

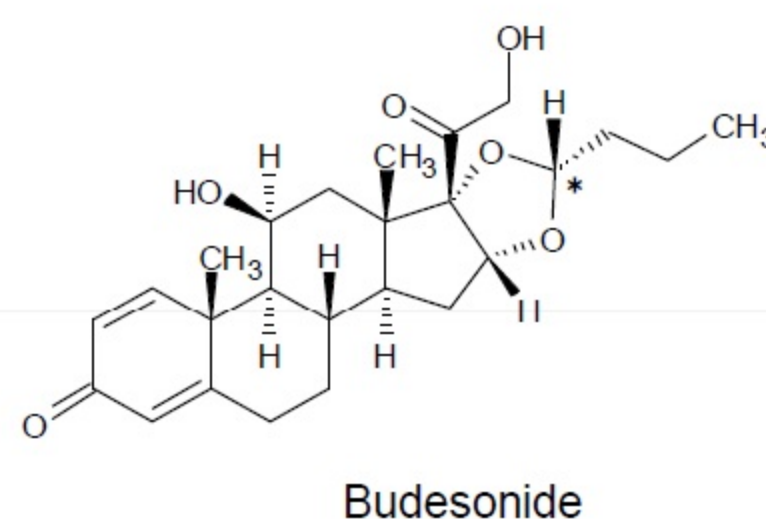
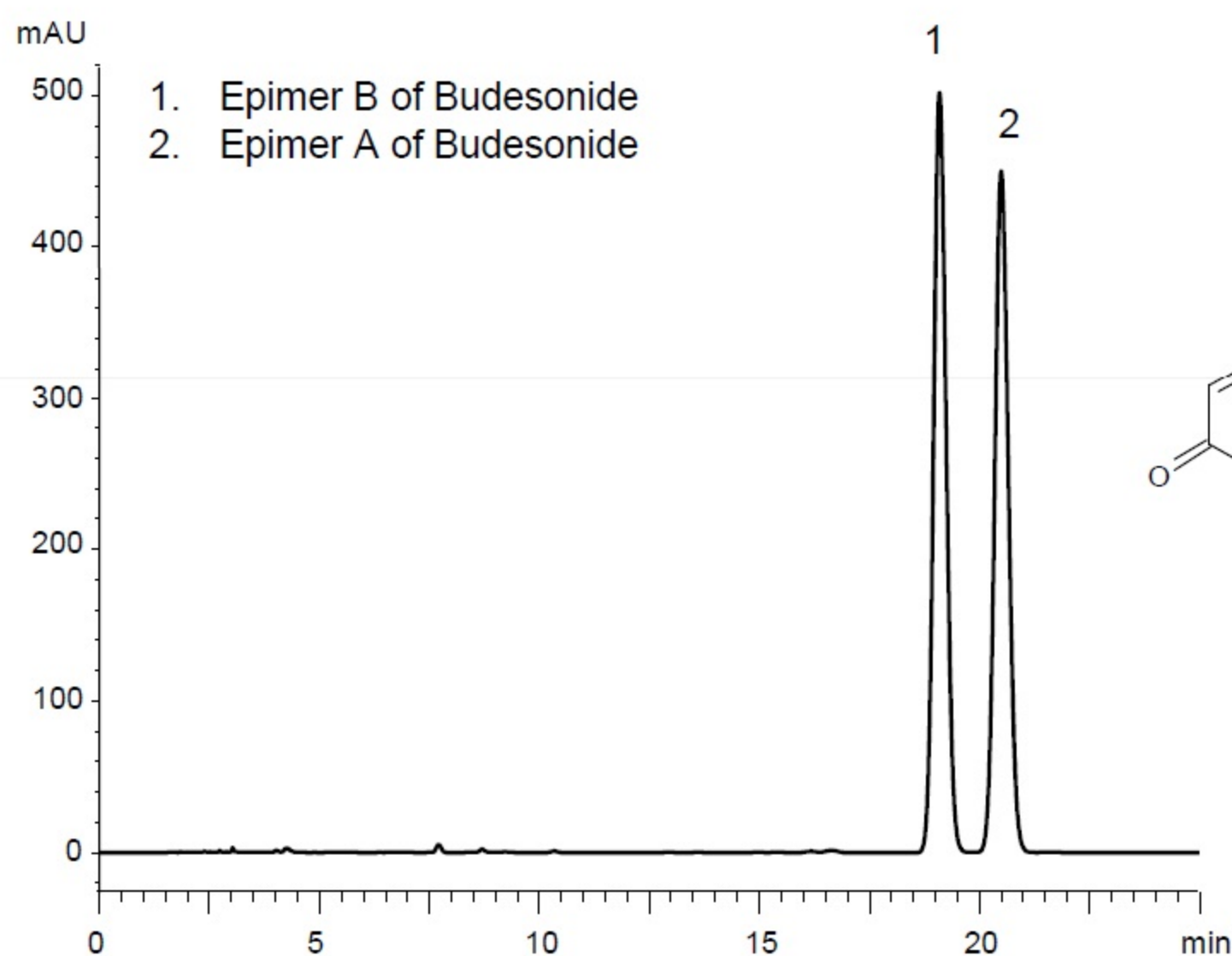
ブデソニド (日本薬局方収載原案記載条件)

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 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 μ L

(The draft for the Japanese Pharmacopoeia; Assay)

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