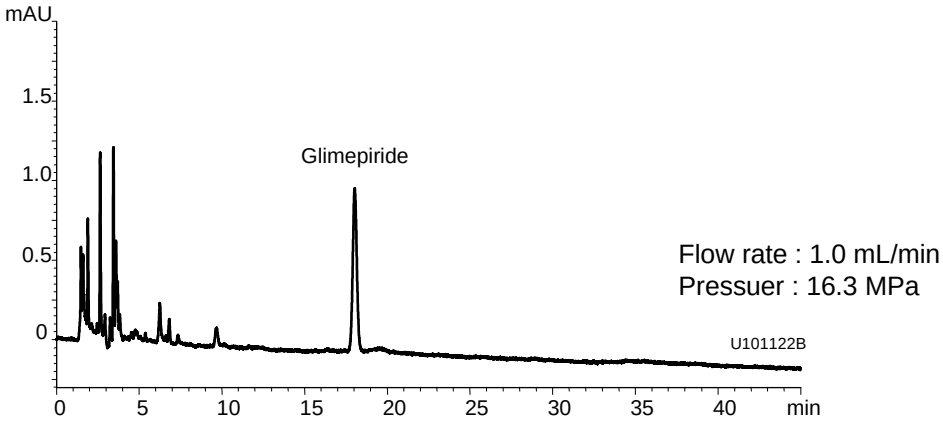
HPLC DATA SHEET

グリメピリド (日本薬局方収載原案記載条件; 類縁物質)

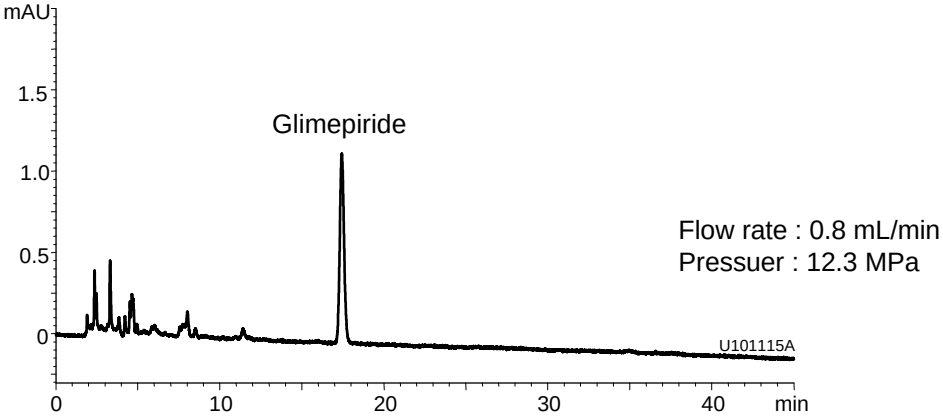
疎水性の異なるC18カラムによる比較

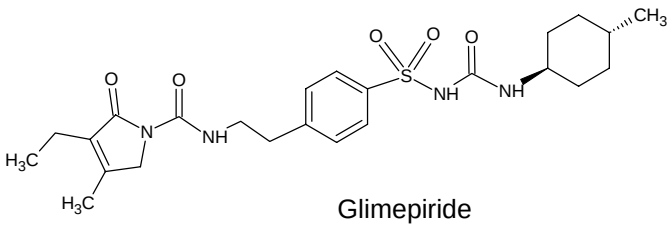
U101216A

J'sphere ODS-M80 (**標準タイプ** C18)



J'sphere ODS-L80 (**低疎水性タイプ** C18)





Glimepiride

	System suitability requirement	result	
		J'sphere ODS-M80	J'sphere ODS-L80
Theoretical plate number (Glimepiride)	≧9000	24600	21300
Tailing factor (Glimepiride)	≦1.5	1.04	1.10

Column : 250 X 4.0 mmI.D. (4 μm, 8 nm)

Eluent : phosphate buffer (pH 2.5)/acetonitrile (50/50)

phosphate buffer : dissolve 0.5 g of NaH_2PO_4 in 500 mL water and adjust pH 2.5 with H_3PO_4

Flow rate : *adjust the flow rate so that the retention time of Glimepiride is about 17 min*

Temperature : 25℃

Detection : UV at 228 nm

Injection : 20 μL

Sample : Glimepiride* (0.0002 mg/mL, correspond to standard solution)

