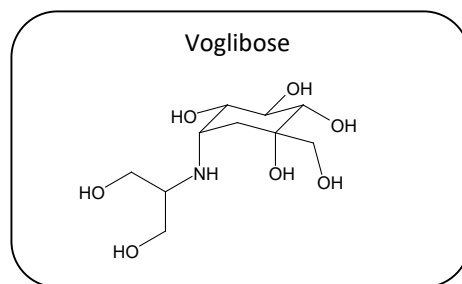


# Analysis of Voglibose Tablet Based on the Japanese Pharmacopoeia, 18th Edition.

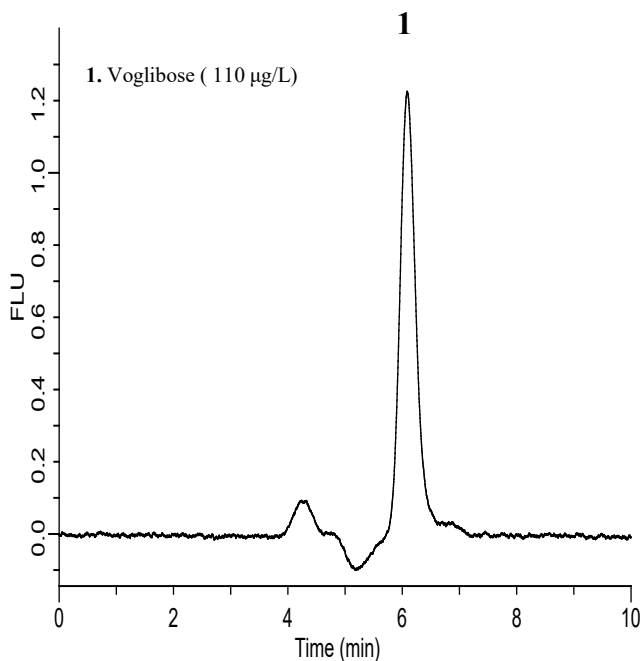
Voglibose tablet is listed in the Japanese Pharmacopoeia and the post-column HPLC-fluorescence method is adopted for dissolution and quantitation method. In pharmacopoeia, cooling down is required by the specified pipe arrangement and at the specified temperature, after the reaction in post-column system. 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 each 100 $\mu$ 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	: <b>2,433 (<math>\geq 2,000</math>)</b>
Symmetry factor	: <b>1.19 (<math>\leq 1.5</math>)</b>
Relative standard deviation	: <b>0.99 % (<math>\leq 3.0</math>)</b>

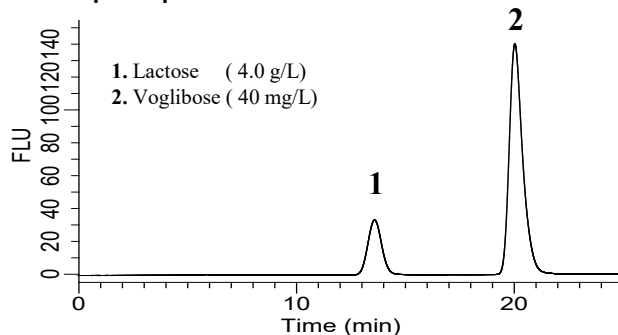
(Table 1)

Table 1: Reproducibility of peak area value

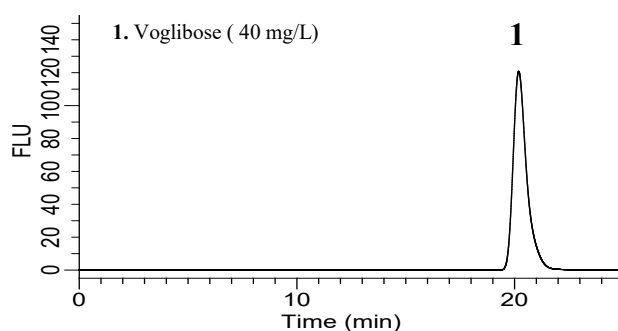
	Peak area value
Average	92130
RSD(%)	0.99

## System Suitability Test for Quantitation Method

### Example of performance confirmation



### Example of reproducibility confirmation



### System suitability test

- For each 50 $\mu$ 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	: <b>OK</b>
Resolution	: <b>5.7 (<math>\geq 4</math>)</b>
Relative standard deviation	: <b>1.23 % (<math>\leq 2.0</math>)</b>

(Table 2)

Table 2: Reproducibility of peak area value

	Peak area value
Average	21149069
RSD(%)	1.23

# HPLC conditions

## • Dissolution

### HPLC condition

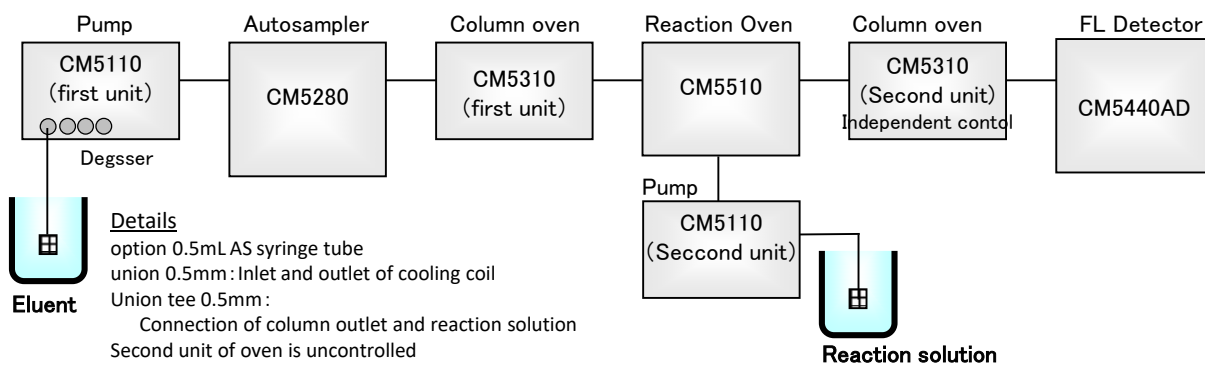
**Column** : Inertsil NH2 (5  $\mu$ m, 150  $\times$  4.0 mm I.D.)  
**Cat. No.** : 5020-05535  
**Eluent** : A) CH<sub>3</sub>CN  
 B) 10 mM Na<sub>2</sub>HPO<sub>4</sub> (pH 6.5; 10 mM NaH<sub>2</sub>PO<sub>4</sub>)  
 A/B = 500/500, v/v (premix)  
**Reaction Solution** : 12 mM NaIO<sub>4</sub> + 50 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  $^{\circ}$ C  
**Reaction temperature** : 100  $^{\circ}$ C  
**Cooling temperature** : 25  $^{\circ}$ 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  $\mu$ L

## • Quantitation method

### HPLC conditions

**Column** : Inertsil NH2 (5  $\mu$ m, 150  $\times$  4.0 mm I.D.)  
**Cat. No.** : 5020-05535  
**Eluent** : A) CH<sub>3</sub>CN  
 B) 10 mM Na<sub>2</sub>HPO<sub>4</sub> (pH 6.5; 10 mM NaH<sub>2</sub>PO<sub>4</sub>)  
 A/B = 600/300 v/v (premix)  
**Reaction solution**: 12 mM NaIO<sub>4</sub> + 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  $^{\circ}$ C  
**Reaction temperature** : 100  $^{\circ}$ C  
**Cooling temperature** : 15  $^{\circ}$ 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  $\mu$ 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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