How to Efficiently Determine Voglibose?

Chromai HPLC–Post-Column Derivatization–Fluorescence Detection Method

Introduction

Voglibose is an antidiabetic drug used to improve postprandial hyperglycemia. As an α-glucosidase inhibitor, it suppresses the activity of intestinal disaccharidases (such as sucrase, maltase, and lactase), thereby slowing the breakdown and absorption of carbohydrates. This helps reduce the rise in blood glucose and assists in controlling postprandial glucose levels. Because voglibose has no UV absorption, the pharmacopoeia recommends a method using post-column derivatization combined with fluorescence detection.

This application is based on the Chinese Pharmacopoeia method for voglibose analysis. An amino column is used for separation with phosphate buffer and acetonitrile as the mobile phase. Taurine and sodium periodate are used as the derivatization reagents for post-column reaction, followed by detection with a fluorescence detector. The method offers a high degree of automation, excellent stability, high sensitivity, and easy operation, making it suitable for the quantitative analysis of voglibose in voglibose tablets.

Experimental Section

1. Instruments

Leaps High-Performance Liquid Chromatography System:

- P40 Quaternary low-pressure gradient pump
- A10C Autosampler
- C10 Column oven
- D50 Fluorescence detector
- R10 Post-column derivatization device

2. Preparation of Solutions

Phosphate buffer: Weigh 1.56 g of disodium dihydrogen phosphate dihydrate and 3.58 g of disodium hydrogen phosphate. Dissolve in water and dilute to 1000 mL. Adjust the pH to 6.5 with phosphoric acid or sodium hydroxide solution.

Sodium octanesulfonate solution: Weigh 0.12 g of sodium octanesulfonate, add 37 mL phosphate buffer, and then add 63 mL acetonitrile.

Fluorescence reagent: Dissolve 6.25 g of taurine and 2.56 g of sodium periodate in water and dilute to 1000 mL.

Standard stock solution (1 mg/mL): Accurately weigh voglibose and dissolve it in the sodium octanesulfonate solution to prepare a 1 mg/mL stock solution.

Calibration solutions: Dilute the stock solution with the sodium octanesulfonate solution to obtain calibration solutions with concentrations of 0.1 μg/mL, 0.2 μg/mL, 0.5 μg/mL, 1 μg/mL, 5 μg/mL, and 10 μg/mL.

3. Chromatographic Conditions

Mobile phase: A: 37% phosphate buffer; B: 63% acetonitrile;

Flow rate: 0.8 mL/min

Column: Lotus NH_2 (4.6 mm × 250 mm, 5 μm)

Injection volume: 100 μL

Column temperature: 40 °C

Fluorescence detector: Excitation wavelength: 350 nm; Emission wavelength: 430 nm;

Derivatization reagent: Fluorescence reagent. Flow rate: 0.8 mL/min. Derivatization temperature: 120 °C

Cooling coil: 2 m, room temperature (25 °C)

