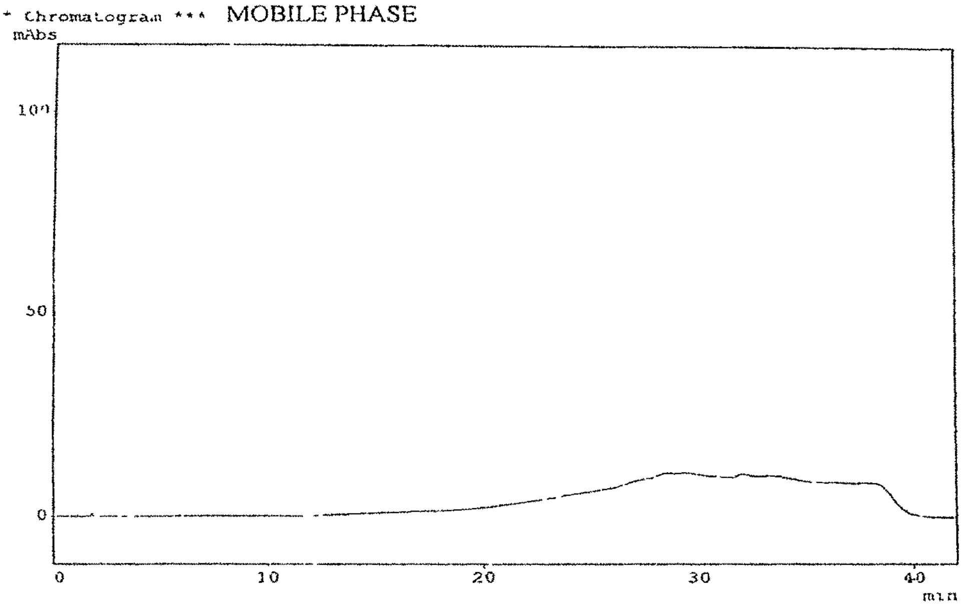
APPENDIX

Appendix

```
CLASS-LC10 Ver  1.60   SYS=1 Ch=1 REPORT.NO=36 DATA=7015V.D01 98/12/24 14 34 50
Sample          . 7015
ID              . BLANK
Type              Unknown
Detector        : SPD-10A Single
Operator        . NRP
Method Name       7015GR.H01
```

Sertraline RS method

*** Chromatogram *** MOBILE PHASE



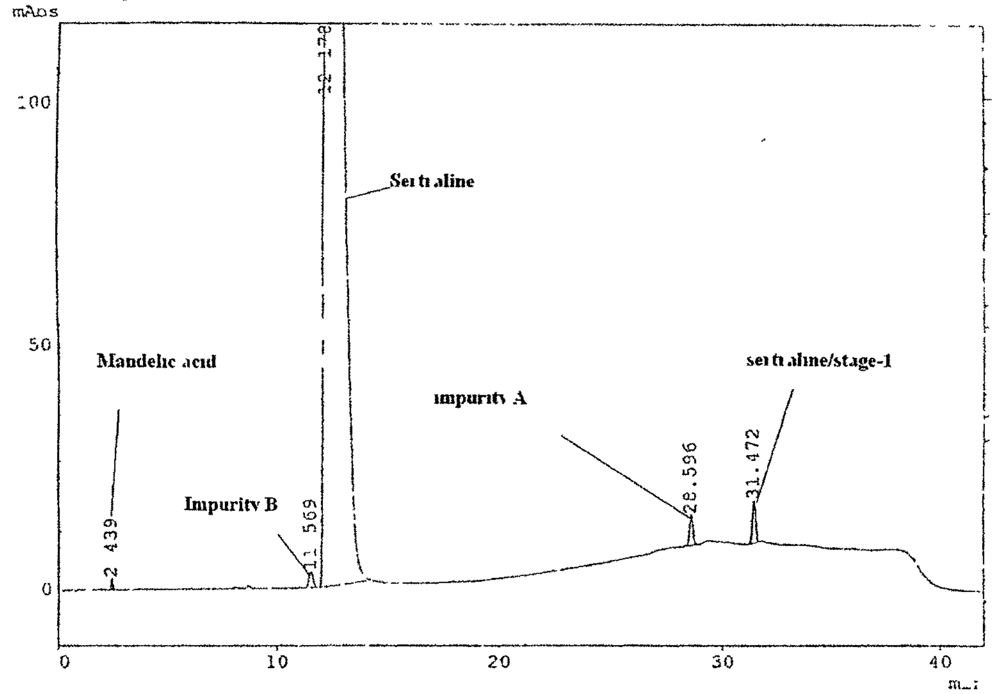

```
*** Peak Report ***
'  No Peak '
```

Figure -82

```
CLASS-LC10 Ver =1.60  SYS=1 Ch=1 REPORT NO=39 DATA=7015V D20
Sample          : 7015
ID                SYS.PRE.
Type              Unkn
Detector          SPD-
Operator          NRP
Method Name       7015GR M01
```

RESOLUTION SOLUTION

*** Chromatogram *** Filename.7015V C20



*** Peak Report ***

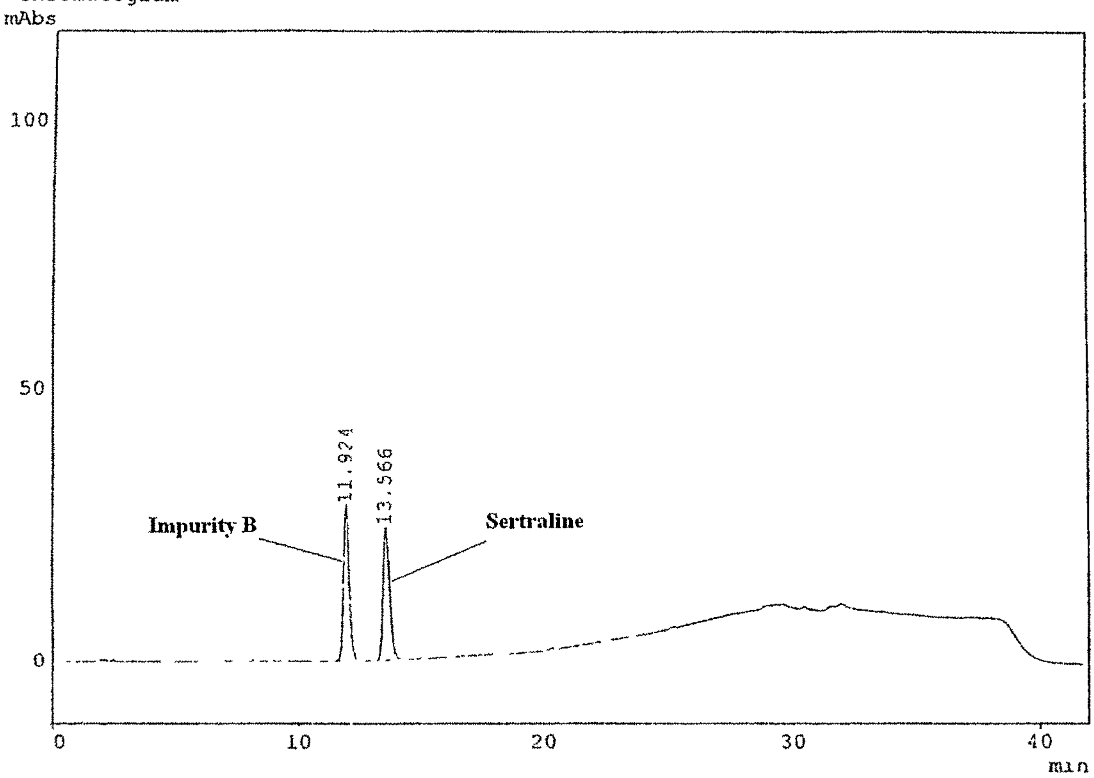
PKNO	TIME	AREA	CONC (%)
1	2.439	11534	0.0845
2	11.569	43584	0.3194
3	12.178	13440051	98.4915
4	28.596	62457	0.4577
5	31.472	88275	0.6469
		13645900	100.0000

Figure-83

CLASS-LC10 Ver.=1 60 SYS=1 Ch=1 REPORT.NO=6 DATA=7015V.D04 98/12/24 17:17:10

Sample	. 7015
ID	· S.S.SOLN
Type	: Unknown
Detector	. SPD-10A Single
Operator	: NRP

*** Chromatogram ** SYSTEM SUITABILITY



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	11.924	459169	50.9613
2	13.566	441845	49.0386
		901014	100.0000

*** Column Performance Report ***

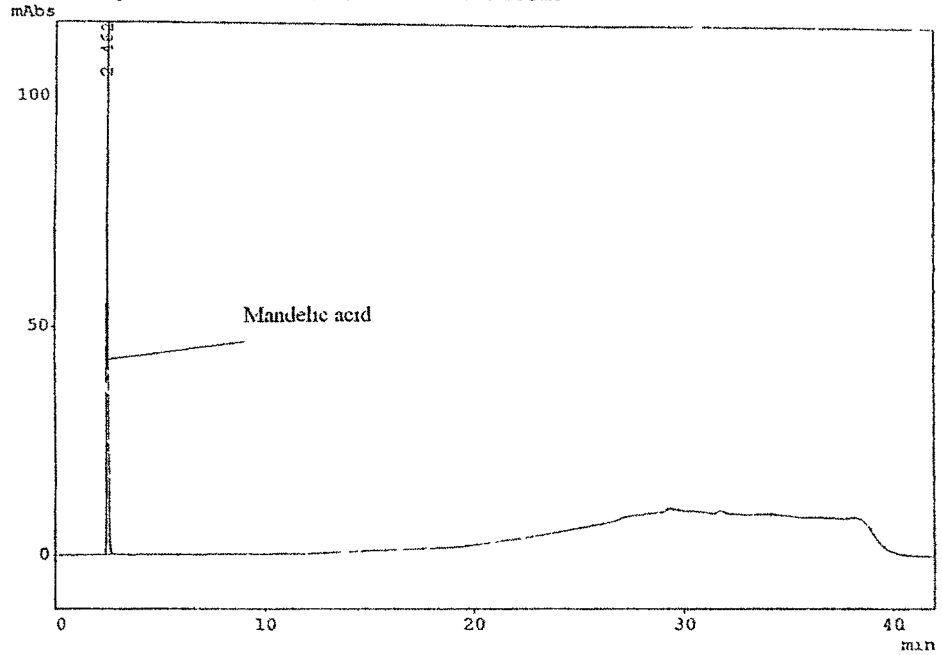
PKNO	R.TIME	Plate #	Tailing	Resolution
1	11.924	12383	1 32	
2	13.566	12454	1.44	3.59

Figure-84

```
CLASS-LC10 Ver =1.60  SYS=1 Ch=1 REPORT NO=19 DATA=7015V D05 98/12/21 18:00:38
Sample              7015
ID                : MD ACID150PPM
Type                Unknown
Detector          : SPD-10A Single
Operator            NRP
Method Name       : 7015GR M01
```

Identification

*** Cnromatogram *** Filename:70 MANDELIC ACID



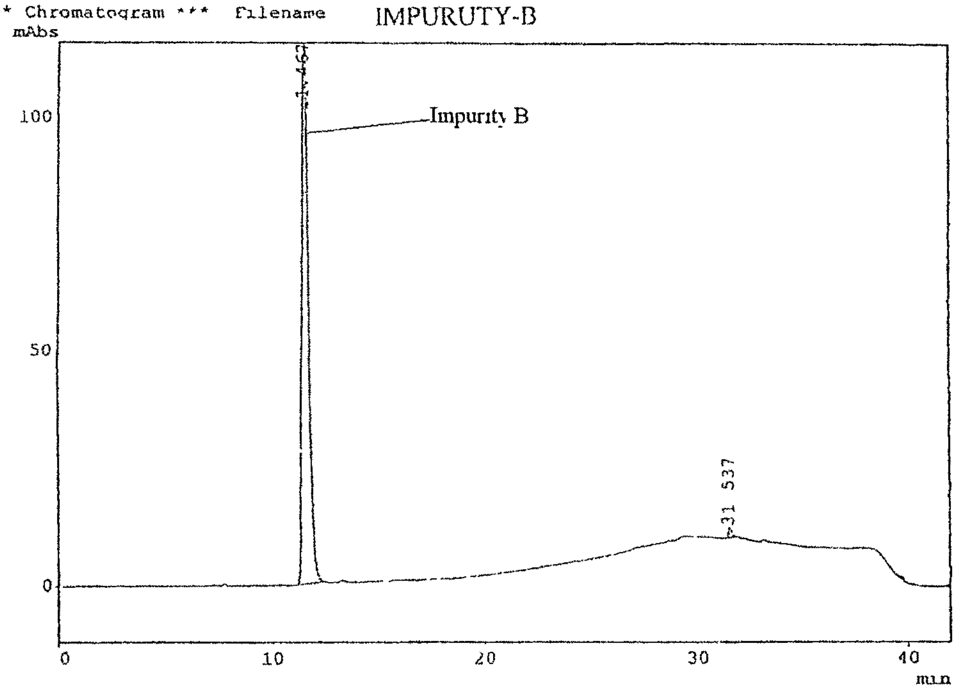

```
*** Peak Report ***
P/NO   TIME        AREA       CONC (%)
  1    2.462       637524     100 0000
----------------------------------------
                   637524     100 0000
```

Figure-85

IDENTIFICATION

```
CLASS-LC10 Ver =1.60  SYS=1 Ch=1 REPORT.NO=28 DATA=7015V D09
Sample          . 7015
ID              . IMP.B-150PPM
Type            . Unknown
Detector        . SPD-10A Single
Operator          NRP
Method Name     . 7015GR.M01
```

*** Chromatogram *** Filename IMPURUTY-B



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	11.467	2541756	99.1580
2	31.537	21584	0.8420
		2563340	100 0000

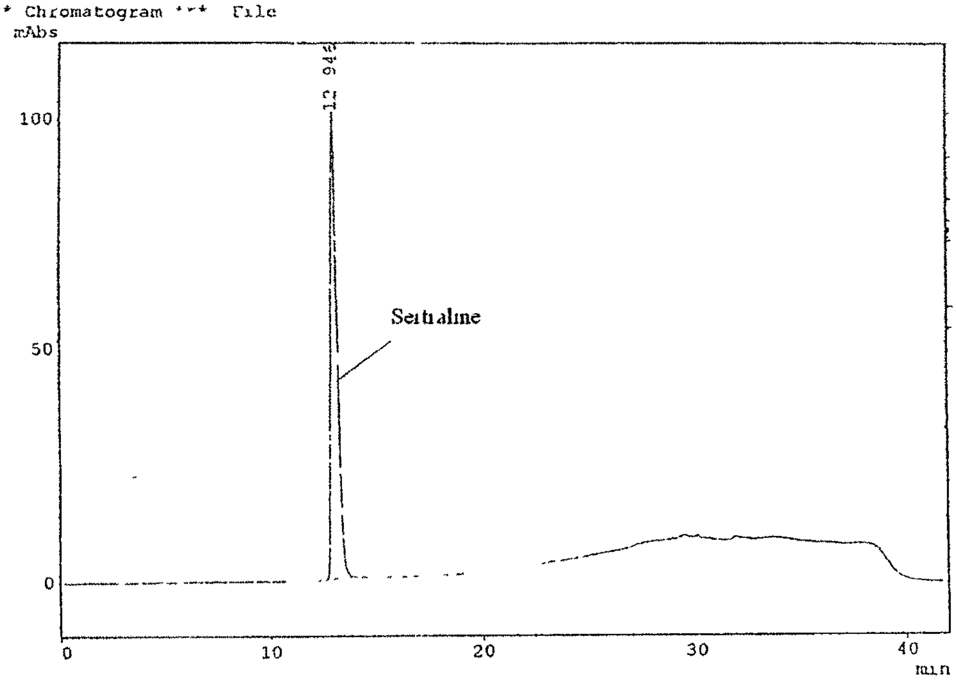
Figure-86

IDENTIFICATION

```
CLASS-LC10 Ver.=1 60  SYS=1 Ch=1 REPORT NO=33 DATA=7015V.D14
Sample          7015
ID            . 7015150PPM
Type            Unknown
Detector      . SPD-10A Single
Operator      . NRP
Method Name     7015GR M01
```

Sertraline

*** Chromatogram *** File



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	12.946	2181301	100 0000
		2181301	100 0000

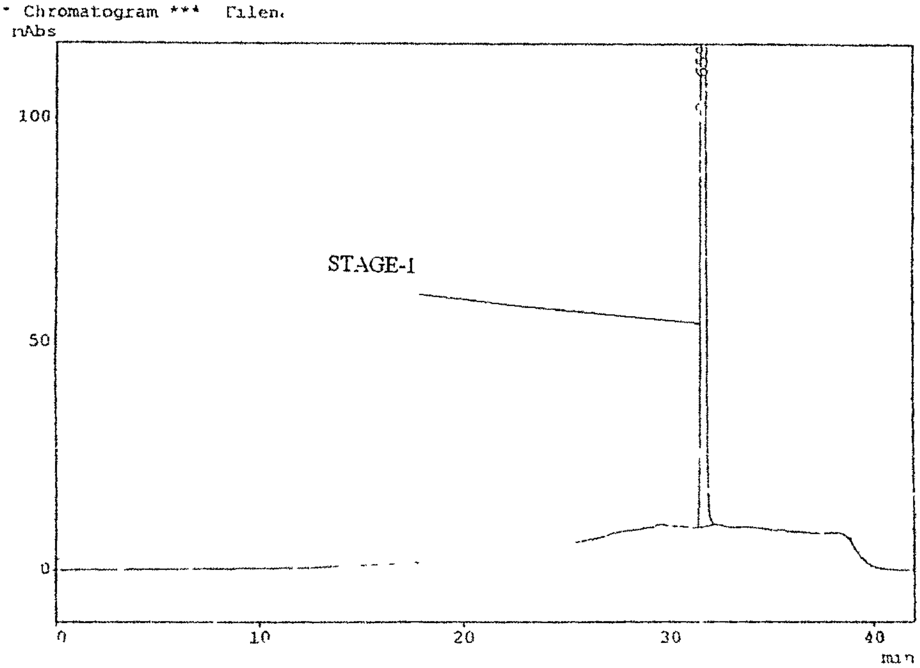
Figure-87

IDENTIFICATION

CLASS-LC10 Ver =1 60 SYS=1 Ch=1 REPORT NO=30 DATA=7015V D11
Sample   7015
ID   STAGE-1, 150PPM
Type   Unknown
Detector   SPD-10A Single
Operator   NRP
Method Name   7015GR M01

SERTRALINE/STAGE-1

*** Chromatogram *** Filen



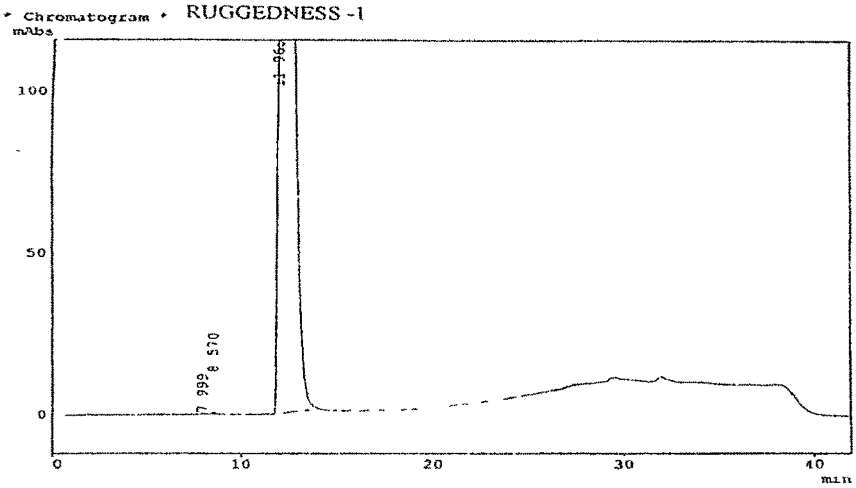
*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	31.659	4954346	100.0000
		4954346	100 0000

Figure-88

```
CLASS-LC10 Ver =1 60   SYS=1 Ch=1 REPORT.NO=7   DATA /015R.D28
Sample          . 7015REG
ID              . 7015RUGG--1
Type            . Unknown
Detector        . SPD-10A Single
Operator        : NRP
Method Name       7015GR.M01
```

*** Chromatogram * RUGGEDNESS -1

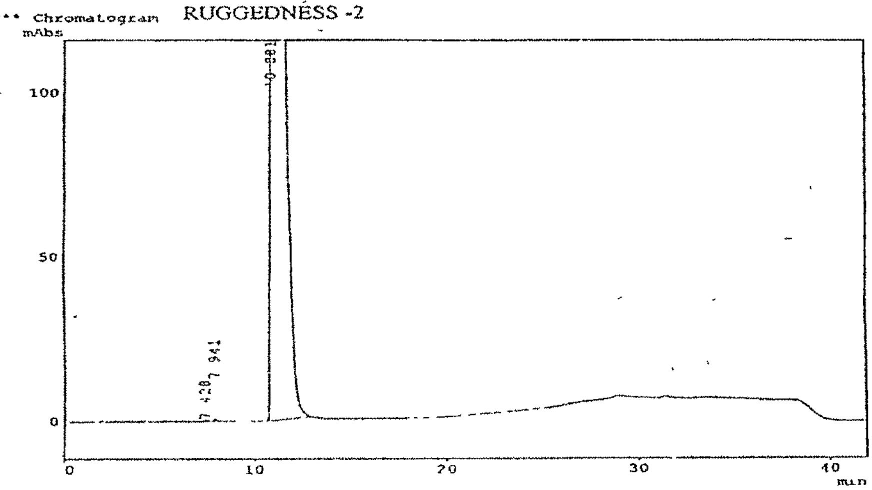


*** Peak Report ***

PKNO	TIME	AREA	CONC [?]
1	7.999	3193	0 0246
2	8 570	7469	0.0576
3	11 965	12957972	99 9178
		12968634	100 0000

```
CLASS-LC10 Ver =1 60   SYS=1 Ch=1 REPORT NO=8   DATA=7015RG D07
Sample            7015rug--1
ID              . rug-smp-1
Type            . Unknown
Detector          SPD-10A Single
Operator          yc
Method Name     . /015GR.M01
```

