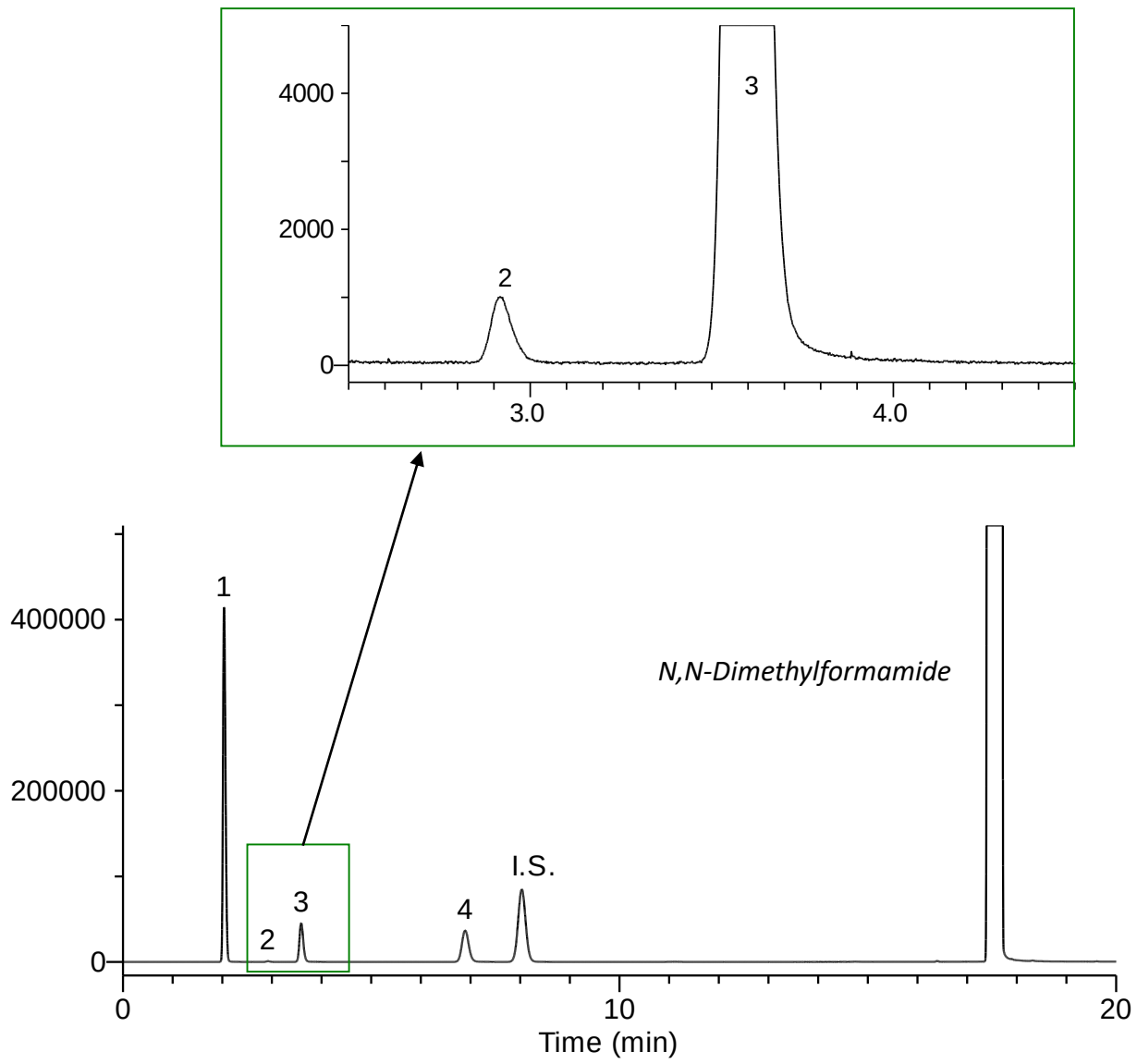
Purity Test of Epirubicin Hydrochloride with Reference to the Japanese Pharmacopoeia

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 µL/mL	4. 1-Propanol	0.32 µL/mL
2. Methanol	0.0068 µL/mL	I.S. 1,4-Dioxane	1.00 µL/mL
3. Ethanol	0.30µL/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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