

InertSearch™ for LC

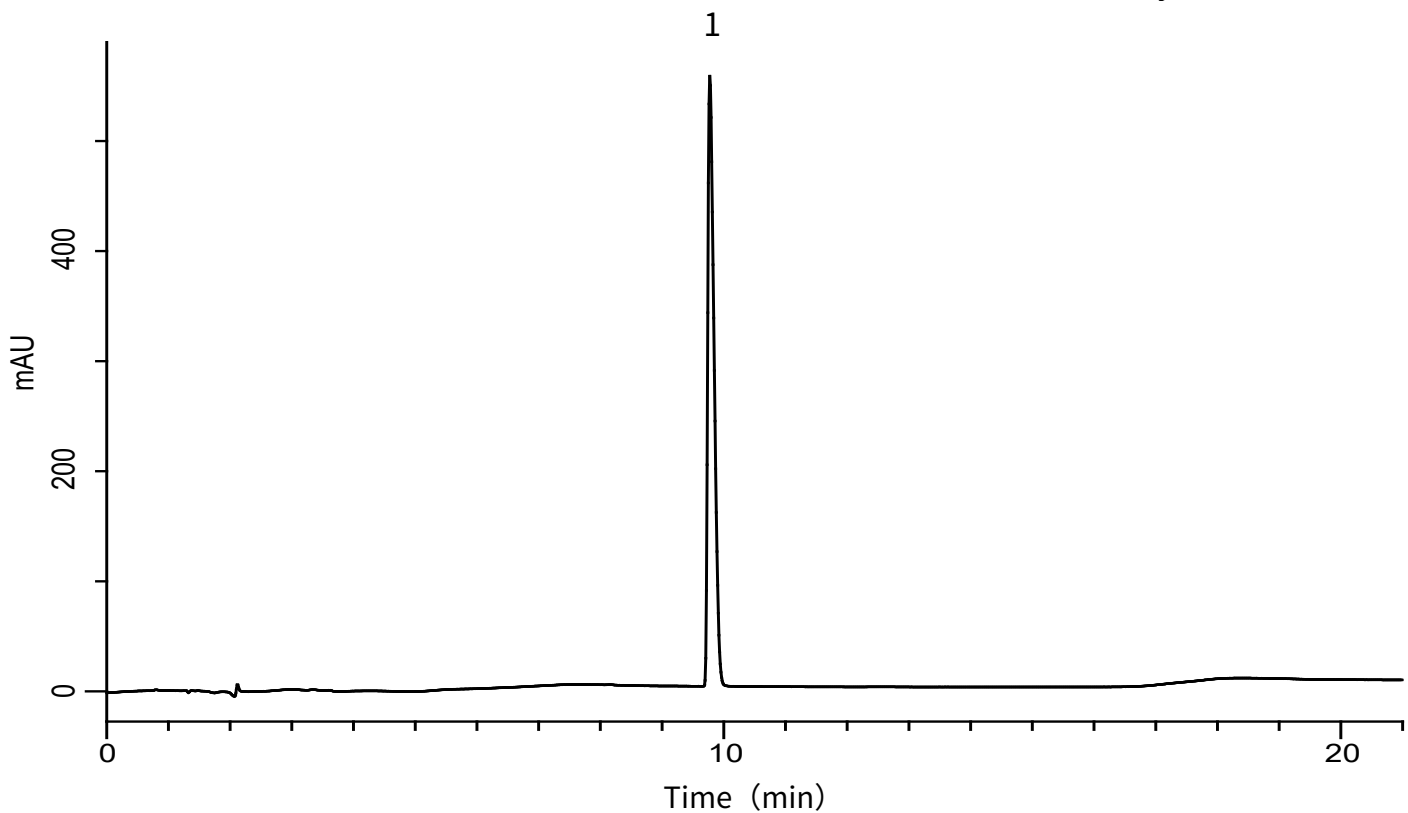
Inertsil® Applications

Analysis of Sitagliptin

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

Data No. LB547-0812

Standard solution of Assay, Procedure 1



Conditions

System	: GL7700 HPLC system	Analyte:	1. Sitagliptin	100 mg/L
Column	: InertSustain C18 (3 µm HP, 150 x 4.6 mm I.D.)			
Column Cat. No.	: 5020-14445			
Eluent	: A) CH ₃ CN			
	: B) CH ₃ CN/Buffer* = 5/95, v/v			

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

Symmetry factor (1) : 1.78 (< 2.0)
RSD of the peak area of 1 (%) (n=6) : 0.03 (< 2.0)

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

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