

Annex C: Boiler Operator Course Details

Steam Engine Driver Course

Grade 2

Boiler Attendant- Examination by interview only.

Course Start Date:

Tutor: Ing. Nicholas Bellizzi

Course Details

The following topics will be taught

1. Temperature, pressure, flowmeters and steam – Basic Concepts
Energy considerations, the concept of using steam
2. Combustion Chemistry- air to fuel ratio, products of combustion, stack evaluation
Fuel chemistry and properties. Burner types and configurations
3. Boiler Construction- packaged fire tube and water tube boilers, main pieces of
equipment. Structural problems and possible damages
4. Boiler Fittings
5. Operations and Logging
6. Maintenance and Testing Requirements
7. Risk Assessment and Boiler Controls. They degree of automation
8. Water Requirements. Basic principles

Annex D: Amino Chemicals GMP Training Response

Amino Chemicals,
A61 Industrial Estate,
Marsa
August 2007

Amino In-House Training Course

The training course performed in house is divided into two sections, namely GMP training and safety training. The training is provided by our qualified production manager.

All employees involved with the production and quality control of API's and in plant maintenance are given the GMP in-house training course. The aim of the course is to explain all of the Standard Operating Procedures, (SOP's) currently in-force throughout the company and the GMP Rules in order to produce products to international pharmaceutical standard.

Each employee is helped to understand the SOP, where to find such documents and how to execute them in order to safeguard the company.

Regarding safety training, each employee is taught the following aspects of basic safety:

- Risk label identification
- Chemical and physical properties of chemicals
- Appropriate handling of chemicals
- Proper use of safety and personal protective equipment.
- Use of fire fighting equipment
- Emergency evacuation plan- execution.

Apart from the in-house training, some personnel are sent for specialized courses such as fire-fighting and first aid, outside our premises. All training is documented accordingly.

Annex D1a:

Atmospheric Emissions from the Scrubber-Dichloromethane



Malta, 24th October 2007

To Whom It May Concern:

The Company Amino Chemicals declares that Dichloromethane is used only for the synthesis of Perindopril Erbumine; the production method for the above synthesis is not a property of Amino Chemicals. The product is manufactured on a tool manufacturing bases for our client Krka of Novo Mesto, Slovenia

Yours truly,

Amino Chemicals Ltd

Plant Manager

A. Sommei

A handwritten signature in blue ink, appearing to be "A. Sommei", with a long horizontal flourish extending to the right.



Qualification of solvents

Definition

“Volatile solvent”: if vapour pressure > 0.01Kpa @ 293.15°C

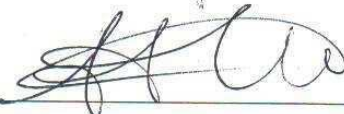
Materials name	Risk phrase	Vapour pressure kpa @ 293.15°K
N,N-Dimethylformamide	R-61	0.36
N,N-Dimethylformamide	R-61	0.20
Dichloromethane	R-40	46.4
Formaldehyde	R-40	0.17

All these solvents are organic volatile compounds

ATMOSPHERIC EMISSIONS FROM THE SCRUBBER

DICHLOROMETHANE

Written by:

 15/10/07

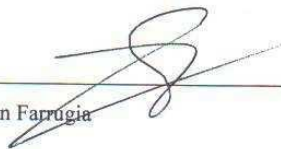
QC Manager Anthony Charles Grech

Reviewed by:

 16-10-07

Plant Manager Antonio Sommei

Approved by:

 16-10-07

QA Manager Jonathan Farrugia

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1.1 Introduction

The method used for the analysis of the atmospheric emissions are the one stated by the NIOSH guidelines (National Institute for Occupational Safety and Health), issued on the 15th August 1994.

The solvent (dichloromethane) was analyzed for since at that moment in time this was being used in the production site for the manufacturing of the active ingredients perindopril erbumine.

The sampling was taken from scrubber Tower AB203 and a diagram of the latter can be seen in Appendix A. The flow of exhaust from the chimney is 2000m³/hr

The sampling was carried out using Drager Sampling Tube 67 28831 (Activated Charcoal Tube Type G). The sampling was performed on 2nd October 2007. Four samples were taken at respective intervals during the day as shown in the table below.

Sample ID	Sampling Time	Sampling Duration
1	9.30	12 mins
2	9.45	12 mins
3	15.00	12 mins
4	15.15	12 mins

The sampling tube contains two layers: one sampling layer and one following layer. During sampling, the substances to be measured are adsorbed by the sampling layer. The following layer verifies whether the adsorption capacity of the sampling layer is adequate.

2.1 Sampling

Sampler: Drager Sampling Tube (Activated Charcoal Tube Type G)

Flow Rate: 0.2l/min

Volume: 2.5 litres

Both tips of the sample tube are broken immediately prior to sampling. The sample tube is inserted tightly into the pump; with arrow on sample tube pointing towards the pump showing the direction of the flow. 2.5 litres of air are sucked through the sample tube maintaining a flow of the pump of 0.2litres/min, thus enabling the activated carbon to adsorb well any solvents present in the air being analysed. Following the sampling the tubes are immediately sealed using polyethylene caps.

3.1 Measurement

The analysis of the samples are carried out using a GC instrument using the following method:

GC Instrument:	Varian 3900
Injector Temperature:	250°C
Detector temperature:	250°C
Column Flow:	2.0ml/min
Column Program:	40°C for 10 minutes
Makeup Flow (Helium):	25ml/min
Hydrogen Flow:	30ml/min
Air Flow:	300ml/min
Solvent Used:	CS ₂

3.1.1 Calibration Curve:

The calibration curve is performed by preparing standards of the solvents under investigation (dichloromethane) of the following concentrations; 0.13mg/ml, 0.52mg/ml, 2.6mg/ml, 5.2mg/ml, 13mg/ml and 26mg/ml.

The above solutions are performed using the following dilutions:

Solution 1

650mg of each solvent in 25ml flask and brought to volume with CS₂ (Sol 1). (26mg/ml)

Solution 2

5ml of Sol 1 in 10ml flask and brought to volume with CS₂ (Sol 2). (13mg/ml)

Solution 3

2ml of Sol 1 in 10ml flask and brought to volume with CS₂ (Sol 3). (5.2mg/ml)

Solution 4

1ml of Sol 1 in 10ml flask and brought to volume with CS₂ (Sol 4). (2.6mg/ml)

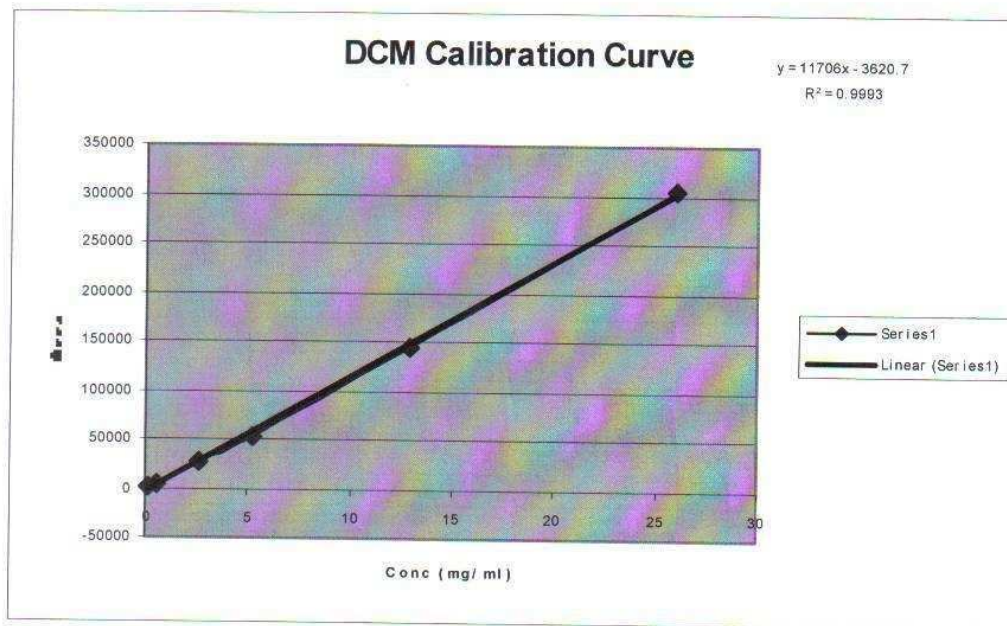
Solution 5

0.2ml of Sol 1 in 10ml flask and brought to volume with CS₂ (Sol 5). (0.52mg/ml)

Solution 6

0.05ml of Sol 1 in 10ml flask and brought to volume with CS₂ (Sol 6). (0.13mg/ml)

DCM							
Conc mg/ml	Standard 1	Standard 2	Standard 3	Sum	Average	STD	RSD
0.13	763	766	797	2326	775	19	2.4
0.52	4301	4291	4353	12945	4315	33	0.8
2.6	25468	25687	30575	81730	27243	2887	10.6
5.2	52714	51558	54012	158284	52761	1228	2.3
13	138638	161224	137002	436864	145621	13537	9.3
26	292997	331993	284015	909005	303002	25506	8.4



3.1.2 Recovery of the Solvents on the Activated Carbon

Known quantities of the solvent was spiked onto the front part of the sampling tube. The tubes were sealed by the polyethylene caps and left to stand for one night. The back part of the sampling tube was discarded, while the front part was placed in a vial and sealed. 3ml of CS₂ were added to the carbon and left to stand for 30 minutes with occasional stirring. The solution was then placed in a GC vial and injected.

