AR226_3301

Accession No.	C03-3619
Study No.	33619

Study Report

Analysis of Impurities in [redacted]
(non-GLP study)

October 14, 2003

Chemicals Evaluation and Research Institute, Japan
--Kurume Laboratory--

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Title:	Analysis of Impurities in [redacted] (non-GLP study)
Commissioned by:	DuPont KK 1-8-1 Shimo-meguro, Meguro-ku, Tokyo 153-0064
Testing Facility:	Kurume Laboratory Chemicals Evaluation and Research Institute, Japan (CERI) 19-14 Chuo-machi, Kurume-shi, Fukuoka Prefecture 830-0023
Purpose of Study:	To determine the levels of impurities present in [redacted]
Schedule:	Study began on: July 28, 2003 Test date: July 28, 2003 Study completed on: October 14, 2003
Personnel:	Coordinator: Yasuko MATSUNOBE,* Testing Section 1 Researcher: Tomohiko YOSHIDA

Approval of Study Report: [signed] Yasuko MATSUNOBE
Study Coordinator
October 14, 2003

* Translator's Note: Spellings of personal names may need to be verified.

Summary

Title of Study

Analysis of Impurities in [redacted] (non-GLP study)

Study Conditions

(1) Concentration of sample furnished: 10.0 g/L
(2) Analysis: Analysis of impurities by high-performance liquid chromatography (HPLC)

Test Results

Content of Sample Furnished:

Test substance:	97.80%
Impurity A	0.38%
Impurity B	1.82%

(The impurities were labeled "A" and "B" in the order of increasing retention time on the HPLC chromatogram.)

1. Test Substance

Name: [redacted]

Lot No.: [redacted]

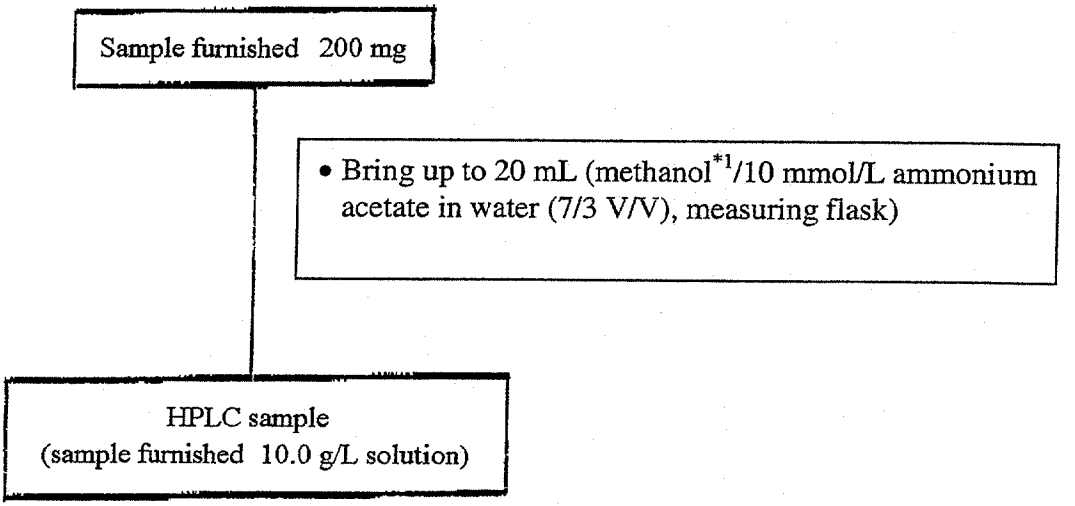
2. Conducting the Study

High-performance liquid chromatography (HPLC) samples prepared as described in section 2.1 below (10.0g /L solutions of the sample furnished) were analyzed under the conditions in section 2.2 on the next page. The test substance and impurity contents within the sample were computed from the surface areas of the test substance and impurity peaks on the resulting HPLC chromatogram.

2.1 Preparation of Samples for Analysis

HPLC samples for analyzing the sample furnished were prepared by carrying out the operations indicated in the flow scheme below.

Flow Scheme



*1: Methanol solution containing 10 mmol/L ammonium acetate

2.2 HPLC Analysis of Samples Furnished

The HPLC samples prepared in section 2.1 above were analyzed based on the following conditions (see Fig. 1).