*** Chromatogram RUGGEDNESS -2



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	7.428	3136	0 0231
2	7.941	7878	0 0580
3	10.881	13583591	99 9190
		13594606	100.0000

Figure-89

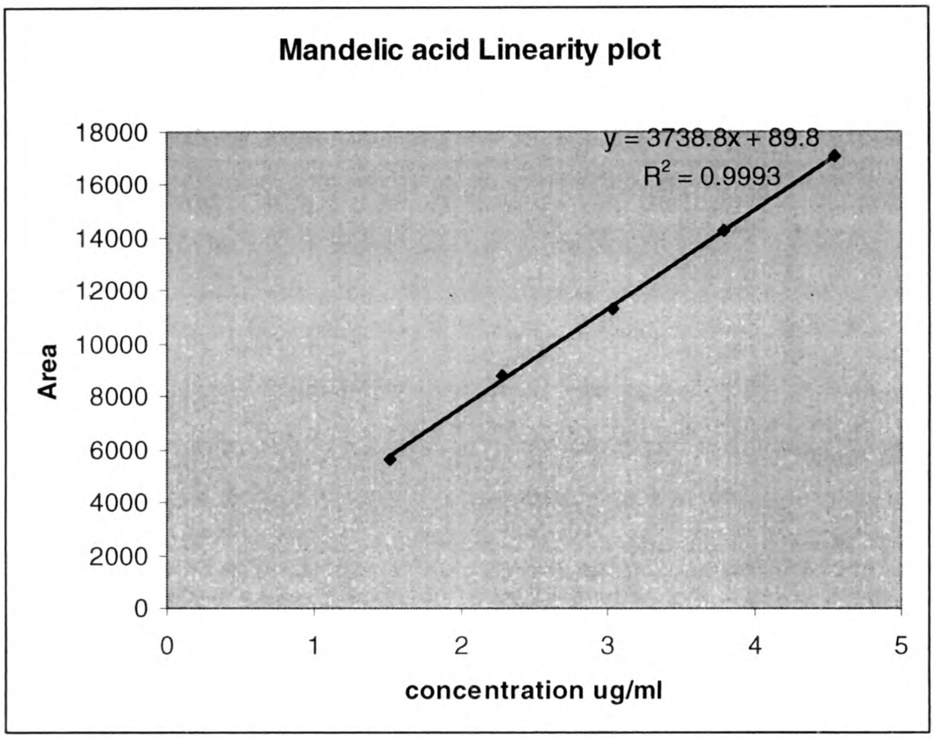


Figure-90

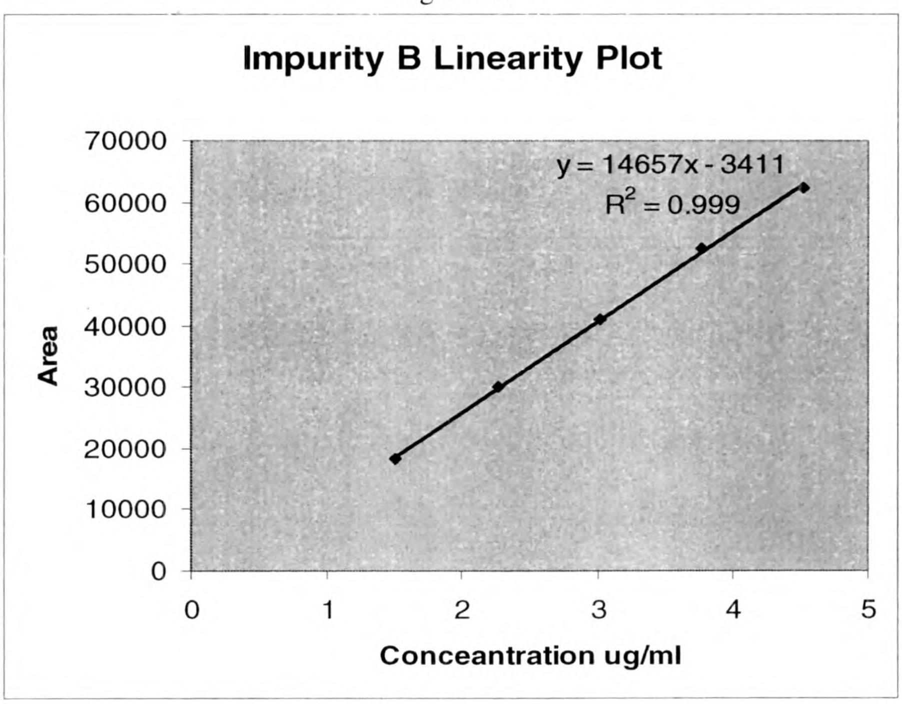


Figure-91

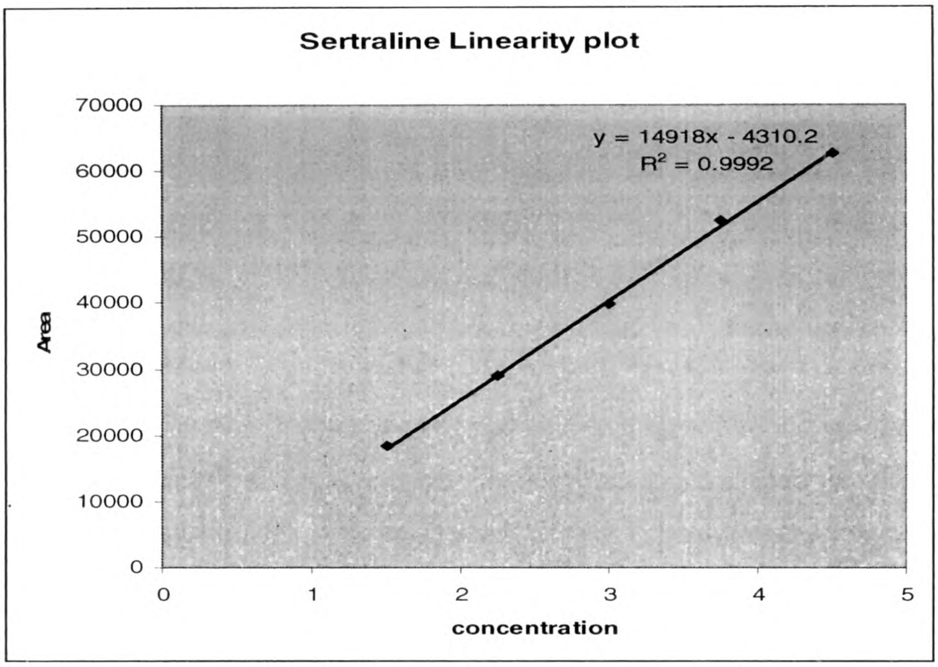


Figure-92

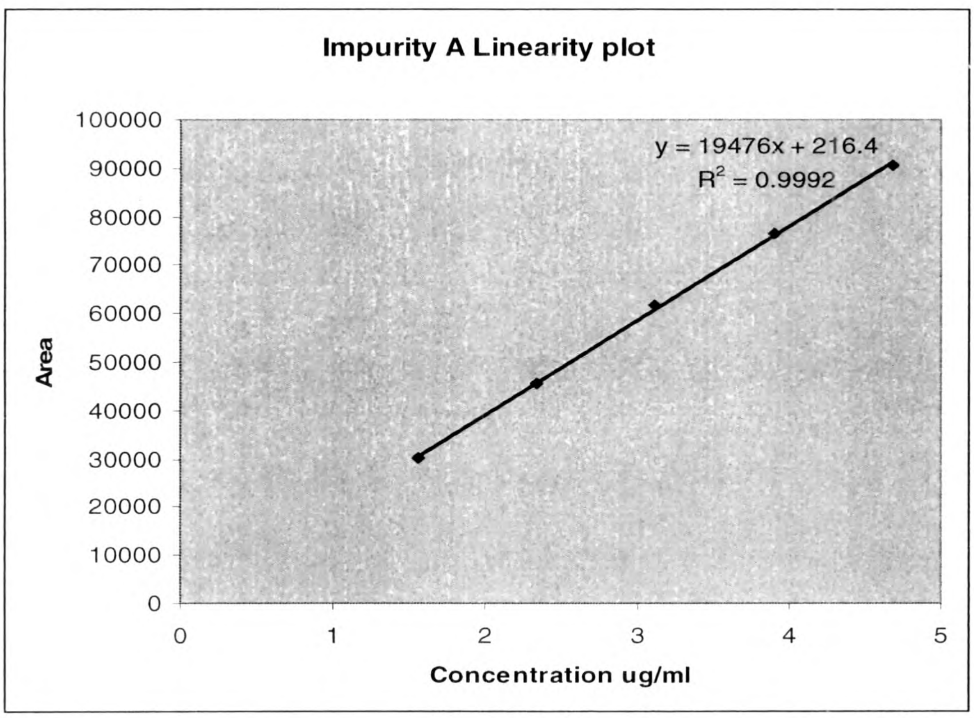
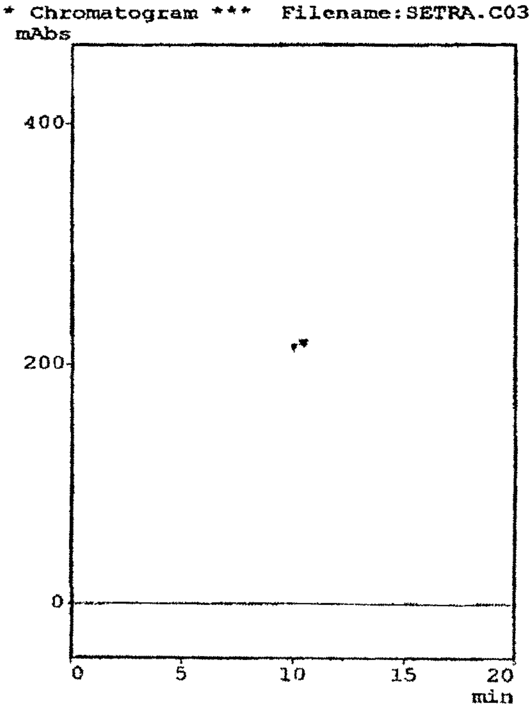


Figure-93

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=251 DATA=SETRA.D03
Sample : SERTRALINE
ID : M.P.
Type : Unknown
Detector : SPD-10A Single
Operator : YDC
Method Name : SETR.MET

*** Chromatogram *** Filename:SETRA.C03

*** Peak Report ***
!! No Peak !!

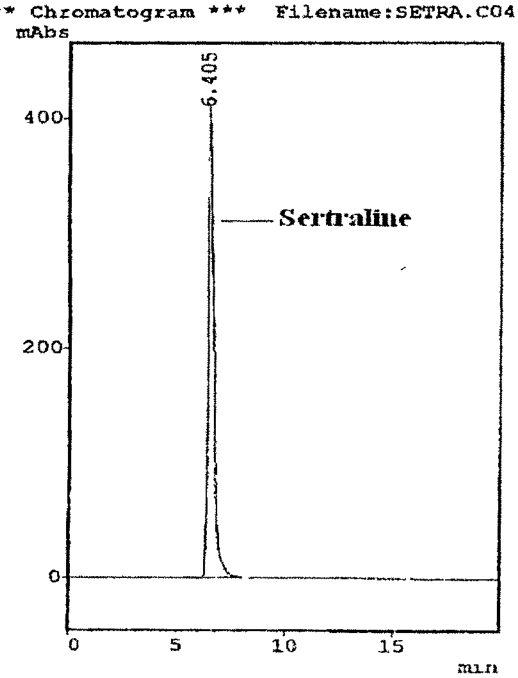


Sertraline assay method
Blank chromatogram

Figure -95

```
CLASS-LC10 Ver.=1.60  SYS=2 Ch=1 REPORT.NO=240 DATA=SETRA.D04
Sample        : SERTRALINE
ID            : SYST.PRE.
Type          : Unknown
Detector      : SPD-10A Single
Operator      : YDC
Method Name   : SETR.MET
```

*** Chromatogram ***   Filename:SETRA.C04



*** Peak Report ***

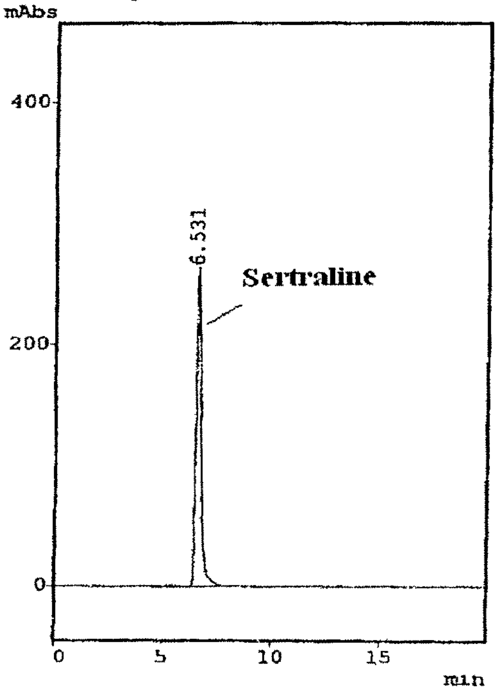
PKNO	TIME	AREA	HEIGHT	MK
1	6.405	7468572	409374	
		7468572	409374	

System precision chromatogram

Figure -96

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=25 DATA=SETRA.D13
Sample   : SERTRALINE
ID   : L1
Type   : Unknown
Detector   : SPD-10A Single
Operator   : YDC
Method Name   : SETR.MET

*** Chromatogram *** Filename:SETRA.C13



*** Peak Report ***

PKNO	TIME	AREA	HEIGHT	MK
1	6.531	4037492	264754	
		4037492	264754	

Linearity chromatogram level 1

*** Column Performance Report ***

R.TIME	Plate #	Tailing
6.531	4626	2.28

Figure-97

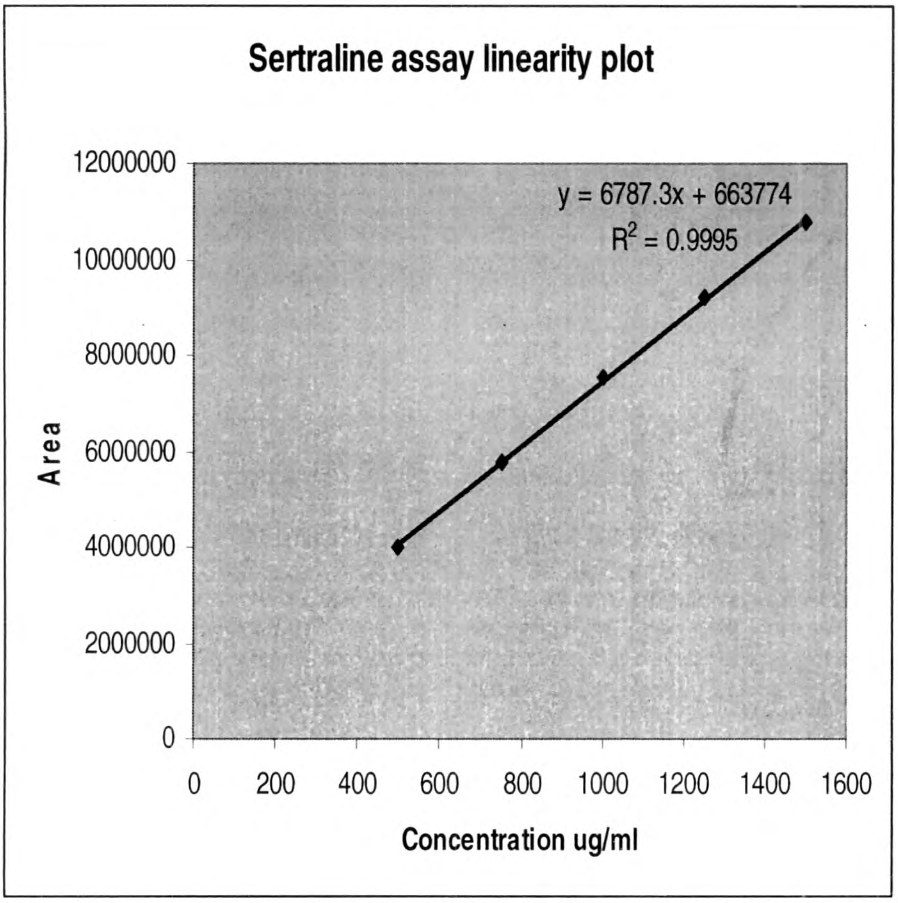
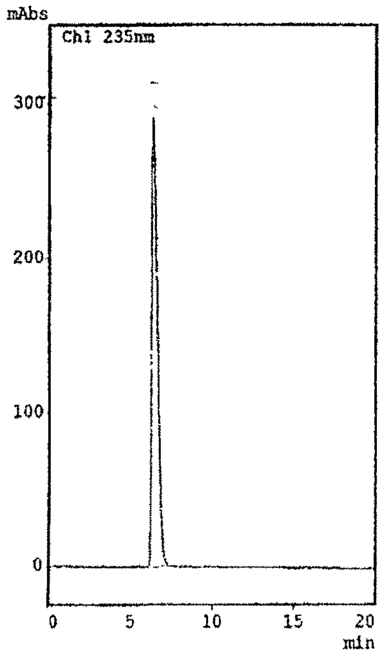

Sertraline assay linearity plot
y = 6787.3x + 663774
R2 = 0.9995
12000000
10000000
8000000
6000000
4000000
2000000
0
Area
0
200
400
600
800
1000
1200
1400
1600
Concentration ug/ml

Figure-98

```
CLASS-M10A Ver.-1.60  SYS=1 REPORT.NO-45 DATA-SETRL.K22
Sample          : SERTRA
ID              : 105oC
Type            : Unknown
Detector        : SPD-M10Avp
Operator        : YDC
Method Name     : SER.MET
```

*** Chromatogram ***



*** Peak Report ***

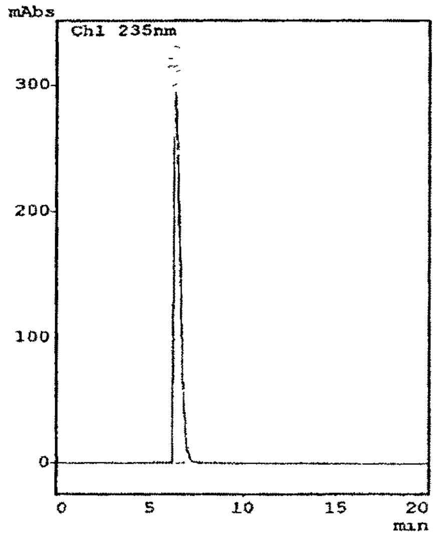
TIME	AREA	MK
6.337	6930454	
	6930454	

Sertraline heated as such at 105 deg C

Figure-99

```
CLASS-M10A Ver.=1.60  SYS=1 REPORT.NO=47 DATA=SETRL.K24
Sample          : SERTRA
ID              : U.V.DEG.
Type            : Unknown
Detector        : SPD-M10Avp
Operator        : YDC
Method Name     : SER.MET
```

*** Chromatogram ***



*** Peak Report ***

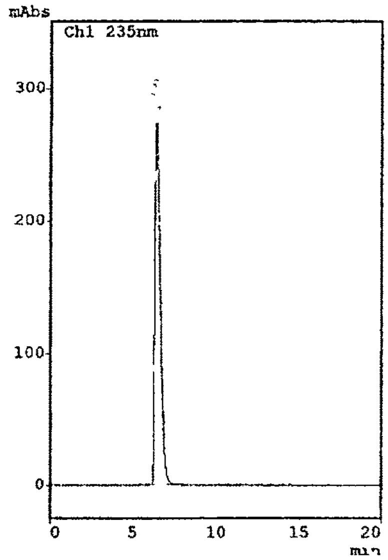
TIME	AREA	MK
6.318	6931898	
	6931898	

UV light degration chromatogram

Figure-100

CLASS-M10A Ver.=1.60 SYS=1 REPORT.NO=49 DATA=SETRL.K26
Sample : SERTRA
ID : NORMAL LIGHT
Type : Unknown
Detector : SPD-M10Avp
Operator : YDC
Method Name : SER.MET

*** Chromatogram ***



*** Peak Report ***

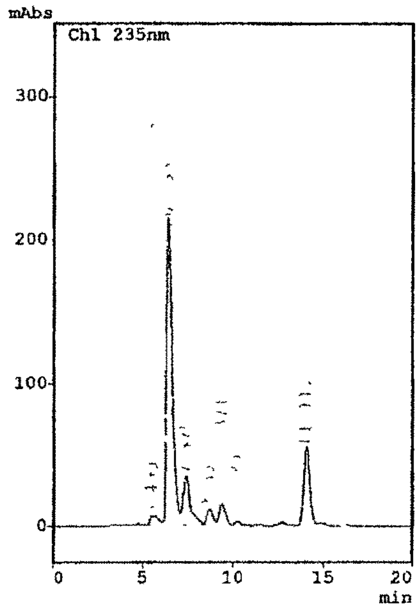
TIME	AREA	MK
6 320	6376680	
	6376680	

Sun light degradation

Figure-101

CLASS-M10A Ver.=1.60 SYS=1 REPORT.NO=52 DATA=SETRL.K29
Sample : SERTRA
ID : KMNO4
Type : Unknown
Detector : SPD-M10Avp
Operator : YDC
Method Name : SER.MET