DCM	Standard 1	Standard 2	Standard 3	Sum	Average	STD	RSD
0.52mg/ml	4939	4865	5867	15671	5224	558.37	10.7
13mg/ml	169140	171824	169944	510908	170303	1377.48	0.8

The recovery of the solvent was calculated using the area of their respective standard concentration.

	mg of solvent spiked	mg of solvent recovered	Desorption efficiency
DCM	1.56	1.89	121.1
	39	45.61	116.9

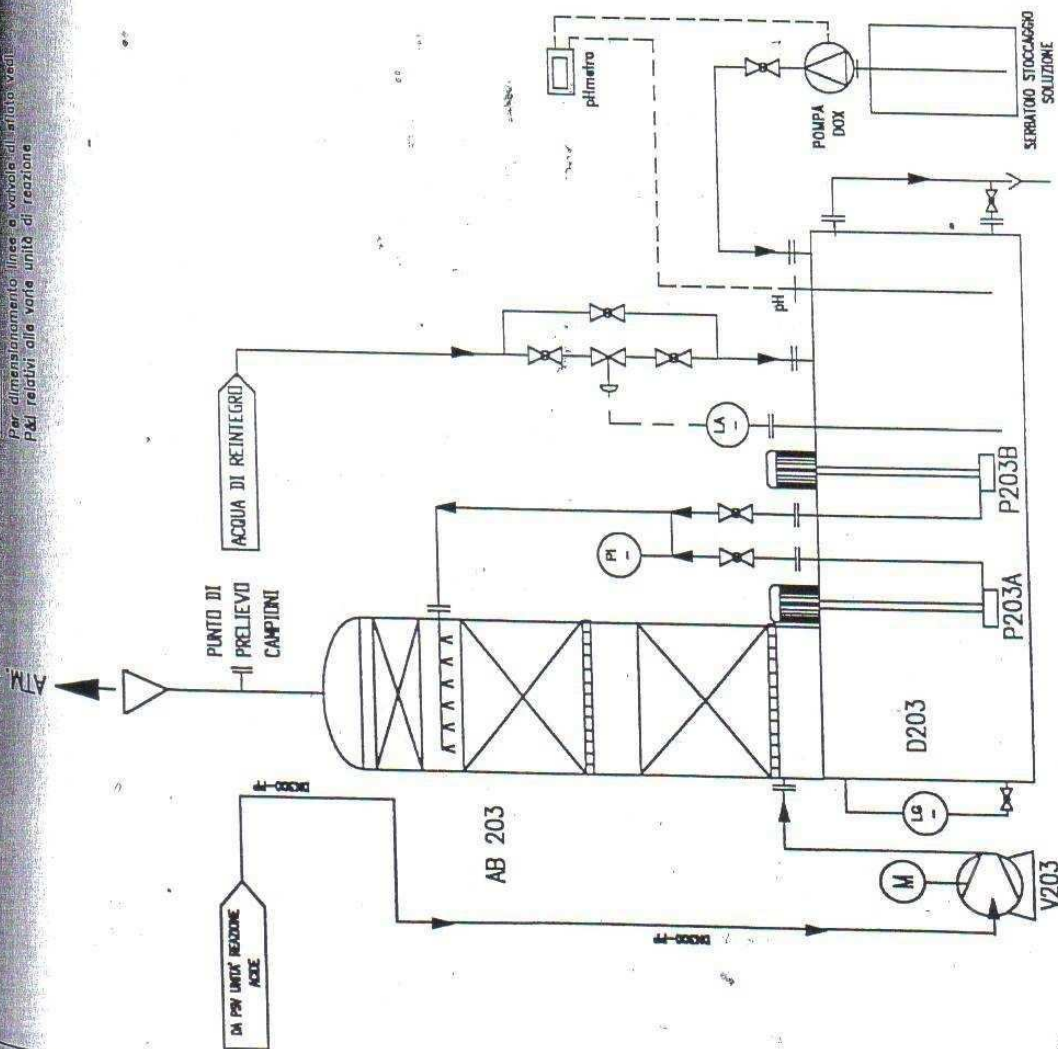
3.1.3 Analysis of sampling tubes from the scrubbers


	DCM	Mg of DCM/2.5ltr
Sample 1 Back	N.D.	N.D.
Sample 1 Front	N.D.	N.D.
Sample 2 Back	N.D.	N.D.
Sample 2 Front	N.D.	N.D.
Sample 3 Back	N.D.	N.D.
Sample 3 Front	N.D.	N.D.
Sample 4 Back	N.D.	N.D.
Sample 4 Front	N.D.	N.D.

Comments

The analysis show that dichloromethane present in the emissions are less then those expressed in the calibration curve (0.13mg/ml) which are equivalent to 37ppm.

Appendix A – Diagram of the Scrubber

[illegible]

p
1	03-07-03	SITUAZIONE AL 03-07-003	R.A.	J.S.	.
0	07-06-83	PRIMA EMISSIONE	V.D.		.
REV.	DATA	DESCRIZIONE	IBBEGN.	CONTR.	APPROV.
 <p style="text-align: center;">AMINO CHEMICALS Ltd. AB1, INDUSTRIAL ESTATE MAIRSEA LOD ODE, MALTA</p>					
		<p style="text-align: center;">AB-203</p> <p style="text-align: center;">SCHEMA DI IMPIANTO</p>			
		<p style="text-align: center;">IMPIANTO DI ASPIRAZIONE E ABBATTIMENTO EFFLUENTI GASSOSI DA VALVOLE SOVRAPPRESSIONE UNITA' REAZIONE ACIDE</p>			
		<p>N° AVI-PD-AB203/BU</p>			

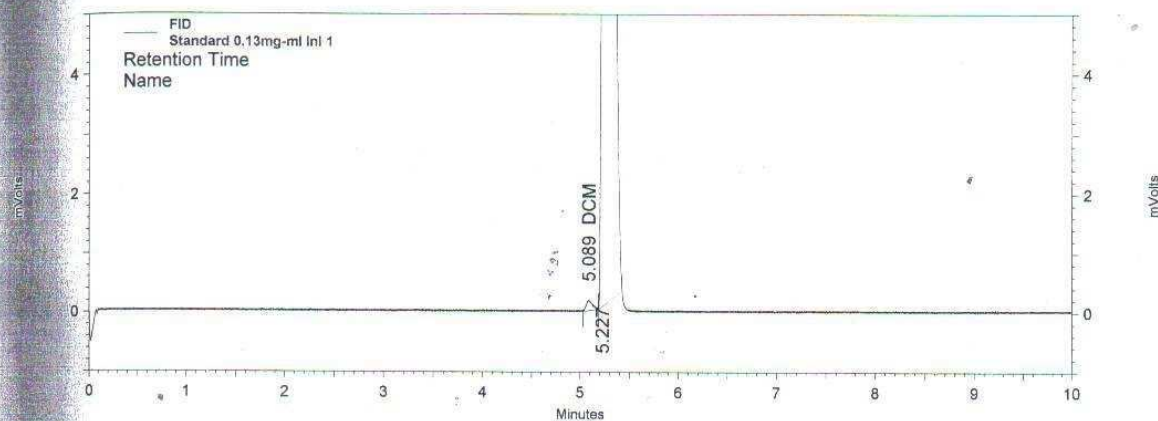
Appendix B – Chromatograms for Calibration Curve



Amino Chemicals

Quality Control

Sample ID: Standard 0.13mg-ml Inl 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve\Standard 0.13mg-ml Inl 1 08-10-2007 14-16-01.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 2
Run time: 08/10/2007 14:17:48
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.089	763	0.678	DCM	0.00
2	5.227	111811	99.322		0.83
Totals		112574	100.000		

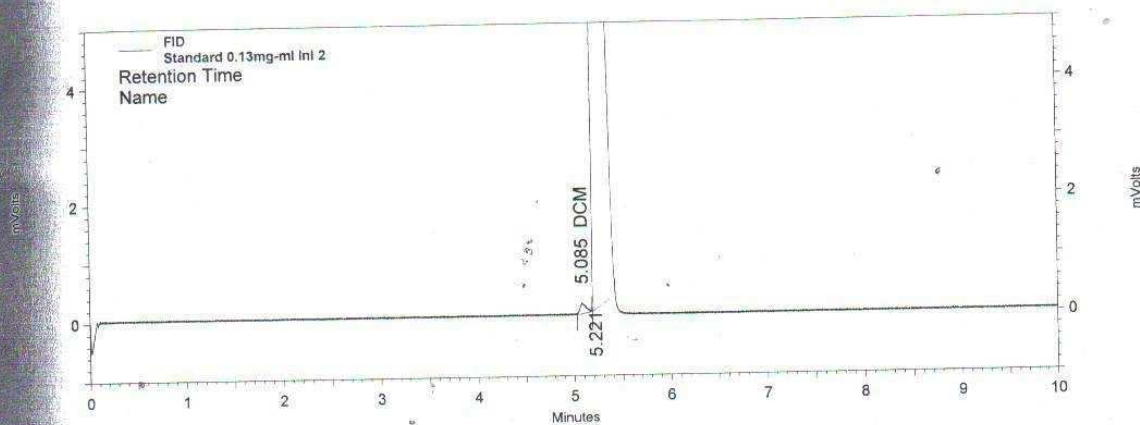
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Amino Chemicals

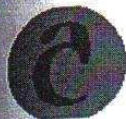
Quality Control

Sample ID: Standard 0.13mg-ml Inl 2
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Curve\Standard 0.13mg-ml Inl 2 08-10-2007 14-28-04.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 2
Run time: 08/10/2007 14:30:53
Operator: Anthony (VPDomain\Anthony)



FID Results		Retention Time	Area	Area Percent	Name	Resolution (USP)
Pk #						
1		5.085	766	0.655	DCM	0.00
2		5.221	116231	99.345		0.80
Totals			116997	100.000		