Apparatus:	Liquid chromatograph-mass spectrometer
Pump:	LC-10ADvp (Shimadzu Corp.)
Detector:	RID-10A (Shimadzu Corp.)
Column oven:	CT0-10ACvp (Shimadzu Corp.)
Degasser:	DGU-12AM (Shimadzu Corp.)
Column:	L-column ODS (CERI); 15 cm × 4.6 mm I.D.
Column temperature:	40°C
Eluting solvent:	Methanol[*1]/10 mmol/L ammonium acetate in water (7/3 V/V)
Flow rate:	1.0 mL/min
Injection rate:	10 μL
Detector output:	1×10^{-4} RIU/V

2.3 Calculation of Test Substance and Impurity Contents

The contents of the test substance and the impurities were calculated based on the following formula. The third decimal place was rounded off, and the results indicated to the second decimal place.

$$\text{Content (\%)} = \frac{AREA(s)}{AREA(t)} \times 100$$

where AREA (s): Surface area of a peak for a test substance or impurity detected on HPLC chromatogram (μV·sec)

AREA (t): Sum of all peak surface areas for test substances and impurities detected on HPLC chromatogram (μV·sec)

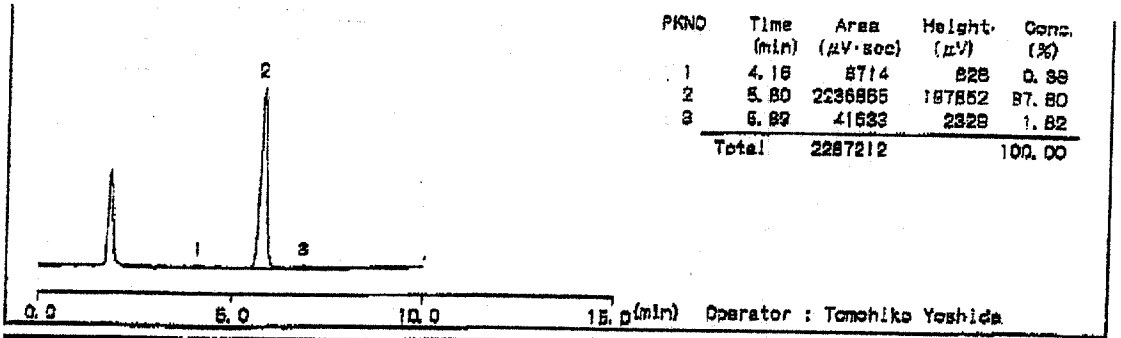
3. Test Results

The results of analysis are given below.

	Retention time (minutes)	Peak surface area (μV·sec)	Content (%)	Figure
Test substance	5.80	2236865	97.80	1
Impurity A*2	4.16	8714	0.38	
Impurity B*2	6.89	41633	1.82	
Total	--	2287212	100	

*2: The impurities were labeled "A" and "B" in the order of increasing retention time on the HPLC chromatogram.

In addition to the above impurities, there was believed to be also some ethanol remaining in the samples furnished. However, a separately conducted study [redacted] confirmed that no residual ethanol was present. Therefore, it appears that the only impurities present in the sample furnished were the two types detected in the present study.

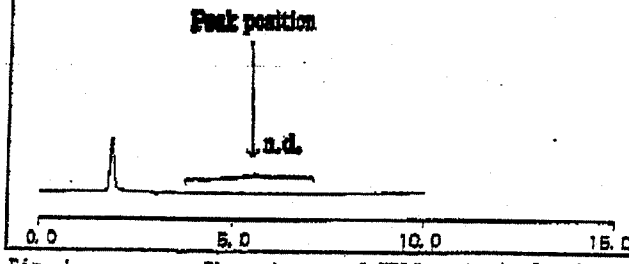


PKNO	Time (min)	Area (μV·sec)	Height (μV)	Conc. (%)
1	4.16	8714	828	0.38
2	5.80	2236865	187852	97.80
3	6.89	41633	2328	1.82
Total		2287212		100.00

Operator : Tomohiko Yoshida

Solvent blank

Operating date : Jul. 28, 2003



PKNO	Time (min)	Area (μV·sec)	Height (μV)	Conc. (%)
Total		0		0.00

Operator : Tomohiko Yoshida

Fig. 1 Chromatogram of HPLC analysis for impurity.

Date : Jul. 28, 2003 Name : T. Yoshida

Translation: Language Services
F. Metreaud
December 3, 2003