*** Chromatogram ***



*** Peak Report ***

TIME	AREA	MK
5.498	179271	
6.335	4778904	V
7.375	941245	V
8.692	243411	V
9.371	350141	V
10.239	56024	V
14.086	1242056	
	7791053	

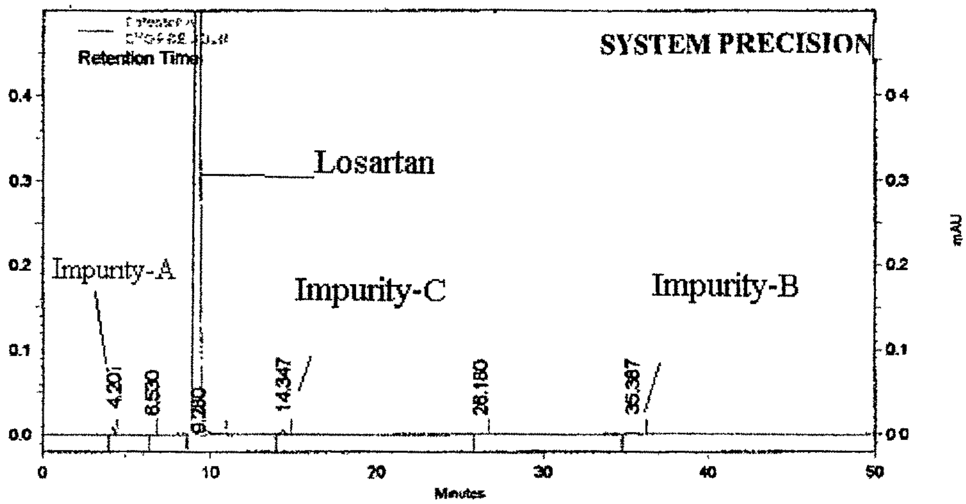
KMNO4 degradation

Figure-102

CLASS-VP V5.02 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\HPLCMET-11\8009LRSVL.met
Data Name: C:\CLASS-VP\DATA\HPLC-11\138009L.D08.dat
User: SYSTEM
Acquired: 5/13/99 11:53:02 PM
Printed: 5/15/99 11:51:15 AM

Losartan RS validation



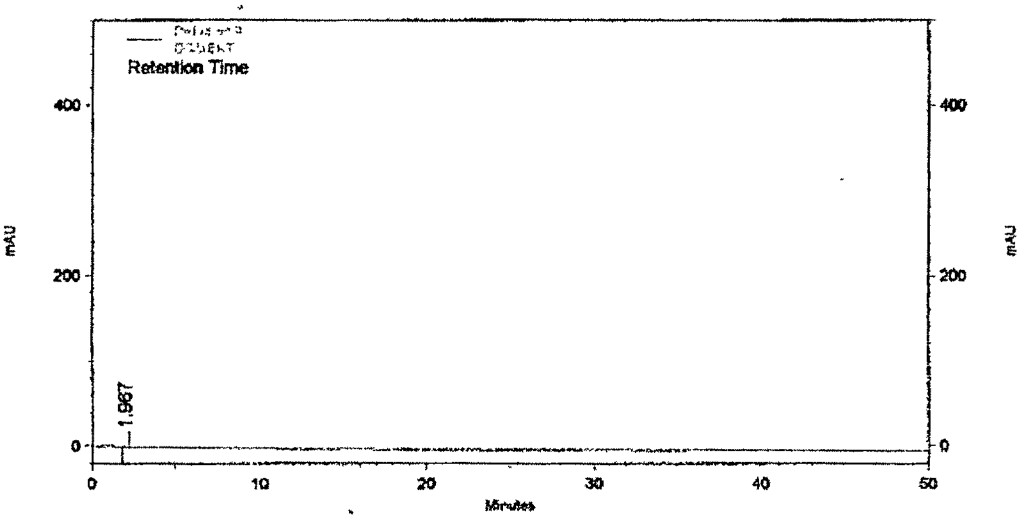
Pk #	Retention Time	Area	Area Percent
1	4.207	68555	0.225
2	6.530	6499	0.021
3	9.280	30289558	99.249
4	14.347	70266	0.230
5	26.180	15786	0.052
6	35.387	68110	0.223
Totals		30518774	100.000

Figure-103

CLASS-VP V5.02 *Area % Report*

Method Name:	**C:\CLASS-VP\METHODS\8009L.met**
Data Name:	**C:\CLASS-VP\8009va.000**
User:	**A.L.Prasad**
Acquired:	**5/1/99 5:49:29 PM**
Printed:	**5/3/99 1:44:10 PM**

Diluent blank



Pk #	Retention Time	Area	Area Percent
1	1.967	7930	100.000

Totals		7930	100.000

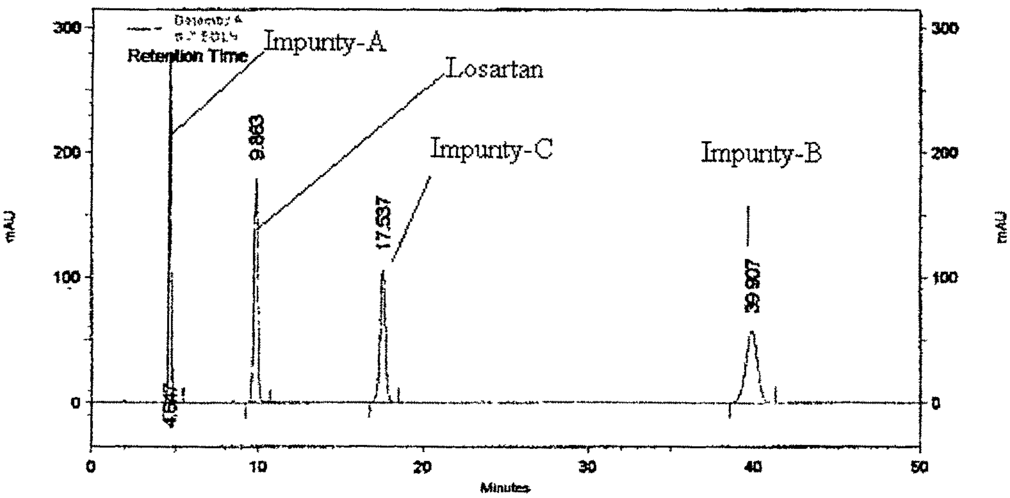
Figure-104

SYSTEM SUITABILITY

CLASS-VP V5.02 *Area % Report*

SYSTEM SUITABILITY CHROMATOGRAM

Method Name:	**C:\CLASS-VP\METHODS\HPLCMET-11\8009LRSVL.met**
Data Name:	**C:\CLASS-VP\DATA\HPLC-11\8009VLD-Rep2.004**
User:	**SYSTEM**
Acquired:	**5/6/99 11:09:22 PM**
Printed:	**5/15/99 2:49:35 PM Sample name: S.S.SOLN**



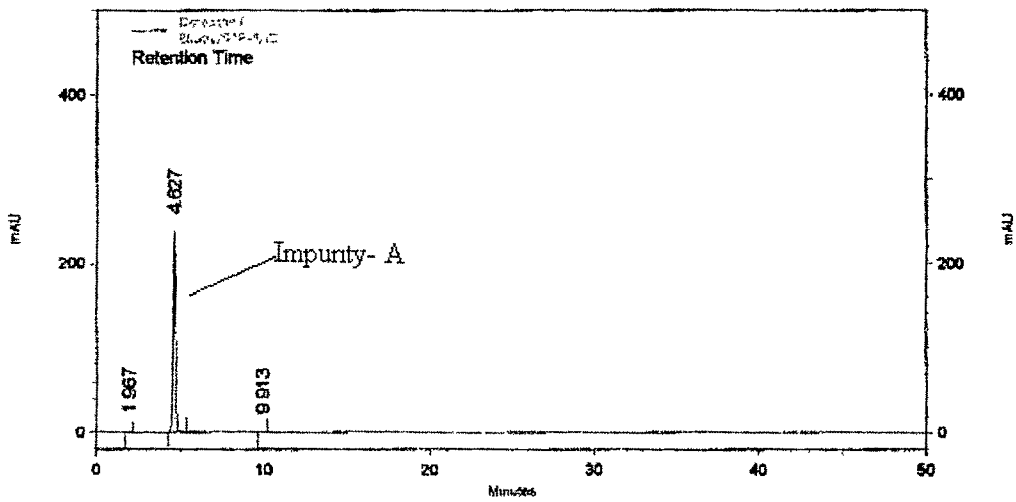
Pk #	Name	Retention Time	Resolution	Asymmetry	Theoretical plates
1		4.647	0.00	1.02	5205.49
2		9.863	15.78	0.96	9559.27
3		17.537	15.22	1.00	13445.81
4		39.907	23.59	0.97	15264.90
Totals					

Figure-105

IDENTIFICATION

CLASS-VP V5.02 *Area % Report*

Method Name: **C:\CLASS-VP\METHODS\8009L.met**
Data Name: **C:\CLASS-VP\8009VA-Rep1.003**
User: **A.L.Prasad**
Acquired: **5/1/99 10:08:46 PM**
Printed: **5/3/99 1:54:14 PM**



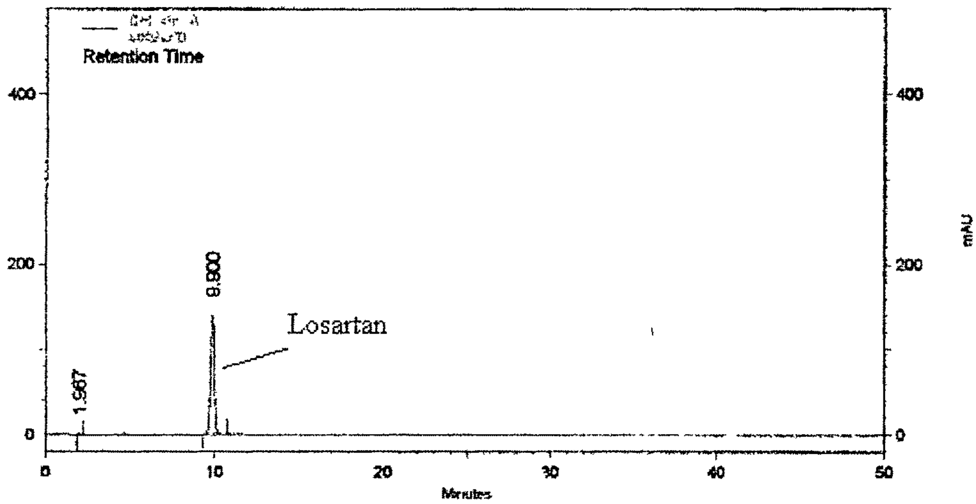
Pk #	Retention Time	Area	Area Percent
1	1.967	10343	0.431
2	4.627	2383497	99.251
3	9 913	7647	0.318
Totals		2401487	100.000

Figure-106

IDENTIFICATION

CLASS-VP V5.02 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\8009L.met**
Data Name: **C:\CLASS-VP\8009VA-Rep1.002**
User: **A.L.Prasad**
Acquired: **5/1/99 8:25:02 PM**
Printed: **5/3/99 1:50:52 PM**



Pk #	Retention Time	Area	Area Percent
1	1.967	8378	0.385
2	9.900	2166947	99.615

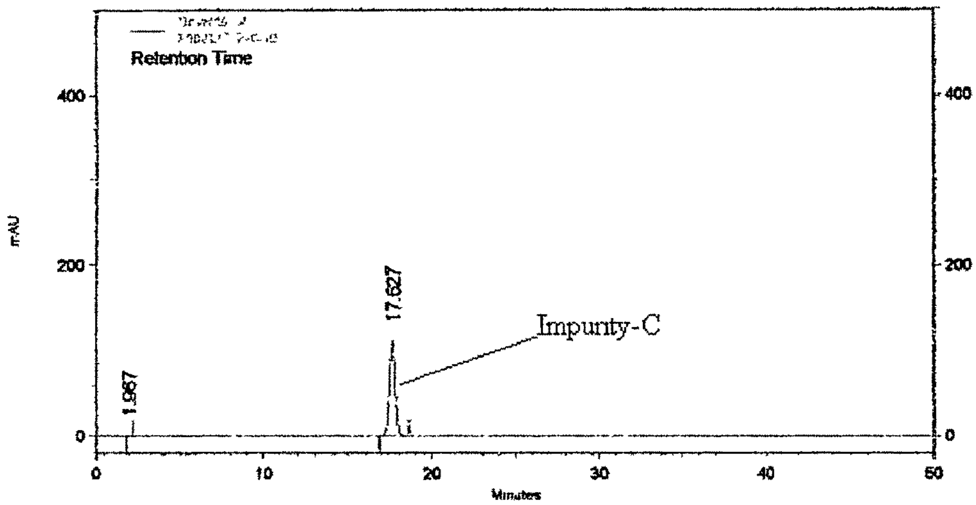
Totals			
		2175325	100.000

Figure-107

IDENTIFICATION

CLASS-VP V5.02 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\8009L.met**
Data Name: **C:\CLASS-VP\8009VA-Rep2.005**
User: **A.L.Prasad**
Acquired: **5/2/99 2:28:10 AM**
Printed: **5/3/99 2:04:36 PM**



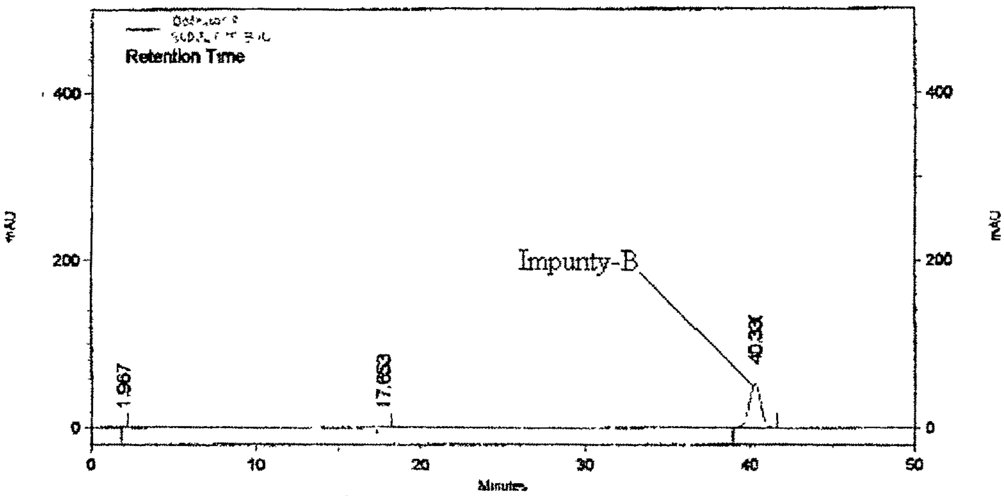
Pk #	Retention Time	Area	Area Percent
1	1.967	9444	0.362
2	17.627	2599016	99.638
Totals		2608460	100.000

Figure-108

IDENTIFICATION

CLASS-VP V5.02 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\8009L.met**
Data Name: **C:\CLASS-VP\8009VA-Rep2.004**
User: **A.L.Prasad**
Acquired: **5/2/99 12:44:27 AM**
Printed: **5/3/99 2:04:07 PM**



Pk #	Retention Time	Area	Area Percent
1	1.967	9396	0.355
2	17.653	15089	0.570
3	40.330	2622972	99.075

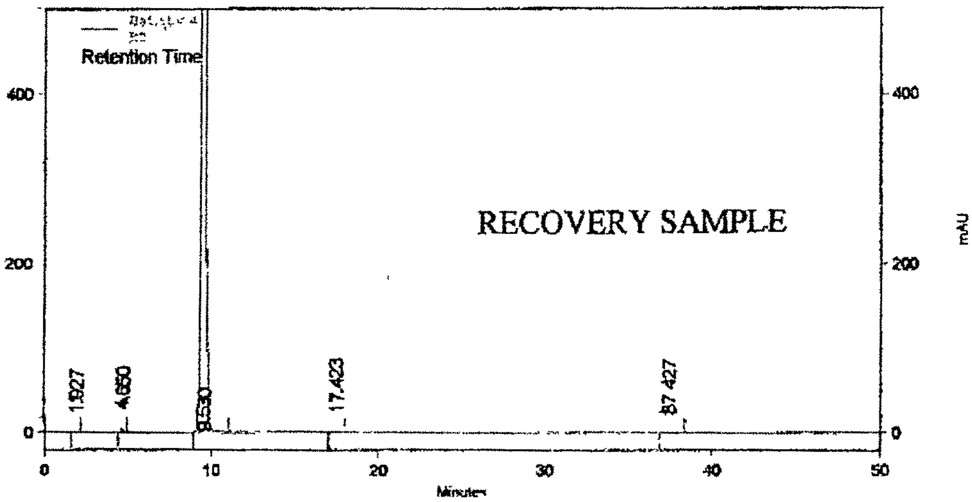
Totals			
		2647457	100.000

Figure-109

CLASS-VP V5.02 *Area % Report*

Method Name: **C:\CLASS-VP\METHODS\HPLCMET-11\8009LRSVL.met**
Data Name: **C:\CLASS-VP\8009V-Rep1.026**
User: **SYSTEM**
Acquired: **5/5/99 5:12:16 PM**
Printed: **5/10/99 10:30:09 AM**

Recovery



Pk #	Retention Time	Area	Area Percent
1	1.927	15260	0.071
2	4.650	47311	0.219
3	9.530	21468136	99.286
4	17.423	48383	0.224
5	37.427	43469	0.201

Totals			
		21622559	100.000

Figure-110

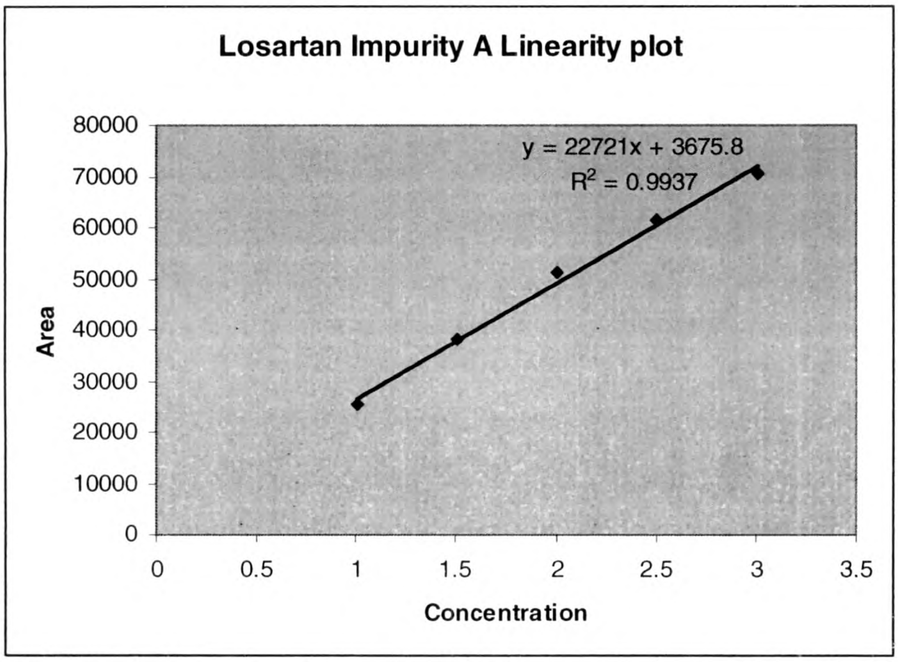


Figure-51

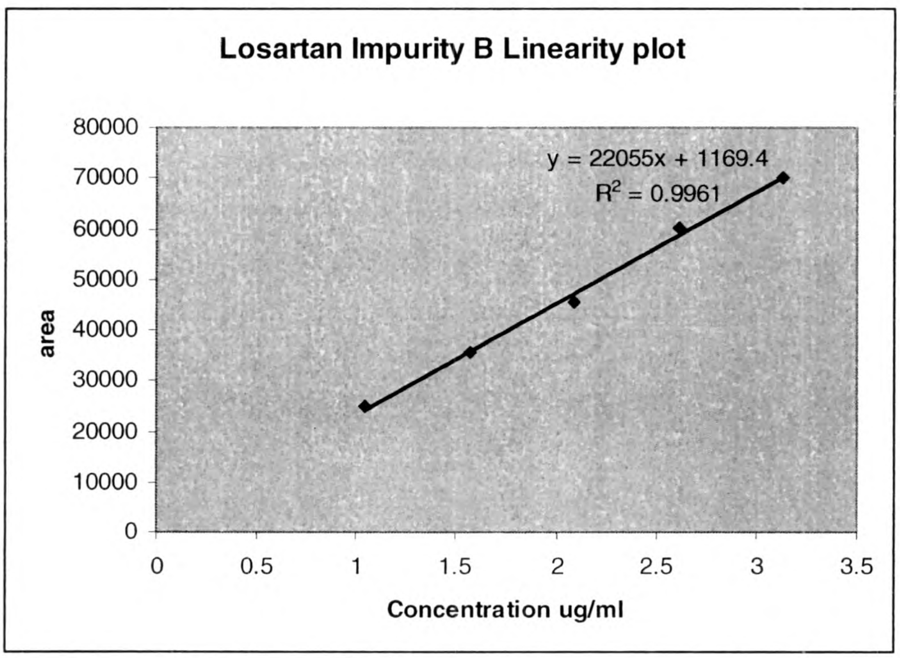


Figure-112

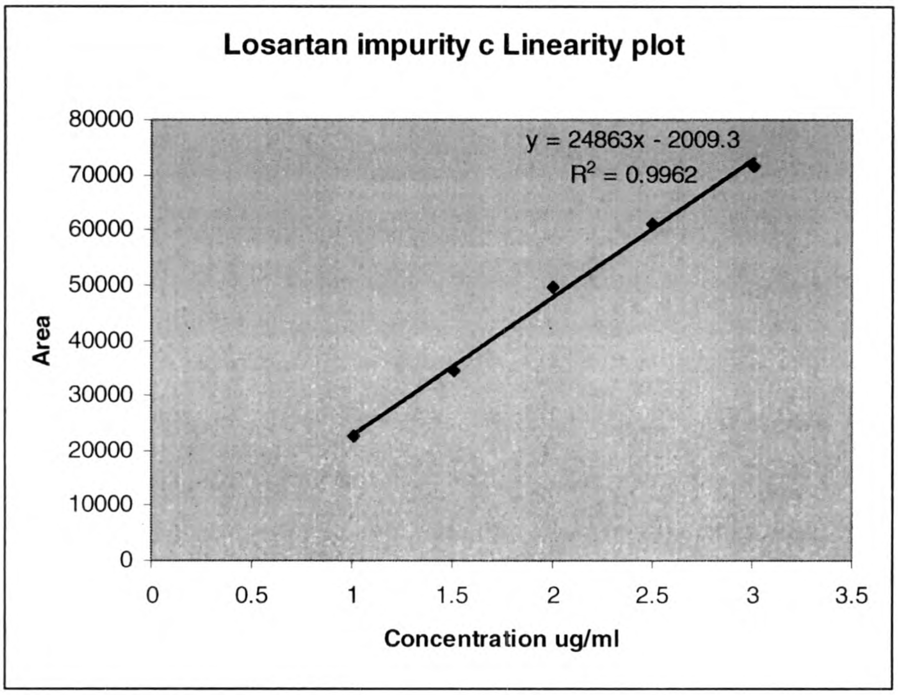

Losartan impurity c Linearity plot
y = 24863x - 2009.3
R2 = 0.9962
Area
Concentration ug/ml
80000
70000
60000
50000
40000
30000
20000
10000
0
0
0.5
1
1.5
2
2.5
3
3.5