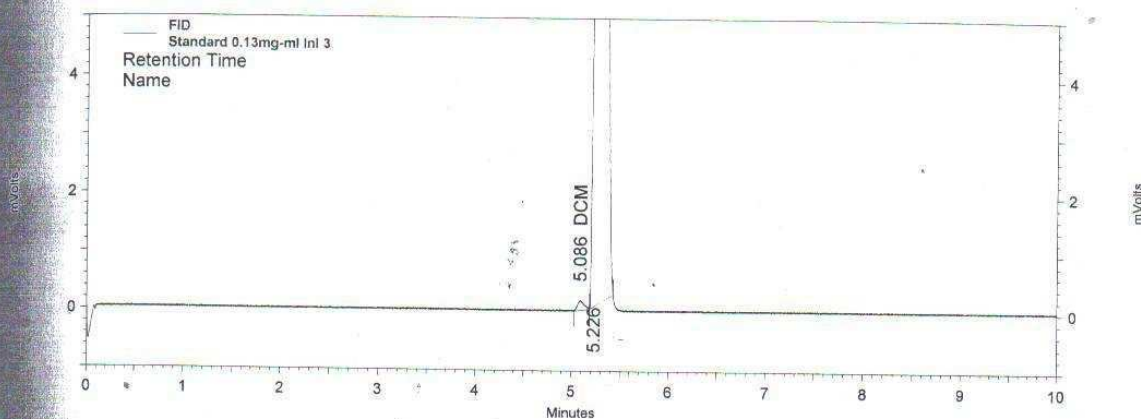
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Amino Chemicals

Quality Control

Sample ID: Standard 0.13mg-ml Inl 3
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Curve\Standard 0.13mg-ml Inl 3 08-10-2007 14-40-57.dat
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Volume inj: 1 µl
Vial: 2
Run time: 08/10/2007 14:43:49
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.086	797	0.709	DCM	0.00
2	5.226	111587	99.291		0.82

Totals		112384	100.00 0		
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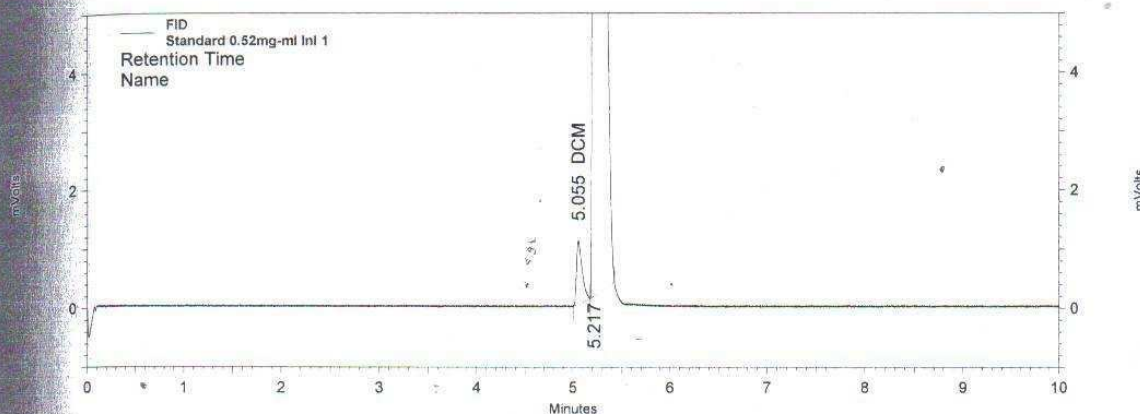
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Amino Chemicals

Quality Control

Sample ID: Standard 0.52mg-ml Inl 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve Standard 0.52mg-ml Inl 1 08-10-2007 14-54-30.dat
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Volume inj: 1 µl
Vial: 3
Run time: 08/10/2007 14:57:30
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.055	4301	3.631	DCM	0.00
2	5.217	114137	96.369		1.01
Totals		118438	100.00 0		

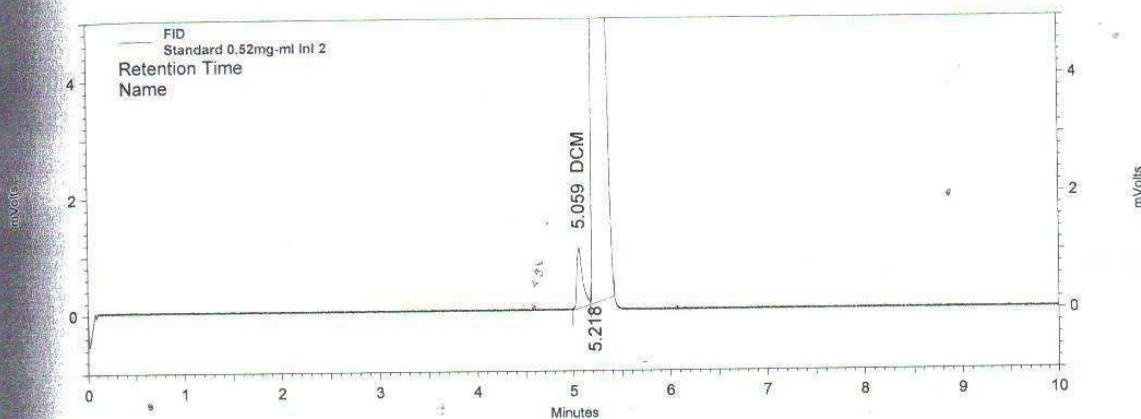
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Amino Chemicals

Quality Control

Sample ID: Standard 0.52mg-ml Inl 2
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Curve\Standard 0.52mg-ml Inl 2 08-10-2007 15-07-38.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 3
Run time: 08/10/2007 15:10:30
Operator: Anthony (VPDomain\Anthony)



FID Results					
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.059	4291	3.688	DCM	0.00
2	5.218	112045	96.312		1.01
Totals		116336	100.000		

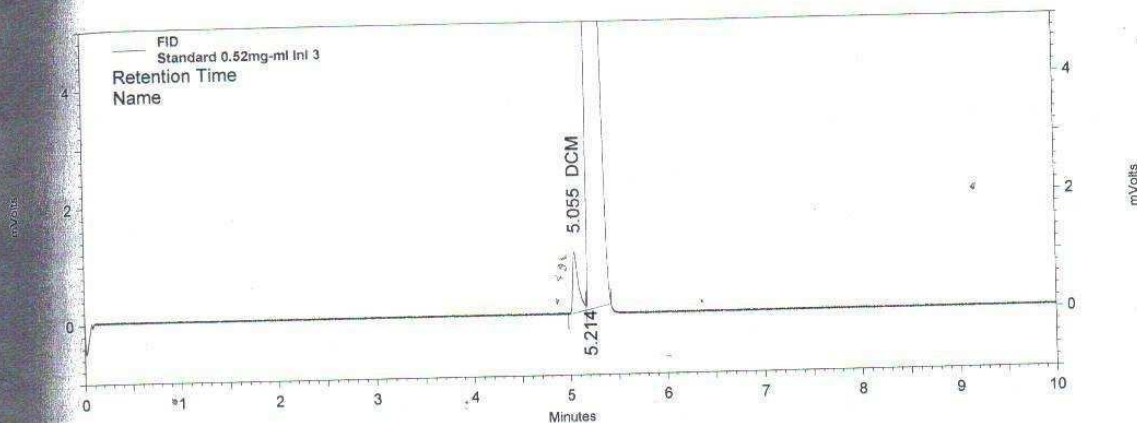
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08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 0.52mg-ml Inl 3
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Curve: Standard 0.52mg-ml Inl 3 08-10-2007 15-20-38.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 3
Run time: 08/10/2007 15:23:33
Operator: Anthony (VPDomain\Anthony)



FID Results Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.055	4353	3.751	DCM	0.00
2	5.214	111706	96.249		1.00

Totals		116059	100.00 0		
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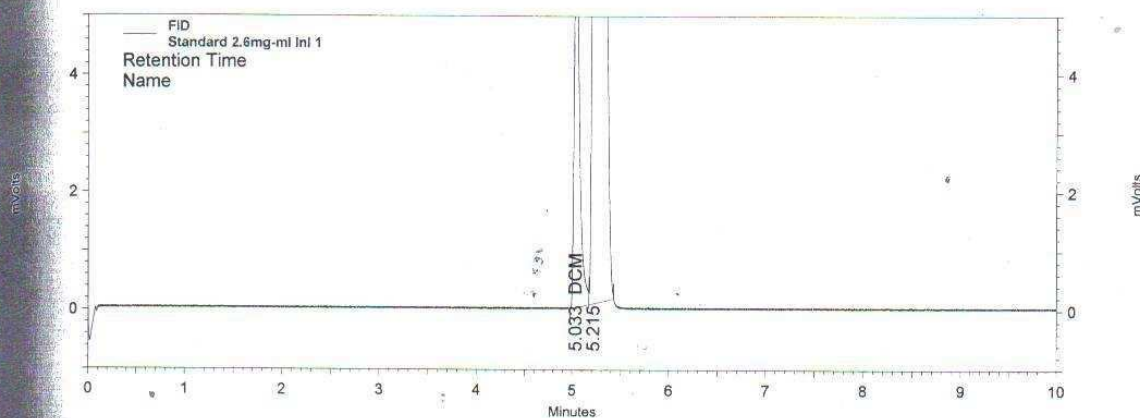
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Amino Chemicals

Quality Control

Sample ID: Standard 2.6mg-ml Inl 1
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Curve\Standard 2.6mg-ml Inl 1 08-10-2007 15-33-44.dat
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Vial: 4
Run time: 08/10/2007 15:36:40
Operator: Anthony (VPDomain\Anthony)

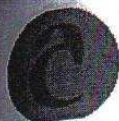


FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.033	25468	18.429	DCM	0.00
2	5.215	112727	81.571		1.20

