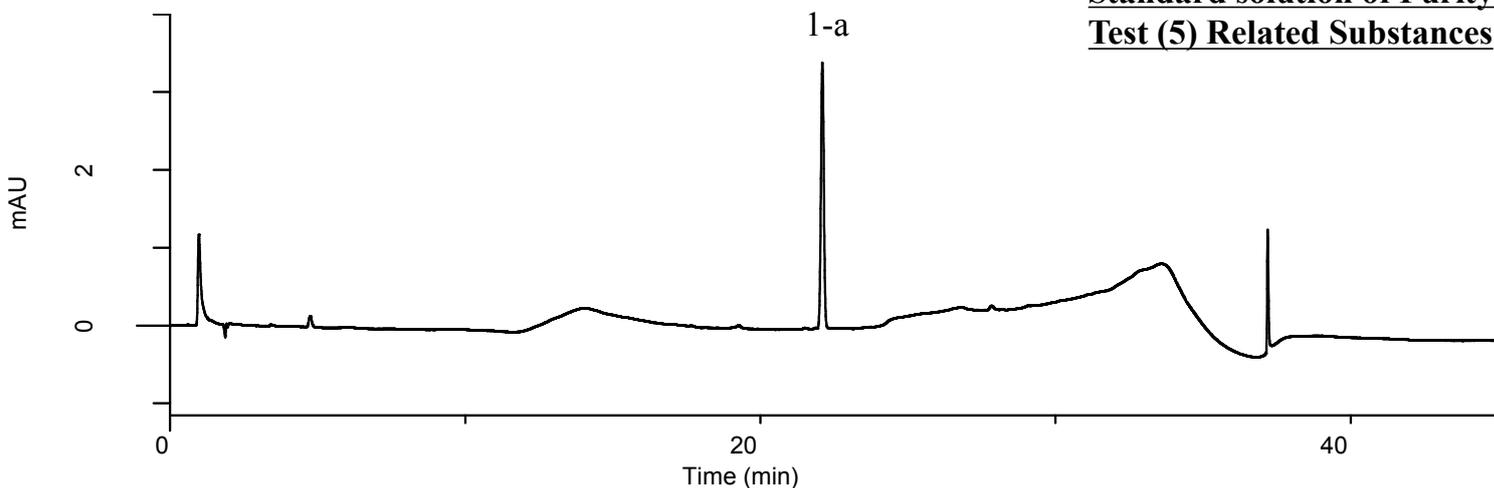


## Analysis of Dexamethasone Sodium Phosphate

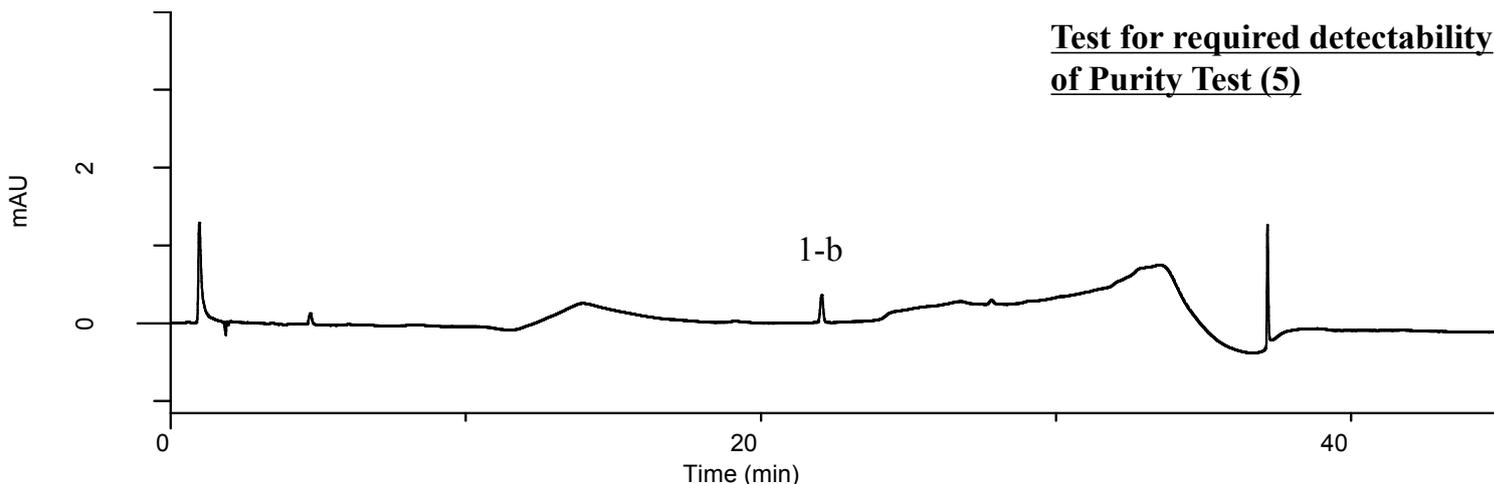
(Under the Condition of the draft for the Japanese Pharmacopoeia,  
Dexamethasone Sodium Phosphate)

Data No. LB526-0812

Standard solution of Purity  
Test (5) Related Substances



Test for required detectability  
of Purity Test (5)



### Conditions

**System** : GL7700 HPLC system  
**Column** : Inertsil ODS-4 (5 μm, 150 x 3.9 mm I.D.)  
**Column Cat. No.** : 5020-87023  
**Eluent** : A) CH<sub>3</sub>CN  
 B) Buffer\*

Time(min)	A(vo%)	B(vo%)
0	12	88
8	20	80
15	20	80
30	40	60
31	12	88
45	12	88

**Flow rate** : 1.0 mL/min  
**Col. Temp.** : 25 °C  
**Detection** : UV 242 nm (UV7750 UV Detector)  
**Injection Vol.** : 15 μL  
**Sample** : Standard

\* Dissolve 7.8 g of NaH<sub>2</sub>PO<sub>4</sub> and 1.88 g of sodium 1-hexanesulfonate in 1900 mL of water. Adjust to pH 3.0 with H<sub>3</sub>PO<sub>4</sub>, and make up to 2000 mL by adding water.

### Analyte:

1. Dexamethasone Phosphate  
 4 mg/L (1-a) or 0.4 mg/L (1-b)

Theoretical plates (1-a) : 22,475 (≥ 10,000)  
 Symmetry factor (1-a) : 1.01 (≤ 2.0)

The peak area ratio of 1-b to 1-a (%)  
 : (7 ≤) 10.1 (≤ 13)

RSD of the peak area of 1-a (n=6)  
 : 0.29 (≤ 1.0)