

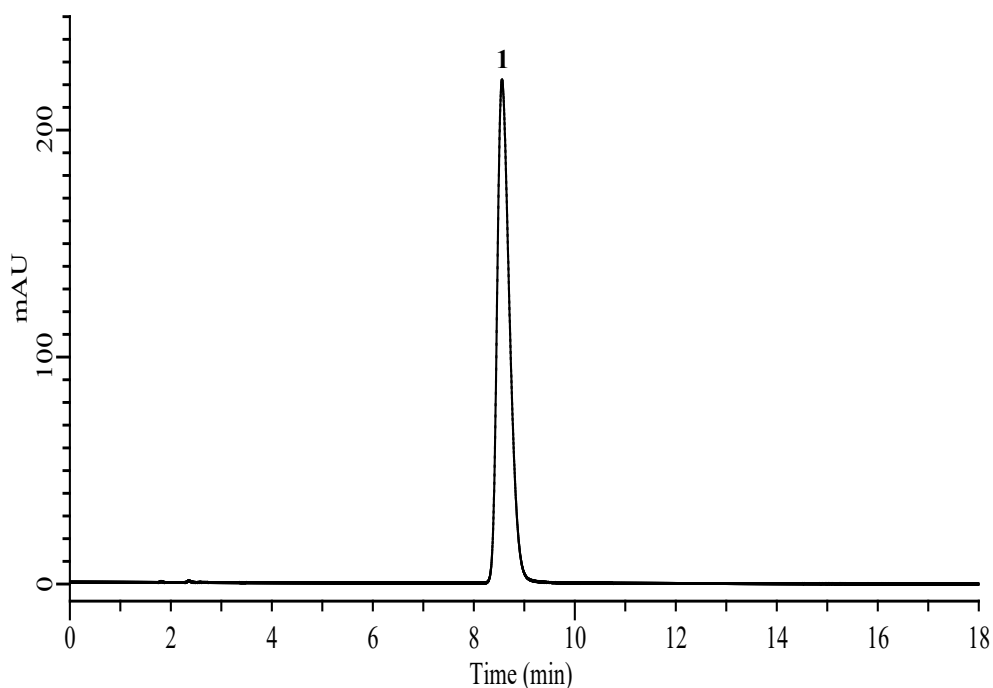
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Analysis of Metformin Hydrochloride Tablets

(Under the Condition of USP43-NF38, Glyburide and Metformin Hydrochloride Tablets)

Data No. LB745-7111



Conditions

System : Chromaster HPLC system (HITACHI)
Column : InertSustain C18 (GL Sciences Inc.)
(10 μ m, 300 x 3.9 mm I.D.)
Column Cat. No. : 5020-90556
Eluent : CH₃CN/Buffer* = 10/90, v/v
Flow Rate : 1.0 mL/min
Col. Temp. : 30 °C
Detection : UV 218 nm
Injection Vol. : 5 μ L
Sample : Standard

Analyte:

1. Metformin 250 mg/L

Tailing factor : (0.8 \leq) 1.41 (\leq 2.0)
RSD of the
peak area (%) (n=6) : 0.34 (\leq 1.5)

* Transfer 1.0 g each of sodium heptanesulfonate and sodium chloride to a 2000-mL volumetric flask. Add 1800 mL of water, and adjust with 0.06 M phosphoric acid to a pH of 3.85. Dilute with water to volume.