Totals		138195	100.00 0		
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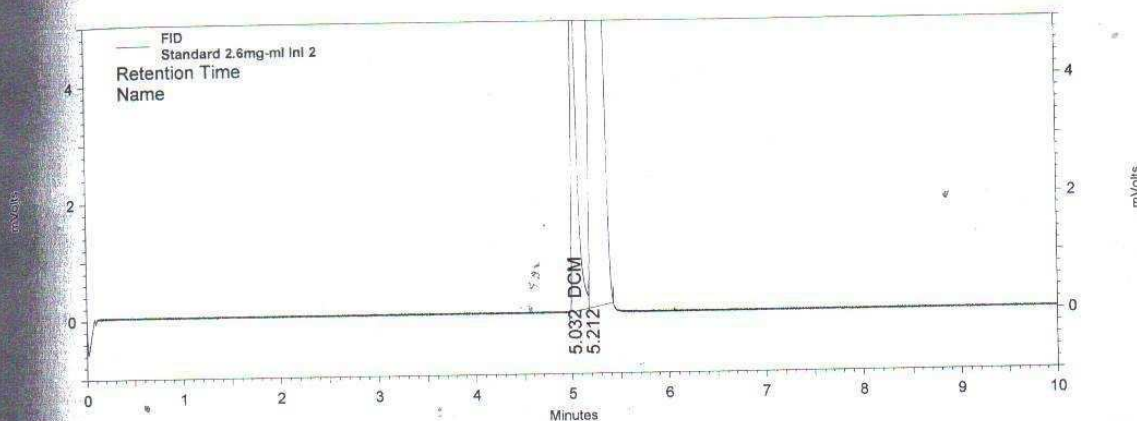
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08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 2.6mg-ml Inl 2
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Curve\Standard 2.6mg-ml Inl 2 08-10-2007 15-46-52.dat
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Volume inj: 1 µl
Vial: 4
Run time: 08/10/2007 15:49:48
Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	5.032	25687	18.456	DCM	0.00	
2	5.212	113495	81.544		1.19	
Totals		139182	100.00 0			

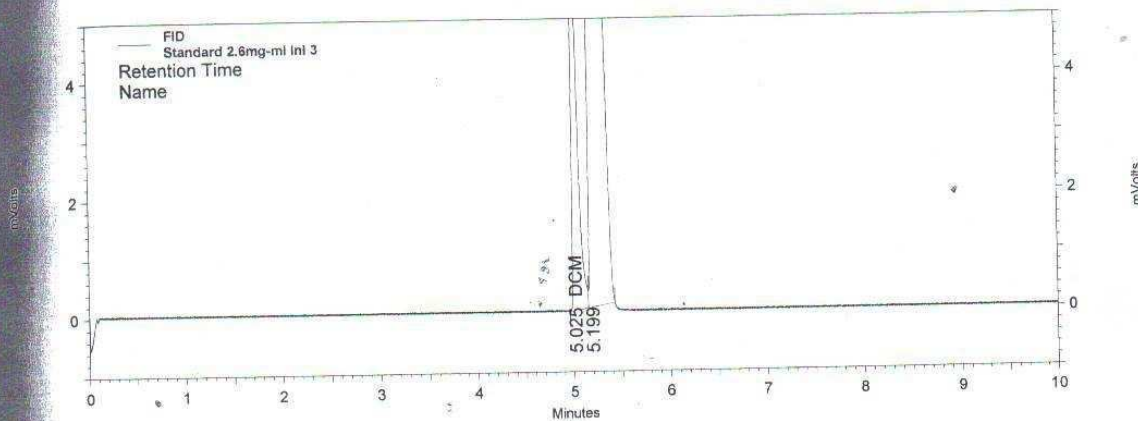
Handwritten signature and date: 09/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 2.6mg-ml Inl 3
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Curve Standard 2.6mg-ml Inl 3 08-10-2007 15-59-54.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 4
Run time: 08/10/2007 16:02:50
Operator: Anthony (VPDomain\Anthony)



FID Results					
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.025	30575	19.511	DCM	0.00
2	5.199	126133	80.489		1.10
Totals		156708	100.00		
			0		

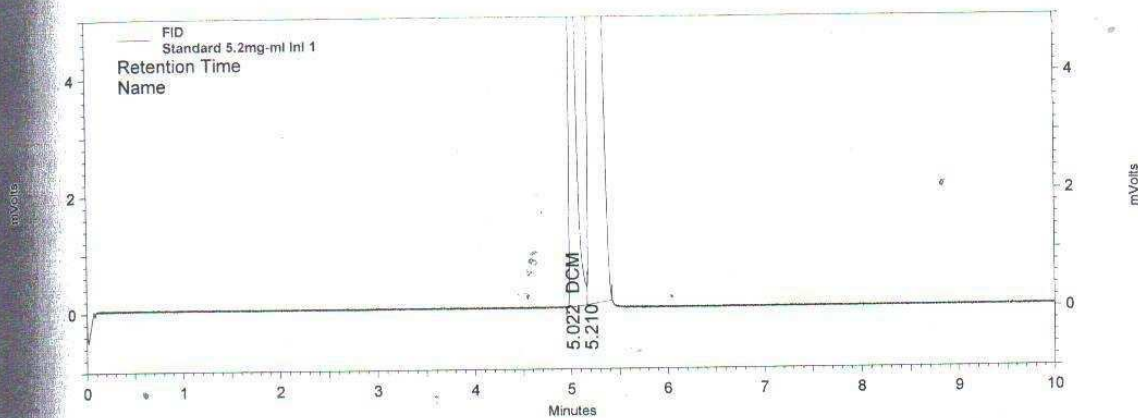
Handwritten signature and date: 08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 5.2mg-ml Inl 1
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Curve\Standard 5.2mg-ml Inl 1 08-10-2007 16-12-57.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 5
Run time: 08/10/2007 16:15:54
Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	5.022	52714	31.906	DCM	0.00	
2	5.210	112502	68.094		1.25	
Totals		165216	100.000			

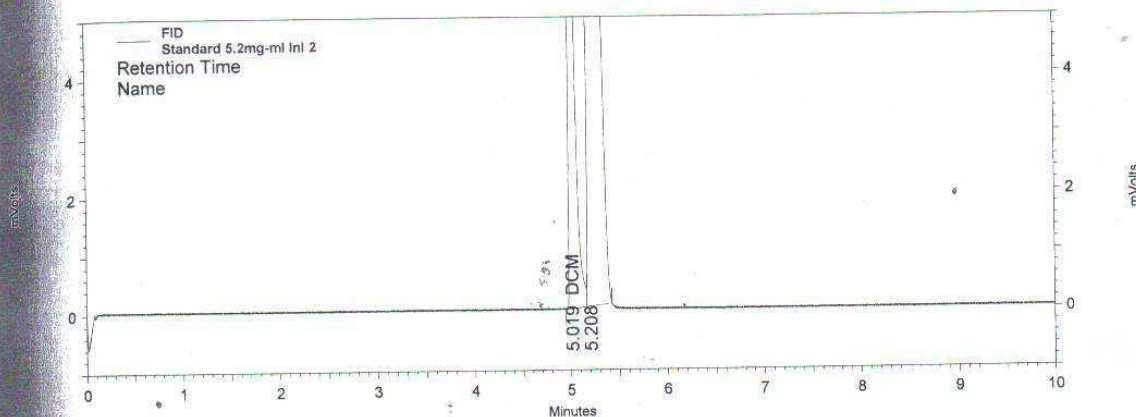
Anthony



Amino Chemicals

Quality Control

Sample ID: Standard 5.2mg-ml Inl 2
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Curve\Standard 5.2mg-ml Inl 2 08-10-2007 16-26-00.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 5
Run time: 08/10/2007 16:28:58
Operator: Anthony (VPDomain\Anthony)



FID Results					
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.019	51558	31.595	DCM	0.00
2	5.208	111628	68.405		1.27
Totals		163186	100.00		0

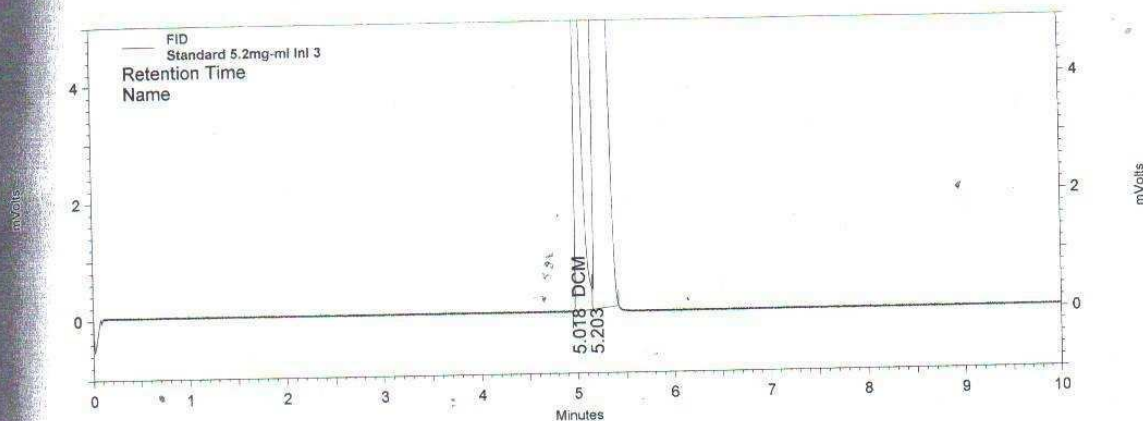
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Amino Chemicals

Quality Control

Sample ID: Standard 5.2mg-ml Inl 3
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve\Standard 5.2mg-ml Inl 3 08-10-2007 16-39-04.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 5
Run time: 08/10/2007 16:42:01
Operator: Anthony (VPDomain\Anthony)



FID Results		Retention Time	Area	Area Percent	Name	Resolution (USP)
Pk #						
1		5.018	54012	32.033	DCM	0.00
2		5.203	114601	67.967		1.23

