PICKERING LABORATORIES

Analysis of Voglibose in Pharmaceutical Formulations

By HPLC with Post-Column Derivatization

Voglibose is an Alpha-Glucosidase inhibitor widely used for the treatment of diabetes. Alpha-glucosidase inhibitors are agents that delay the glucose absorption at the intestinal level and thereby prevent a sudden surge of glucose after a meal. Vogilbose is the safest and most effective drug of its class.

Since Vogibose has no UV chromophore, post-column derivatization is employed to produce a fluorescent derivative.

This abstract describes a very sensitive and robust analytical method for the analysis of Voglibose in pharmaceutical tablets. Simple sample preparation and fast analysis time allow for using this method in high throughput environments.

Method

Analytical Conditions

Column: Restek Pinnacle II Amino, 5 um, (250 x 4.6) mm, Catalog # 9217575

Temperature: 35 °C

Flow Rate: 0.6 mL/min

Mobile Phase: Sodium phosphate buffer, 20 mM pH 6.5 / Acetonitrile (37 : 63)

Injection Volume: 50 µL

Note: We strongly recommend that the column be flushed with acetonitrile water (80:20) for twenty minutes before making any injections.

Sample Preparation

Crush 5 tablets and mix with 25 mL of mobile phase. Sonicate for 10 min and filter liquid portion through 0.45 µm filter. Put in HPLC autosampler vial and inject 50 µL.

Post-Column Conditions

Post-Column System: Onyx PCX, Pinnacle PCX or Vector PCX

Heated Reactor Volume: 3.5 mL

Temperature: 100 °C

Cooling Coil: 0.15 mL (at room temperature)

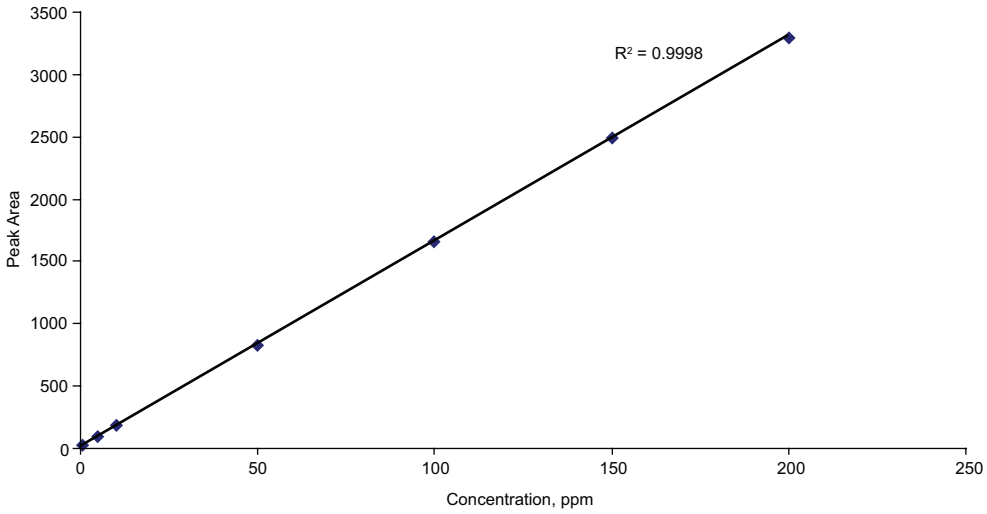
Reagent: Taurine (6.25 g), Sodium Periodate (2.56 g) in 1000 mL of water

Flow Rate: 0.6 mL/min

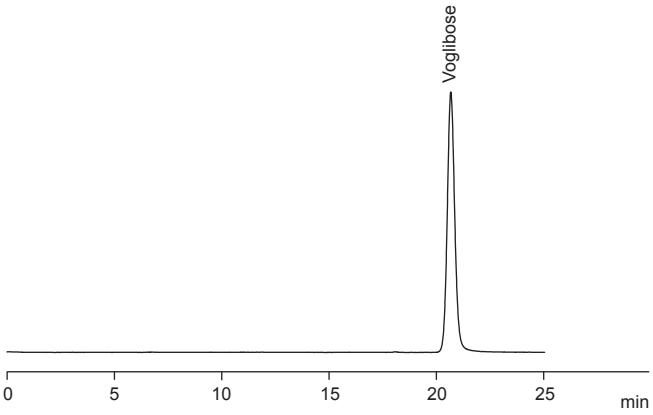
Detection: FLD
λ_{ex}: 350 nm, λ_{em}: 430 nm

Repeatability Studies for Different Concentration Levels

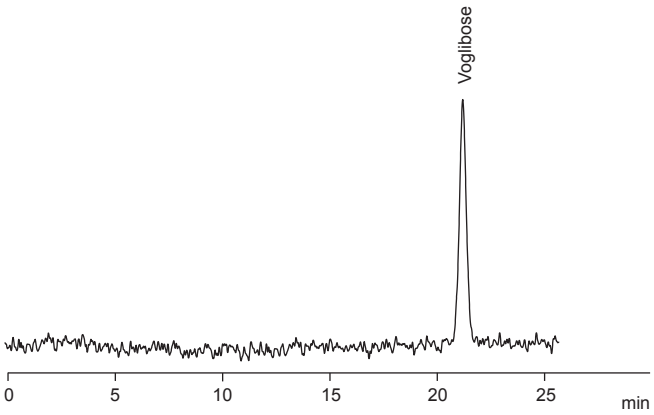
	0.5 ppm	100 ppm
Average RT, min	21.25	21.26
RSD, %, N = 6	0.36	0.08
Average Peak Area	9.22	1,562.69
RSD, %, N = 6	1.48	0.79



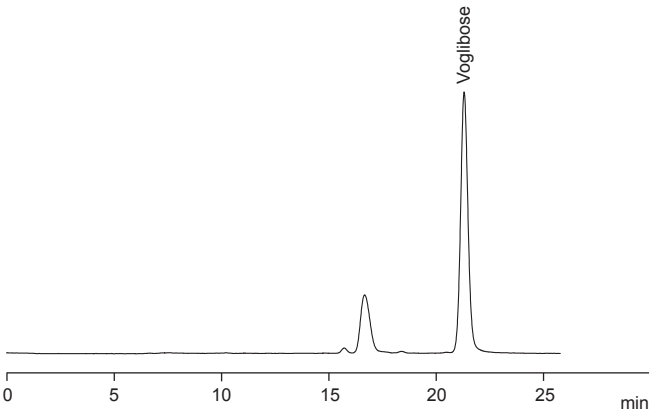
Calibration Curve for Analytical Range 0.5-200 ppm



Chromatogram of Voglibose Standard, 50 ppm, 50 µL Injection



Chromatogram of Voglibose Standard, 0.5 ppm, 50 uL Injection



Chromatogram of Voglibose Tablets (VolixTM, 0.2 mg), 50 µL Injection