

InertSearch™ for LC

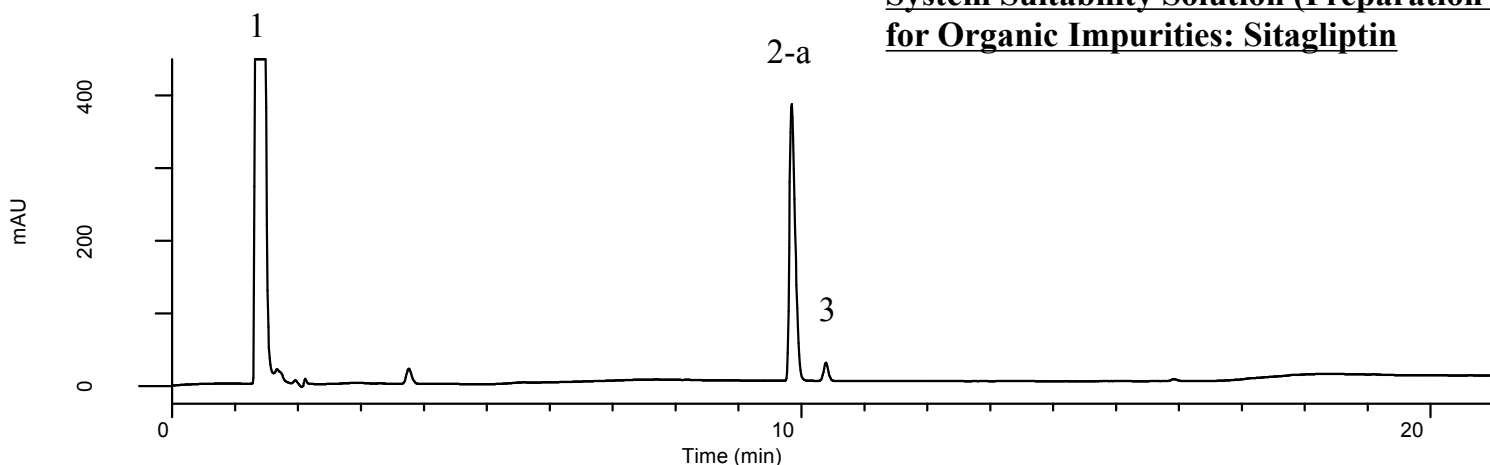
Inertsil™ Applications

Analysis of Sitagliptin

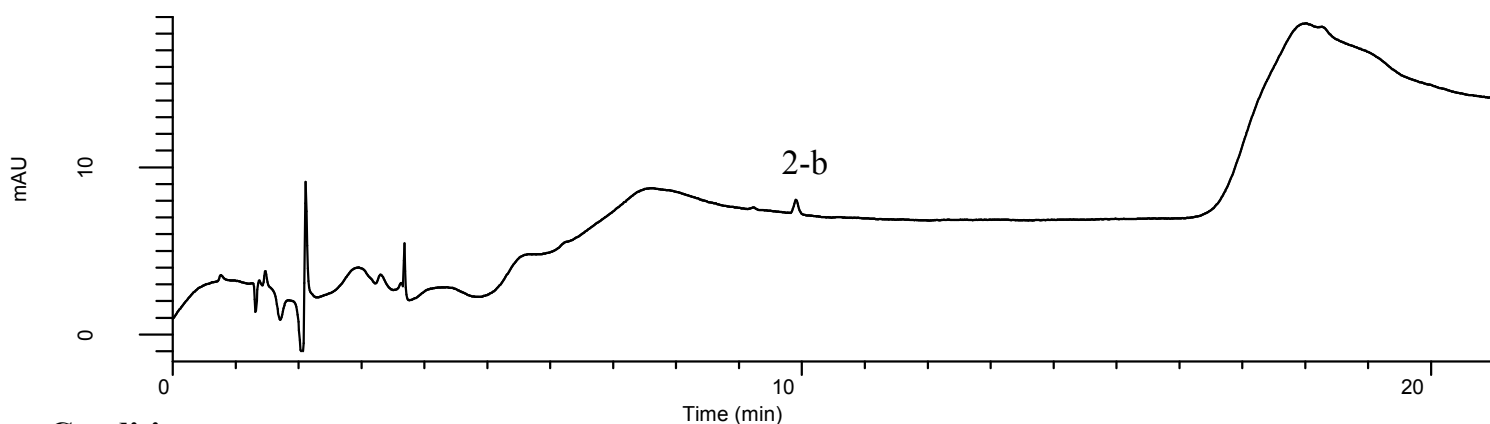
(Under the Condition of draft for USP, Sitagliptin and Metformin Hydrochloride Tablets)

Data No. LB548-0812

System Suitability Solution (Preparation 2) for Organic Impurities: Sitagliptin



Sensitivity Solution (0.1 mg/L) for Organic Impurities: Sitagliptin



Conditions

System : GL7700 HPLC system
Column : InertSustain C18 (3 μ m HP, 150 x 4.6 mm I.D.)
Column Cat. No. : 5020-14445
Eluent : A) CH₃CN
B) CH₃CN/Buffer* = 5/95, v/v

Analyte:

1. Metformin
2. Sitagliptin
3. Fumarate adduct of Sitagliptin

Resolution (2-a, 3) : 3.40 (> 1.5)
S/N for 2-b : 40.0 (> 10)

Time(min)	A(vol%)	B(vol%)
0	13	87
2	13	87
21	47	53
21.01	13	87
25	13	87

Flow rate : 1.0 mL/min
Col. Temp. : 40 °C
Detection : UV 205 nm (UV7750 UV Detector)
Injection Vol. : 20 μ L
Sample : Standard

* 3.45 g/L of monobasic sodium phosphate (0.025 M). Adjust with phosphoric acid to a pH of 2.5.