

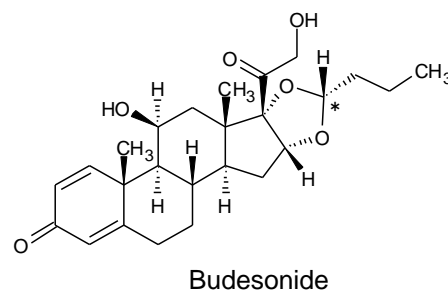
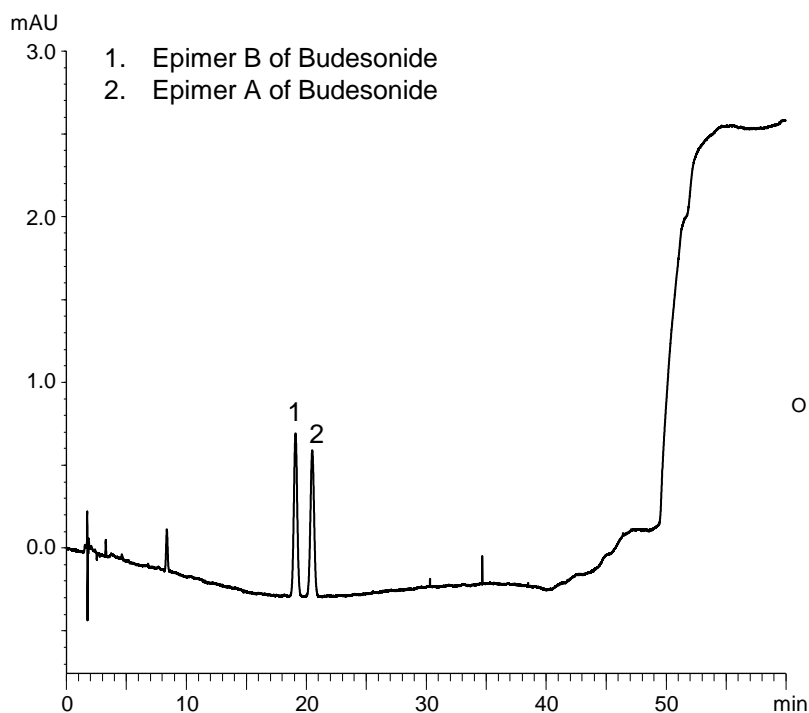
ブデソニド (日本薬局方収載原案記載条件)

Budesonide (The draft for the Japanese Pharmacopoeia)

P220322B

System suitability solution\*2  
(1 µg/mL Budesonide)

	System suitability requirement	Result
SN ratio (Epimer A of Budesonide)	≥ 10	40
Resolution (1,2)	≥ 1.5	2.7



Column : YMC-Pack ODS-A (3 µm, 20 nm)  
150 X 4.6 mm I.D.

Eluent : A) phosphate buffer (pH 3.2)\*1/acetonitrile/ethanol (34/16/1)  
B) phosphate buffer (pH 3.2)\*1/acetonitrile (1/1)  
0%B (0-38 min), 0-100%B (38-50 min), 100%B (50-60 min)

\*1 Add 100 mL of H<sub>3</sub>PO<sub>4</sub> (1→200) to 900 mL of NaH<sub>2</sub>PO<sub>4</sub> · 2H<sub>2</sub>O (1→250), adjust pH 3.2 with 1M NaOH

Flow rate : 1.0 mL/min

Temperature : 50°C

Detection : UV at 240 nm

Injection : 20 µL

(The draft for the Japanese Pharmacopoeia; Related substances)

\*2 System suitability solution was prepared from Budesonide supplied as a reagent for laboratory use.

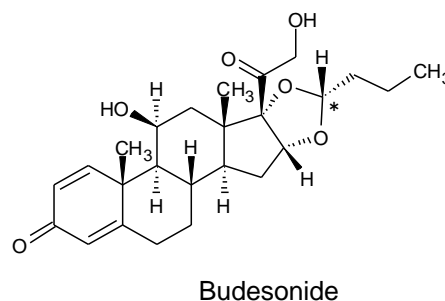
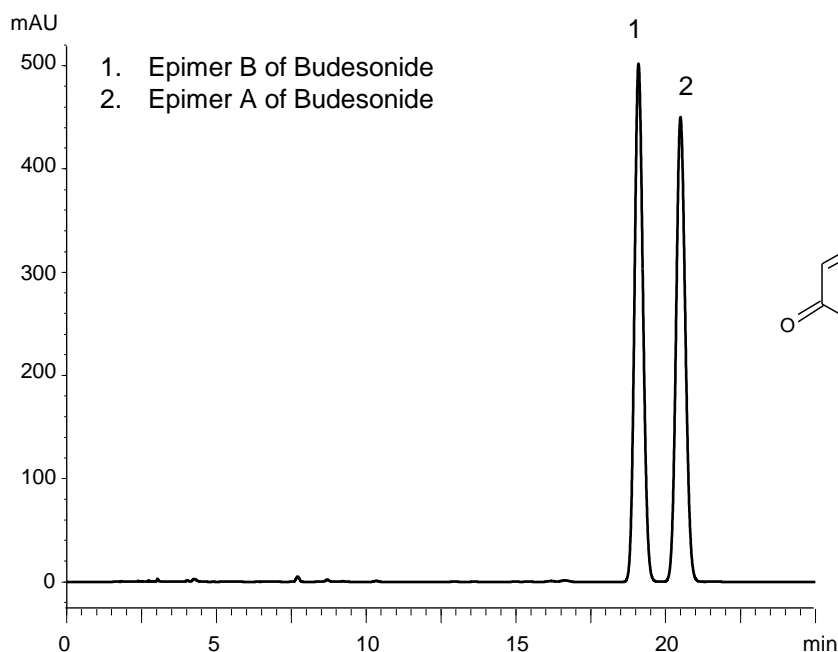
ブデソニド (日本薬局方収載原案記載条件)

