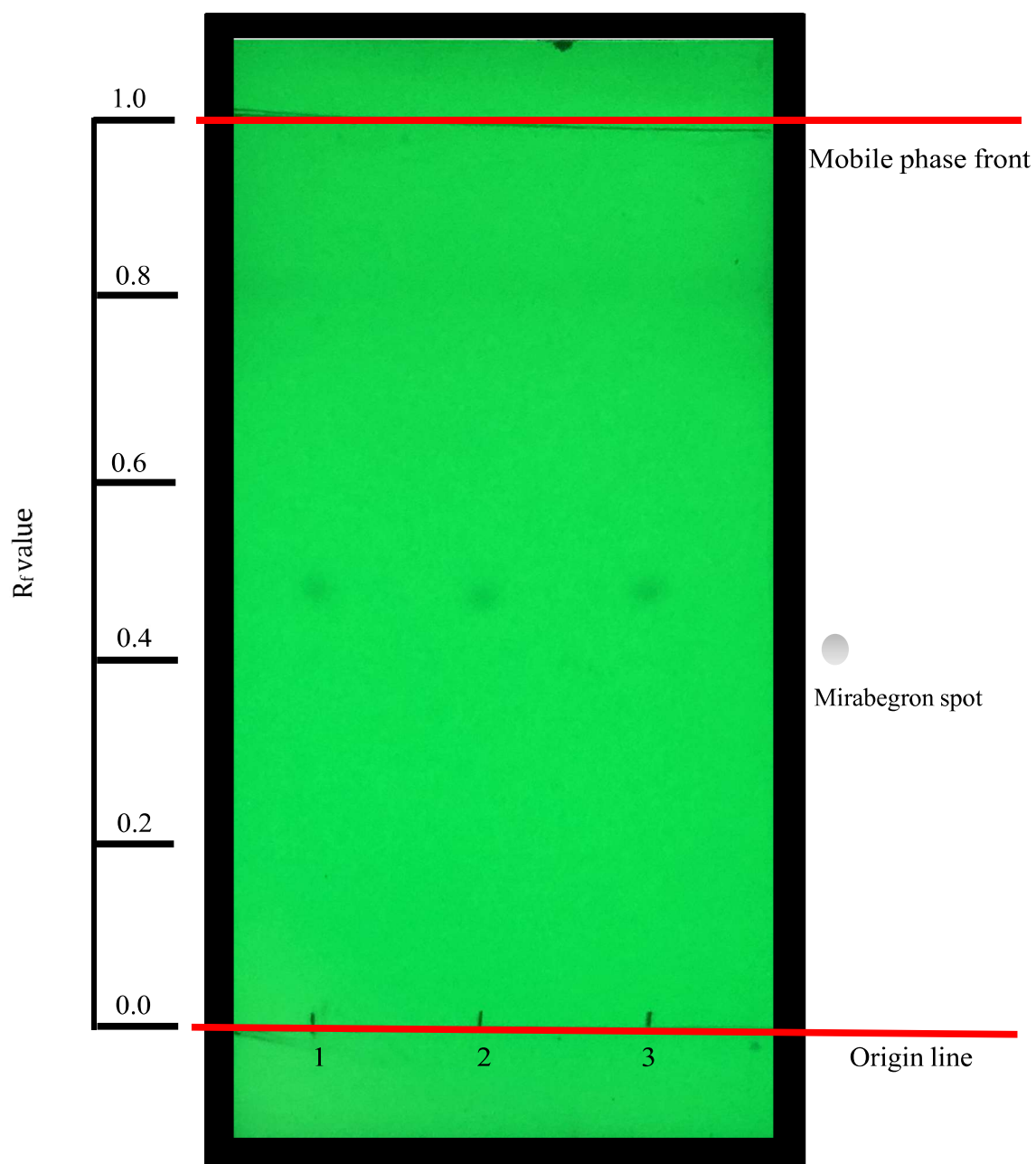0.0 — Origin line

1   2   3

Plate observed under ultraviolet light at 254 nm.

Lane 1: Low standard (85%) = 0.0765 μg
Lane 2: 100% sample = 0.0900 μg
Lane 3: High standard (115%) = 0.104 μg