Totals			168613	100.00 0		
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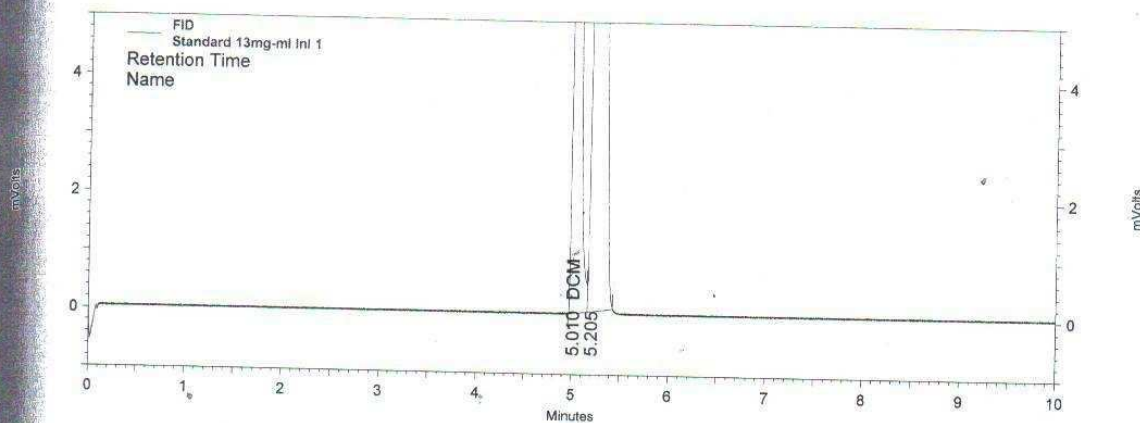
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Amino Chemicals

Quality Control

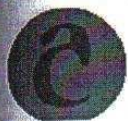
Sample ID: Standard 13mg-ml Inl 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve\Standard 13mg-ml Inl 1 08-10-2007 16-52-09.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 6
Run time: 08/10/2007 16:55:07
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.010	138638	55.170	DCM	0.00
2	5.205	112656	44.830		1.29
Totals		251294	100.00		

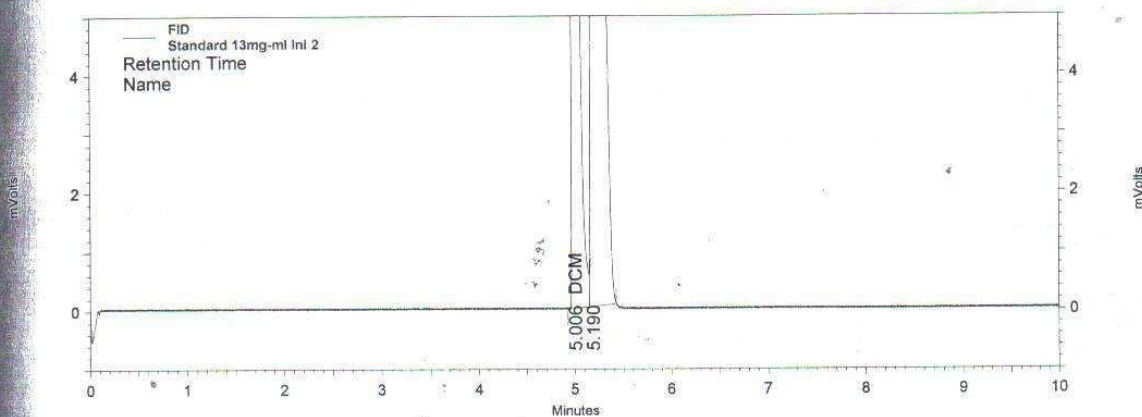
09/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 13mg-ml Inl 2
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Curve\Standard 13mg-ml Inl 2 08-10-2007 17-05-14.dat
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Volume inj: 1 µl
Vial: 6
Run time: 08/10/2007 17:08:14
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.006	161224	56.501	DCM	0.00
2	5.190	124123	43.499		1.18
Totals		285347	100.00 0		

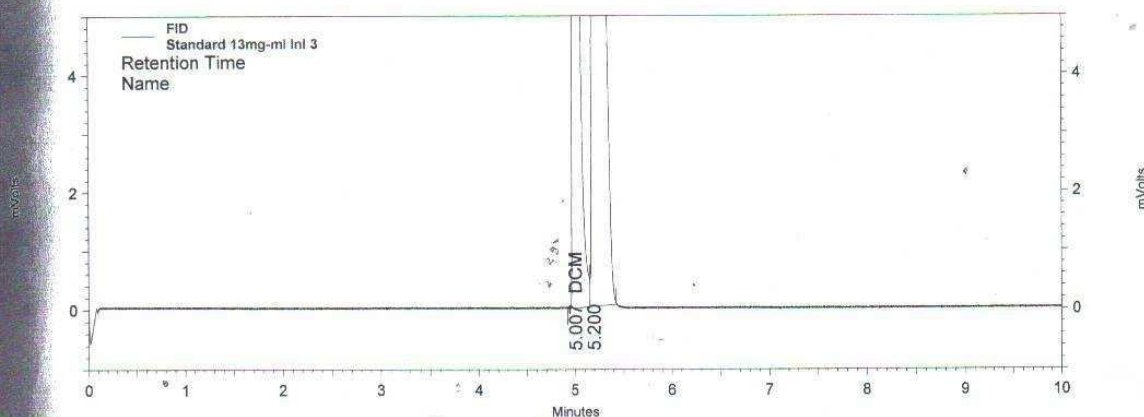
Handwritten signature/initials
08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 13mg-ml Inl 3
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve\Standard 13mg-ml Inl 3 08-10-2007 17-18-19.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 6
Run time: 08/10/2007 17:21:18
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.007	137002	55.010	DCM	0.00
2	5.200	112048	44.990		1.29
Totals		249050	100.000		

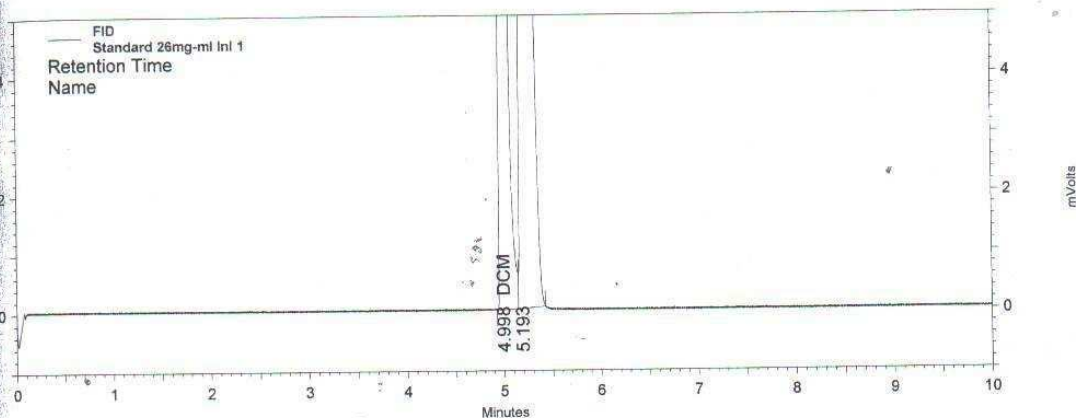
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08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 26mg-ml Inl 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve: Standard 26mg-ml Inl 1 08-10-2007 17-31-24.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 7
Run time: 08/10/2007 17:34:25
Operator: Anthony (VPDomain\Anthony)



FID Results					
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.998	292997	72.201	DCM	0.00
2	5.193	112810	27.799		1.30
Totals		405807	100.00 0		

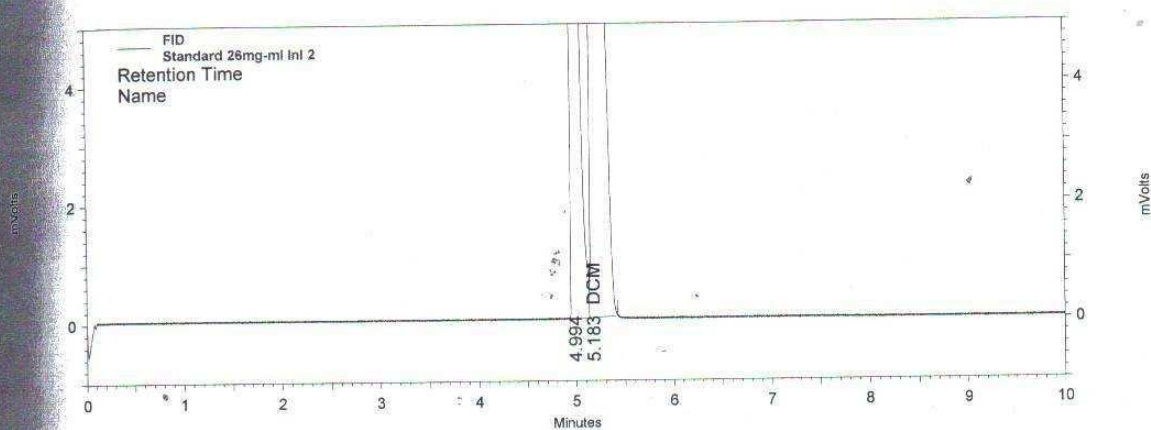
Handwritten signature and date: 08/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 26mg-ml Inl 2
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration
Curve\Standard 26mg-ml Inl 2 08-10-2007 17-44-32.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 7
Run time: 08/10/2007 17:47:33
Operator: Anthony (VPDomain\Anthony)



FID Results		Retention Time	Area	Area Percent	Name	Resolution (USP)
Pk #						
1		4.994	331993	72.989		0.00
2		5.183	122858	27.011	DCM	1.21
Totals			454851	100.00 0		