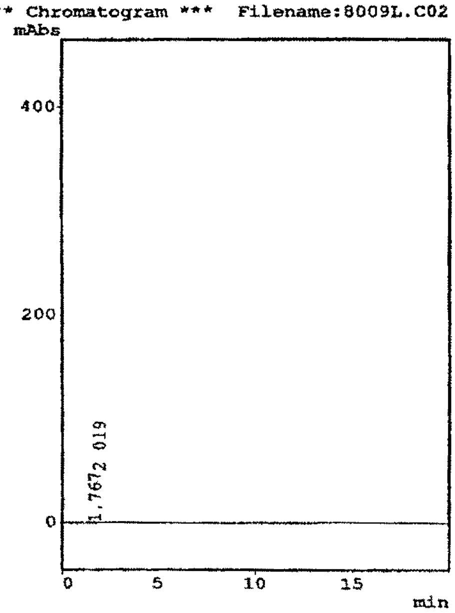
Figure-113

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=216 DATA=8009L.D02

Losartan Assay validation

Sample : 8009L
ID : DILUENT
Type : Unknown
Detector : SPD-10A Single
Operator : YDC
Method Name : 8009L.MET

*** Chromatogram *** Filename:8009L.C02



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	1.767	2510	30.7801
2	2 019	5645	69.2199
		8156	100.0000

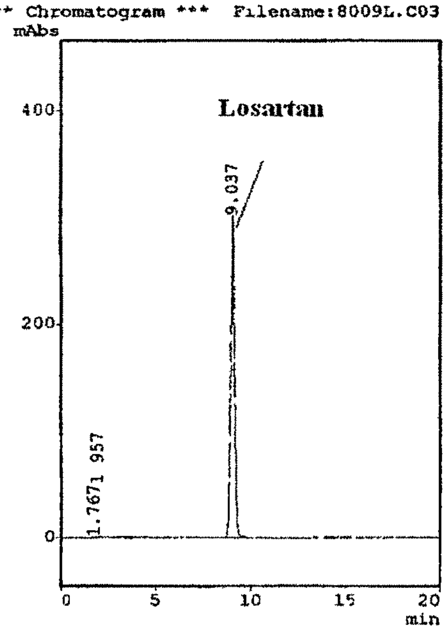
Figure-114

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=217 DATA=8009L.D03

Sample : 8009L
ID : SYS.PRE.
Type : Unknown
Detector : SPD-10A Single
Operator : YDC
Method Name : 8009L.MET

System Precision

*** Chromatogram *** Filename:8009L.C03



*** Peak Report ***

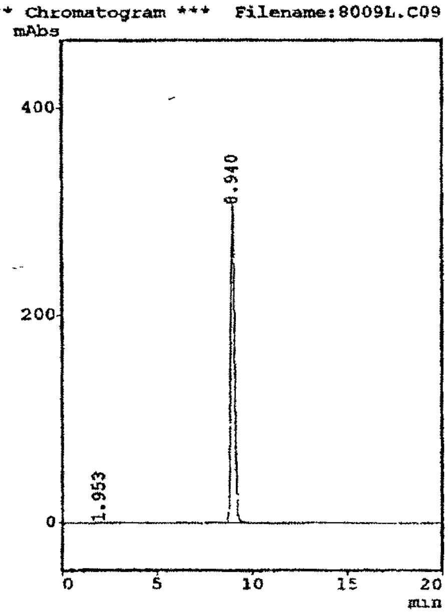
PKNO	TIME	AREA	CONC [%]
1	1.767	2878	0.0651
2	1.957	7112	0.1609
3	9.037	4409189	99.7739
		4419180	100.0000

Figure-115

```
CLASS-LC10 Ver.=1.60  SYS=1 Ch=1 REPORT.NO=223 DATA=8009L.D09
Sample          : 8009L
ID              : SOLN.STSBIL.
Type            : Unknown
Detector        : SPD-10A Single
Operator        : YDC
Method Name     : 8009L.MET
```

Solution stability study

*** Chromatogram ***   Filename:8009L.C09



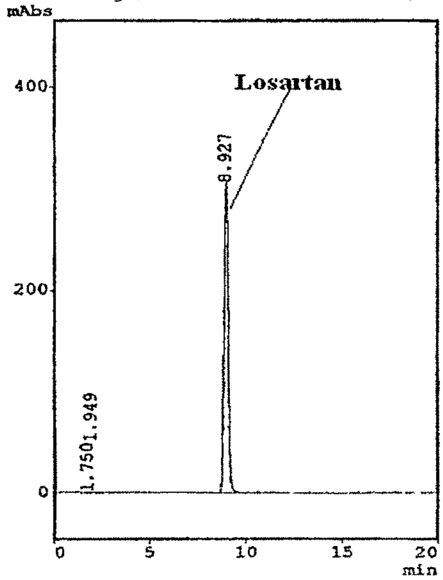
*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	1.953	8925	0.2031
2	8.940	4385612	99.7969
		4394537	100.0000

Figure-116

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=224 DATA=8009L.D10
Sample : 8009L
ID : MET.PRE.STD **Method precision**
Type : Unknown
Detector : SPD-10A Single
Operator : YDC
Method Name : 8009L.MET

*** Chromatogram *** Filename:8009L.C10



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	1.750	1718	0.0391
2	1.949	6098	0.1389
3	8.927	4383074	99.8220
		4390890	100.0000

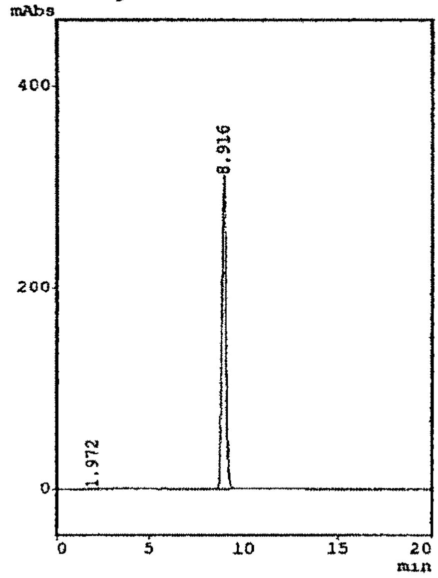
Figure-117

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=253 DATA=8009L.D39 99/01/08 03:49:48

Sample : 8009L
ID : RUGG.SPL.
Type : Unknown
Detector : SPD-10A Single
Operator : YDC
Method Name : 8009L.MET

Ruggedness experiment

*** Chromatogram *** Filename:8009L.C39



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	1.972	11075	0.2485
2	8.916	4445604	99.7515
		4456680	100.0000

Figure-118

CLASS-LC10 Ver.=1.60 SYS=1 Ch=1 REPORT.NO=300 DATA=8009N.D10

Sample : 8009L

ID : LIN-1

Linearity level 1

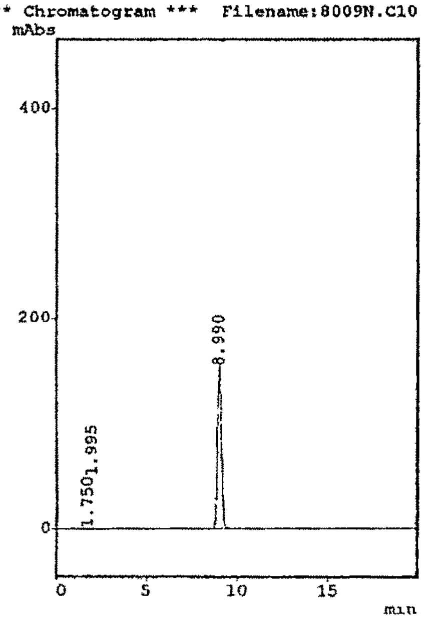
Type : Unknown

Detector : SPD-10A Single

Operator : YDC

Method Name : 8009L.MET

*** Chromatogram *** Filename:8009N.C10



*** Peak Report ***

PKNO	TIME	AREA	CONC [%]
1	1.750	2075	0.0923
2	1.995	6377	0.2837
3	8.990	2239500	99.6240
		2247953	100 0000

Figure-119

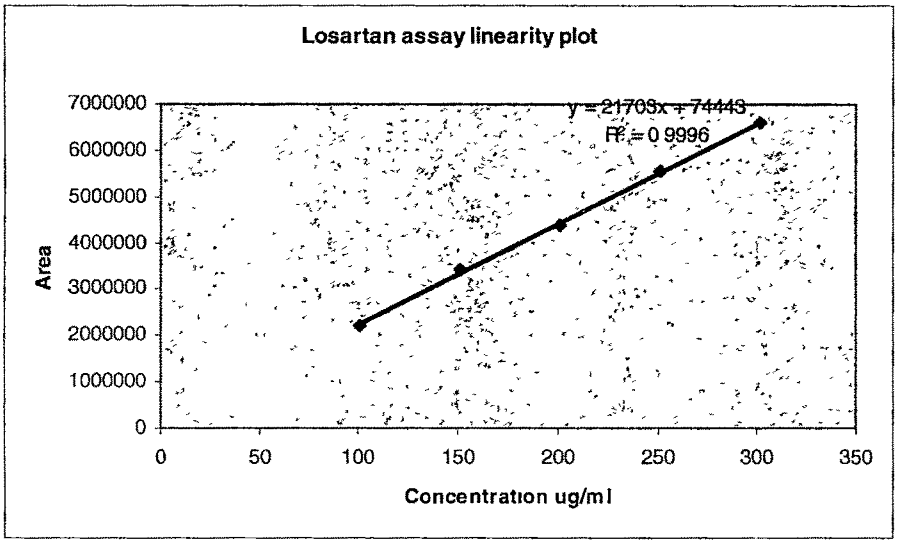
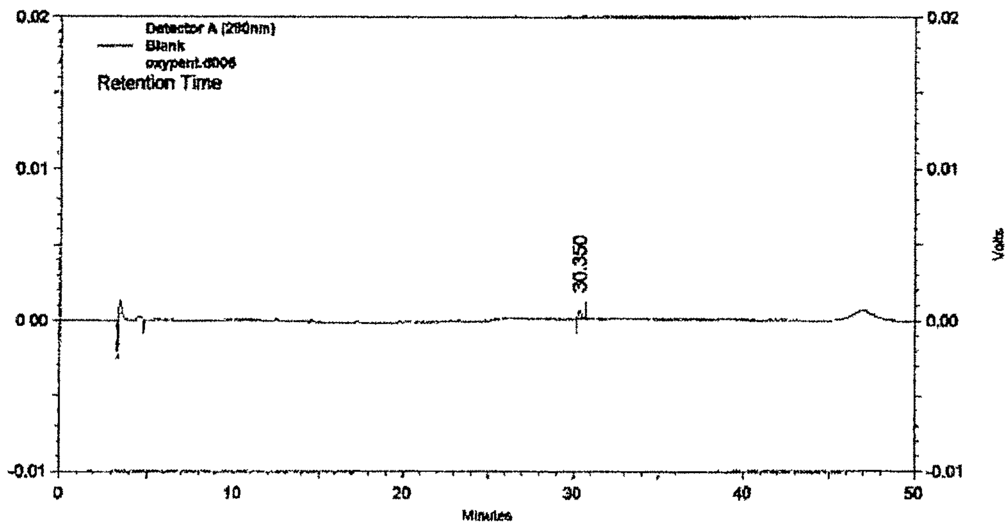

Losartan assay linearity plot
y = 21703x + 74443
R² = 0 9996
Area
7000000
6000000
5000000
4000000
3000000
2000000
1000000
0
0
50
100
150
200
250
300
350
Concentration ug/ml

Figure-120

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d006
Acquired: 7/7/99 3:17:32 PM
Sample name: Blank

Blank- Pentoxifylline



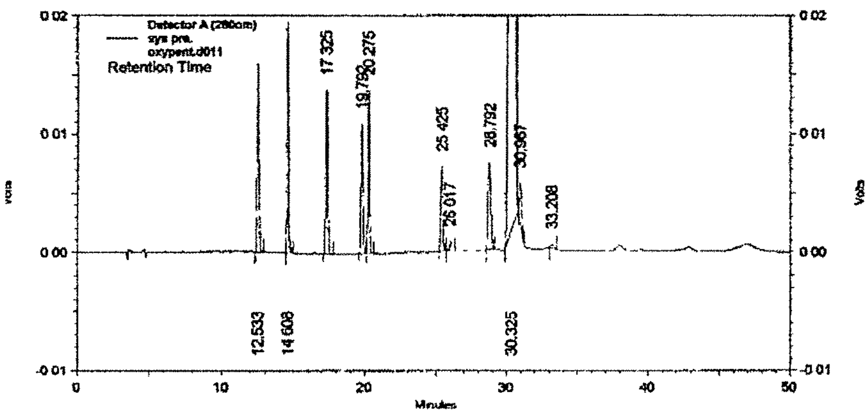
Pk #	Retention Time	Area	Area Percent
1	30.350	6954	100.00
Totals		6954	100.00

Figure-121

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d011
Acquired: 7/7/99 7:37:07 PM
Sample name: sys.pre.

System precision chromatogram



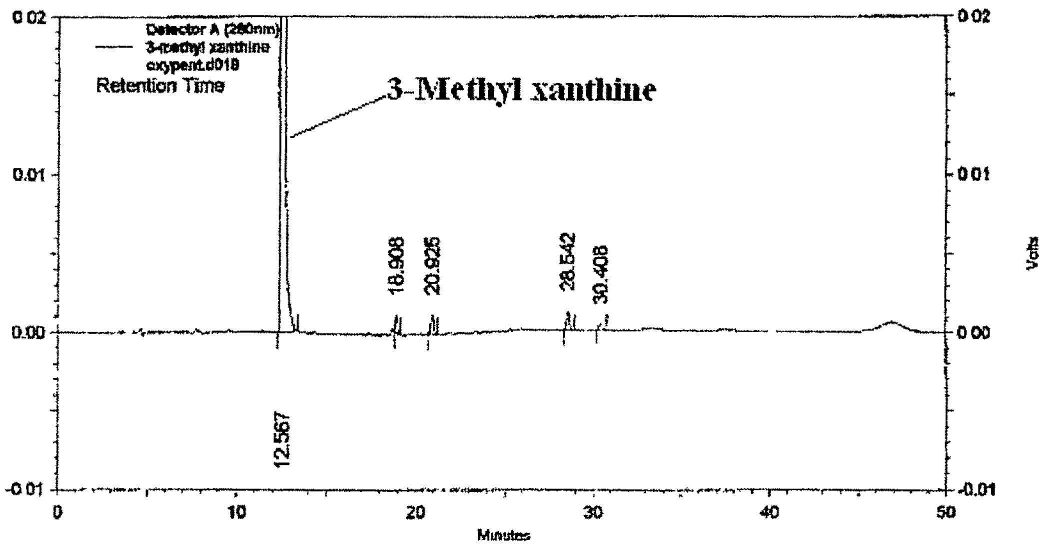
Pk #	Retention Time	Area	Area Percent
1	12.533	125831	0.34
2	14 608	129895	0.35
3	17 325	118458	0.32
4	19 792	96343	0 26
5	20.275	126021	0.34
6	25 425	70323	0 19
7	26.017	7615	0 02
8	28.792	97134	0.26
9	30.325	36730516	97 82
10	30.967	42611	0 11
11	33 208	5633	0.02
Totals		37550380	100 00

Figure-122

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met**
Data Name: **C:\YDC\oxypent.d018**
Acquired: **7/8/99 1:39:29 AM**
Sample name: **3-methyl xanthine**

Identification



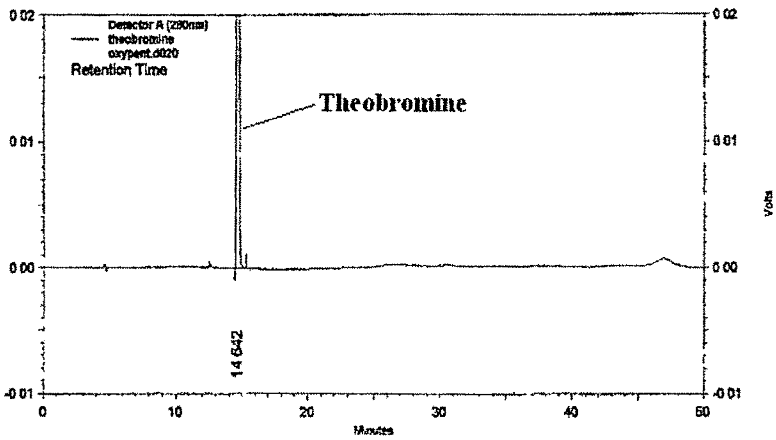
Pk #	Retention Time	Area	Area Percent
1	12.567	6113675	99.31
2	18.908	8786	0.14
3	20.925	13414	0.22
4	28.542	15582	0.25
5	30.408	5004	0.08

Totals		6156461	100.00

Figure-123

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d020
Acquired: 7/8/99 3:23:05 AM
Sample name: theobromine



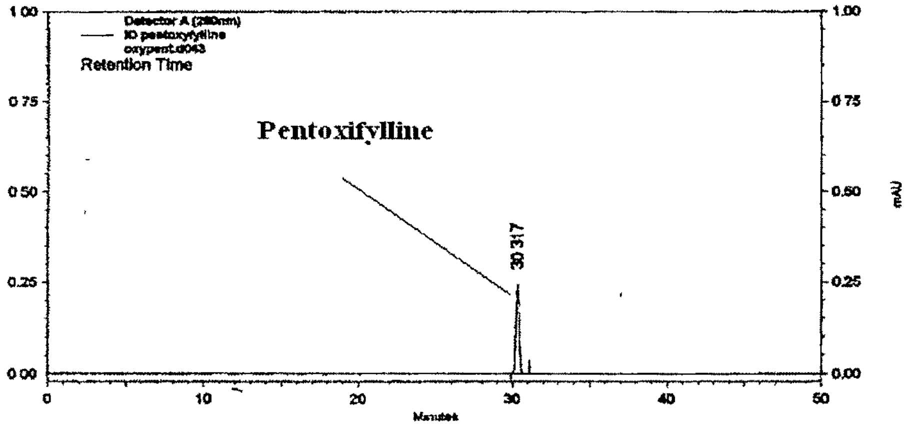
Pk #	Retention Time	Area	Area Percent
1	14.642	6267350	100.00

Totals			
		6267350	100.00

Figure-124

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d043
Acquired: 7/10/99 6:00:40 PM
Sample name: ID pentoxyfylline

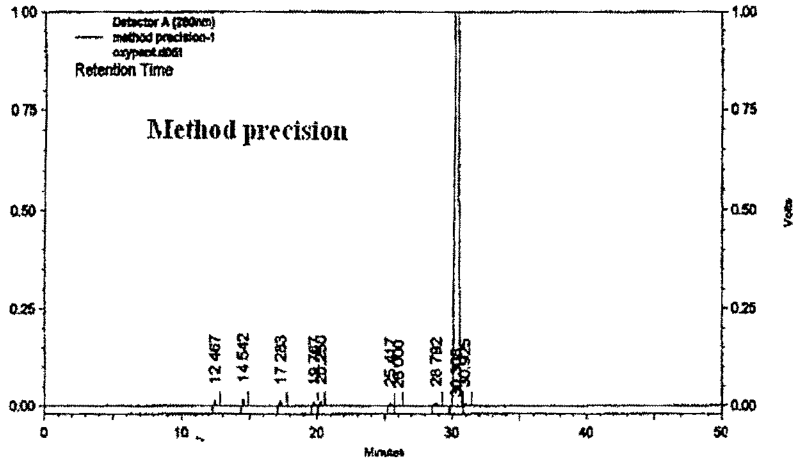


Pk #	Retention Time	Area	Area Percent
1	30 317	3848851	100.00
Totals		3848851	100.00