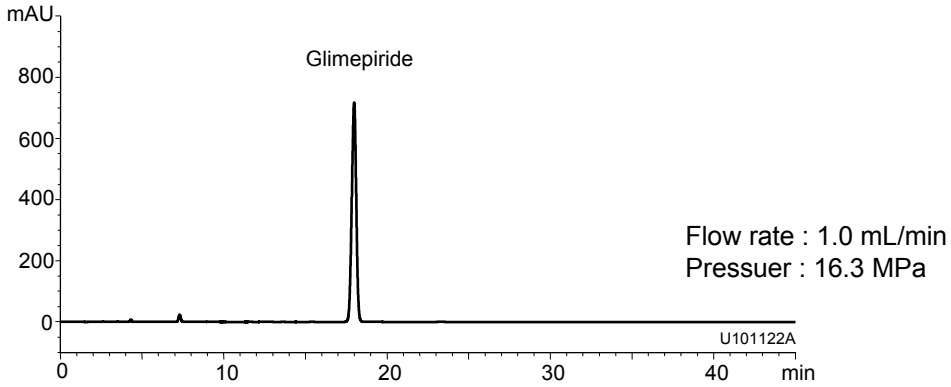
* A reagent for laboratory use

HPLC DATA SHEET

グリメピリド (日本薬局方収載原案記載条件; 定量法)

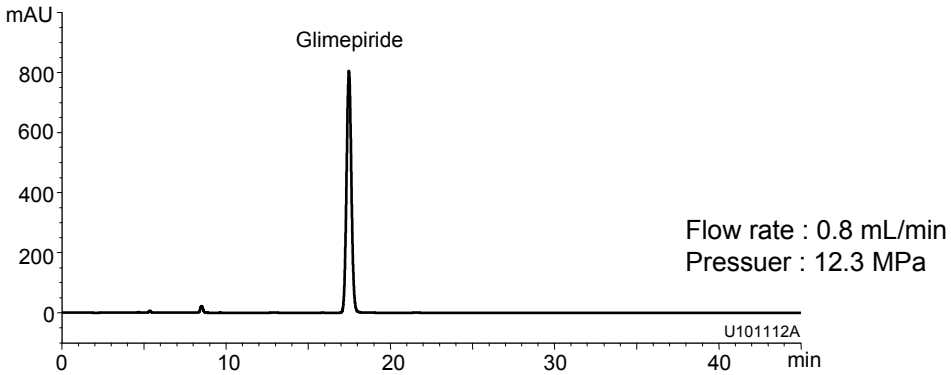
疎水性の異なるC18カラムによる比較 U101215A

J'sphere ODS-M80 (標準タイプ C18)

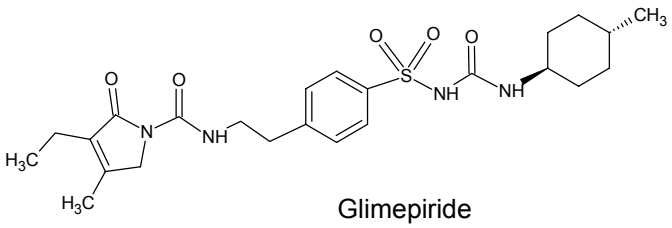


Flow rate : 1.0 mL/min
Pressuer : 16.3 MPa

J'sphere ODS-L80 (低疎水性タイプ C18)



Flow rate : 0.8 mL/min
Pressuer : 12.3 MPa



Glimepiride

	System suitability requirement	result	
		J'sphere ODS-M80	J'sphere ODS-L80
Theoretical plate number (Glimepiride)	≧9000	20400	18400
Tailing factor (Glimepiride)	≦1.5	0.98	1.12

Column : 250 X 4.0 mmI.D. (4 μm, 8 nm)
Eluent : phosphate buffer (pH 2.5)/acetonitrile (50/50)
phosphate buffer : dissolve 0.5 g of NaH_2PO_4 in 500 mL water and adjust pH 2.5 with H_3PO_4
Flow rate : *adjust the flow rate so that the retention time of Glimepiride is about 17 min*
Temperature : 25℃
Detection : UV at 228 nm
Injection : 20 μL
Sample : Glimepiride* (0.2 mg/mL, correspond to standard solution)

