

Bisoprolol Fumarate

The method for bisoprolol fumarate 5 mg tablets was published in the Minilab Manual, Supplement 2015 to Volume II, Method 6.81, pages 8-11. It was modified by elimination the need for staining the plate with ninhydrin for detection. The Minilab method states that “bisoprol itself stays invisible and no spots should be detected” when the plate is observed at 254 nm. Bisoprolol fumarate TLC spots were found to quench fluorescence under 254 nm UV light after heating the mobile phase developed plate. Users may consider that elimination of the need for a staining reagent makes this method safer, faster, and more convenient, especially for use in the field.

In the modified method, the exact procedures published in the Minilab manual were carried out with a few exceptions. Instead of two 5 mg reference tablet for the standard, commercial analytical grade standard (bisoprolol, USP, Sigma No. H0J057 200 MG) was used. The volumes of solvents were changed accordingly to give the same concentration as is designated in the Minilab manual for the sample and standard solutions, 1.25 mg/mL, and 2.00 uL volumes were spotted on the plate. Instead of staining the plate with ninhydrin after developing it with methanol-glacial acetic acid (20:0.1) mobile phase to produce colored spots in daylight as shown in the photograph on page 11 of the Minilab Manual, the plate was heated on a hotplate (e.g., for 25 min at 180°C), and bisoprolol was detected as fluorescence quenching spots under 254 nm UV light as is shown in the photograph of a plate below.

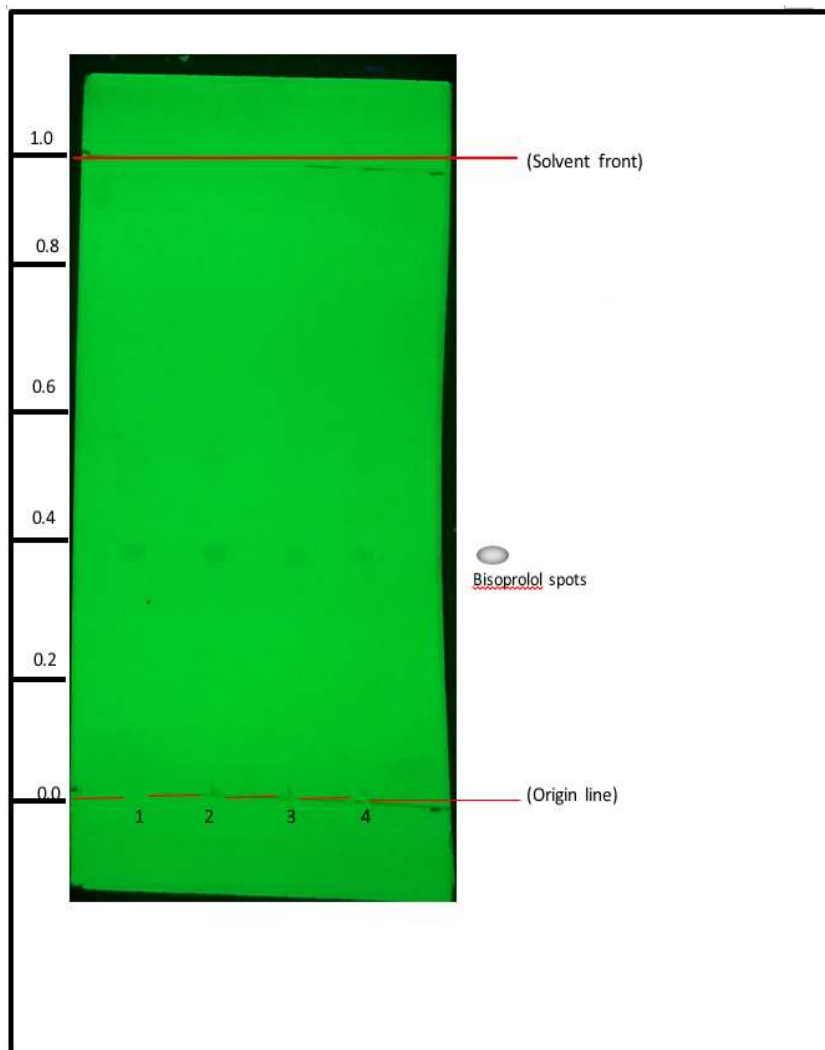
XI CHROMATOPLATE
OBSERVED UNDER 254 NM
UV LIGHT

Run No.1:
Upper working standard
representing 100% of total
bisoprolol

Run No.2:
A product of good quality
with acceptable bisoprolol
content

Run No.3:
A product of poor quality with
unacceptable low bisoprolol
content

Run No.4:
Lower working standard
representing 80% of total
bisoprolol



(*A drug product of poor quality was simulated by diluting the 100% working sample solution of a drug product of good quality with water to one-third of the theoretical value.)

This modified method was developed and tested by Yiru Gu and Joseph Sherma, Department of Chemistry, Lafayette College, Easton, PA, USA., in July, 2019. Yiru Gu's research was supported a Camille and Henry Dreyfus Senior Scientist Mentor Program award to JS and by the Lafayette College Excel Scholars program.