Figure-125

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d051
Acquired: 7/11/99 12:54:46 AM
Sample name: method precision-1



Pk #	Retention Time	Area	Area Percent
1	12.467	121337	0.31
2	14.542	126375	0.33
3	17.283	114432	0 30
4	19.767	90703	0.23
5	20.250	115606	0.30
6	25 417	74592	0.19
7	26.000	10628	0.03
8	28.792	93120	0.24
9	30 308	37853050	97.85
10	30.925	84782	0 22

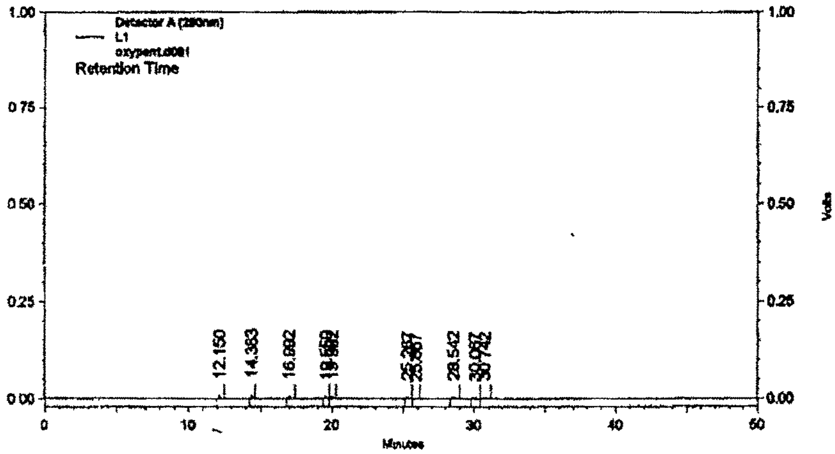
Totals			
		38684645	100.00

Figure-126

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d081
Acquired: 7/13/99 7:18:24 PM
Sample name: L1

Linearity level-1



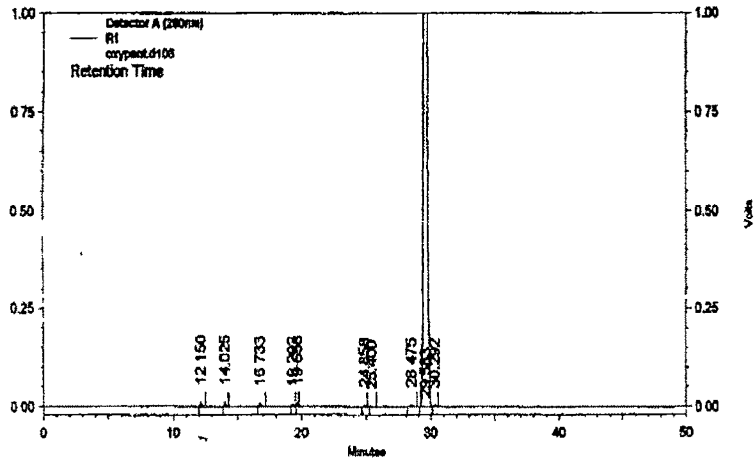
Pk #	Retention Time	Area	Area Percent
1	12 150	62500	13 76
2	14.383	63618	14.00
3	16.992	58357	12.84
4	19.550	46151	10 16
5	19.992	56138	12.36
6	25 267	32019	7.05
7	25.867	3707	0.82
8	28.542	50754	11.17
9	30 067	41390	9.11
10	30.742	39738	8 75
Totals		454372	100.00

Figure-127

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d106
Acquired: 7/21/99 3:53:48 AM
Sample name: R1

Recovery 1 chromatogram



Pk #	Retention Time	Area	Area Percent
1	12 150	84607	0.22
2	14 025	86519	0.22
3	16 733	79100	0 21
4	19.292	61394	0.16
5	19.658	74473	0.19
6	24.858	43628	0 11
7	25.400	5839	0.02
8	28.475	67876	0.18
9	29.583	38013351	98 56
10	30 292	52976	0.14

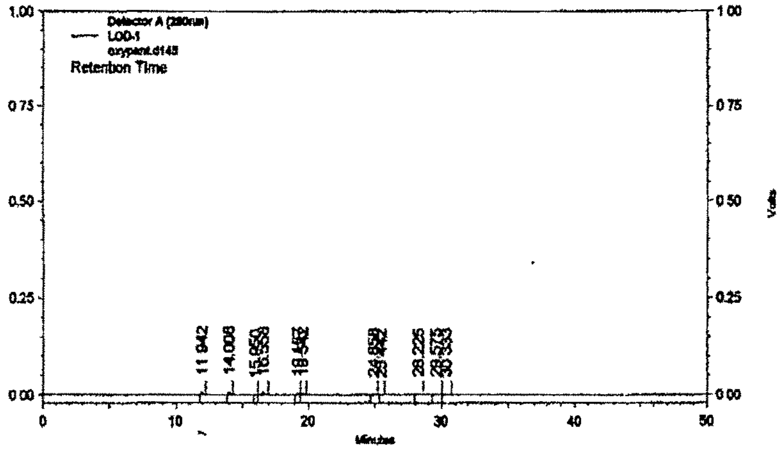
Totals		38569763	100 00

Figure-128

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d145
Acquired: 7/22/99 8:09:17 PM
Sample name: LOD-1

LOD & LOQ level-1



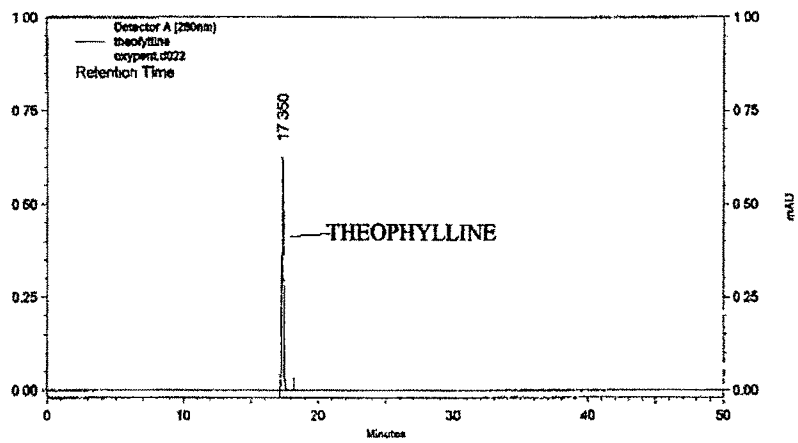
Pk #	Retention Time	Area	Area Percent
1	11 942	55395	13.72
2	14 008	56140	13.91
3	15 950	1173	0.29
4	16.558	52681	13.05
5	19 167	40341	9.99
6	19 542	49369	12.23
7	24.858	28148	6.97
8	25.442	2944	0 73
9	28 225	42026	10.41
10	29.575	39706	9.84
11	30 333	35691	8.84
Totals		403614	100.00

Figure-129

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d022
Acquired: 7/8/99 5:06:47 AM
Sample name: theofylline

Identification

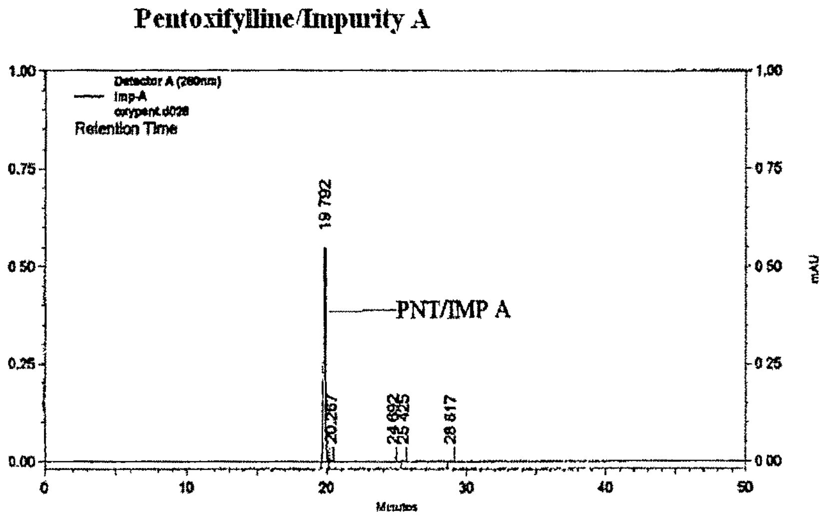


Pk #	Retention Time	Area	Area Percent
1	17 350	5499819	100 00
Totals		5499819	100 00

Figure-130

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d026
Acquired: 7/8/99 8:33:52 AM
Sample name: Imp-A



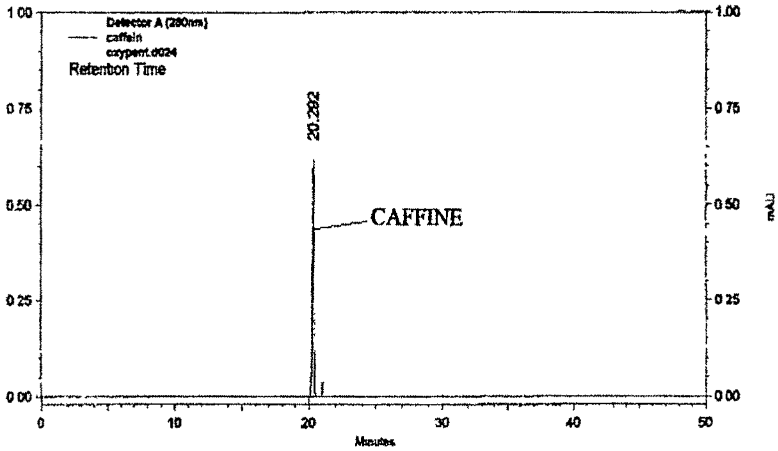
Pk #	Retention Time	Area	Area Percent
1	19 792	4841939	98.97
2	20.267	21831	0.45
3	24 692	7159	0.15
4	25 425	10178	0.21
5	28.817	11224	0.23

Totals		4892331	100 00

Figure-131

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d024
Acquired: 7/8/99 6:50:22 AM
Sample name: caffein **Caffine identification**

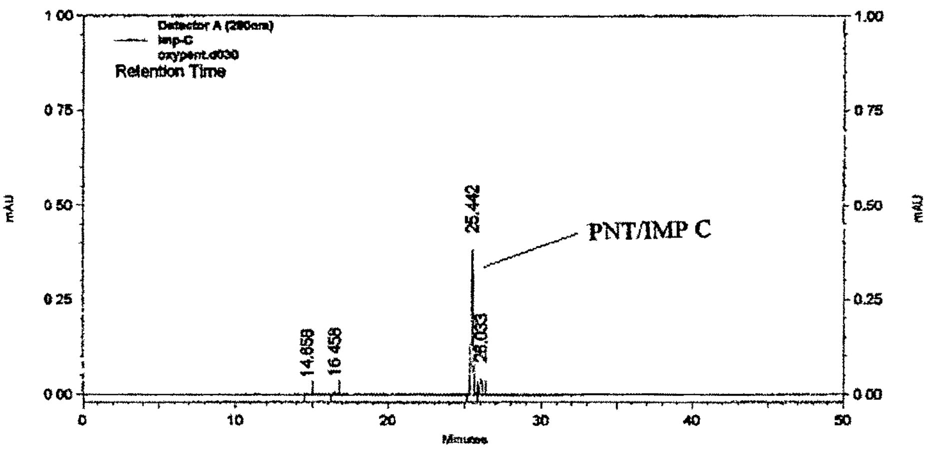


Pk #	Retention Time	Area	Area Percent
1	20 292	5712729	100 00
Totals		5712729	100 00

Figure-132

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met**
Data Name: **C:\YDC\oxypent.d030**
Acquired: **7/8/99 12:06:49 PM**
Sample name: **imp-C** PNT/Impurity A



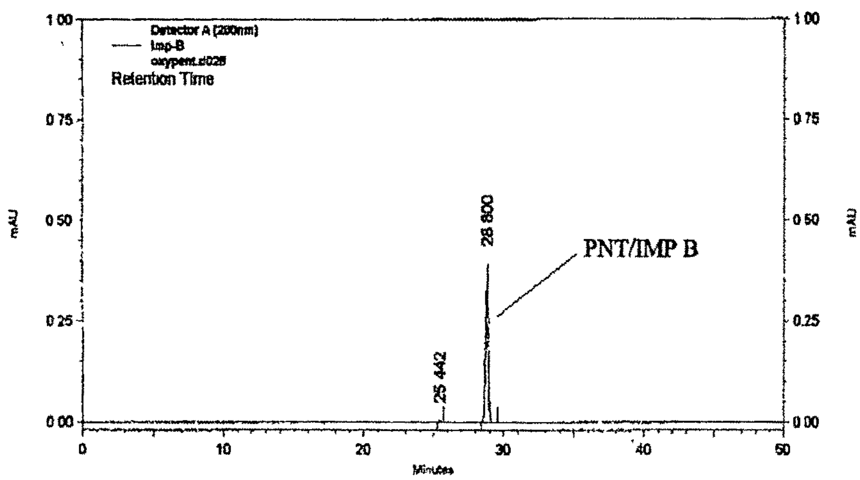
Pk #	Retention Time	Area	Area Percent
1	14.658	12061	0.28
2	16.458	40776	0.96
3	25.442	3781965	88.93
4	26.033	417962	9 83
Totals		4252764	100.00

Figure-133

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\oxypent.d028
Acquired: 7/8/99 10:17:32 AM
Sample name: imp-B

PNT/Impurity B



Pk #	Retention Time	Area	Area Percent
1	25.442	38073	0 72
2	28.800	5263704	99.28

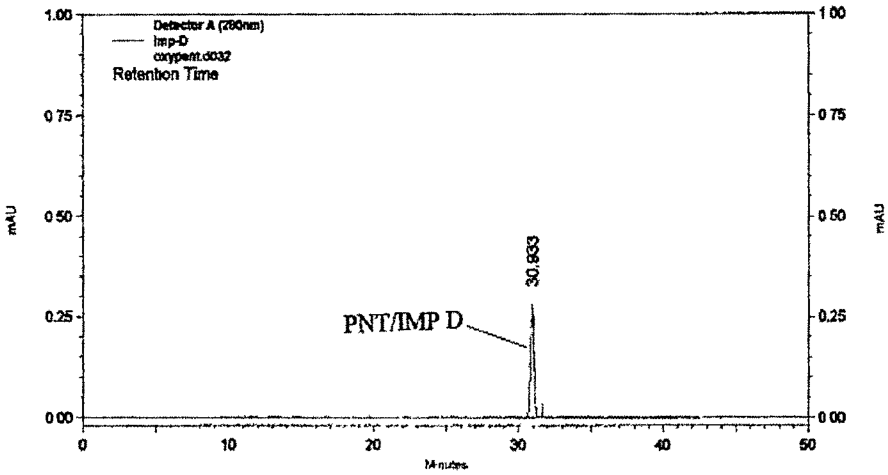
Totals		5301777	100 00

Figure-134

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met**
Data Name: **C:\YDC\oxypent.d032**
Acquired: **7/8/99 1:50:20 PM**
Sample name: **imp-D**

PNT / Impurity D



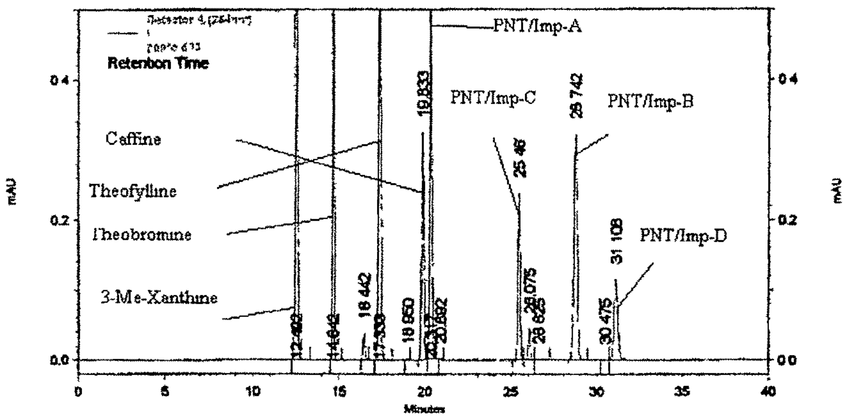
Pk #	Retention Time	Area	Area Percent
1	30 933	4535391	100.00
Totals		4535391	100.00

Figure-135

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP-ver5.03\METHODS\HPLC-11\Pentoxy.met
Data Name: C:\YDC\pento.d03
Acquired: 7/1/99 6:46:44 PM
Seq.Name : C:\CLASS-VP-ver5.03\SEQUENCE\HPLC-11\Pento-stabi.seq
Sample name: I

All component mix for identification



Pk #	Retention Time	Area	Name
1	12.492	5724967	3-Me-Xanthine
2	14 642	5685816	Theobromine
3	16.442	287965	
4	17 333	5458517	Theophylline
5	18.950	8469	
6	19.833	2839590	Caffein
7	20.317	4749684	Imp-A
8	20.892	7250	
9	25.467	2343231	Imp-C
10	26 075	438208	
11	26 625	8628	
12	28 742	4299308	Imp-B
13	30.475	8443	
14	31.108	1887679	Imp-D

