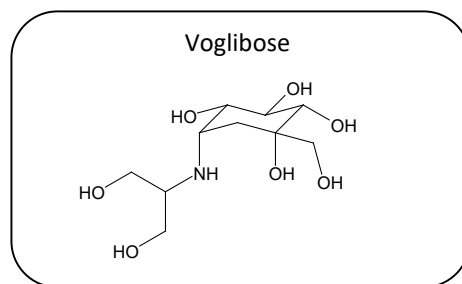


Analysis of Voglibose Tablet Based on the Japanese Pharmacopoeia, 18th Edition.

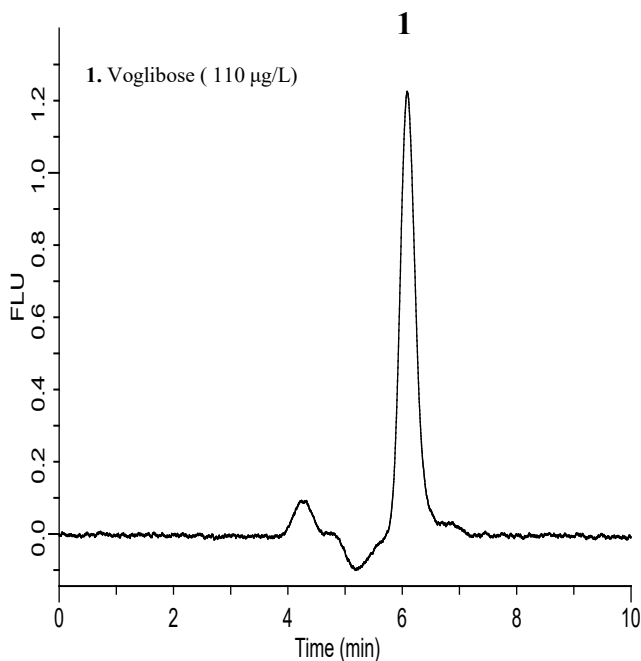
Voglibose tablet is listed in the Japanese Pharmacopoeia and the post-column HPLC-fluorescence method is adopted for dissolution and quantitation method. In pharmacopoeia, cooling down is required by the specified pipe arrangement and at the specified temperature, after the reaction in post-column system. This time we used Chromaster (HITACHI), installing two sets of ovens can fulfill the requirement. (K. Suzuki)



Structures are created using Chemistry 4-D Draw which is provided by ChemInnovation Software, Inc.

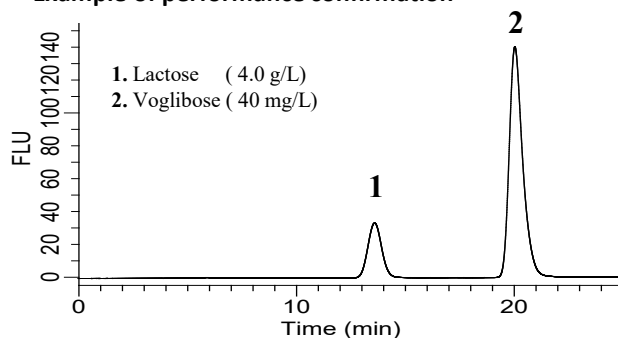
System Suitability Test for Dissolution

Example of performance / reproducibility confirmation

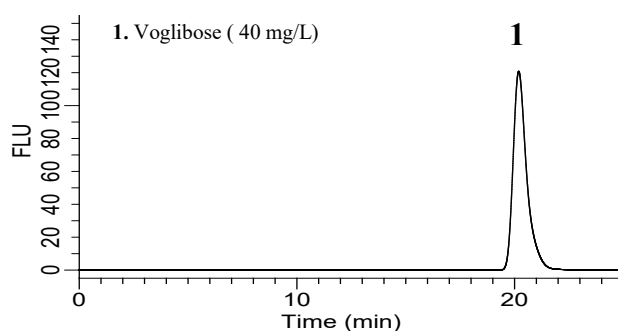


System Suitability Test for Quantitation Method

Example of performance confirmation



Example of reproducibility confirmation



System suitability test

- For each 100 μ L of standard solution, the peak theoretical plate number and the symmetry factor are more than 2000 plates and less than 1.5, respectively.
- When the analysis is repeated 6 times, the relative standard deviation of peak area is less than 3.0%.

