

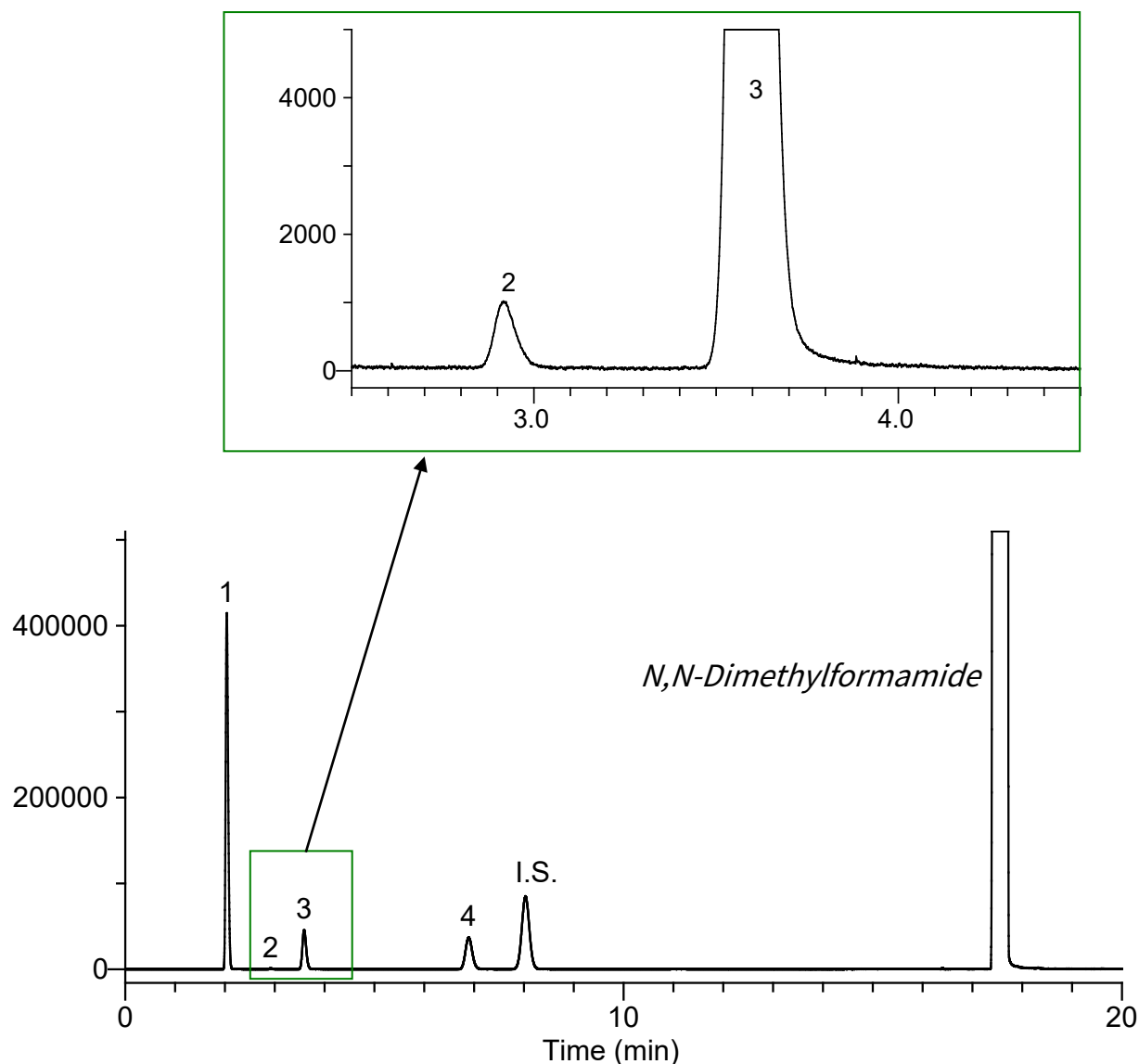
Purity Test of Epirubicin Hydrochloride with Reference to the Japanese Pharmacopoeia

Epirubicin Hydrochloride is a drug used in the treatment of various cancers. It is particularly important in the treatment of breast cancer.

A purity test was made for acetone, methanol, ethanol, 1-propanol, 1,4-dioxane (internal standard).

The standard was diluted with N,N-dimethylformamide. The resolution of acetone and 1,4-dioxane (internal standard) and the relative standard deviation of acetone, methanol, ethanol, and 1-propanol were calculated; excellent results were obtained.

Example: Measurement of standard



Analyte :

1. Acetone	1.25 $\mu\text{L/mL}$	4. 1-Propanol	0.32 $\mu\text{L/mL}$
2. Methanol	0.0068 $\mu\text{L/mL}$	I.S. 1,4-Dioxane	1.00 $\mu\text{L/mL}$
3. Ethanol	0.30 $\mu\text{L/mL}$		

* The resolution between Acetone and 1,4-Dioxane is 32.1.

Conditions

System	: GC - FID
Column	: InertCap WAX 0.53 mm I.D. × 30 m df = 1.00 μm
Col. Temp.	: 40 °C (11 min hold) - 10 °C/min - 90 °C - 50 °C/min - 130 °C (30 min hold)
Carrier Gas	: He 25 kPa
Injection	: Split 1:15 120 °C
Detection	: FID Range 10 ⁰ 150 °C
Sample Size	: Analyte in N,N-Dimethylformamide 1.0 μL

Relative standard deviation

Area repeatability (*n* = 6)

	Acetone	Methanol	Ethanol	1-Propanol	1,4-Dioxane (I.S.)
1 st	1398456	4260	241586	351661	899222
2 nd	1396842	4272	241729	352627	901190
3 rd	1394689	4300	240834	351744	897514
4 th	1393229	4209	240332	350138	895809
5 th	1385342	4111	239718	349265	891042
6 th	1383033	4085	239039	349311	890195
Ave.	1391932	4206	240540	350791	895829
SD	6302	89	1055	1413	4422
RSD (%)	0.5	2.1	0.4	0.4	0.5

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