Totals		33747755	

Figure-136

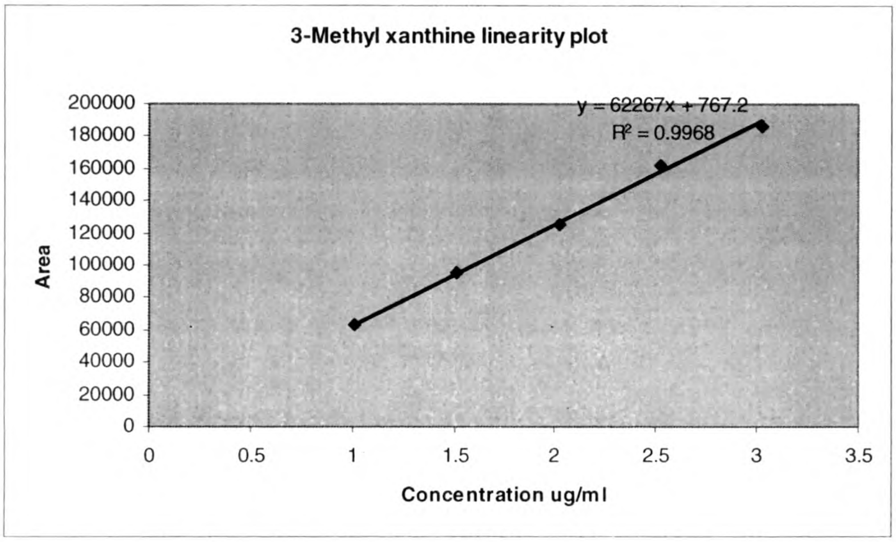


Figure-137

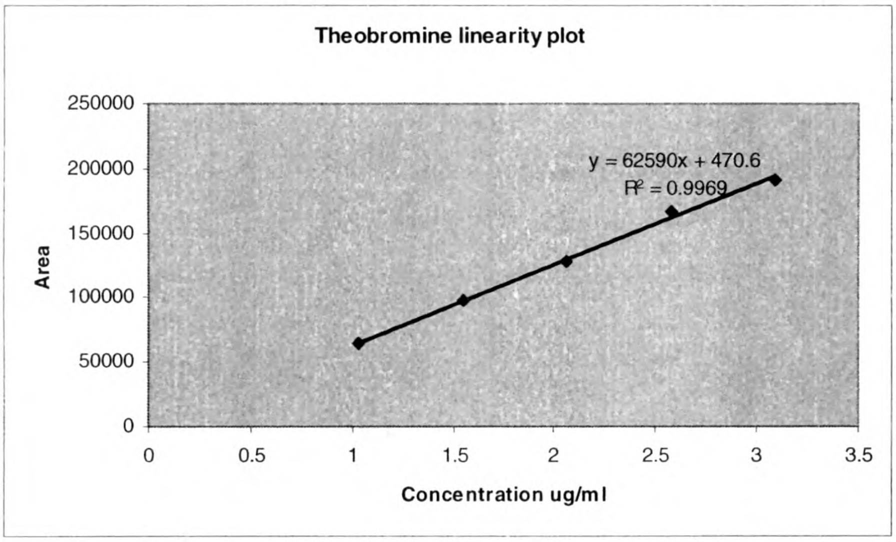


Figure-138

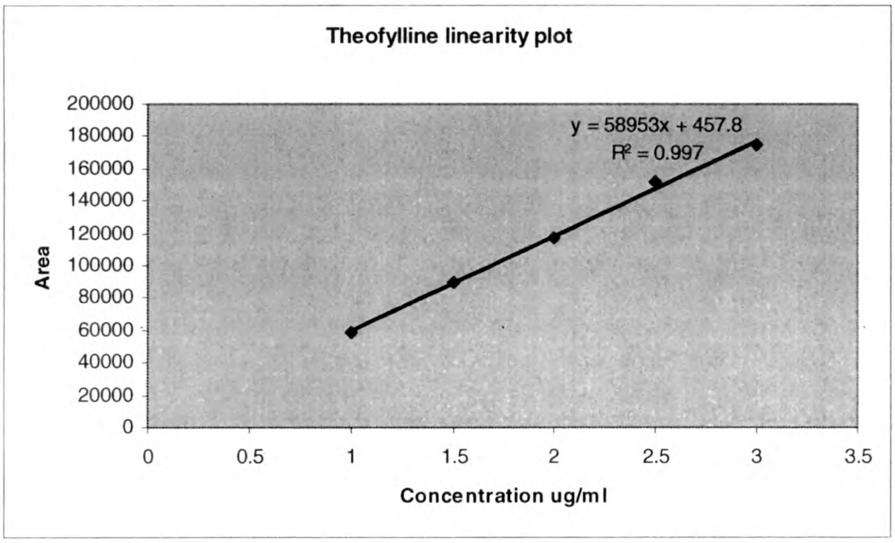


Figure-139

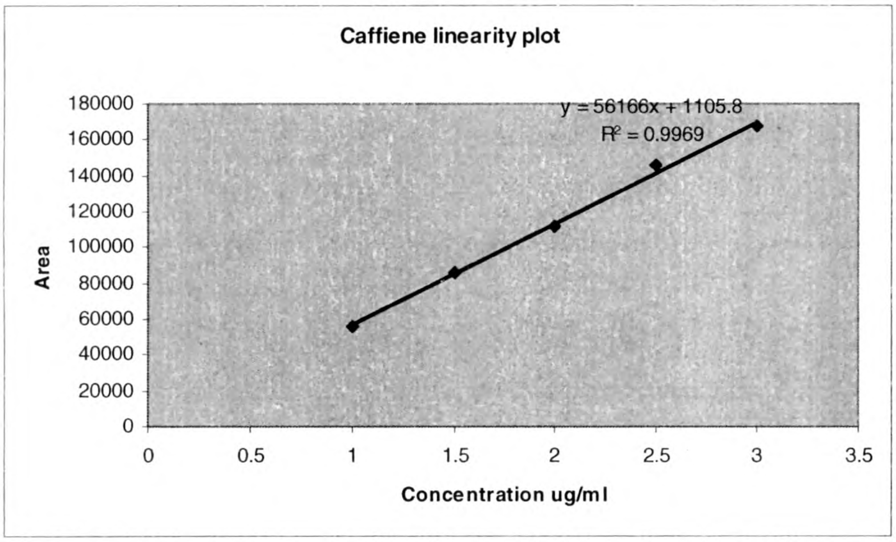


Figure-140

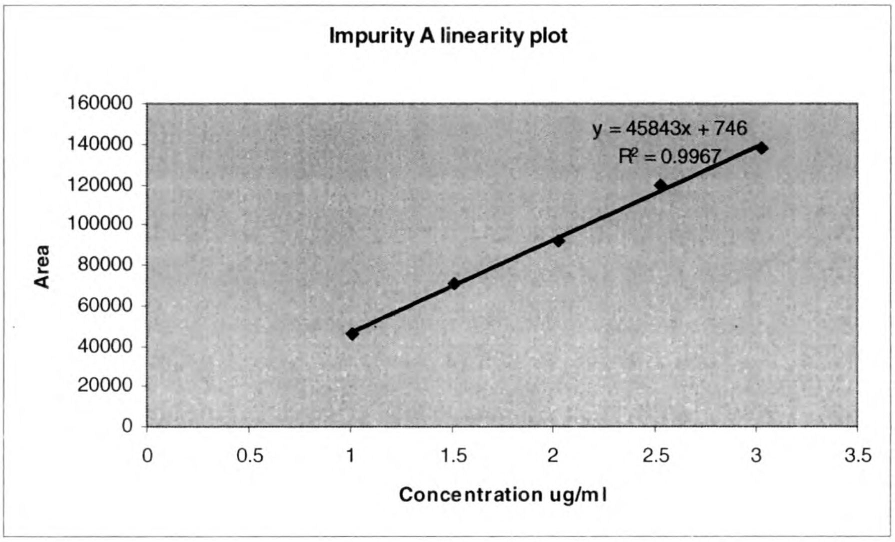


Figure-141

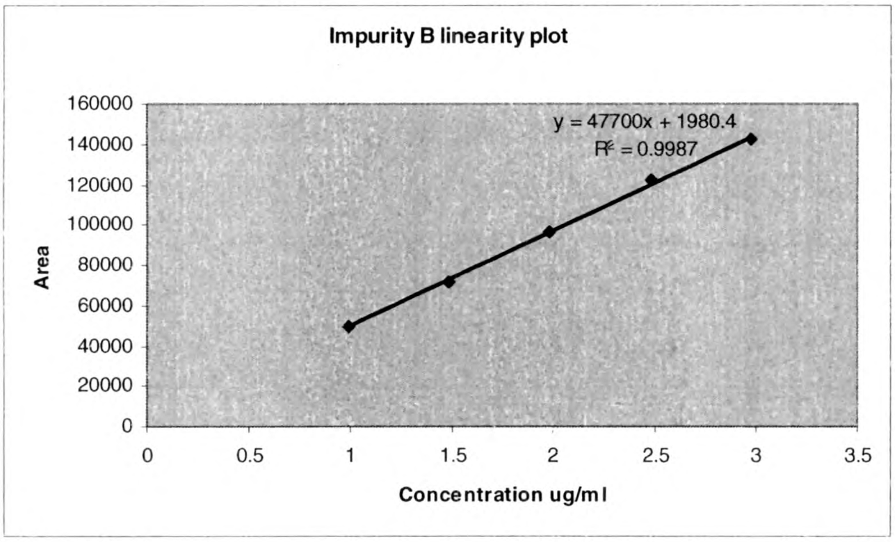


Figure-142

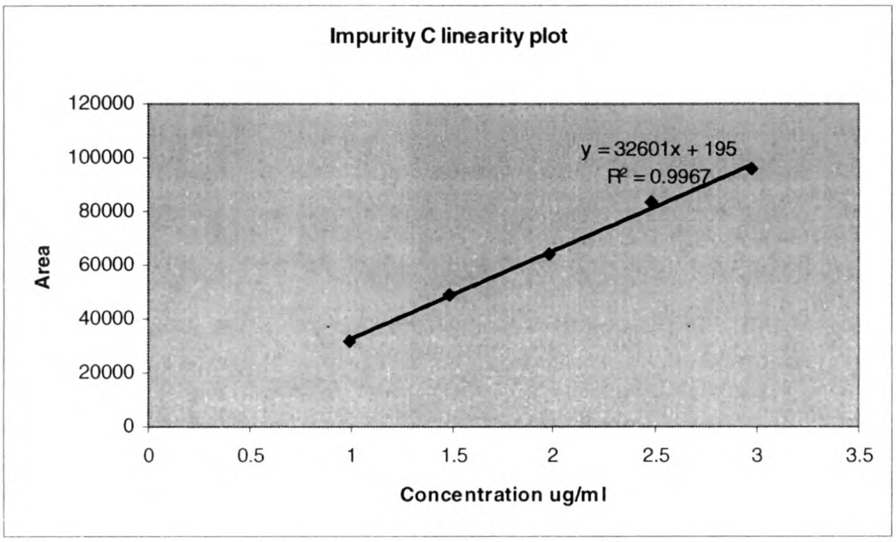


Figure-143

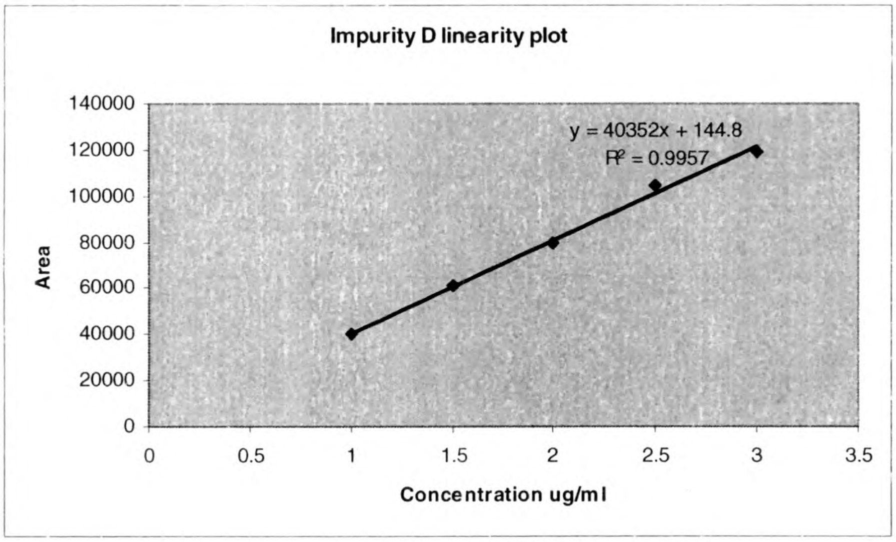


Figure-144

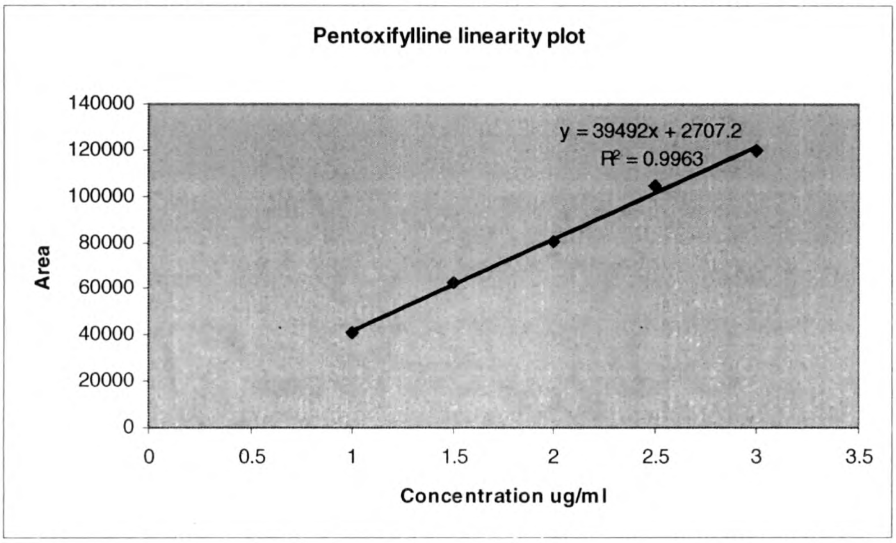


Figure-145

Pantoprazole related substances method chromatograms

MOBILE PHASE

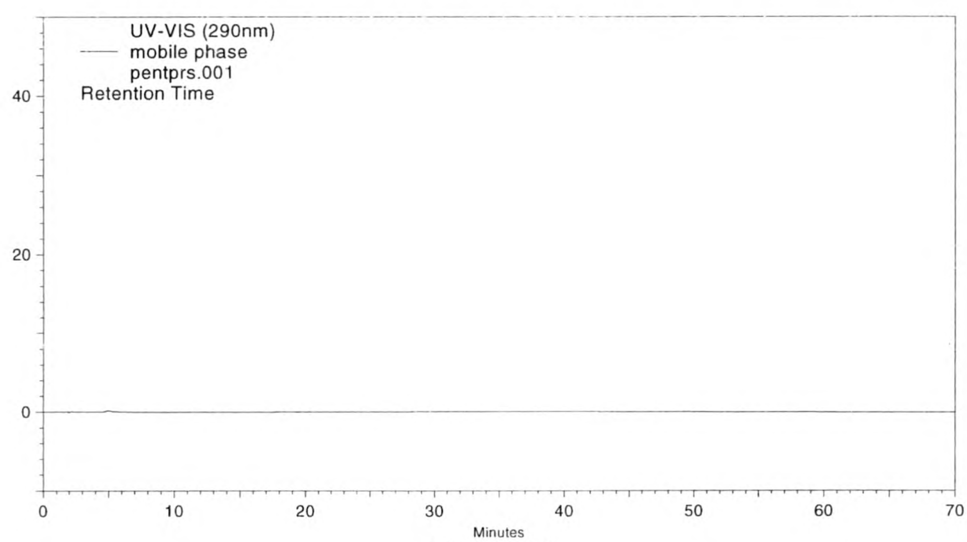


Figure-146

SYSTEM SUITABILITY SOLN

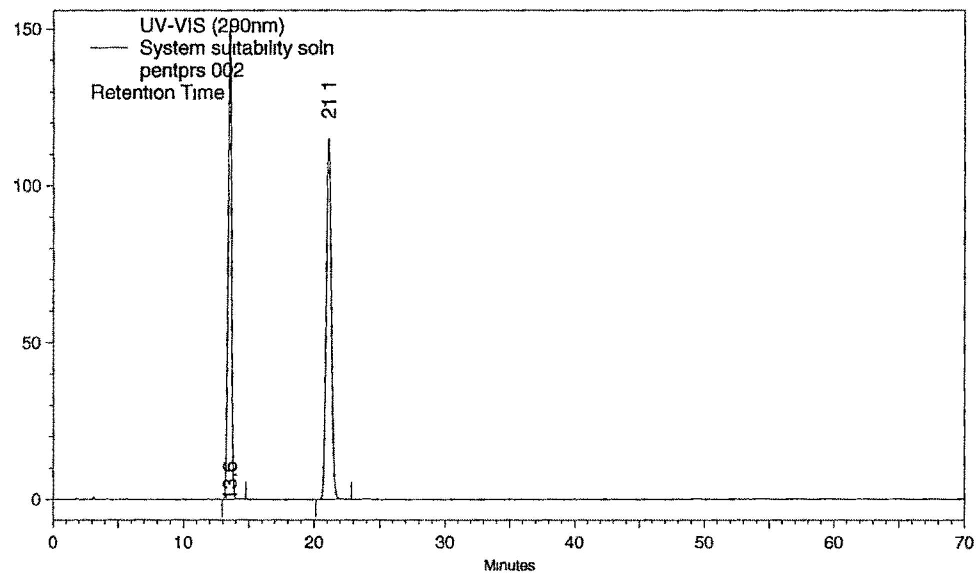


Figure-147

IDENIFICATION

PANTOPRAZOLE IMPURITY B

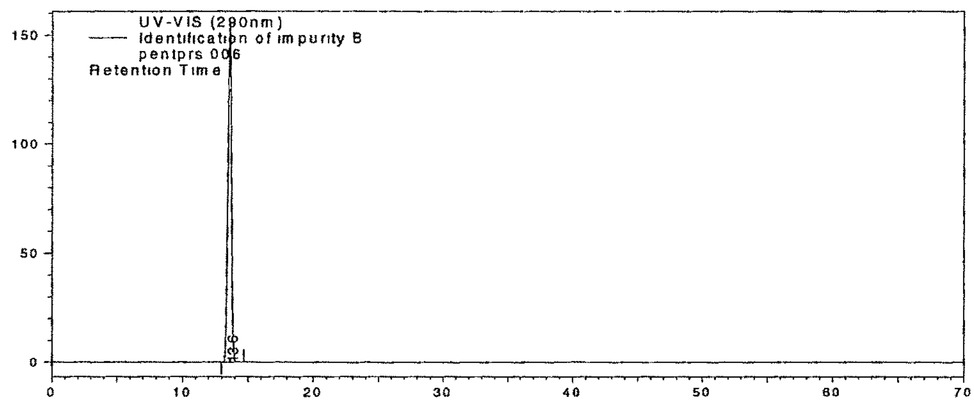


Figure-148

PANTOPRAZOLE

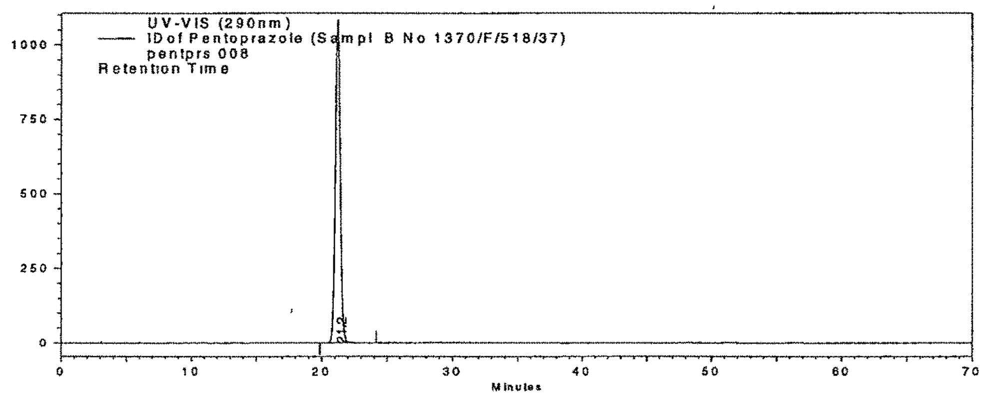


Figure-149

PANTOPRAZOLE IMPURITY A

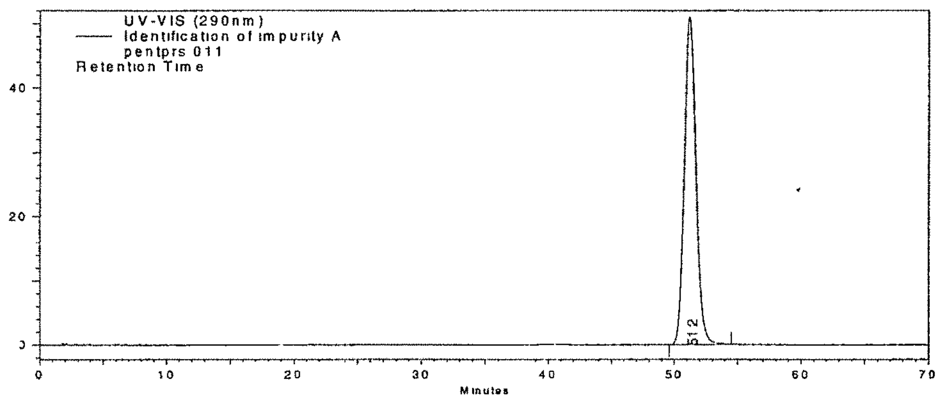


Figure-150

LINEARITY PLOT OF PANTOPRAZOLE

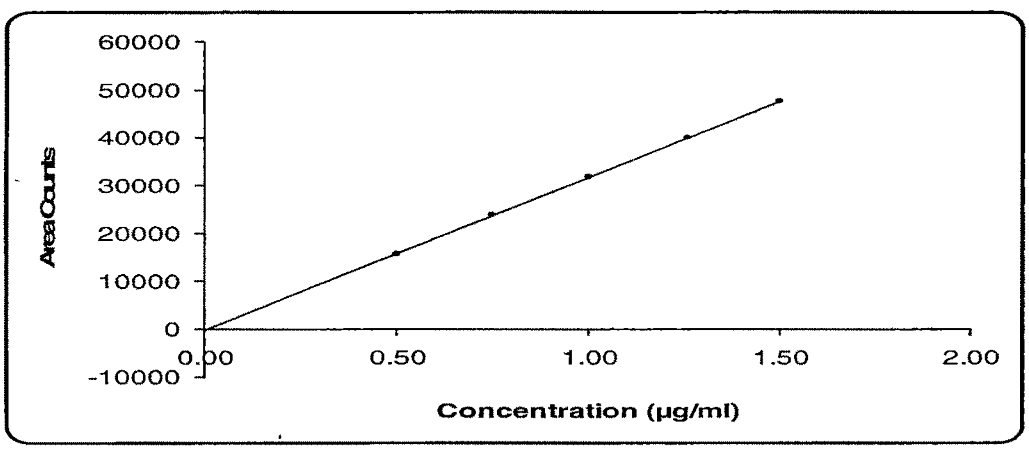


Figure-151

PANTOPRAZOLE IMPURITY A

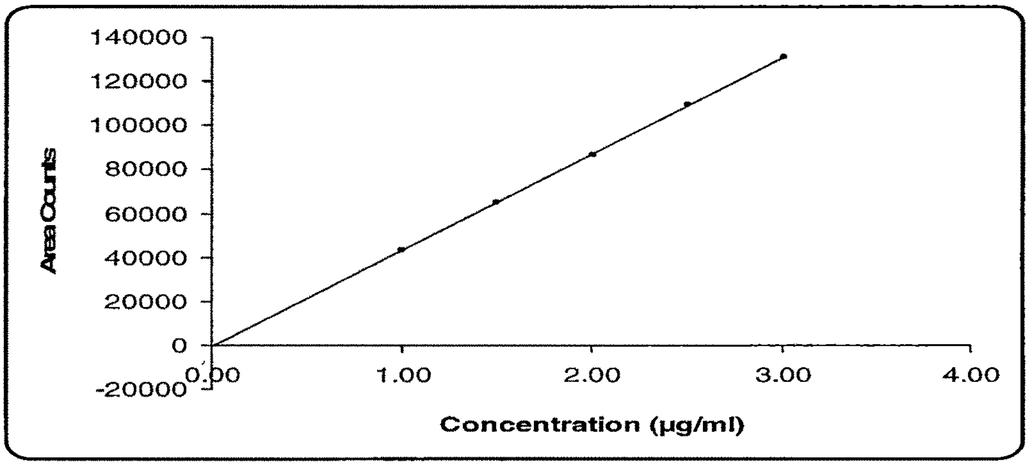


Figure-152

PANTOPRAZOLE IMPURITY B

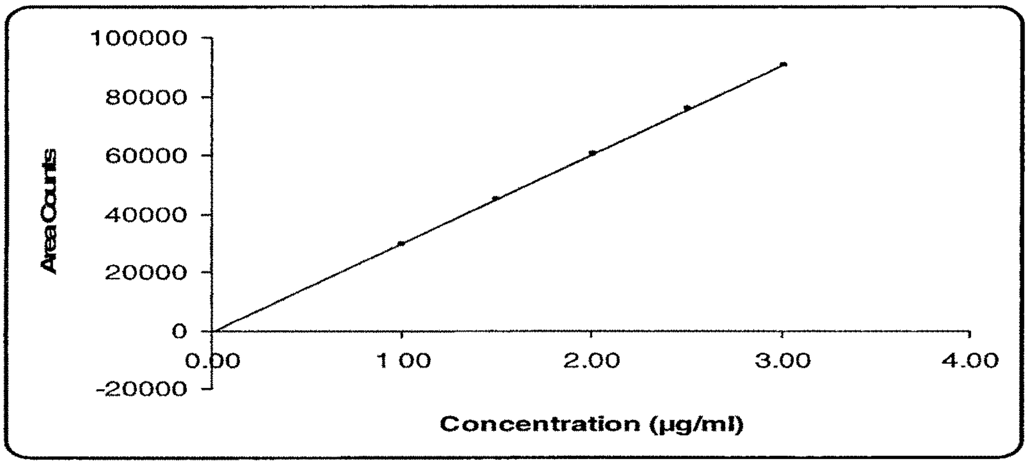


Figure-153

DEGRADATION STUDY

PANTOPRAZOLE STANDARD

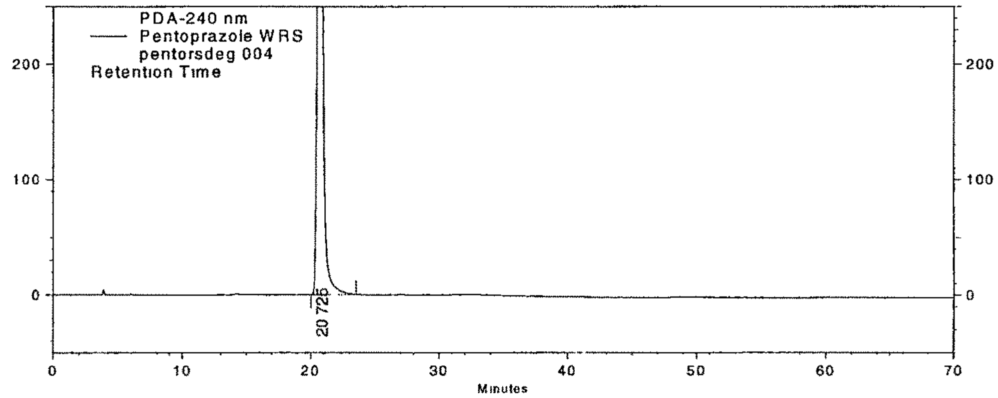


Figure-154

ACID DEGRADATION

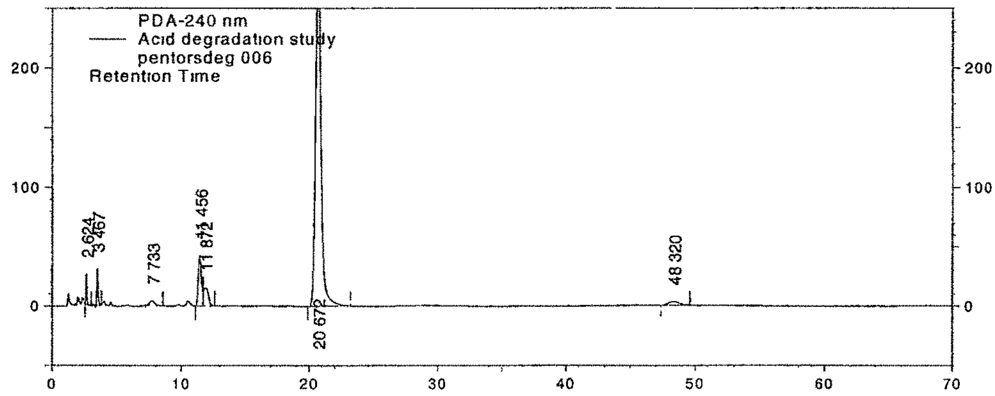


Figure-155

ALKALI DEGRADATION

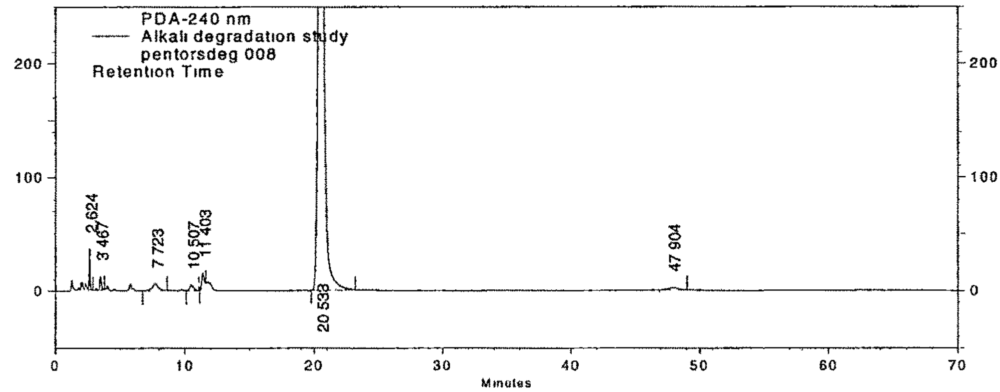


Figure-156

