SafePharm Laboratories

Triclocarban (TCC) CAS# 101-20-2:

DETERMINATION OF VAPOUR PRESSURE

SPL PROJECT NUMBER: 2224/0001

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QUALITY ASSURANCE REPORT

Inspection of the routine and repetitive procedures that constitute the study is process based (as defined by OECD) and is designed to encompass the major phases at or about the time this study was in progress.

This report has been audited by Safepharm Quality Assurance Unit, and is considered to be an accurate account of the data generated and of the procedures followed.

In each case, the outcome of QA evaluation is reported to the Study Director and Management on the day of evaluation. Audits of study documentation, and process inspections appropriate to the type and schedule of this study were as follows:

§ 31 January 2006	Protocol Compliance Audit
01, 08 February 2006	Vapour Pressure
§ 31 March 2006	Draft Report Audit
§ Date of QA Signature	Final Report Audit

§ Evaluation specific to this study

..... DATE: 12 APR 2006

For Safepharm Quality Assurance Unit*

***Authorised QA Signatures:**

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Deputy Head of Department:	JM Crowther MIScT MRQA
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GLP COMPLIANCE STATEMENT

The work described was performed in compliance with UK GLP standards (Schedule 1, Good Laboratory Practice Regulations 1999 (SI 1999/3106 as amended by SI 2004/0994)). These Regulations are in accordance with GLP standards published as OECD Principles on Good Laboratory Practice (revised 1997, ENV/MC/CHEM(98)17); and are in accordance with, and implement, the requirements of Directives 2004/9/EC and 2004/10/EC.

These international standards are acceptable to the Regulatory agencies of the following countries: Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Japan, Republic of Korea, Luxembourg, Mexico, The Netherlands, New Zealand, Norway, Poland, Portugal, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, the United Kingdom, and the United States of America.

This report fully and accurately reflects the procedures used and data generated.

..... DATE: 12 APR 2006

S P Tremain
STUDY DIRECTOR

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SUMMARY

Method. The test procedure was Method A4 specified in Commission Directive 92/69/EEC (which constitutes Annex V of Council Directive 67/548/EEC).

Result. The test material has been determined to have a vapour pressure of 4.6×10^{-11} Pa at 25°C, using a vapour pressure balance.

Triclocarban (TCC) CAS# 101-20-2:

DETERMINATION OF VAPOUR PRESSURE

1. INTRODUCTION

The vapour pressure of the test material has been determined. The method employed was Method A4 specified in Commission Directive 92/69/EEC (which constitutes Annex V of Council Directive 67/548/EEC).

Testing was conducted between 09 February 2006 and 14 February 2006.

2. TEST MATERIAL

2.1 Description, Identification and Storage Conditions

Sponsor's identification	:	Triclocarban (TCC) CAS# 101-20-2
Description	:	white powder
Batch number	:	CHPHNA0196
Date received	:	02 February 2006
Storage conditions	:	room temperature, in the dark

The integrity of supplied data relating to the identity, purity and stability of the test material is the responsibility of the Sponsor.

3. ARCHIVES

Unless instructed otherwise by the Sponsor, all original data and the final report will be retained in the Safepharm archives for five years, after which instructions will be sought as to further retention or disposal.

4. VAPOUR PRESSURE

4.1 Method

The vapour pressure was determined using a vapour pressure balance with measurements being made at several temperatures and linear regression analysis used to calculate the vapour pressure at 25 °C. Testing was conducted using Method A4 of Commission Directive 92/69/EEC (which constitutes Annex V of Council Directive 67/548/EEC).

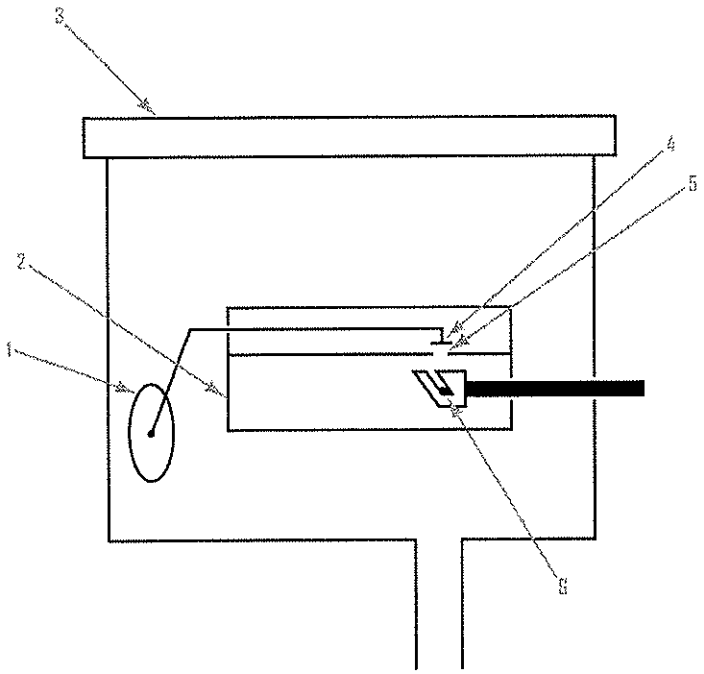
4.1.1 Procedure

The vapour pressure was determined using a vapour pressure balance. The temperature of the sample was controlled electronically. The mass and temperature readings were recorded automatically into a computer file.

A diagram of the cross-section of the vapour pressure balance is represented in Figure 4.1. After evacuating the system, opening the shutter above the sample oven causes the escaping vapour jet to be directed at the scale pan. The difference in mass readings with the orifice covered and uncovered is proportional to the vapour pressure at the given oven temperature.

A sequence of runs was started after a sample of test material had been under vacuum for approximately 71½ hours. Temperature and pressure readings were taken between 185 and 195 °C with a one hour dwell at 185 °C between runs.

Figure 4.1 Schematic Diagram of the Apparatus Used



1	Microbalance
2	Oven
3	Glass viewing panel
4	Balance pan
5	Shutter with orifice
6	Test sample

4.1.2 Calculation

The vapour pressure is related to the observed mass difference by Equation 4.1.

Equation 4.1

$$Vp = \frac{\delta m.g}{A}$$

where:

Vp	=	vapour pressure (Pa)
δm	=	mass difference (kg)
g	=	acceleration due to gravity (9.813 m s^{-2})
A	=	area of the orifice ($7.06858 \times 10^{-6} m^2$)

Vapour pressure is related to temperature by Equation 4.2.

Equation 4.2

$$\text{Log}_{10}\,[\text{Vp (Pa)}] = \frac{\text{slope}}{\text{temperature (K)}} + \text{intercept}$$

A plot of Log_{10} Vp (Pa) versus reciprocal temperature (1/T(K)) therefore gives a straight line graph.

The vapour pressure of the sample was measured over a range of temperatures to enable extrapolation to 298.15 K.

4.2 Results

Run 1

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
186	459.15	0.002177937	142.55	1.426E-07	0.197895921	-0.703563157
187	460.15	0.002173204	153.37	1.534E-07	0.212916853	-0.671789961
188	461.15	0.002168492	175.02	1.750E-07	0.242972600	-0.614442699
189	462.15	0.002163800	184.78	1.848E-07	0.256521980	-0.590875416
190	463.15	0.002159128	208.78	2.088E-07	0.289840129	-0.537841485
191	464.15	0.002154476	224.08	2.241E-07	0.311080449	-0.507127283
192	465.15	0.002149844	243.61	2.436E-07	0.338193093	-0.470835267
193	466.15	0.002145232	270.46	2.705E-07	0.375467771	-0.425427335
194	467.15	0.002140640	279.81	2.798E-07	0.388447967	-0.410667147
195	468.15	0.002136067	308.29	3.083E-07	0.427985503	-0.368570941

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 1 gives the following statistical data using an unweighted least squares treatment.