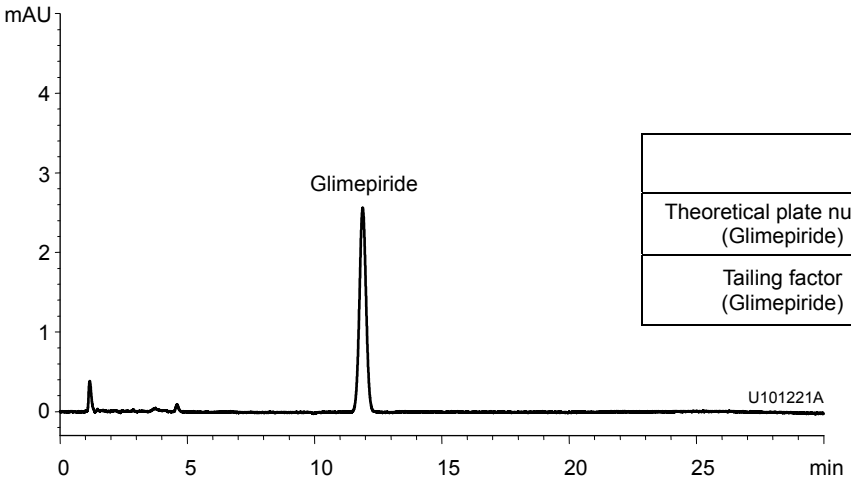
* A reagent for laboratory use

HPLC DATA SHEET

グリメピリド錠
Glimepiride Tablets

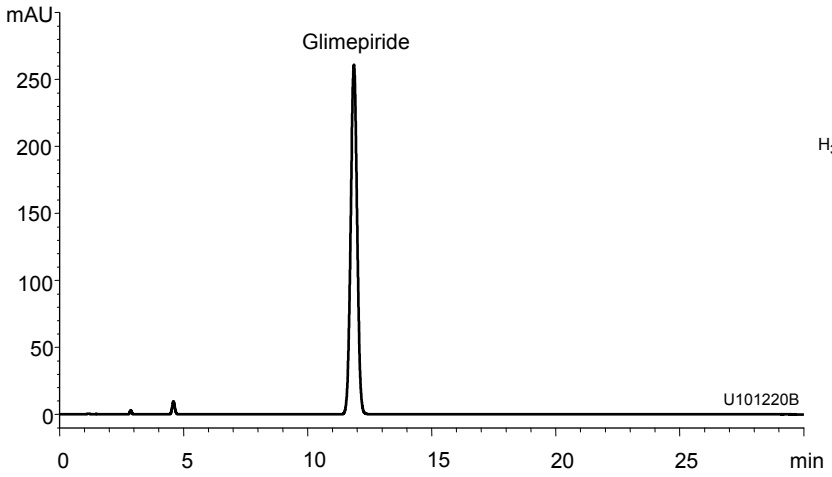
U101222A

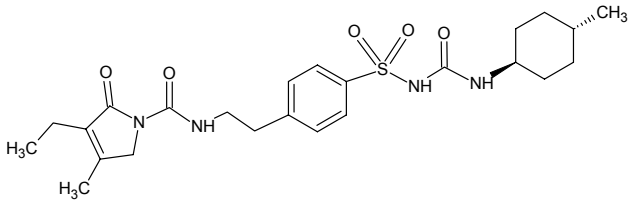
A) Standard solution*
(0.0018 mg/mL Glimepiride)



	System suitability requirement	result
Theoretical plate number (Glimepiride)	≧6000	9700
Tailing factor (Glimepiride)	≦1.5	1.02

B) Sample solution*
(0.18 mg/mL Glimepiride)





Glimepiride

Column	:	YMC-Triart C18 (5 μm, 12 nm) 125 X 4.0 mmI.D.
Eluent	:	phosphate buffer (pH 3.5)/acetonitrile (50/50) *phosphate buffer : dissolve 0.5 g of NaH_2PO_4 in 500 mL water and adjust pH 3.5 with H_3PO_4 (1→5)*
Flow rate	:	0.75 mL/min
Temperature	:	25℃
Detection	:	UV at 228 nm
Injection	:	5 μL

