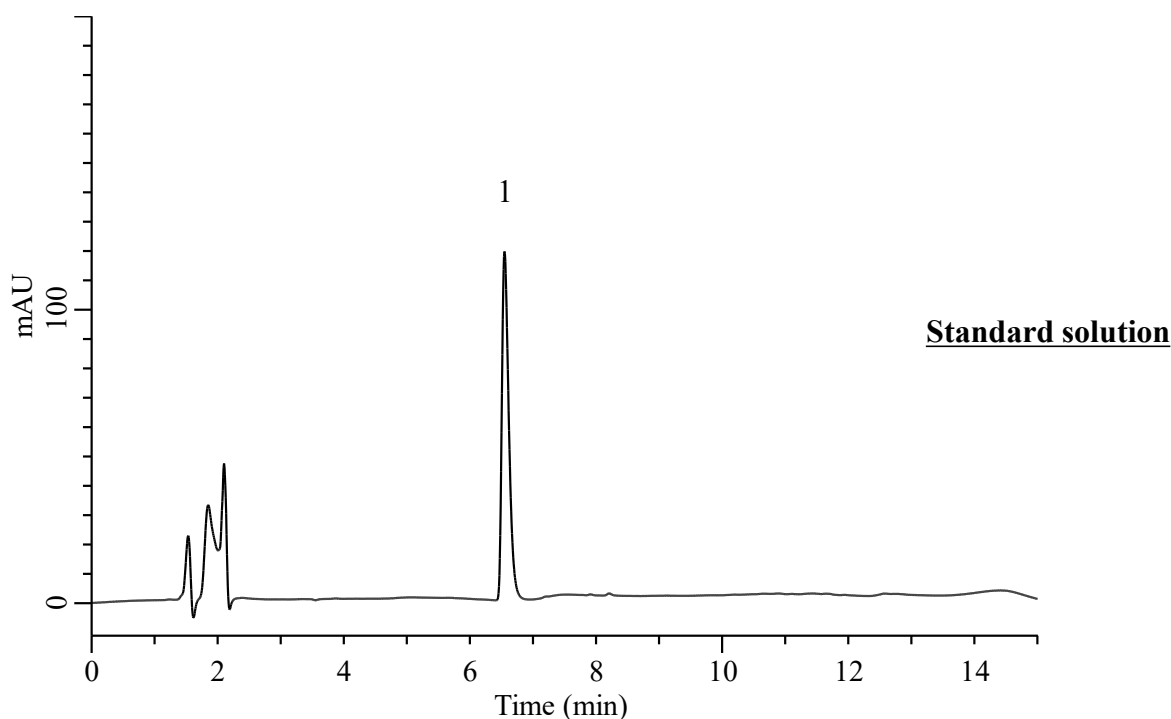


Analysis of Formoterol fumarate

(Under the Condition of draft for USP, Formoterol Fumarate Inhalation Solution, ASSAY)



Conditions

System : Chromaster PLUS (HITACHI)
Column : InertCore C8 (GL Sciences Inc.)
(2.6 μ m, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-17538
Eluent : A) CH₃CN/Buffer*=75/25
B) CH₃CN/Buffer*=10/90

Analyte:

1. Formoterol fumarate 2.0 μ g/mL

Tailing factor : 1.56 ($\leq$ 2.0)

RSD of
the peak area (%) (n=6) : 0.42 ($\leq$ 2.0)

Time (min)	A (vol%)	B (vol%)
0	10	90
2	10	90
8	80	20
9	80	20
10	10	90
15	10	90

Flow Rate : 0.8 mL/min
Col. Temp. : 35 $^{\circ}$ C
Autosampler Temp.: 10 $^{\circ}$ C
Detection : UV 214 nm (Chromaster 5430 DAD)
Injection Vol. : 100 μ L
Sample : Standard in CH₃OH/H₂O= 5/95, v/v

*: 1.6 g/L of sodium phosphate, monobasic, dihydrate and 0.2 mL/L of triethylamine in water. Adjust with diluted phosphoric acid to a pH of 3.1.