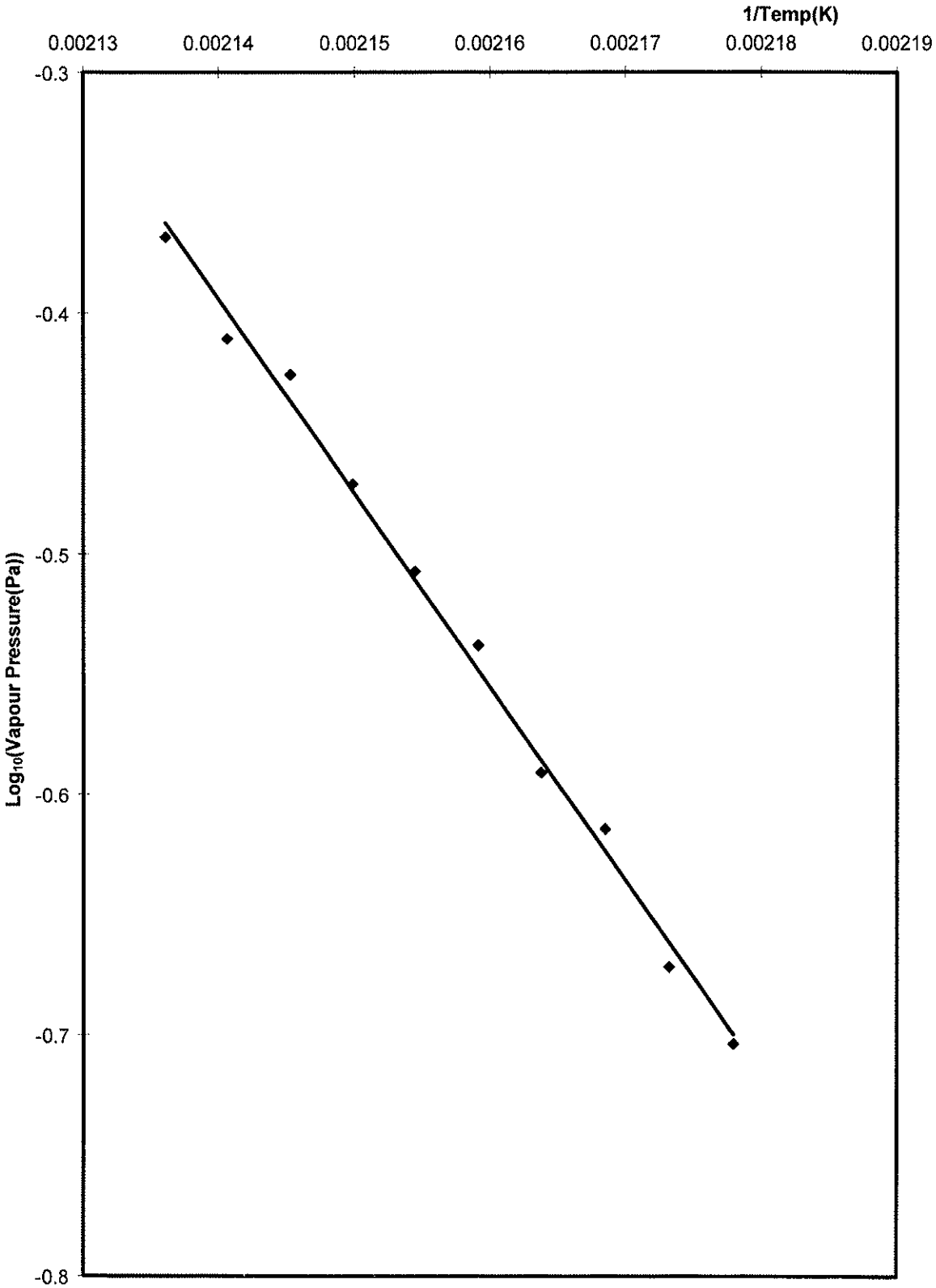
Slope	-8051.338
Standard deviation in slope	211.728
Intercept	16.836
Standard deviation in intercept	0.457

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8051.338 /temp(K) + 16.836.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.169.

Run 1 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 2

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
186	459.15	0.002177937	128.72	1.287E-07	0.178696338	-0.747884348
187	460.15	0.002173204	139.13	1.391E-07	0.193148085	-0.714109594
188	461.15	0.002168492	149.79	1.498E-07	0.207946896	-0.682047558
189	462.15	0.002163800	163.46	1.635E-07	0.226924358	-0.644118884
190	463.15	0.002159128	181.28	1.813E-07	0.251663084	-0.599180486
191	464.15	0.002154476	196.66	1.967E-07	0.273014464	-0.563814344
192	465.15	0.002149844	210.57	2.106E-07	0.292325108	-0.534133882
193	466.15	0.002145232	231.89	2.319E-07	0.321922730	-0.492248358
194	467.15	0.002140640	252.80	2.528E-07	0.350951167	-0.454753309
195	468.15	0.002136067	278.27	2.783E-07	0.386310052	-0.413063991

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 2 gives the following statistical data using an unweighted least squares treatment.

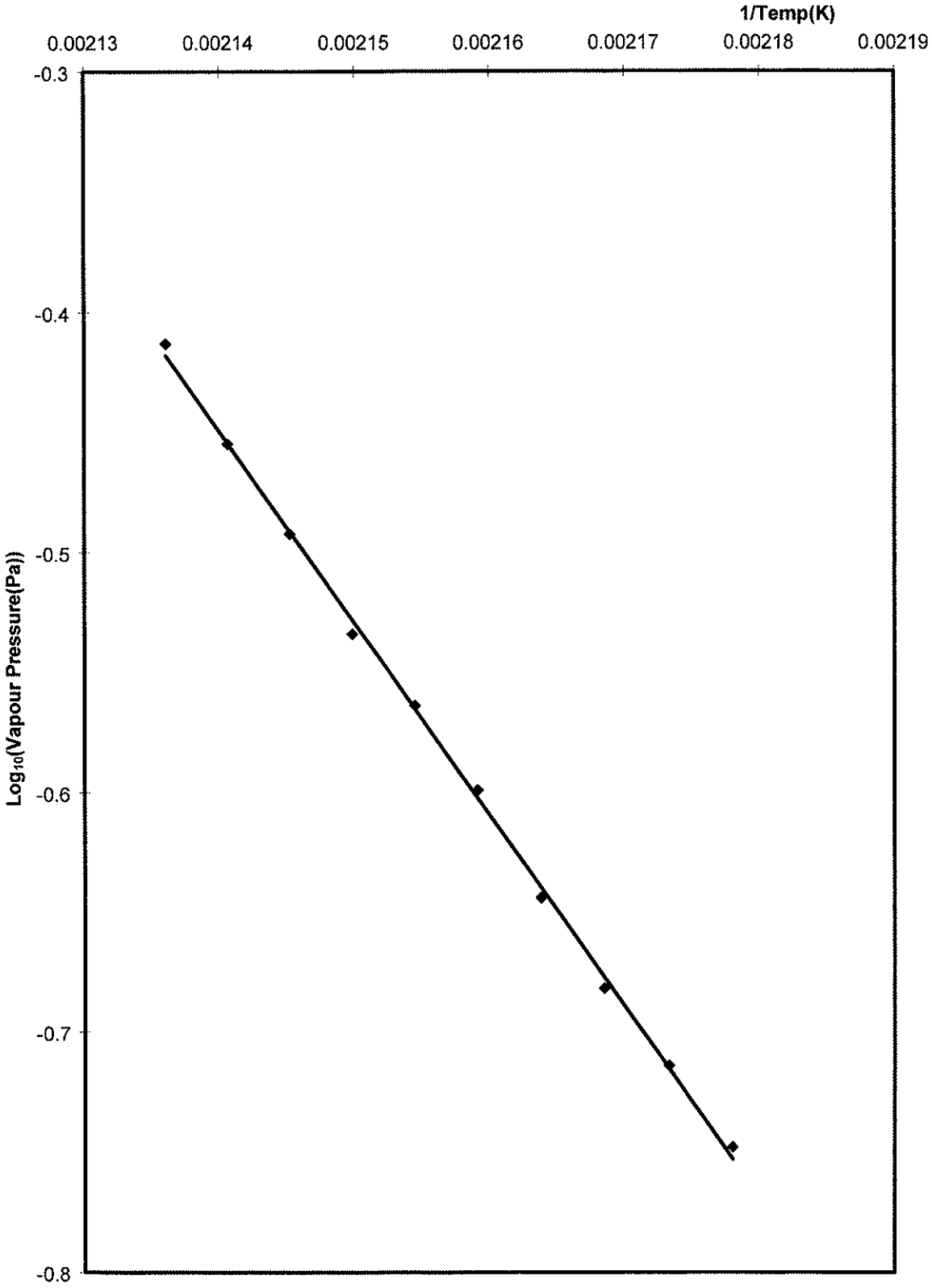
Slope	-8002.269
Standard deviation in slope	98.951
Intercept	16.675
Standard deviation in intercept	0.213