4. Results

1. Standard Chromatogram

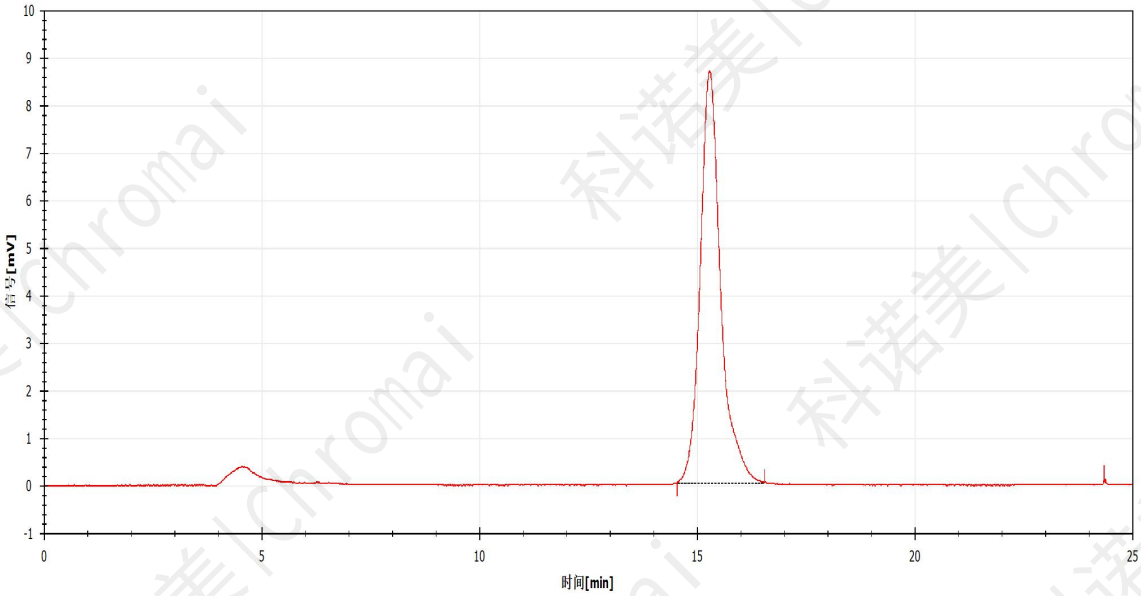

Figure 1 Typical Chromatogram of Voglibose

2. Linearity and Limit of Detection (LOD)

Inject the calibration solutions at concentrations of 0.1 µg/mL, 0.2 µg/mL, 0.5 µg/mL, 1 µg/mL, 5 µg/mL, and 10 µg/mL in order from low to high. Plot the calibration curve using concentration versus peak area. The correlation coefficient for voglibose within the linear range is greater than 0.9999.

Table 1 Results of Linearity and Limit of Detection

化合物 Compound	线性范围（µg/mL） Linear Range (µg/mL)	线性方程 Linear Equation	相关系数 Correlation Coefficient	检出限（µg/mL） LOD (µg/mL)
伏格列波糖 Voglibose	0.1~10	y = 147.5583 x – 2.6008	0.9999	0.0012

3. Precision

Inject the 2 µg/mL solution six consecutive times. Calculate the precision of the retention time and peak area. Results are shown in Table 2.

Table 2 Precision Results

Compound	Retention Time RSD (%)	Peak Area RSD (%)
Voglibose	0.15%	1.14%

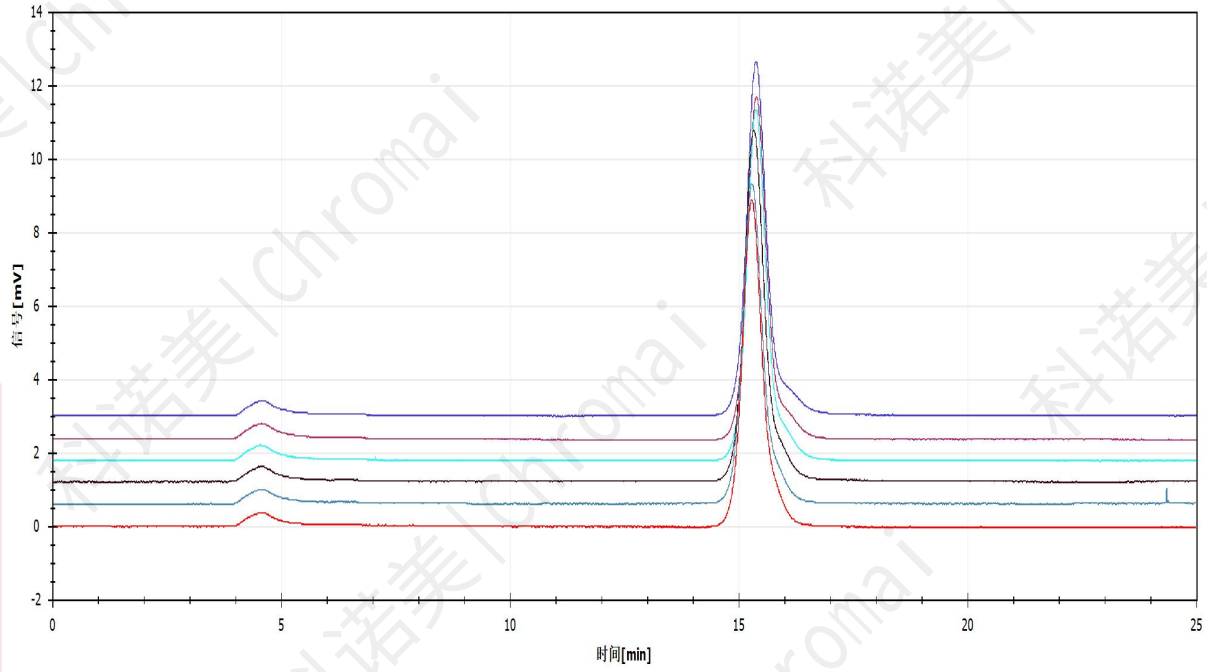

Figure 2 Voglibose Precision Chromatogram

Conclusion

In this application, the Chromai Leaps UHPLC system combined with the R10 post-column derivatization unit was used to evaluate the analytical method for determining voglibose content, following the Chinese Pharmacopoeia. Within the linear range, the correlation coefficient was greater than 0.9999. The retention time precision was 0.15%, peak area precision was 1.14%, and the limit of detection (LOD) was 0.012 μg/mL, meeting the requirements of the pharmacopoeia.