

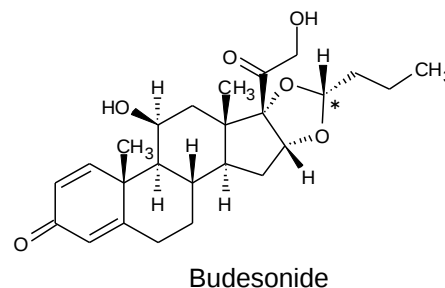
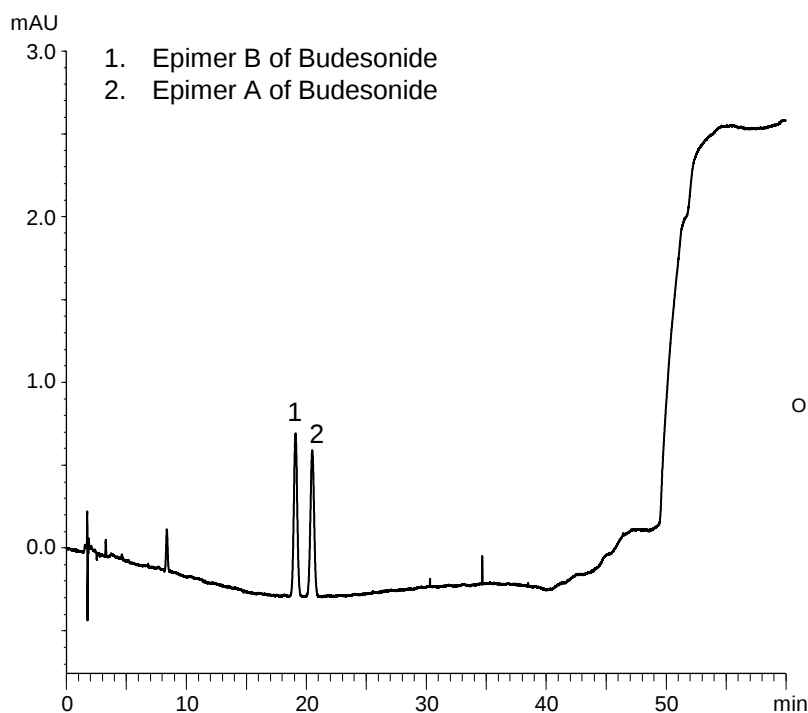
ブデソニド（日本薬局方収載原案記載条件）

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_3PO_4 (1→200) to 900 mL of $NaH_2PO_4 \cdot 2H_2O$ (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.

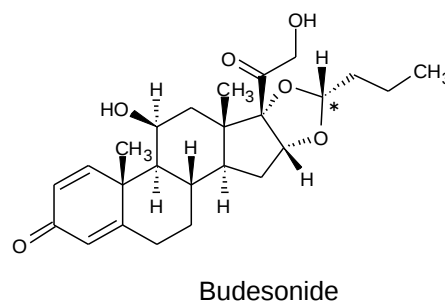
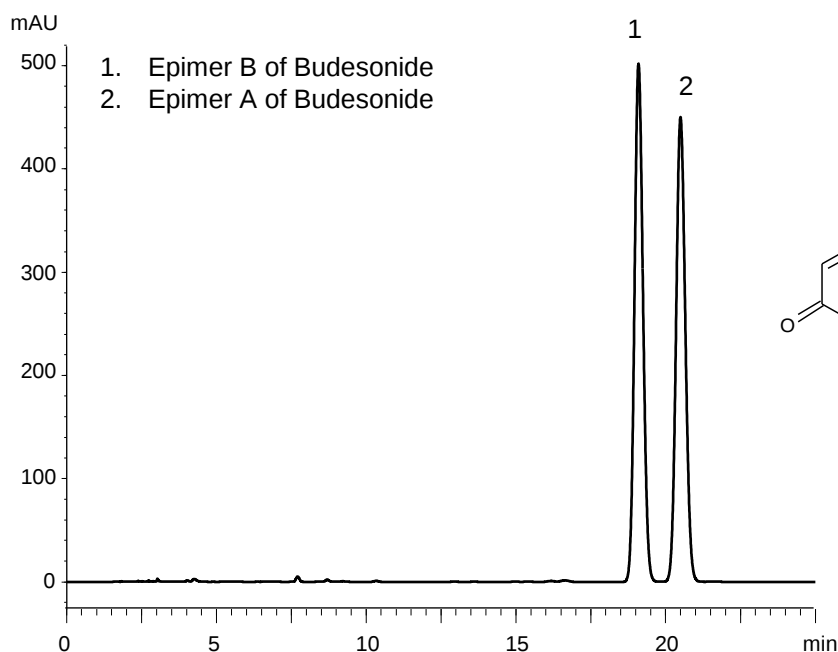
ブデソニド（日本薬局方収載原案記載条件）

Budesonide (The draft for the Japanese Pharmacopoeia)

P220322C

	System suitability requirement	Result
Resolution (1,2)	≥ 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 μ m, 20 nm)
150 X 4.6 mmI.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 μ L

(The draft for the Japanese Pharmacopoeia; Assay)

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