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8002.269/temp(K) + 16.675.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.164.

Run 2 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 3

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
185	458.15	0.002182691	115.37	1.154E-07	0.160163118	-0.795437486
186	459.15	0.002177937	127.17	1.272E-07	0.176544541	-0.753145707
187	460.15	0.002173204	133.03	1.330E-07	0.184679722	-0.733580788
188	461.15	0.002168492	143.93	1.439E-07	0.199811715	-0.699379053
189	462.15	0.002163800	157.52	1.575E-07	0.218678116	-0.660194676
190	463.15	0.002159128	171.03	1.710E-07	0.237433458	-0.624458083
191	464.15	0.002154476	185.84	1.858E-07	0.257993532	-0.588391182
192	465.15	0.002149844	202.92	2.029E-07	0.281704948	-0.550205525
193	466.15	0.002145232	215.62	2.156E-07	0.299335802	-0.523841337
194	467.15	0.002140640	239.70	2.397E-07	0.332765011	-0.477862345
195	468.15	0.002136067	260.29	2.603E-07	0.361349206	-0.442072895

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 3 gives the following statistical data using an unweighted least squares treatment.

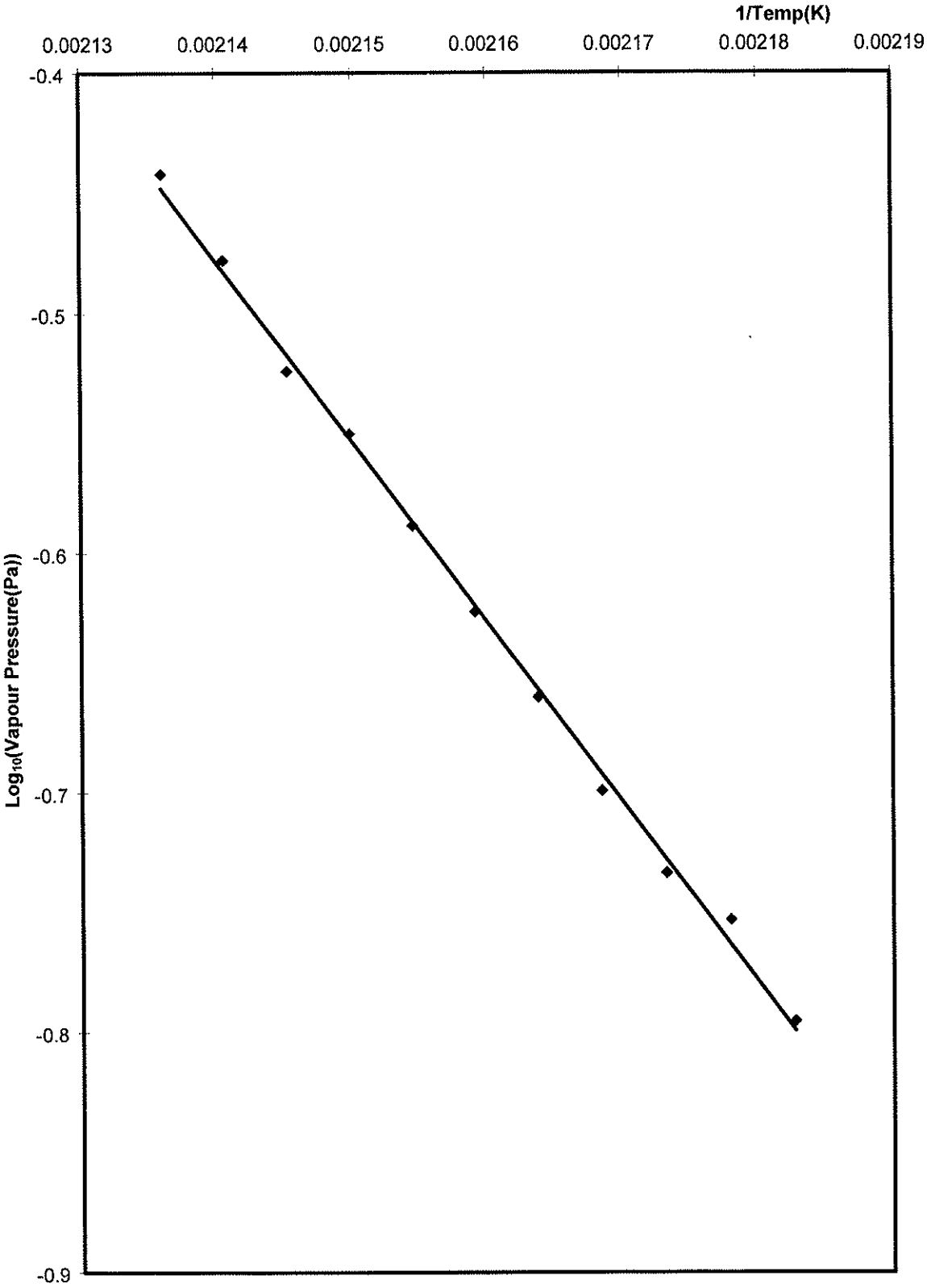
Slope	-7539.449
Standard deviation in slope	123.884
Intercept	15.657
Standard deviation in intercept	0.267

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -7539.449/temp(K) + 15.657.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -9.631.

