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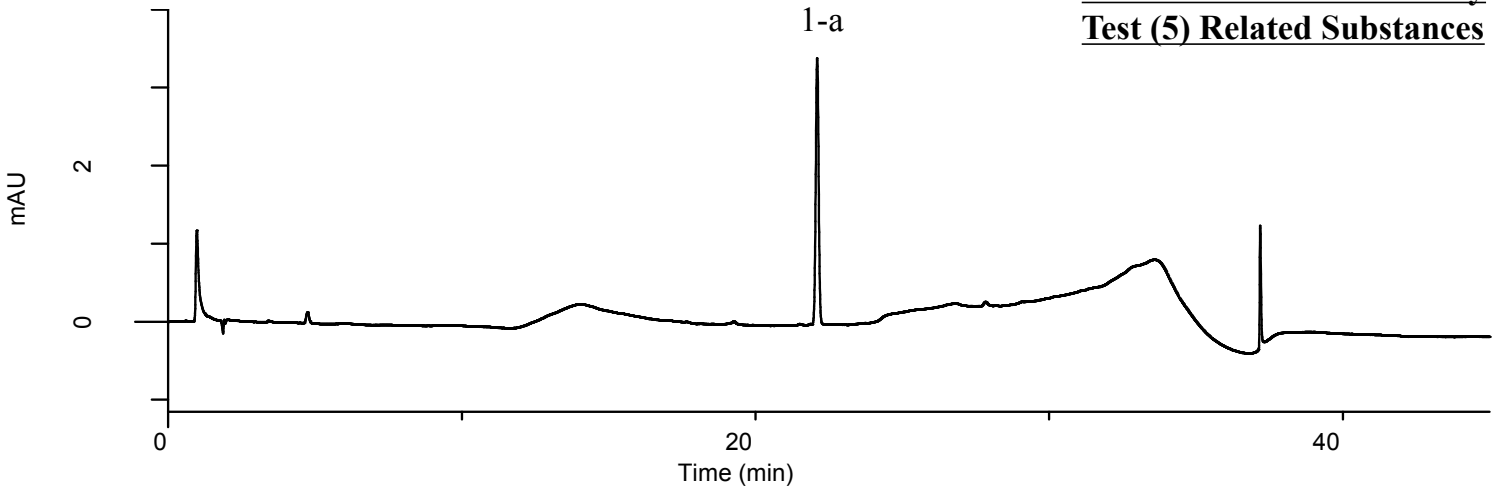
Inertsil® Applications

Analysis of Dexamethasone Sodium Phosphate

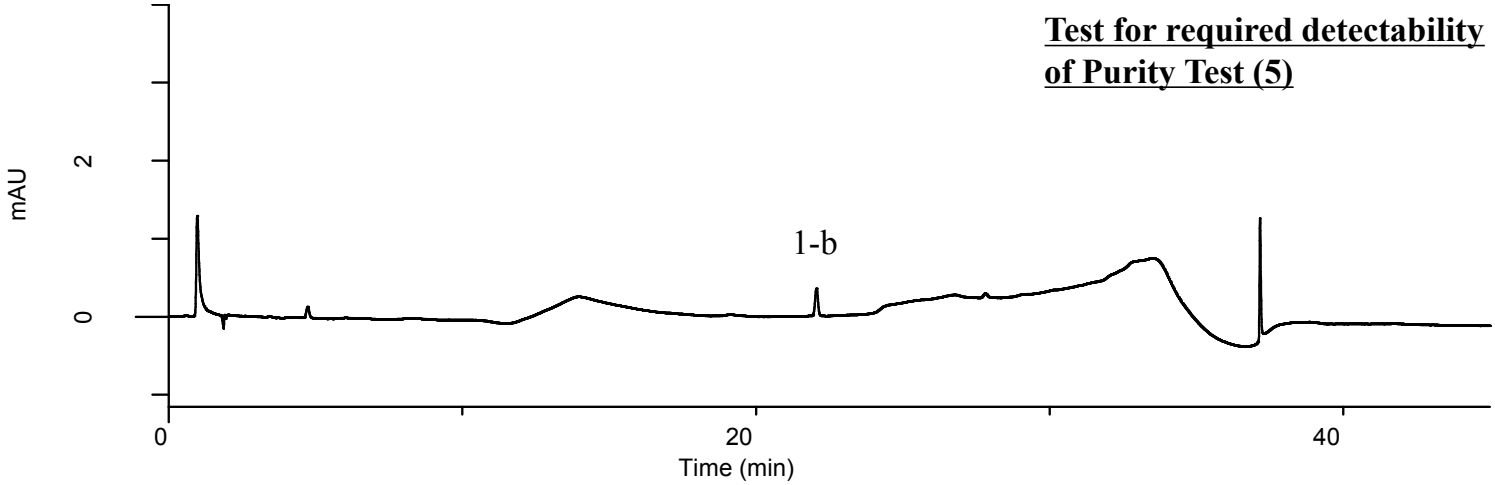
(Under the Condition of the draft for the Japanese Pharmacopoeia, Dexamethasone Sodium Phosphate)

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_3CN
B) Buffer*

Time(min)	A(vol%)	B(vol%)
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 ℃
Detection : UV 242 nm (UV7750 UV Detector)
Injection Vol. : 15 μL
Sample : Standard

* Disolve 7.8 g of NaH_2PO_4 and 1.88 g of sodium 1-hexanesulfonate in 1900 mL of water. Adjust to pH 3.0 with H_3PO_4, 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)

GL Sciences