DEGRADATION STUDY

PEROXIDE DEGRADATION

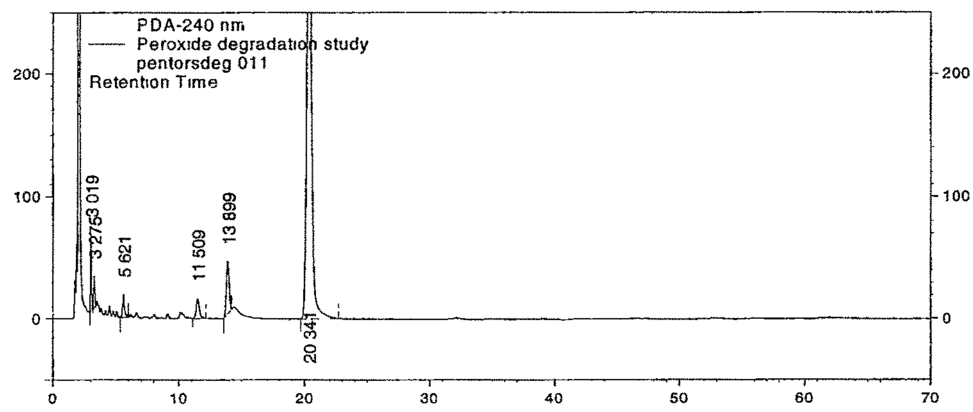


Figure-157

THERMAL DEGRADATION

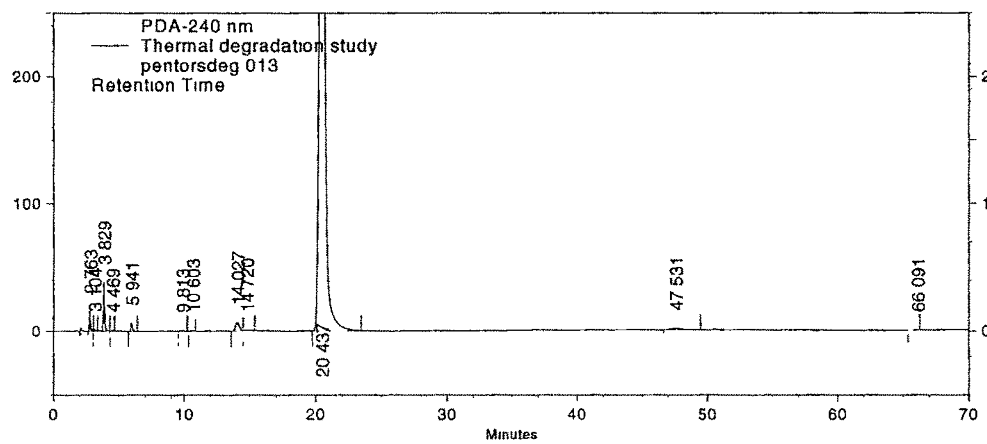


Figure-158

SUN LIGHT DEGRADATION

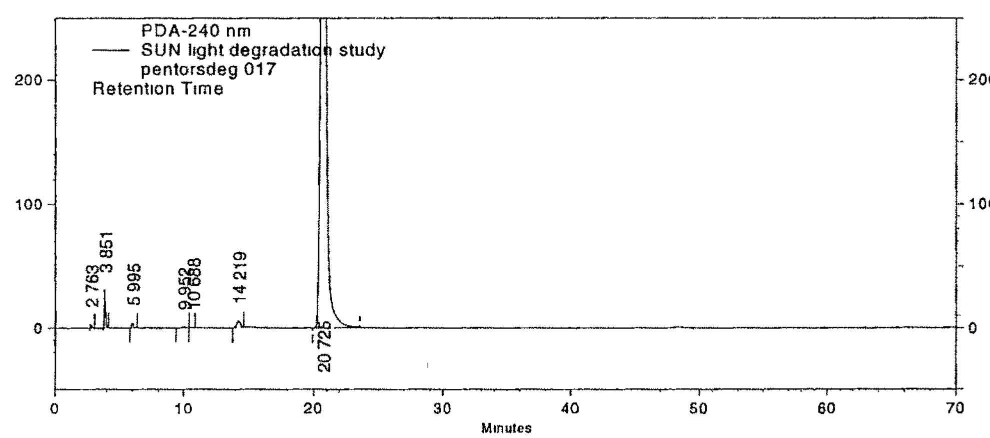


Figure-159

RUGGEDNESS OF METHOD

ORIGINAL CONDITION

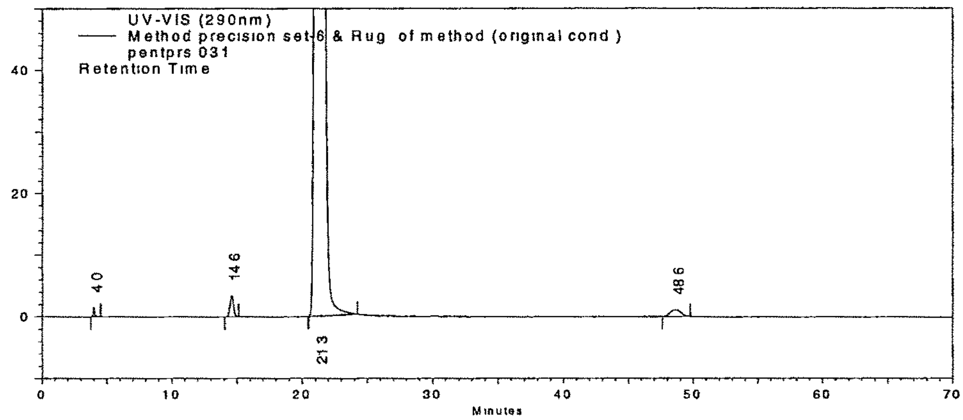


Figure-160

CHANGE IN ANALYST

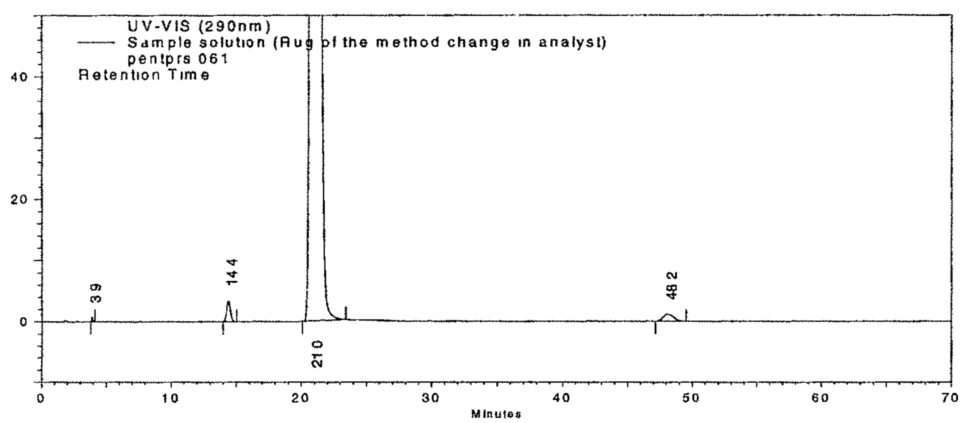


Figure-161

CHANGE IN MOBILE PHASE

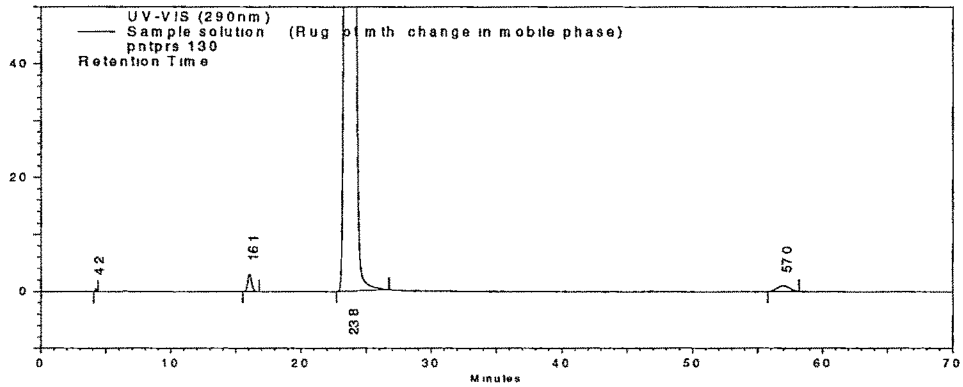


Figure-162

RUGGEDNESS OF METHOD
CHANGE IN COLUMN

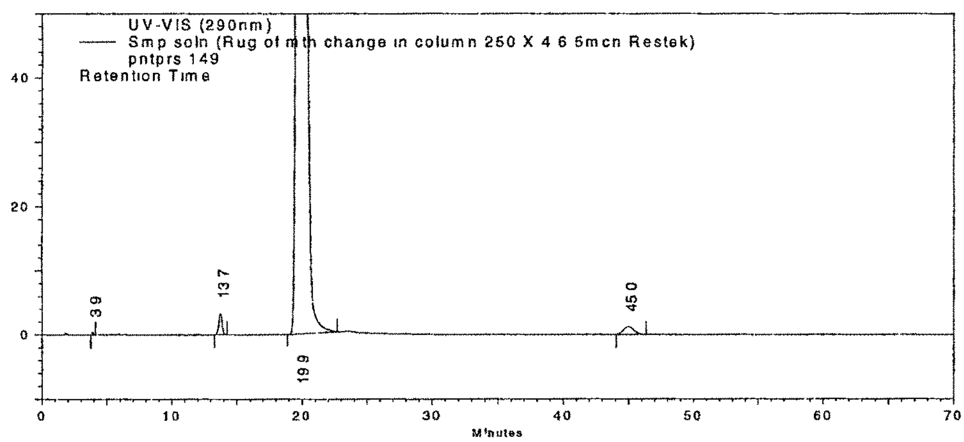


Figure-163

CHANGE IN COLUMN OVEN

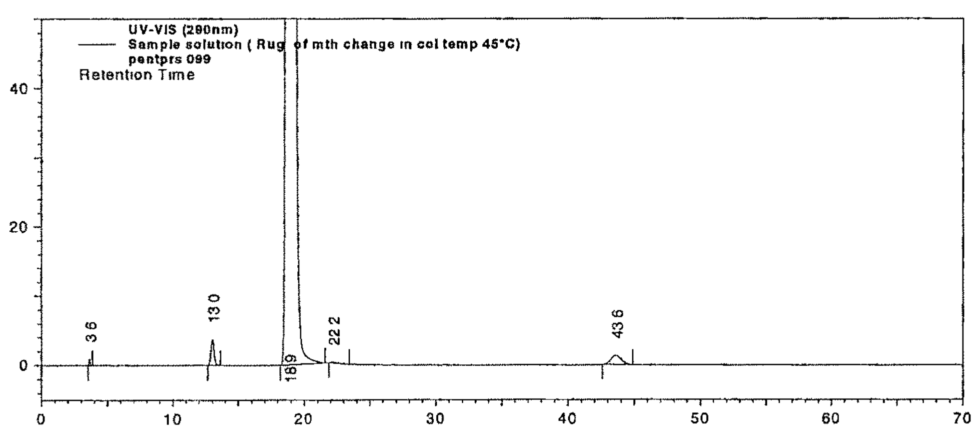


Figure-164

CHANGE IN INSTRUMENT

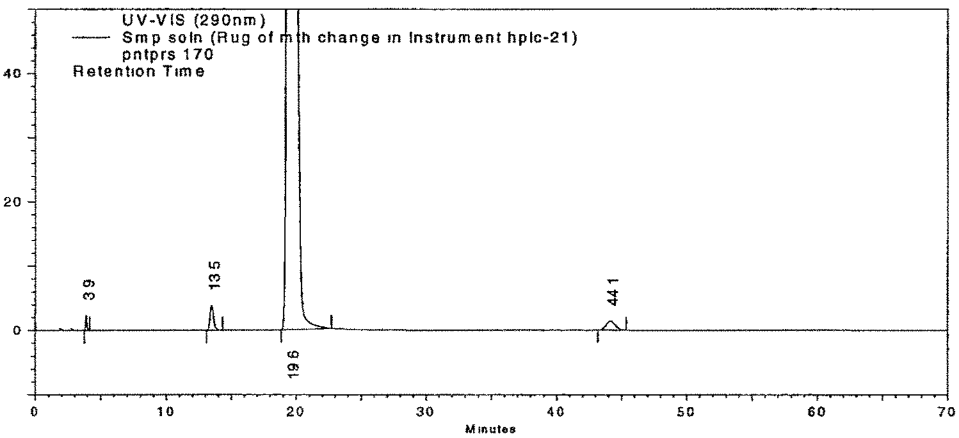
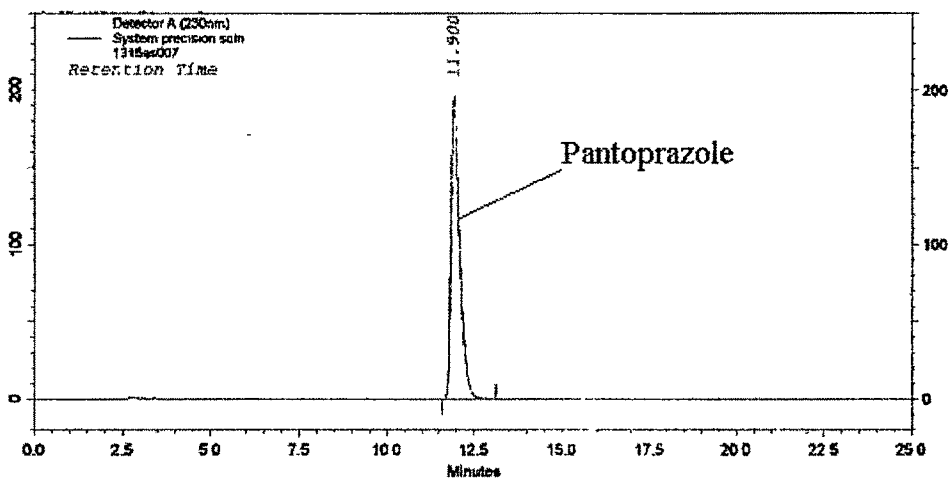


Figure-165

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: **C:\CLASS-VP\METHODS\1315.met**
Data Name: **C:\CLASS-VP\DATA\1315AS\1315as007**
Acquired: **07/17/2000 7:04:44 PM**
Sample name: **System precision soln.**

System precision Assay



Detector A (230nm)

Pk #	Retention Time	Area	Area %	Asymmetry
1	11.900	3306315	100.000	1.91

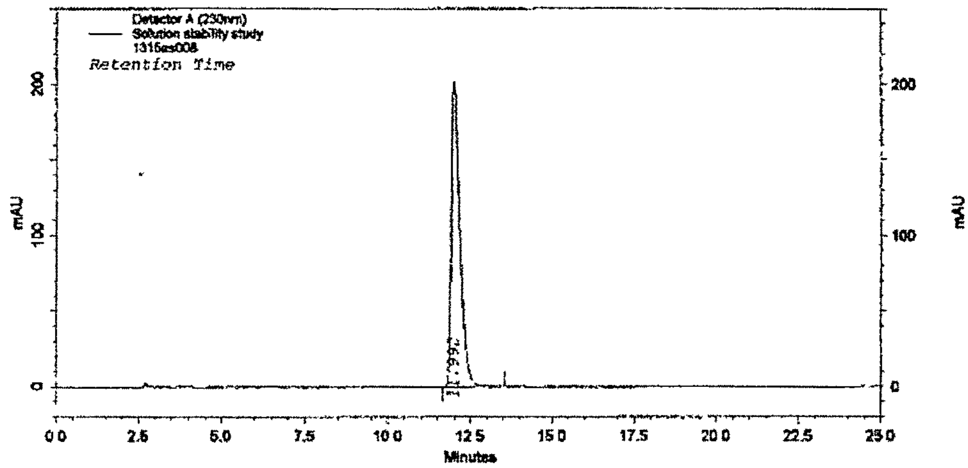
Totals				
		3306315	100.000	

Figure-166

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: **C:\CLASS-VP\METHODS\1315.met**
Data Name: **C:\CLASS-VP\DATA\1315AS\1315as008**
Acquired: **07/17/2000 7:32:08 PM**
Sample name: **Solution stability study**

Solution Stability study



Detector A (230nm)