Run 3 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 4

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
186	459.15	0.002177937	116.43	1.164E-07	0.161634669	-0.791465481
187	460.15	0.002173204	122.45	1.225E-07	0.169991972	-0.769571589
188	461.15	0.002168492	134.41	1.344E-07	0.186595516	-0.729098798
189	462.15	0.002163800	144.99	1.450E-07	0.201283266	-0.696192329
190	463.15	0.002159128	158.42	1.584E-07	0.219927547	-0.657720370
191	464.15	0.002154476	174.28	1.743E-07	0.241945290	-0.616282827
192	465.15	0.002149844	194.62	1.946E-07	0.270182421	-0.568342911
193	466.15	0.002145232	211.06	2.111E-07	0.293005353	-0.533124445
194	467.15	0.002140640	230.83	2.308E-07	0.320451178	-0.494238127
195	468.15	0.002136067	255.40	2.554E-07	0.354560633	-0.450309486

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 4 gives the following statistical data using an unweighted least squares treatment.

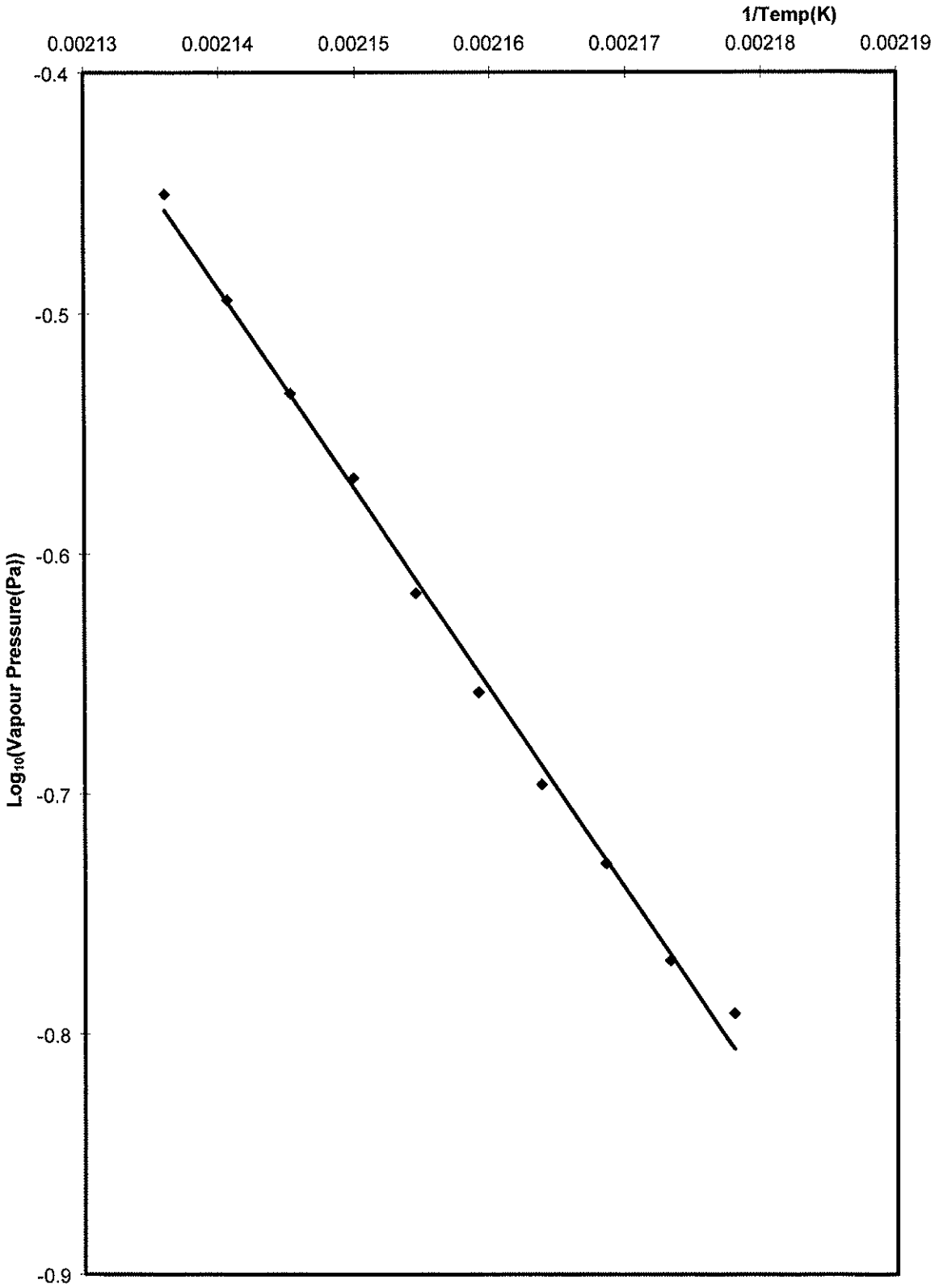
Slope	-8338.890
Standard deviation in slope	177.961
Intercept	17.355
Standard deviation in intercept	0.384

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8338.890/temp(K) + 17.355.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.613.

Run 4 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 5

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
185	458.15	0.002182691	108.38	1.084E-07	0.150459207	-0.822581232
186	459.15	0.002177937	112.77	1.128E-07	0.156553652	-0.805336798
187	460.15	0.002173204	128.56	1.286E-07	0.178474217	-0.748424515
188	461.15	0.002168492	137.02	1.370E-07	0.190218864	-0.720746416
189	462.15	0.002163800	144.83	1.448E-07	0.201061145	-0.696671848
190	463.15	0.002159128	161.02	1.610E-07	0.223537013	-0.650650556
191	464.15	0.002154476	178.51	1.785E-07	0.247817614	-0.605867829
192	465.15	0.002149844	193.65	1.937E-07	0.268835813	-0.570512877
193	466.15	0.002145232	213.01	2.130E-07	0.295712453	-0.529130386
194	467.15	0.002140640	235.06	2.351E-07	0.326323502	-0.486351647
195	468.15	0.002136067	254.18	2.542E-07	0.352866961	-0.452389003

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 5 gives the following statistical data using an unweighted least squares treatment.