Result this time

Theoretical plate number	: 2,433 ($\geq 2,000$)
Symmetry factor	: 1.19 (≤ 1.5)
Relative standard deviation	: 0.99 % (≤ 3.0)

(Table 1)

Table 1: Reproducibility of peak area value

	Peak area value
Average	92130
RSD(%)	0.99

System suitability test

- For each 50 μ L of this test solution, lactose and voglibose elute in order and the degree of separation is greater than 4
- When the analysis is repeated 6 times, the relative standard deviation of peak area is less than 2.0%.

Result this time

Order of elution	: OK
Resolution	: 5.7 (≥ 4)
Relative standard deviation	: 1.23 % (≤ 2.0)

(Table 2)

Table 2: Reproducibility of peak area value

	Peak area value
Average	21149069
RSD(%)	1.23

HPLC conditions

• Dissolution

HPLC condition

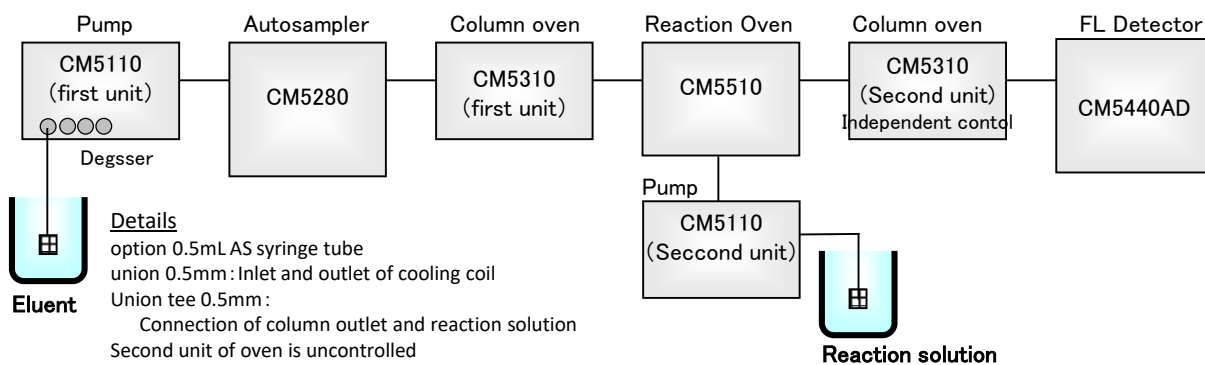
Column : Inertsil NH2 (5 μ m, 150 \times 4.0 mm I.D.)
Cat. No. : 5020-05535
Eluent : A) CH₃CN
 B) 10 mM Na₂HPO₄ (pH 6.5; 10 mM NaH₂PO₄)
 A/B = 500/500, v/v (premix)
Reaction Solution : 12 mM NaIO₄ + 50 mM Taurine
Reaction coil : PTFE 0.5 mm ID x 22 m
 (20 m (inside of oven) + 2 m (for connection))
Flow rate : Eluent; 0.85 mL/min
 Reaction solution; 0.85 mL/min
 * Adjusted in order for the retention time to be 6 min.
Column temperature : 25 °C
Reaction temperature : 100 °C
Cooling temperature : 25 °C
Cooling coil : PTFE 0.33 mm ID x 2.5 m
 (2 m (Inside of oven) + 0.5 m (for connection))
Detection : FL Ex 350 nm, Em 430 nm (PMT Low)
Injection volume : 100 μ L

• Quantitation method

HPLC conditions

Column : Inertsil NH2 (5 μ m, 150 \times 4.0 mm I.D.)
Cat. No. : 5020-05535
Eluent : A) CH₃CN
 B) 10 mM Na₂HPO₄ (pH 6.5; 10 mM NaH₂PO₄)
 A/B = 600/300 v/v (premix)
Reaction solution: 12 mM NaIO₄ + 50 mM Taurine
Reaction coil : PTFE 0.5 mm ID x 22 m
 (20 m (inside of oven) + 2 m (for connection))
Flow rate : eluent; 0.56 mL/min
 reaction solution; 0.56 mL/min * Adjusted in order for the
 retention time to be approximately 20 min.
Column temperature : 25 °C
Reaction temperature : 100 °C
Cooling temperature : 15 °C
Cooling coil : PTFE 0.33 mm ID x 2.5 m
 (2 m (inside of oven) + 0.5 m (for connection))
Detection : FL Ex 350 nm, Em 430 nm (PMT Low)
Injection volume : 50 μ L

Flow daigram



Instrument used (only for reference)

● HPLC System Hitachi HPLC system Chromaster

No.	Name of product	Model number
1	Organizer	
2	Detector (FL)	5440AD
3	Column oven	5310
4	Autosampler	5280
5	Pump	5110
6	Reaction oven	5510



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