Handwritten signature and date:
09/10/07



Amino Chemicals

Quality Control

Sample ID: Standard 26mg-ml Inl 3

File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Calibration

Curve\Standard 26mg-ml Inl 3 08-10-2007 17-57-40.dat

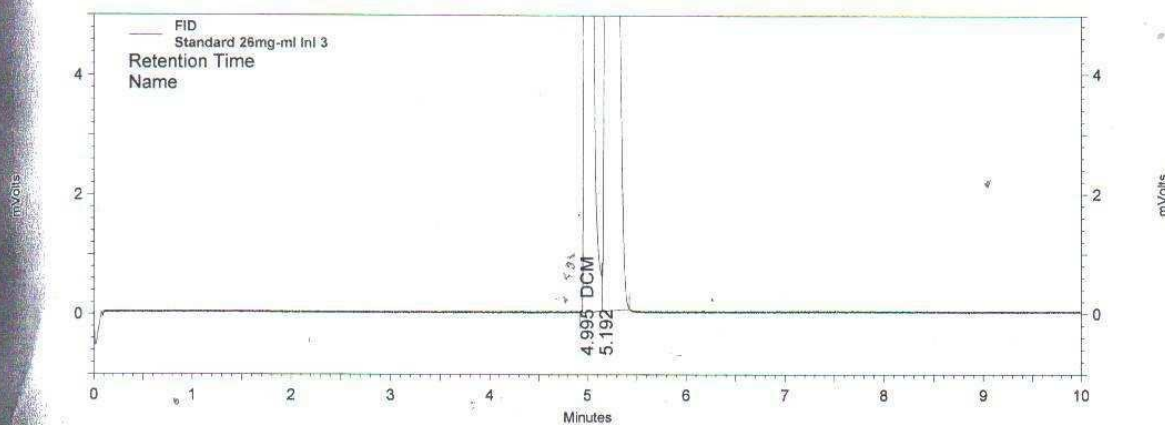
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met

Volume inj: 1 µl

Vial: 7

Run time: 08/10/2007 18:00:41

Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.995	284015	71.921	DCM	0.00
2	5.192	110886	28.079	DCM	1.32
Totals		394901	100.00 0		

Handwritten signature and date: 05/10/07

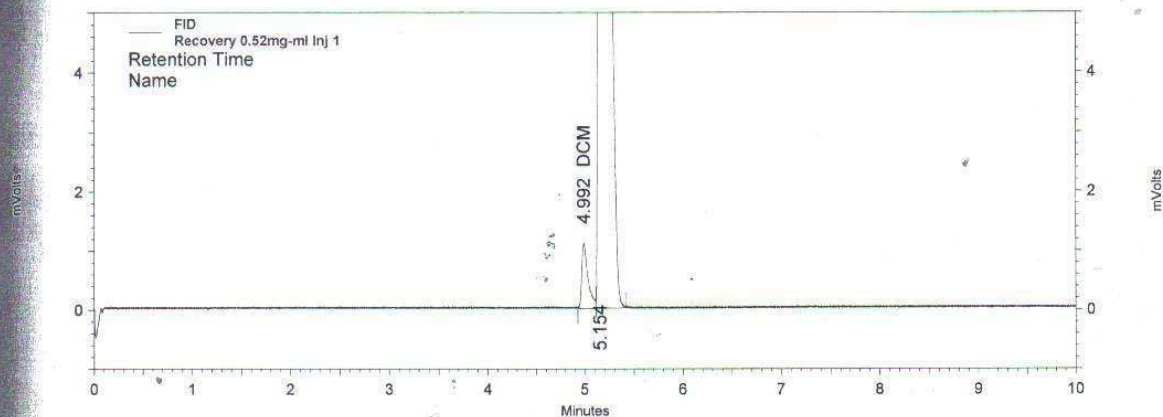
Appendix C – Chromatograms for Recovery



Amino Chemicals

Quality Control

Sample ID: Recovery 0.52mg-ml Inj 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery
0.52mg-ml Inj 1 09-10-2007 08-35-58.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 8
Run time: 09/10/2007 08:37:57
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.992	4939	4.258	DCM	0.00
2	5.154	111049	95.742		1.02

Totals		115988	100.00 0		
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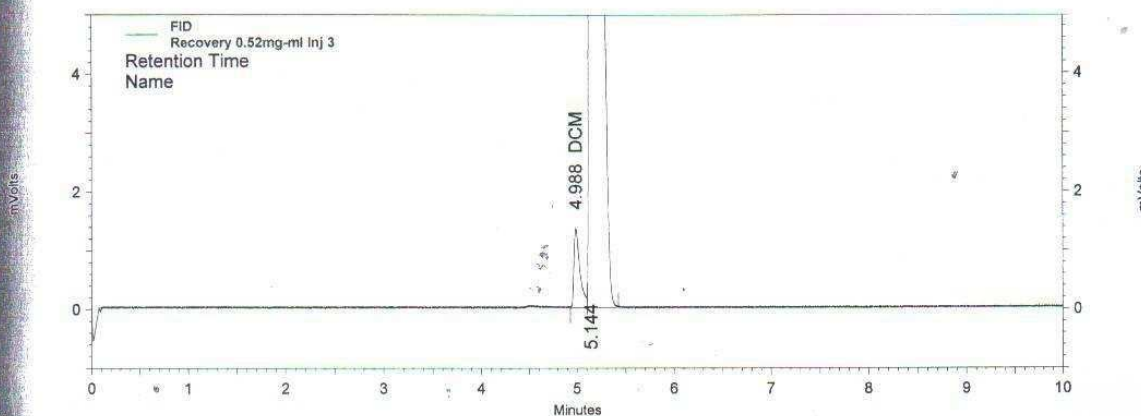
Handwritten signature/initials
09/10/07



Amino Chemicals

Quality Control

Sample ID: Recovery 0.52mg-ml Inj 3
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery
0.52mg-ml Inj 3 09-10-2007 09-01-33.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 8
Run time: 09/10/2007 09:04:37
Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	4.988	5867	4.502	DCM	0.00	
2	5.144	124464	95.498		0.94	

Totals		130331	100.00 0			
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for analysis



Amino Chemicals

Quality Control

Sample ID: Recovery 0.52mg-ml Inj 2

File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery 0.52mg-ml Inj 2 09-10-2007 08-49-31.dat

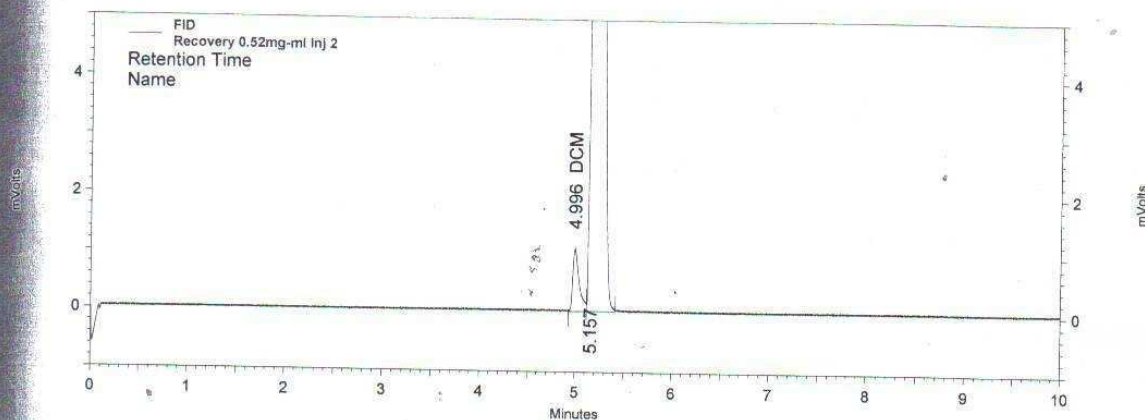
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met

Volume inj: 1 µl

Vial: 8

Run time: 09/10/2007 08:51:26

Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.996	4865	4.189	DCM	0.00
2	5.157	111266	95.811		1.00
Totals		116131	100.00 0		

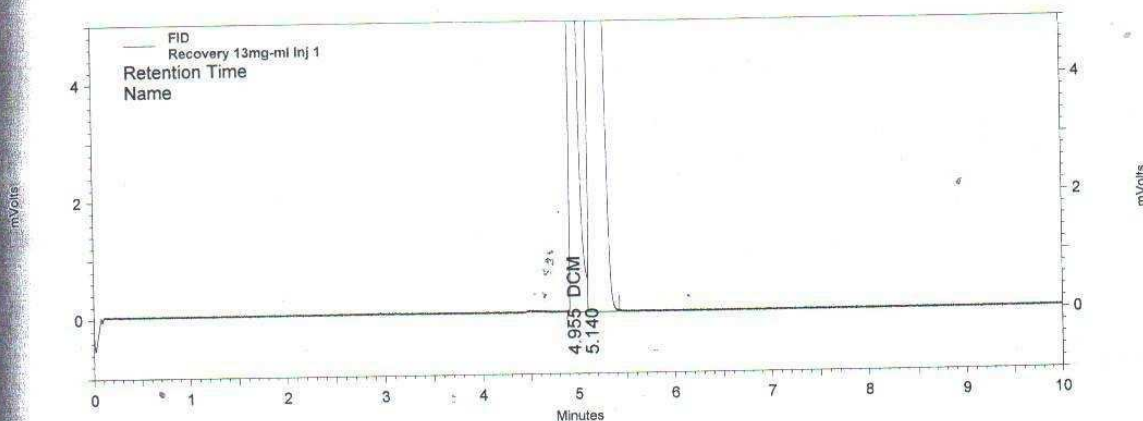
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Amino Chemicals

Quality Control

Sample ID: Recovery 13mg-ml Inj 1
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery
13mg-ml Inj 1 09-10-2007 09-14-39.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 9
Run time: 09/10/2007 09:18:00
Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	4.955	169140	57.661	DCM	0.00	1.19
2	5.140	124197	42.339			
Totals		293337	100.00 0			

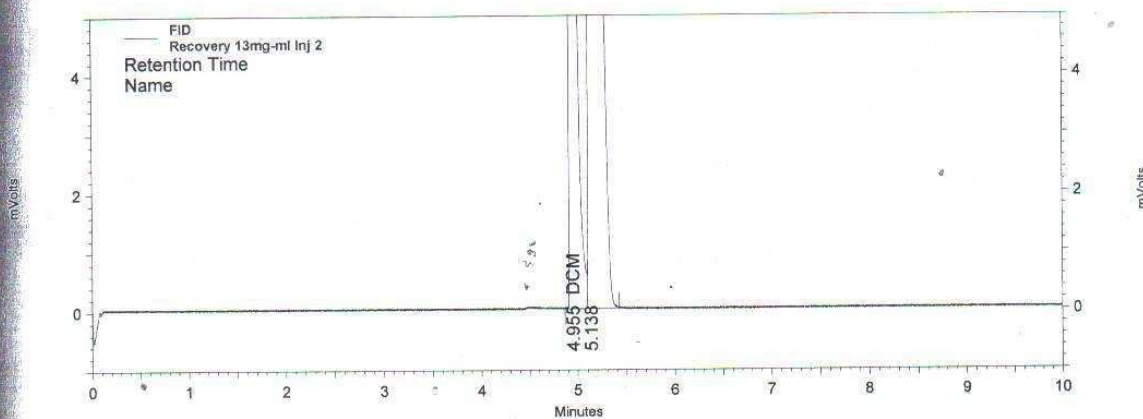
Handwritten signature/initials.