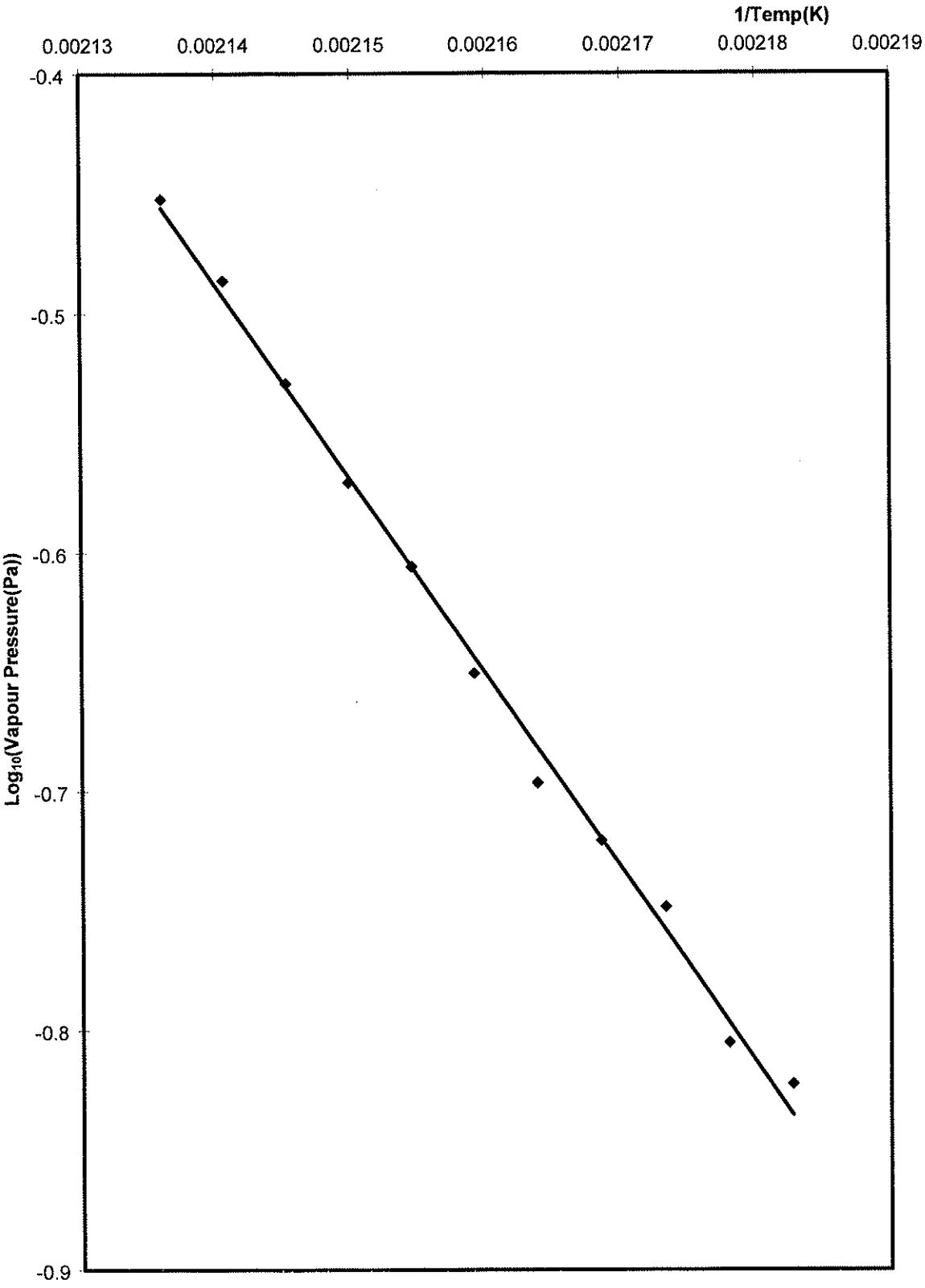
Slope	-8141.034
Standard deviation in slope	177.361
Intercept	16.934
Standard deviation in intercept	0.383

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8141.034/temp(K) + 16.934.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.371.

Run 5 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 6

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
185	458.15	0.002182691	106.51	1.065E-07	0.147863168	-0.830139994
186	459.15	0.002177937	116.92	1.169E-07	0.162314915	-0.789641572
187	460.15	0.002173204	124.49	1.245E-07	0.172824014	-0.762395912
188	461.15	0.002168492	131.16	1.312E-07	0.182083683	-0.739728971
189	462.15	0.002163800	143.85	1.439E-07	0.199700654	-0.699620513
190	463.15	0.002159128	164.03	1.640E-07	0.227715664	-0.642607094
191	464.15	0.002154476	176.32	1.763E-07	0.244777333	-0.611228802
192	465.15	0.002149844	192.83	1.928E-07	0.267697443	-0.572355777
193	466.15	0.002145232	204.06	2.041E-07	0.283287560	-0.547772496
194	467.15	0.002140640	226.52	2.265E-07	0.314467794	-0.502423826

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 6 gives the following statistical data using an unweighted least squares treatment.

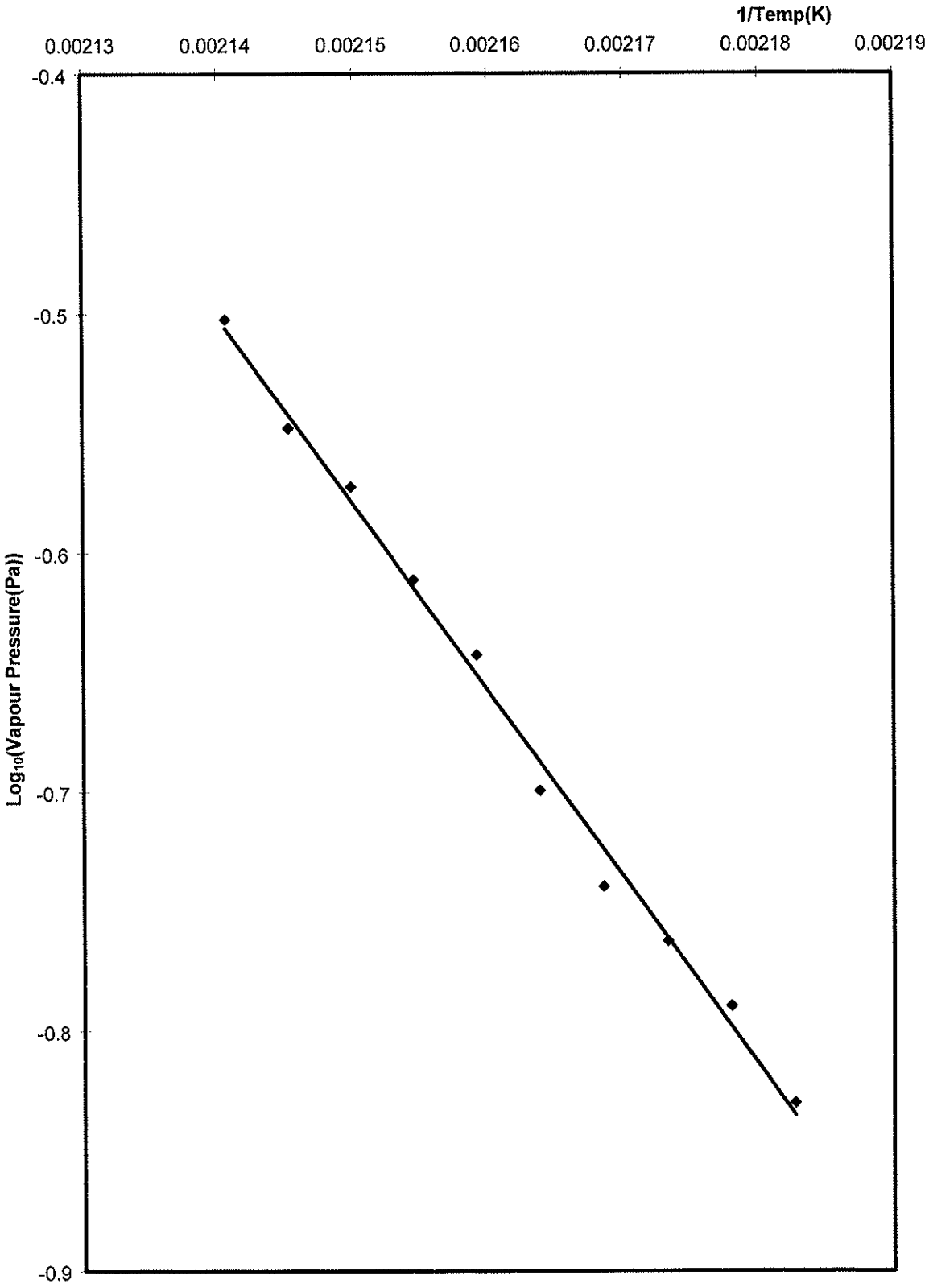
Slope	-7827.430
Standard deviation in slope	212.348
Intercept	16.250
Standard deviation in intercept	0.459

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -7827.430/temp(K) + 16.250.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.004.