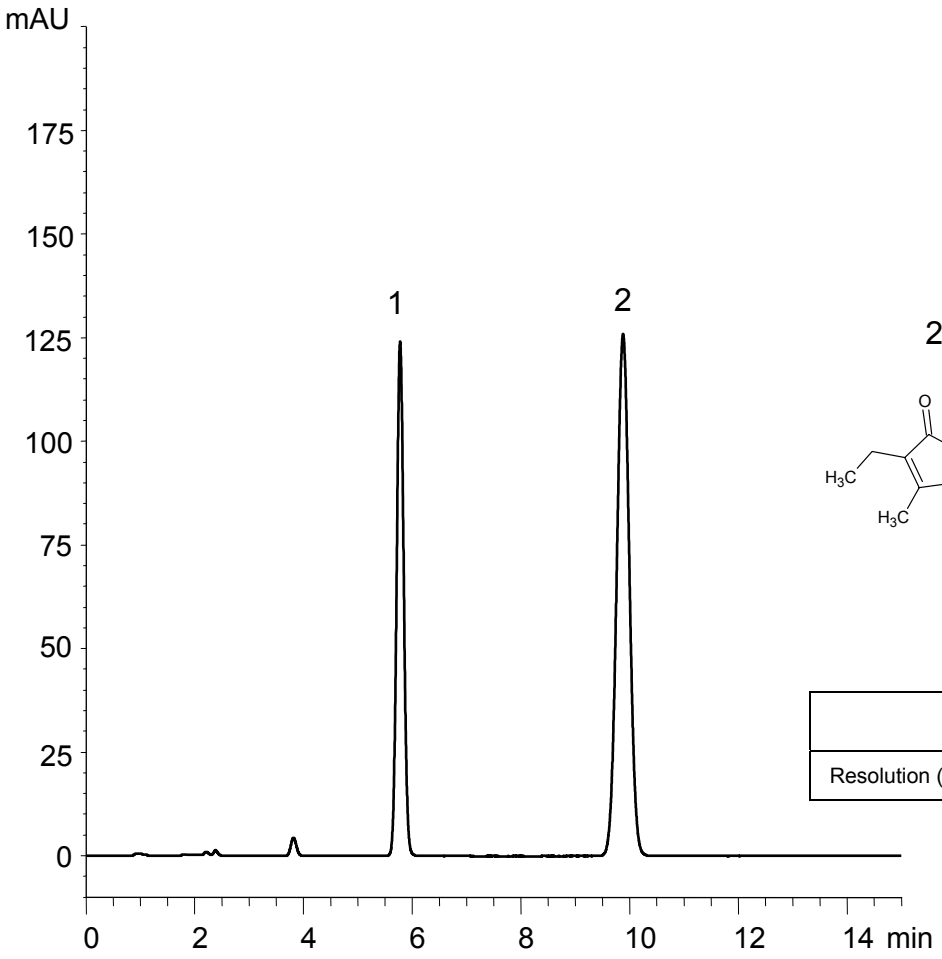
(The draft for the Japanese Pharmacopoeia; Related substances)

* All standard and sample solutions were prepared from Glimepiride supplied as a reagent for laboratory use.

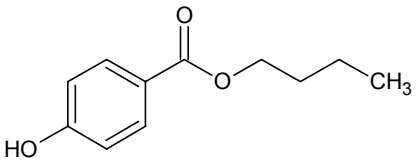
HPLC DATA SHEET

グリメピリド錠
Glimepiride Tablets

U101220A

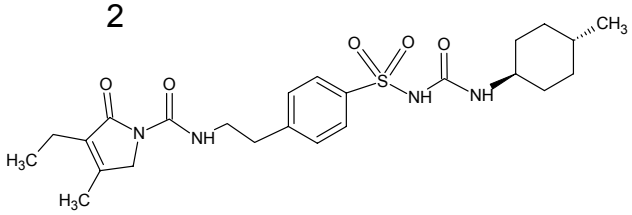


1



Butyl *p*-hydroxybenzoate (I.S.)

2



Glimepiride

	System suitability requirement	result
Resolution (1, 2)	≧6	12.5

Column	:	YMC-Triart C18 (5 μm, 12 nm) 125 X 4.0 mmI.D.
Eluent	:	phosphate buffer (pH 3.5)/acetonitrile (50/50) *phosphate buffer : dissolve 0.5 g of NaH_2PO_4 in 500 mL water and adjust pH 3.5 with H_3PO_4 (1→5)*
Flow rate	:	0.9 mL/min
Temperature	:	25℃
Detection	:	UV at 228 nm
Injection	:	10 μL
Sample	:	1. Butyl *p*-hydroxybenzoate (0.12 mg/mL) 2. Glimepiride* (0.06 mg/mL)

(The draft for the Japanese Pharmacopoeia; Assay)

* Glimepiride: A reagent for laboratory use