Budesonide (The draft for the Japanese Pharmacopoeia)

P220322C

	System suitability requirement	Result
Resolution (1,2)	$\geq 1.5$	2.6
Relative standard deviation for the sum of the peak areas of the two budesonide epimers (n=6)	$\leq 1.0\%$	0.32%

Standard solution\*2  
(0.5 mg/mL Budesonide)



Column : YMC-Pack ODS-A (3  $\mu$ m, 20 nm)  
150 X 4.6 mm I.D.

Eluent : phosphate buffer (pH 3.2)\*1/acetonitrile/ethanol (34/16/1)

\*1 Add 100 mL of  $H_3PO_4$  (1 $\rightarrow$ 200) to 900 mL of  $NaH_2PO_4 \cdot 2H_2O$  (1 $\rightarrow$ 250), adjust pH 3.2 with 1M NaOH

Flow rate : 1.0 mL/min

Temperature : 50°C

Detection : UV at 240 nm

Injection : 20  $\mu$ L

(The draft for the Japanese Pharmacopoeia; Assay)

\*2 Standard solution was prepared from Budesonide supplied as a reagent for laboratory use.

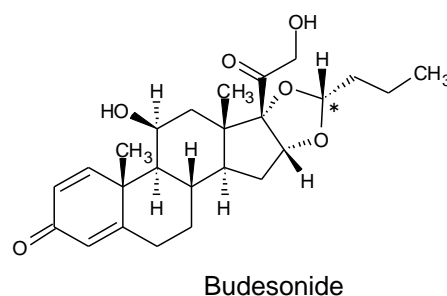
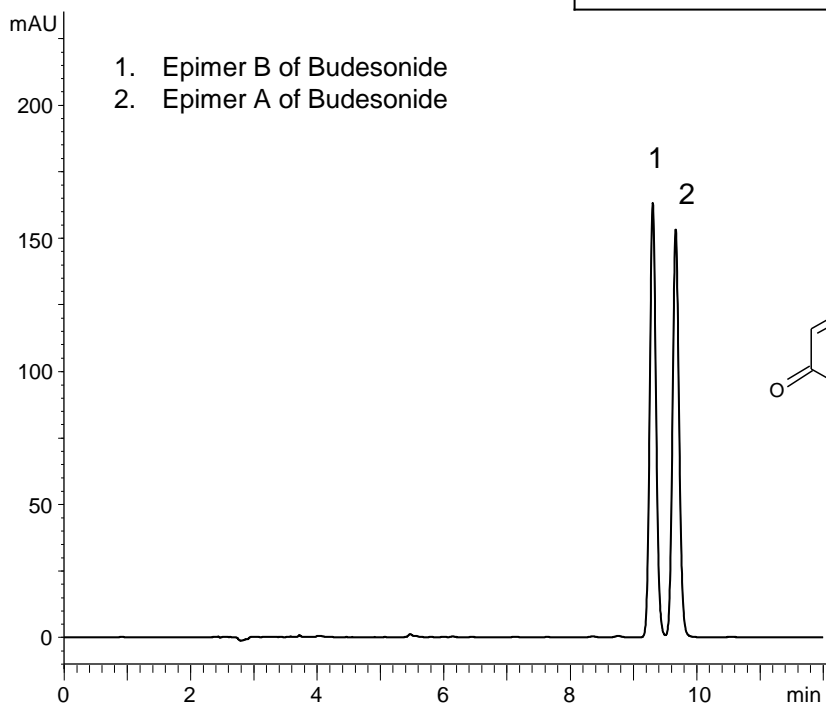
ブデソニド (米国薬局方記載条件)

Budesonide (The United State Pharmacopeia)

P220324D

	System suitability requirement	Result
Resolution (1,2)	$\geq 1.2$	1.9
Relative standard deviation for the sum of the peak areas of the two budesonide epimers (n=5)	$\leq 1.0\%$	0.053%

Standard solution\*2  
(0.06 mg/mL Budesonide)



Column : YMC-Pack ODS-A (3  $\mu$ m, 20 nm)

250 X 4.6 mm I.D.

Eluent : buffer (pH 3.9)\*1/acetonitrile (55/45)

\*1 0.5 mL of glacial acetic acid in 1 L of water, adjust pH 3.9 with KOH

Flow rate : 1.0 mL/min

Temperature : 50°C

Detection : UV at 240 nm

Injection : 20  $\mu$ L

(The United State Pharmacopeia 42nd; Assay)

\*2 Standard solution was prepared from Budesonide supplied as a reagent for laboratory use.