

InertSearch™ for LC

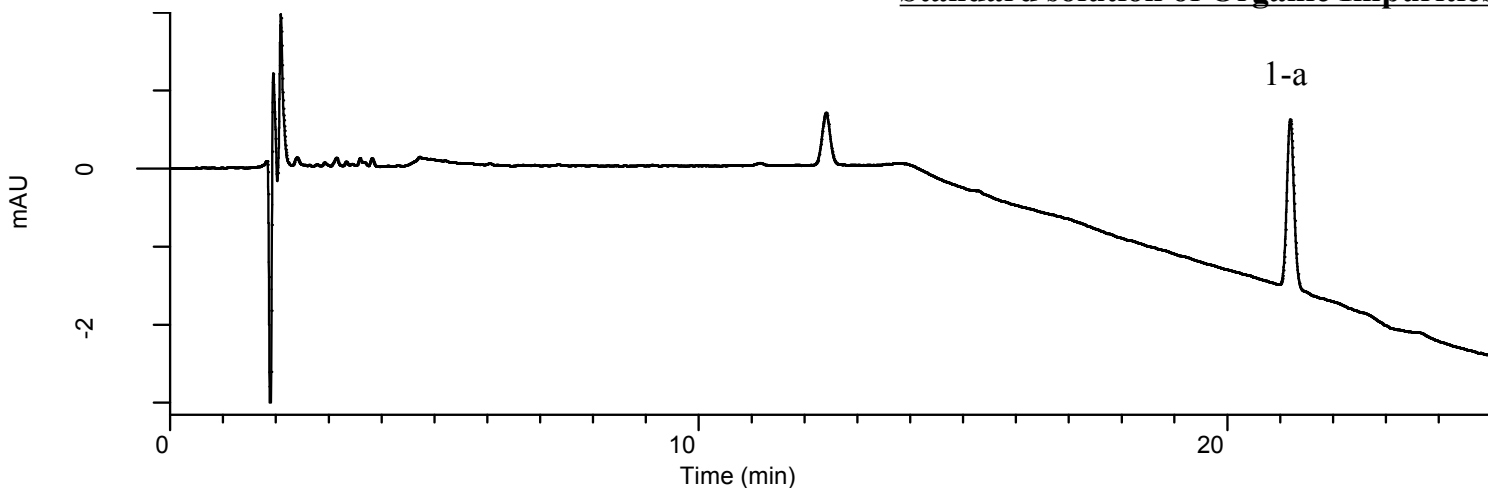
Inertsil™ Applications

Analysis of Cinacalcet Hydrochloride

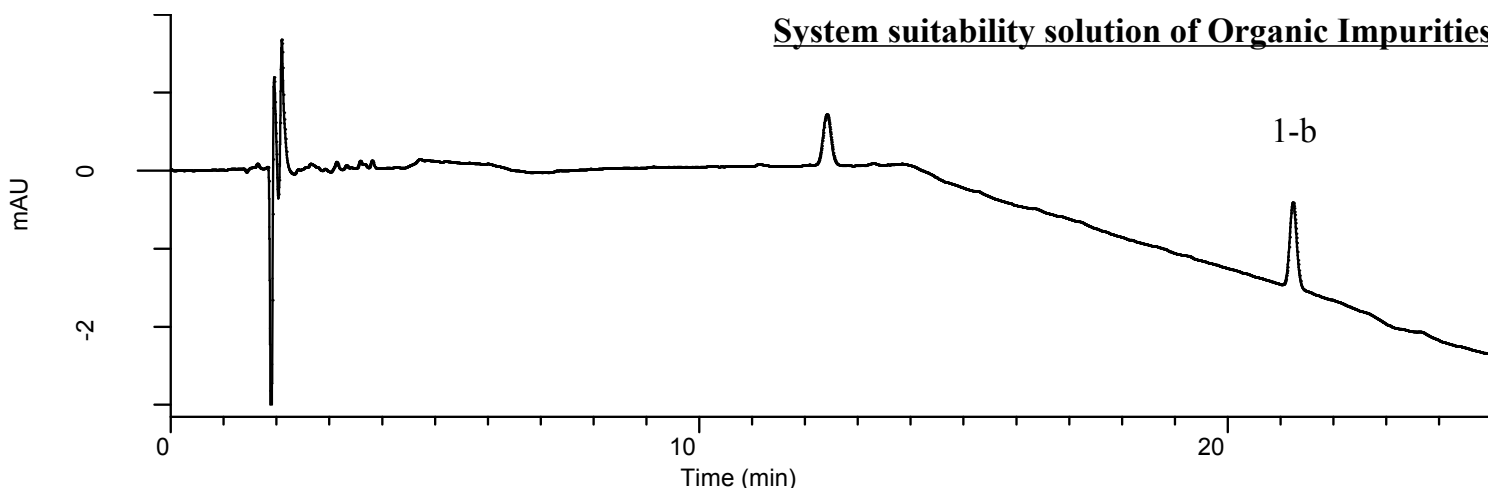
(Under the Condition of draft for USP)

Data No. LB546-0812

Standard solution of Organic Impurities



System suitability solution of Organic Impurities



Conditions

System : GL7700 HPLC system
Column : InertSustainSwift C18 (3 μ m HP, 250 x 4.6 mm I.D.)
Column Cat. No. : 5020-88226
Eluent : A) CH₃CN
 : B) CH₃CN/Buffer* = 45/55, v/v

Analyte:

1. Cinacalcet
0.2 mg/L (1-a) or 0.1 mg/L (1-b)

Time(min)	A(vol%)	B(vol%)
0	0	100
10	0	100
20	30	70
25	40	60

RSD of the peak area of 1-a (%)(n=6) : 1.23 (< 5.0)

S/N for 1-b : 113 (>10)

Flow rate : 1.3 mL/min
Col. Temp. : 40 °C
Detection : UV 210 nm (UV7750 UV Detector)
Injection Vol. : 20 μ L
Sample : Standard

* 0.02 M monobasic potassium phosphate. Adjust with 2 N potassium hydroxide to a pH of 6.2.