Run 6 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 7

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
187	460.15	0.002173204	118.63	1.186E-07	0.164688833	-0.783335848
188	461.15	0.002168492	127.58	1.276E-07	0.177113726	-0.751747781
189	462.15	0.002163800	144.10	1.441E-07	0.200047718	-0.698866398
190	463.15	0.002159128	154.76	1.548E-07	0.214846529	-0.667871658
191	464.15	0.002154476	169.08	1.691E-07	0.234726358	-0.629438140
192	465.15	0.002149844	183.23	1.832E-07	0.254370183	-0.594533797
193	466.15	0.002145232	205.69	2.057E-07	0.285550417	-0.544317201
194	467.15	0.002140640	227.66	2.277E-07	0.316050406	-0.500243647
195	468.15	0.002136067	245.48	2.455E-07	0.340789132	-0.467514264

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run gives the following statistical data using an unweighted least squares treatment.

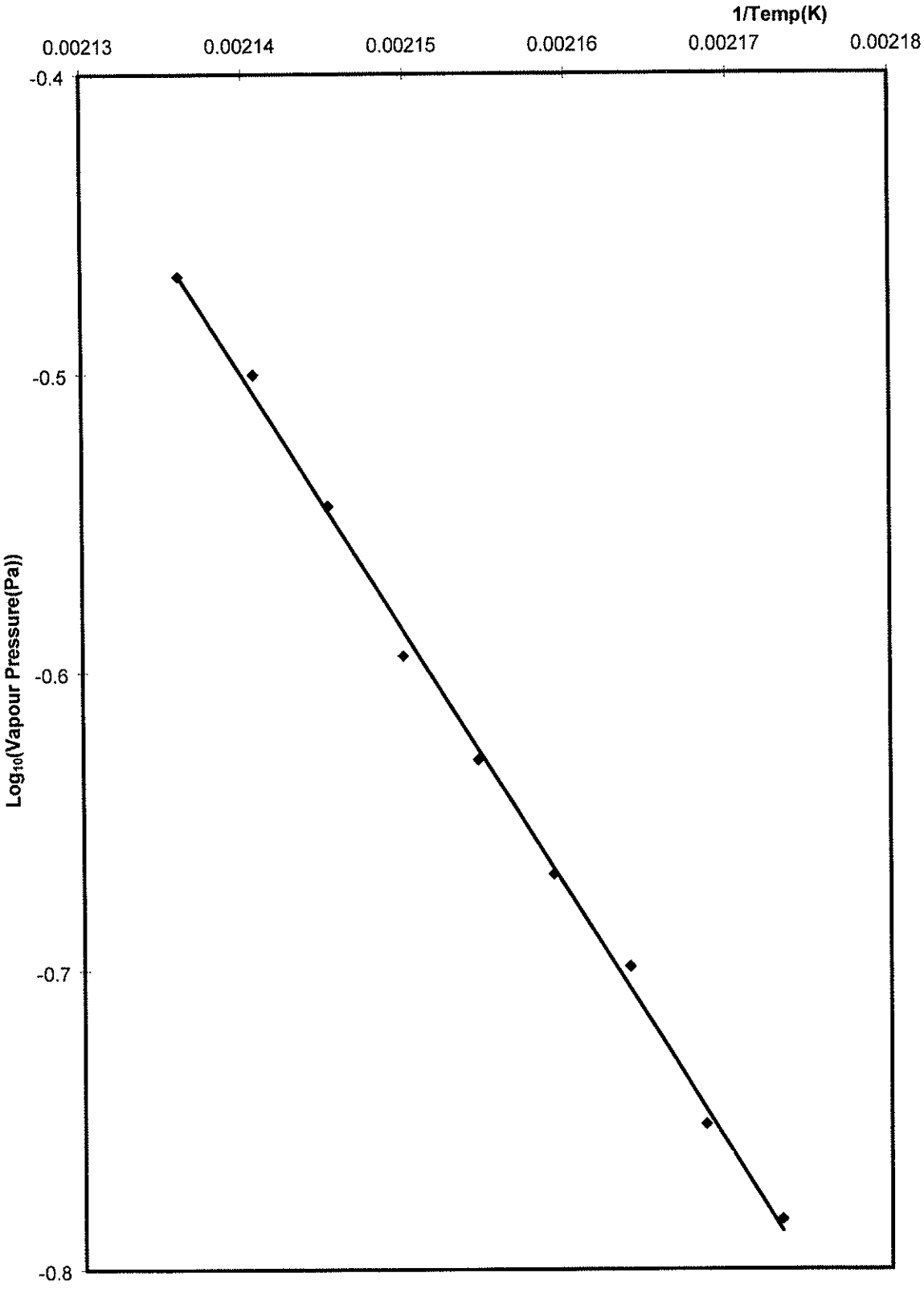
Slope	-8617.040
Standard deviation in slope	159.406
Intercept	17.939
Standard deviation in intercept	0.343

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8617.040/temp(K) + 17.939.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.962.

Run 7 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 8

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
185	458.15	0.002182691	104.23	1.042E-07	0.144697944	-0.839537641
186	459.15	0.002177937	112.77	1.128E-07	0.156553652	-0.805336798
187	460.15	0.002173204	121.40	1.214E-07	0.168534303	-0.773311692
188	461.15	0.002168492	127.66	1.277E-07	0.177224786	-0.751475539
189	462.15	0.002163800	138.32	1.383E-07	0.192023597	-0.716645398
190	463.15	0.002159128	152.40	1.524E-07	0.211570245	-0.674545412
191	464.15	0.002154476	170.70	1.707E-07	0.236975333	-0.625296858
192	465.15	0.002149844	187.79	1.878E-07	0.260700632	-0.583857917
193	466.15	0.002145232	204.88	2.049E-07	0.284425930	-0.546030813
194	467.15	0.002140640	226.93	2.269E-07	0.315036979	-0.501638466
195	468.15	0.002136067	246.70	2.467E-07	0.342482804	-0.465361229

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 8 gives the following statistical data using an unweighted least squares treatment.