Amino Chemicals

Quality Control

Sample ID: Recovery 13mg-ml Inj 2
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery
13mg-ml Inj 2 09-10-2007 09-28-18.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 9
Run time: 09/10/2007 09:31:23
Operator: Anthony (VPDomain\Anthony)



FID Results

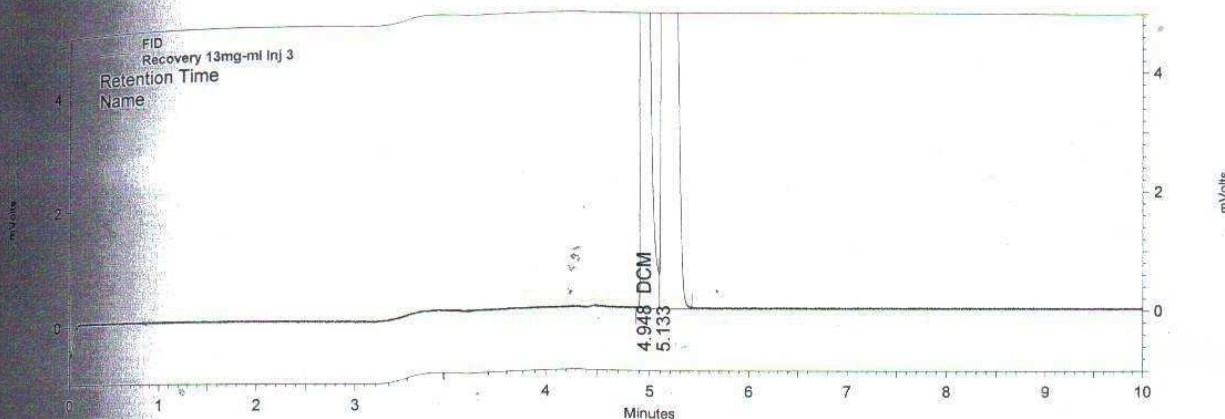
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.955	171824	57.725	DCM	0.00
2	5.138	125837	42.275		1.18
Totals		297661	100.00 0		

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09/10/07

Amino Chemicals

Quality Control

Sample ID: Recovery 13mg-ml Inj 3
 File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Recovery\Recovery
 13mg-ml Inj 3 09-10-2007 09-41-41.dat
 Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
 Volume inj: 1 µl
 Vial: 9
 Run time: 09/10/2007 09:44:46
 Operator: Anthony (VPDomain\Anthony)



FID Results Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.948	169944	57.635	DCM	0.00
2	5.133	124919	42.365		1.19
Totals		294863	100.00 0		

Handwritten signature and date:
 09/10/07

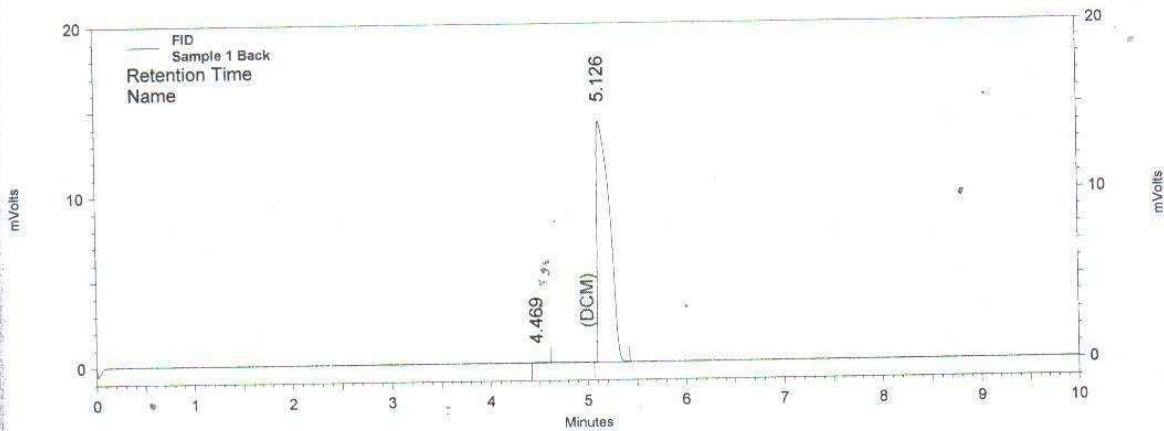
Appendix D – Chromatograms of Samples



Amino Chemicals

Quality Control

Sample ID: Sample 1 Back
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 1
Back 09-10-2007 10-24-14.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 1
Run time: 09/10/2007 10:25:59
Operator: Anthony (VPDomain\Anthony)



FID Results Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.469	354	0.285	DCM	0.00
2	5.126	123723	99.715		0.00
Totals		124077	100.00 0		

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02/10/07



Amino Chemicals

Quality Control

Sample ID: Sample 1 Front

File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 1

Front 09-10-2007 10-36-00.dat

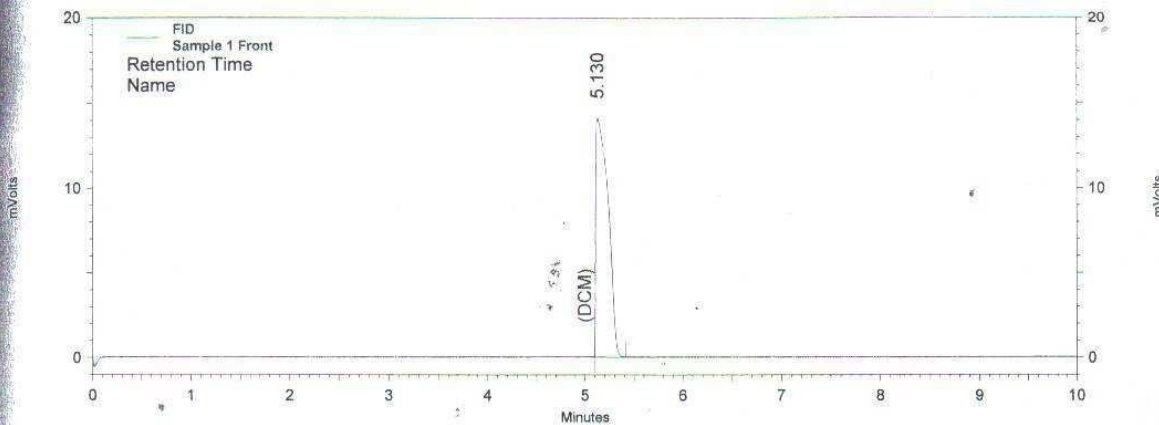
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met

Volume inj: 1 µl

Vial: 2

Run time: 09/10/2007 10:39:10

Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	5.130	122800	100.00 0	DCM	0.00
Totals		122800	100.00 0		

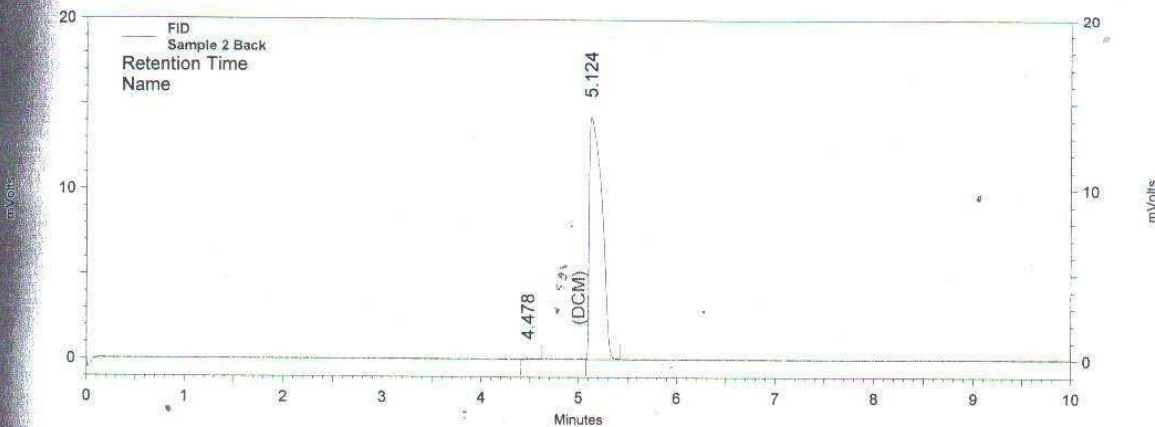
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2/10/07



Amino Chemicals

Quality Control

Sample ID: Sample 2 Back
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 2
Back 09-10-2007 10-49-26.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 3
Run time: 09/10/2007 10:52:21
Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	4.478	407	0.324	DCM	0.00	
2	5.124	125263	99.676		0.00	
Totals		125670	100.000			