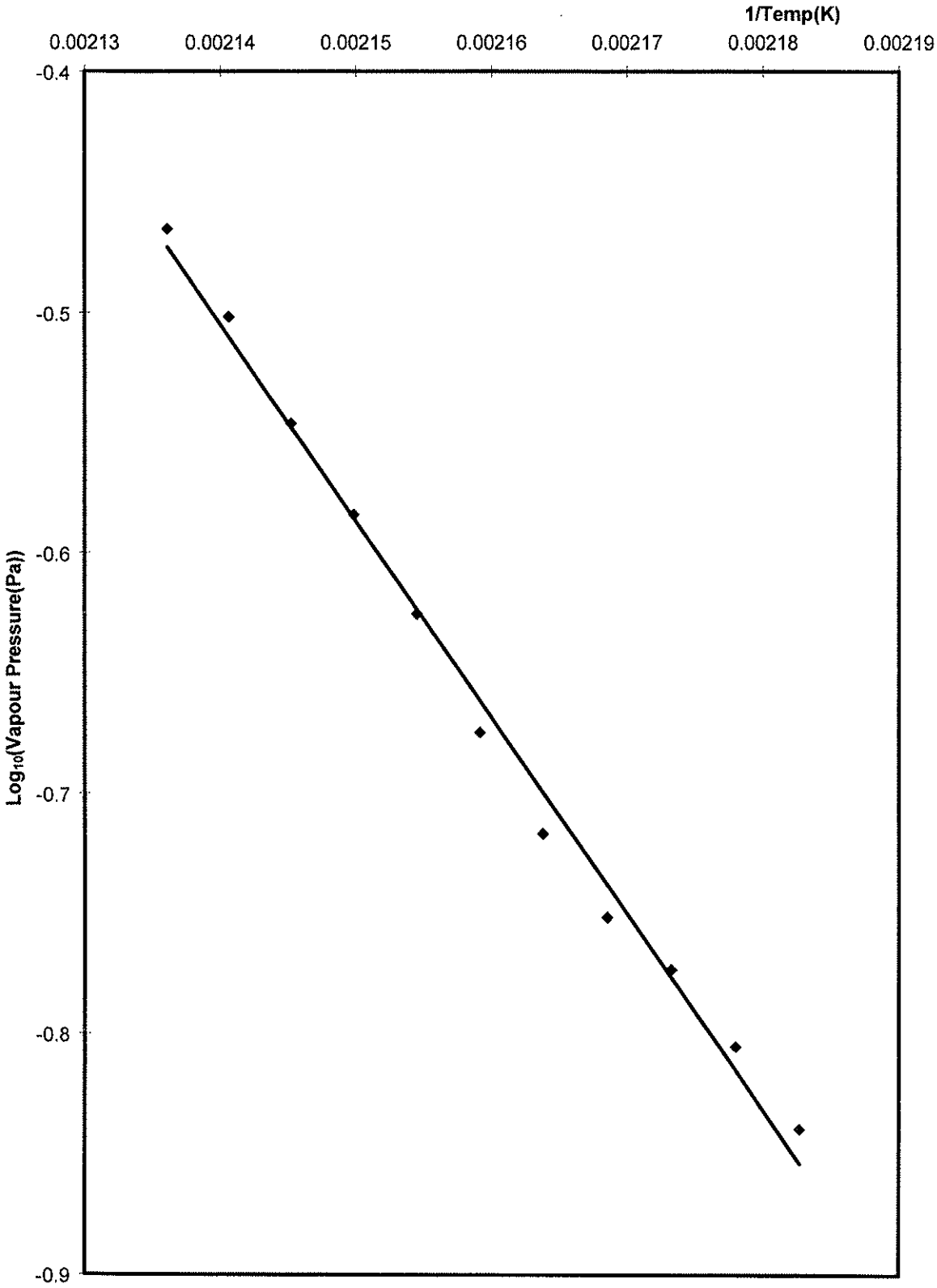
Slope	-8174.706
Standard deviation in slope	226.461
Intercept	16.989
Standard deviation in intercept	0.489

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8174.706/temp(K) + 16.989.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.429.

Run 8 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 9

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
186	459.15	0.002177937	111.47	1.115E-07	0.154748918	-0.810372378
187	460.15	0.002173204	120.66	1.207E-07	0.167506993	-0.775967058
188	461.15	0.002168492	128.80	1.288E-07	0.178807398	-0.747614516
189	462.15	0.002163800	142.23	1.422E-07	0.197451679	-0.704539169
190	463.15	0.002159128	154.02	1.540E-07	0.213819220	-0.669953260
191	464.15	0.002154476	168.83	1.688E-07	0.234379294	-0.630080758
192	465.15	0.002149844	187.79	1.878E-07	0.260700632	-0.583857917
193	466.15	0.002145232	204.63	2.046E-07	0.284078866	-0.546561074
194	467.15	0.002140640	224.16	2.242E-07	0.311191509	-0.506972261
195	468.15	0.002136067	243.69	2.437E-07	0.338304153	-0.470692671

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 9 gives the following statistical data using an unweighted least squares treatment.

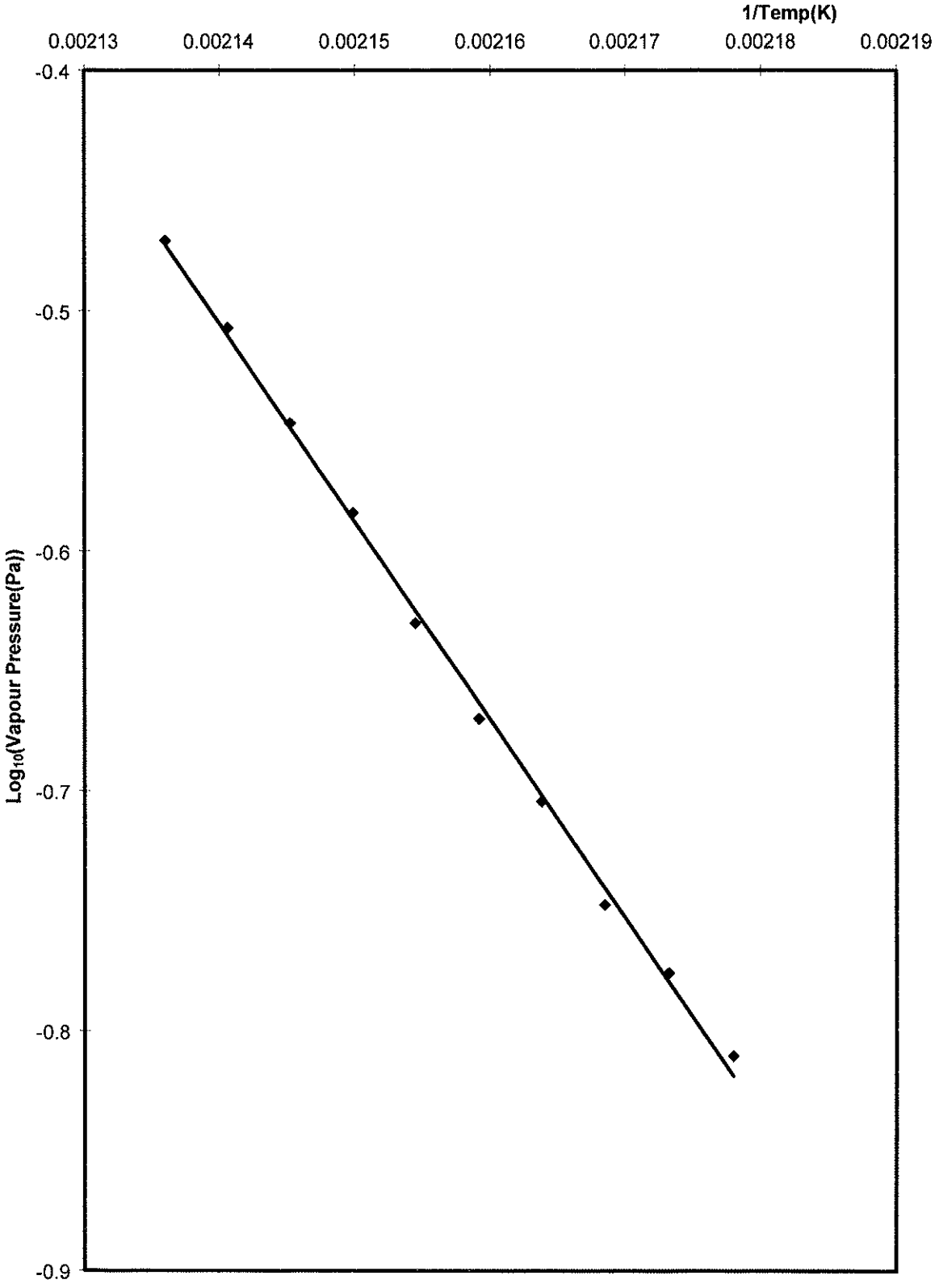
Slope	-8267.554
Standard deviation in slope	128.991
Intercept	17.187
Standard deviation in intercept	0.278

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8267.554/temp(K) + 17.187.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.542.