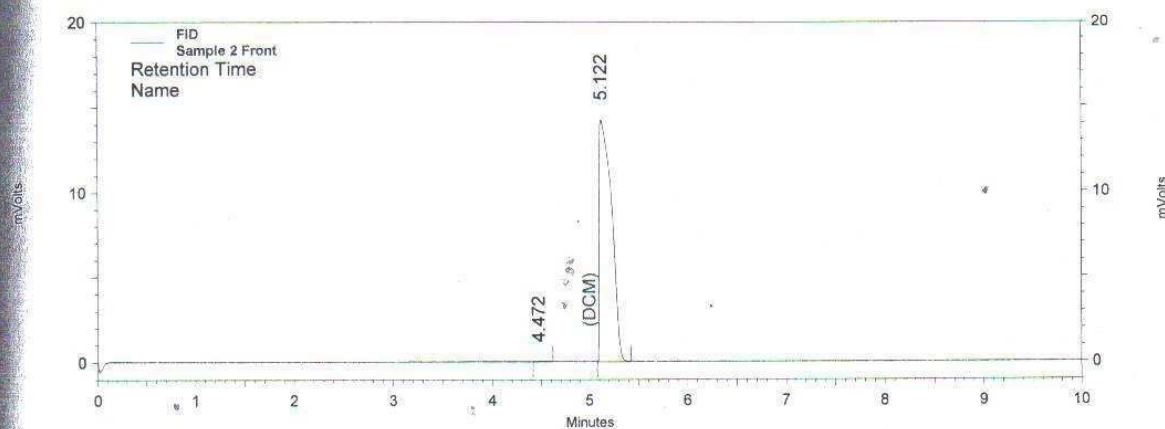
09/10/07



Amino Chemicals

Quality Control

Sample ID: Sample 2 Front
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 2
Front 09-10-2007 11-02-46.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 4
Run time: 09/10/2007 11:06:02
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.472	317	0.256	DCM	0.00
2	5.122	123431	99.744		0.00
Totals		123748	100.00 0		

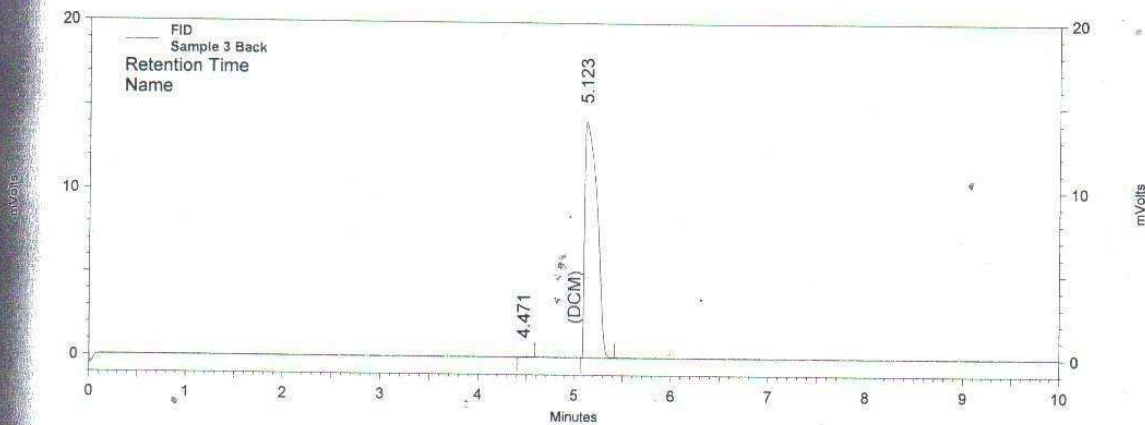
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Amino Chemicals

Quality Control

Sample ID: Sample 3 Back
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 3
Back 09-10-2007 11-16-31.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 5
Run time: 09/10/2007 11:19:30
Operator: Anthony (VPDomain\Anthony)



FID Results

Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.471	355	0.286	DCM	0.00
2	5.123	123694	99.714		0.00
Totals		124049	100.00 0		

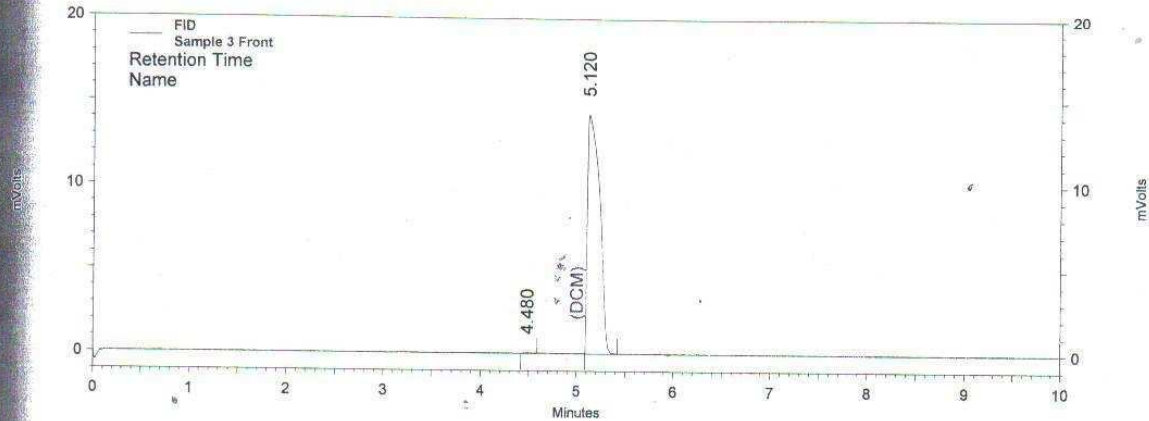
Handwritten signature/initials



Amino Chemicals

Quality Control

Sample ID: Sample 3 Front
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 3
Front 09-10-2007 11-29-40.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 6
Run time: 09/10/2007 11:32:40
Operator: Anthony (VPDomain\Anthony)



FID Results

PK #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.480	343	0.278		0.00
2	5.120	123248	99.722	DCM	0.00
Totals		123591	100.000		

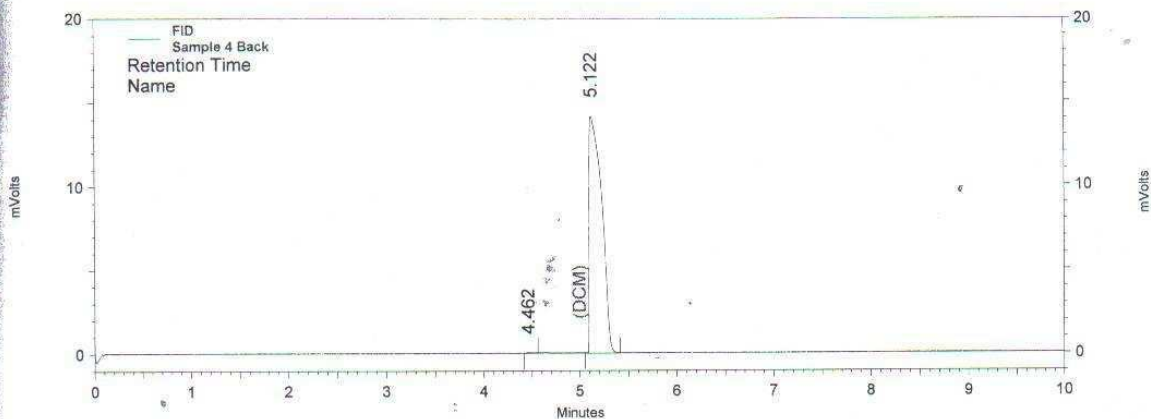
Handwritten signature/initials
09/10/07



Amino Chemicals

Quality Control

Sample ID: Sample 4 Back
File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 4 Back 09-10-2007 11-42-48.dat
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met
Volume inj: 1 µl
Vial: 7
Run time: 09/10/2007 11:45:49
Operator: Anthony (VPDomain\Anthony)



FID Results					
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)
1	4.462	281	0.227	DCM	0.00
2	5.122	123436	99.773		0.00
Totals		123717	100.000		

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09/10/07



Amino Chemicals

Quality Control

Sample ID: Sample 4 Front

File: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Chromatograms\DCM\Samples\Sample 4

Front 09-10-2007 11-55-57.dat

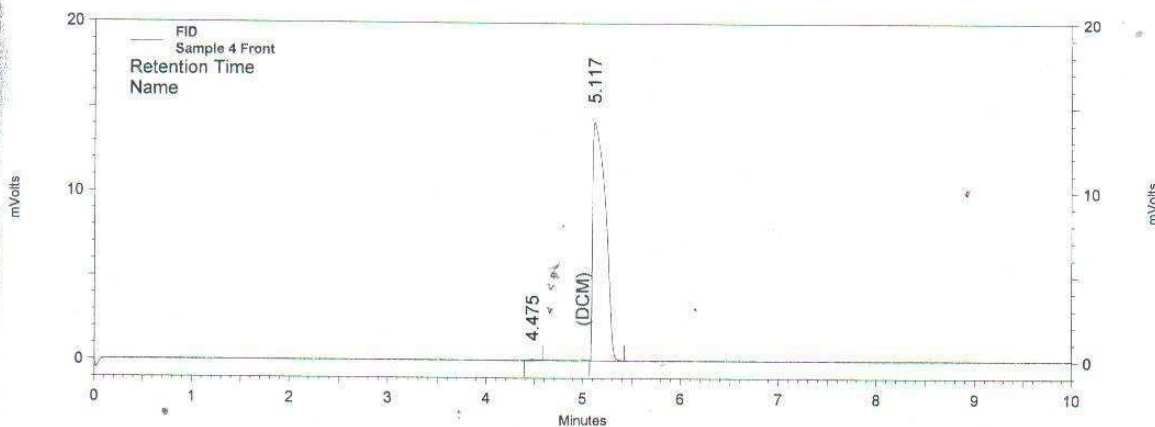
Method: \\Vp7server\VP7Data\Projects\Default\2007\GC\Solvent in Atmos\Methods\Solvent In atm GC4.met

Volume inj: 1 µl

Vial: 8

Run time: 09/10/2007 11:59:00

Operator: Anthony (VPDomain\Anthony)



FID Results						
Pk #	Retention Time	Area	Area Percent	Name	Resolution (USP)	
1	4.475	440	0.350	DCM	0.00	
2	5.117	125157	99.650		0.00	
Totals		125597	100.000			

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09/10/07