Run 9 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Run 10

Temperature (°C)	Temperature (K)	Reciprocal Temperature (K^{-1})	Mass Difference (µg)	Mass Difference (kg)	Vapour Pressure (Pa)	Log_{10} Vp
187	460.15	0.002173204	118.14	1.181E-07	0.164008587	-0.785133412
188	461.15	0.002168492	126.85	1.269E-07	0.176100299	-0.754239907
189	462.15	0.002163800	142.39	1.424E-07	0.197673800	-0.704050889
190	463.15	0.002159128	153.21	1.532E-07	0.212694732	-0.672243266
191	464.15	0.002154476	168.42	1.684E-07	0.233810109	-0.631136716
192	465.15	0.002149844	180.87	1.809E-07	0.251093899	-0.600163840
193	466.15	0.002145232	197.80	1.978E-07	0.274597076	-0.561304091
194	467.15	0.002140640	220.34	2.203E-07	0.305888371	-0.514437034
195	468.15	0.002136067	237.91	2.379E-07	0.330280032	-0.481117682

A plot of Log_{10} (vapour pressure (Pa)) versus reciprocal temperature (1/T(K)) for Run 10 gives the following statistical data using an unweighted least squares treatment.

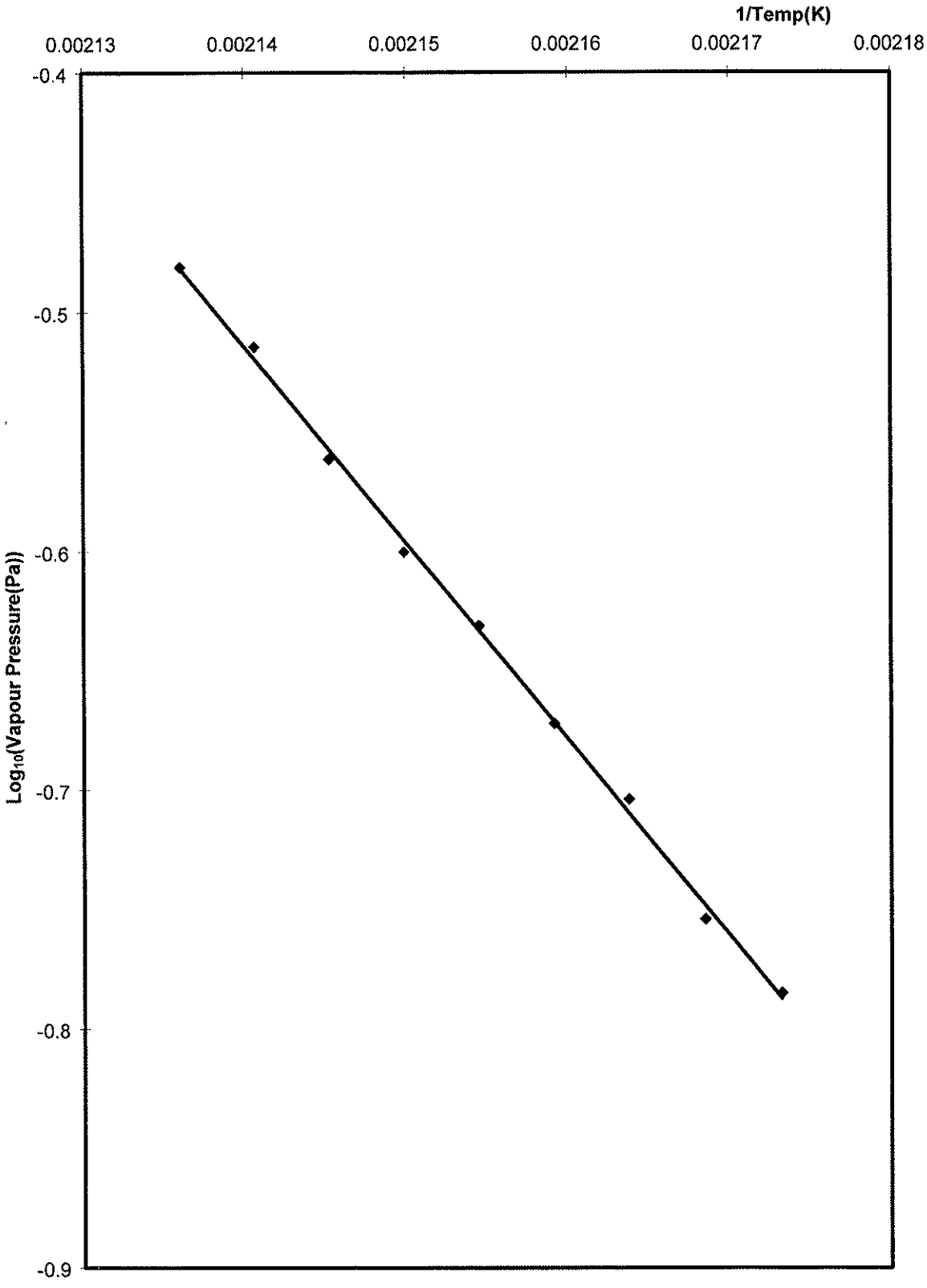
Slope	-8232.625
Standard deviation in slope	126.246
Intercept	17.104
Standard deviation in intercept	0.272

The results obtained indicate the following vapour pressure relationship:

Log_{10} (Vp (Pa)) = -8232.625/temp(K) + 17.104.

The above yields a vapour pressure (Pa) at 298.15 K with a common logarithm of -10.509.

Run 10 - Graph of Log_{10} Vapour Pressure vs Reciprocal Temperature



Summary of Results

Run	Log_{10} [Vp(25°C)]
1	-10.169
2	-10.164
3	-9.631
4	-10.613
5	-10.371
6	-10.004
7	-10.962
8	-10.429
9	-10.542
10	-10.509
Mean	-10.339
Vapour Pressure	4.6×10^{-11} Pa

The test material did not change in appearance under the conditions used in the determination.

4.3 Conclusion

The vapour pressure of the test material has been determined to be 4.6×10^{-11} Pa at 25 °C.

Appendix 1 Statement of GLP Compliance in accordance with Directive 2004/9/EC

Department of Health

THE DEPARTMENT OF HEALTH OF THE GOVERNMENT OF THE UNITED KINGDOM

GOOD LABORATORY PRACTICE

STATEMENT OF COMPLIANCE
IN ACCORDANCE WITH DIRECTIVE 2004/9/EC

LABORATORY	TEST TYPE
SafePharm Laboratories Ltd. **Shardlow Business Park** **London Road** **Shardlow** **Derby** **DE72 2GD**	**Analytical Chemistry** **Environmental Fate** **Environmental Toxicity** **Mutagenicity** **Phys/Chem Testing** **Toxicology**

DATE OF INSPECTION

30th August 2005

A general inspection for compliance with the Principles of Good Laboratory Practice was carried out at the above laboratory as part of the UK GLP Compliance Programme.

At the time of inspection no deviations were found of sufficient magnitude to affect the validity of non-clinical studies performed at these facilities.

Bryan J Wright 21/11/05.

Mr. Bryan J. Wright
Head, UK GLP Monitoring Authority