Pk #	Retention Time	Area	Area %	Asymmetry
1	11.992	3491742	100.000	1.98

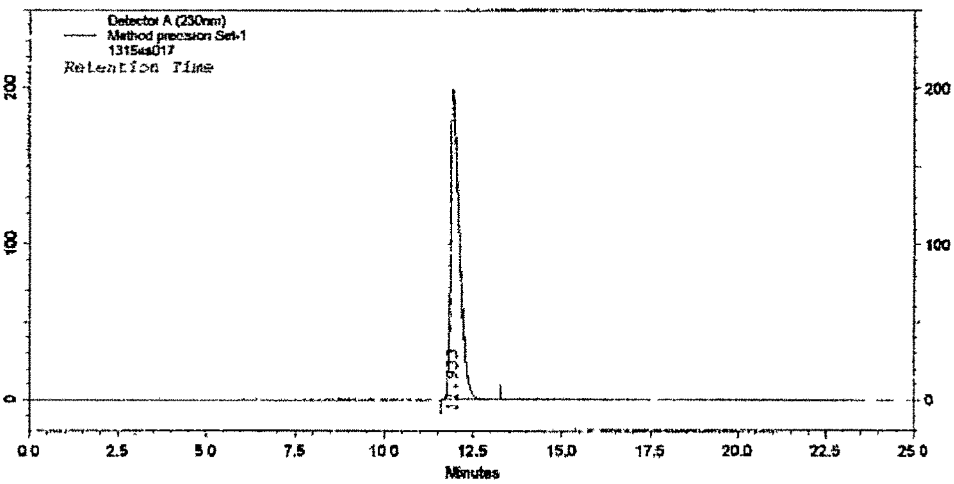
Totals		3491742	100.000	

Figure-167

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\1315.met**
Data Name: **C:\CLASS-VP\DATA\1315AS\1315as017**
Acquired: **07/17/2000 11:38:06 PM**
Sample name: **Method precision Set-1**

Method precision set-1



Detector A (230nm)

Pk #	Retention Time	Area	Area %	Asymmetry
1	11.933	3413452	100.000	1.94

Totals		3413452	100.000	

Figure-168

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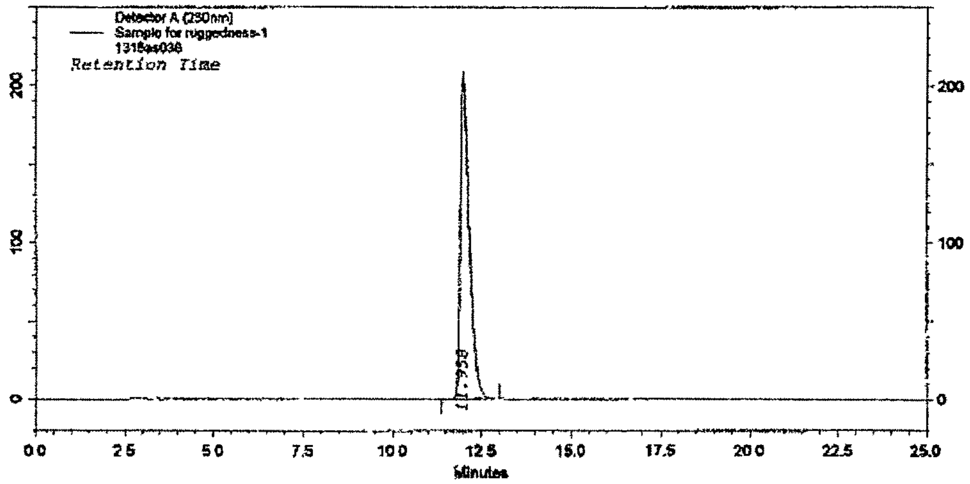
Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\1315.met
Data Name: C:\CLASS-VP\DATA\1315AS\1315as036
Acquired: 07/18/2000 8:17:14 AM
Sample name: Sample for ruggedness-1

Ruggedness

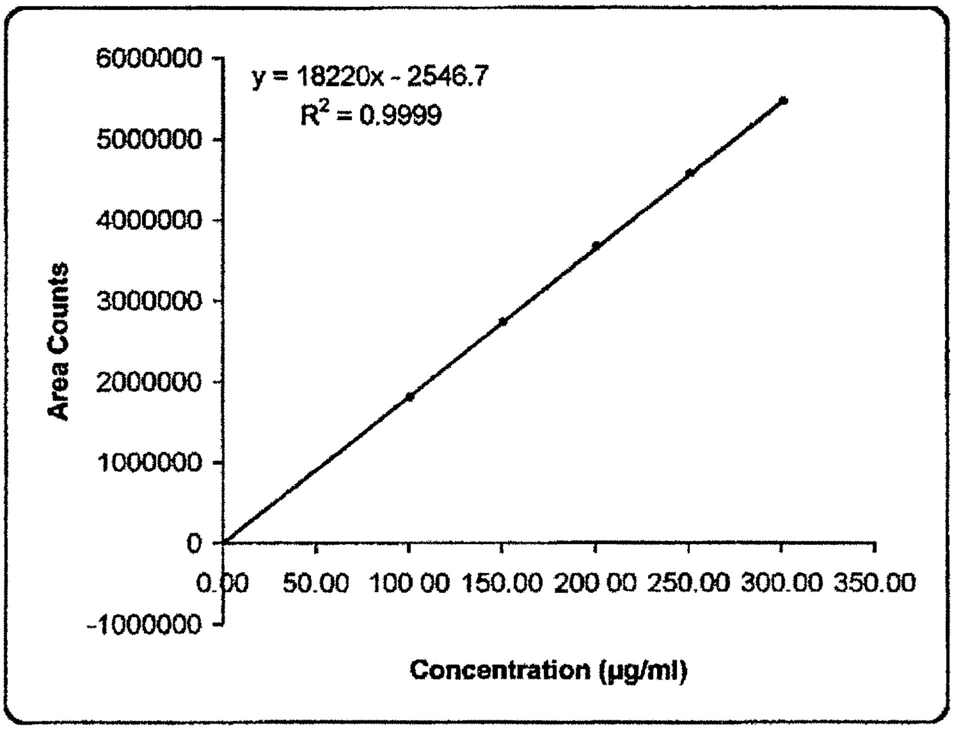


Detector A (230nm)

Pk #	Retention Time	Area	Area %	Asymmetry
1	11.958	3653089	100.000	2.01

Totals		3653089	100.000	

Figure-169



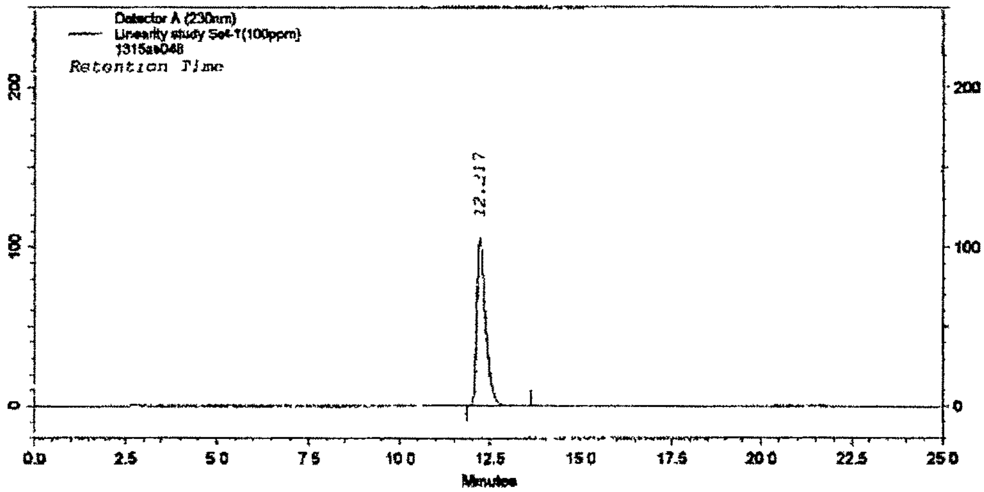
y = 18220x - 2546.7
R^2 = 0.9999
6000000
5000000
4000000
3000000
2000000
1000000
0
-1000000
Area Counts
0.00
50.00
100 00
150.00
200 00
250.00
300.00
350.00
Concentration (µg/ml)

Figure-170

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\1315.met
Data Name: C:\CLASS-VP\DATA\1315AS\1315as048
Acquired: 07/18/2000 6:50:10 PM
Sample name: Linearity study Set-1(100ppm)

Linearity set-1



Detector A (230nm)

Pk #	Retention Time	Area	Area %	Asymmetry
1	12.217	1785714	100.000	1.65
Totals		1785714	100.000	

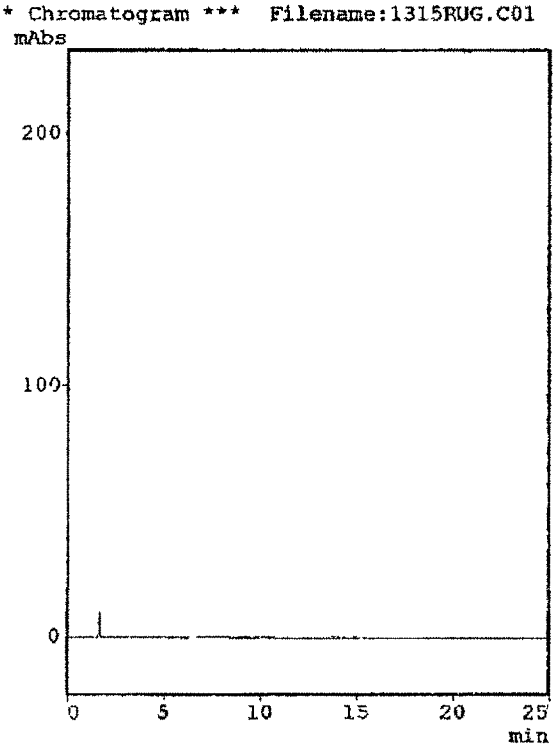
Figure-171

CLASS-LC10 Ver.=1.63 SYS=2 Ch=2 REPORT.NO=1 DATA=1315RUG.D01 00/07/21 10:2

ID : mobile phase
Type : Unknown
Detector : SPD-10A Single
Operator : ALP
Method Name : 1315.MET

Pantoprazole assay Blank

*** Chromatogram *** Filename:1315RUG.C01



*** Peak Report ***
!! No Peak !!

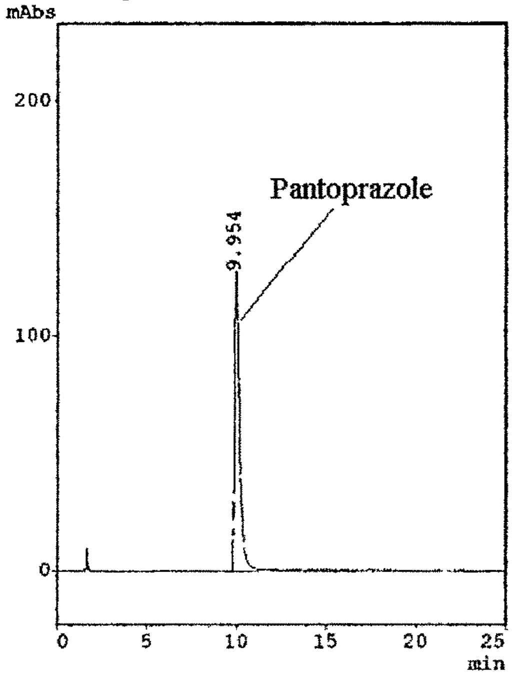
*** Peak Time Table ***
!! No Peak !!

Figure-172

CLASS-LC10 Ver.=1.63 SYS=2 Ch=2 REPORT.NO=8 DATA=1315RUG.D08 00/07/21 13:26:48

ID	: 1315 Sample	Pantoprazole sample
Type	: Unknown	Ruggedness experiment
Detector	: SPD-10A Single	
Operator	: ALP	
Method Name	: 1315.MET	

*** Chromatogram *** Filename:1315RUG.C08



*** Peak Report ***

TIME	AREA	CONC
9.954	2466697	100.00
	2466697	100.00

*** Peak Time Table ***

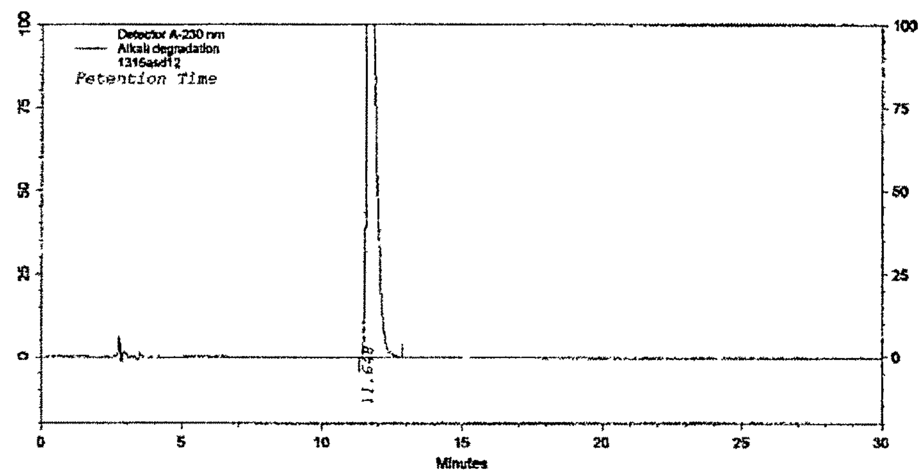
PKNO	R.TIME	I.TIME	F.TIME	A/H(sec)	RRT	NAME
1	9.954	9.583	12.750	19.66		

Figure-173

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\1315asdeg.met**
Data Name: **C:\CLASS-VP\DATA\1315deg\1315asd12**
Acquired: **07/22/2000 6:49:40 PM**
Sample name: **Alkali degradation**

Alkali degradation



Detector A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	11.648	3625867	100 000	100.00000

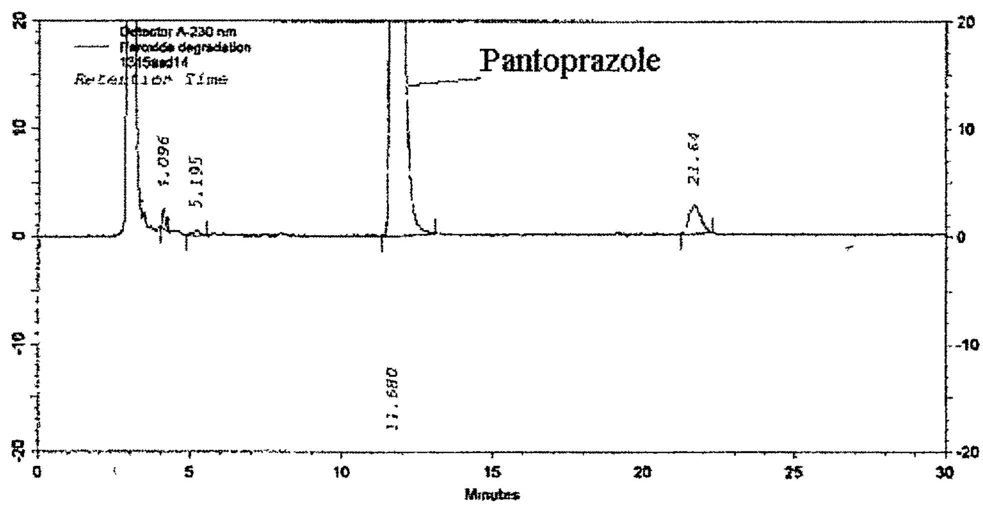
Totals				
		3625867	100.000	

Figure-174

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: **C:\CLASS-VP\METHODS\1315asdeg.met**
Data Name: **C:\CLASS-VP\DATA\1315deg\1315asd14**
Acquired: **07/22/2000 7:55:02 PM**
Sample name: **Peroxide degradation**

Peroxide degradation



Detector
A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	4.096	12543	0.388	100.00000
2	5 195	8756	0.271	100 00000
3	11 680	3140120	97.135	100.00000
4	21.643	71322	2.206	100.00000

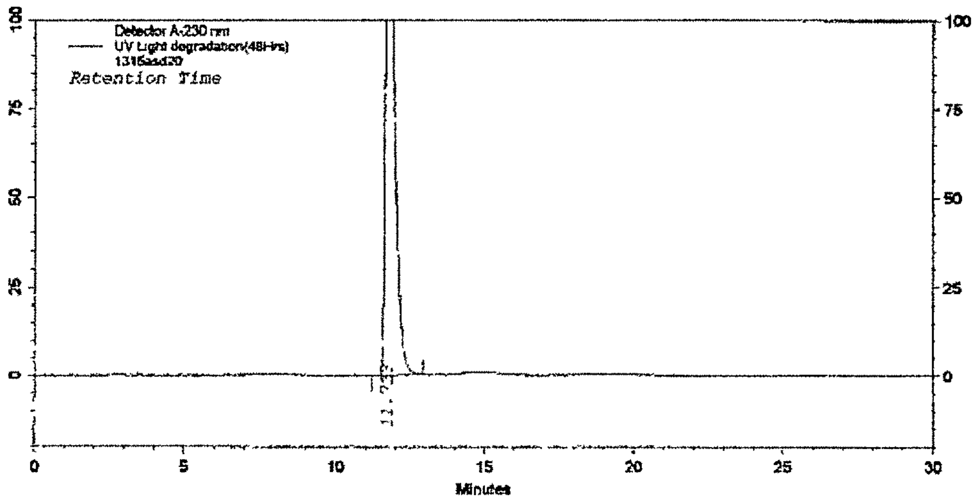
Totals		3232741	100.000	

Figure-175

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\1315asdeg.met
Data Name: C:\CLASS-VP\DATA\1315deg\1315asd20
Acquired: 07/22/2000 11:11:22 PM
Sample name: UV Light degradation(48Hrs)

UV light degradation



Detector A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	11.723	3225969	100.000	100.00000

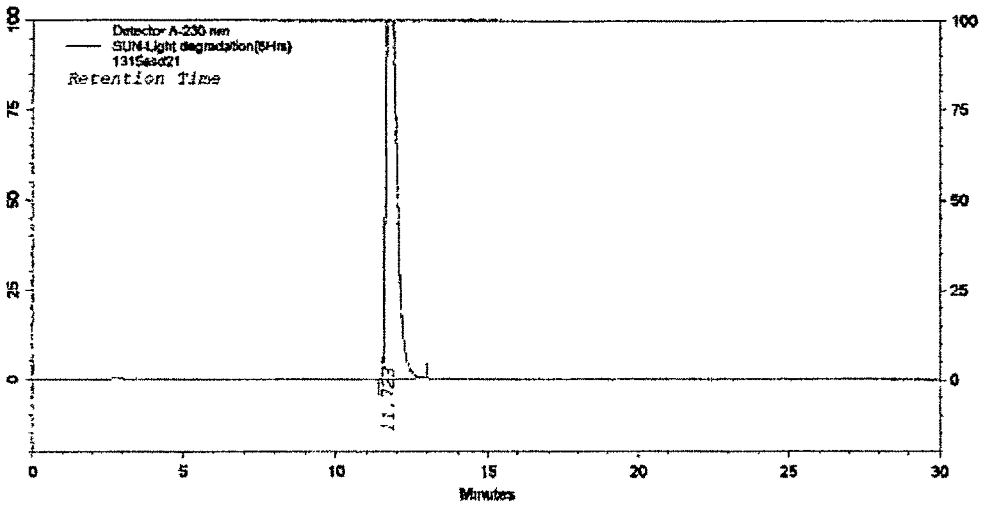
Totals		3225969	100.000	

Figure-176

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: **C:\CLASS-VP\METHODS\1315asdeg.met**
Data Name: **C:\CLASS-VP\DATA\1315deg\1315asd21**
Acquired: **07/22/2000 11:44:03 PM**
Sample name: **SUN-Light degradation(8Hrs)**

Sun light degradation



Detector
A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	11.723	3255304	100.000	100.00000

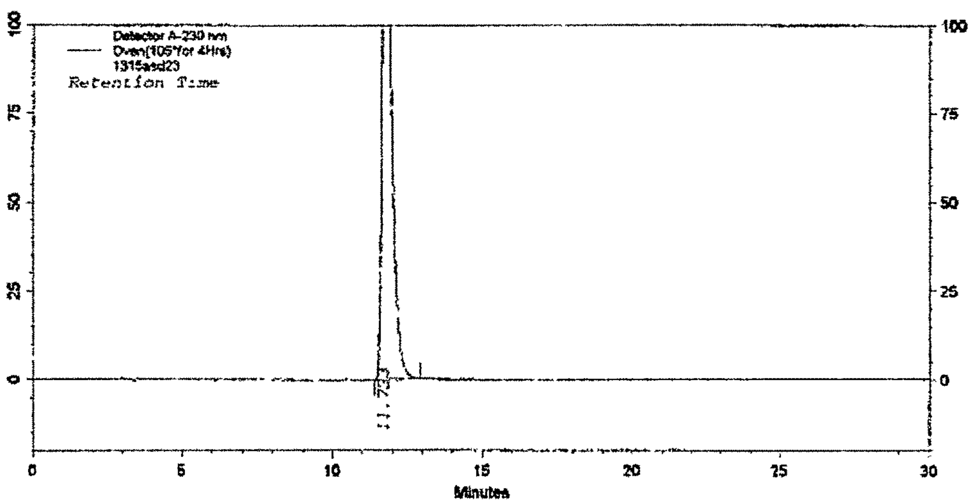
Totals		3255304	100 000	

Figure-177

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\1315asdeg.met
Data Name: C:\CLASS-VP\DATA\1315deg\1315asd23
Acquired: 07/23/2000 12:49:23 AM
Sample name: Oven(105*for 4Hrs)

Thermal degradation



Detector A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	11.723	3519066	100.000	100 00000

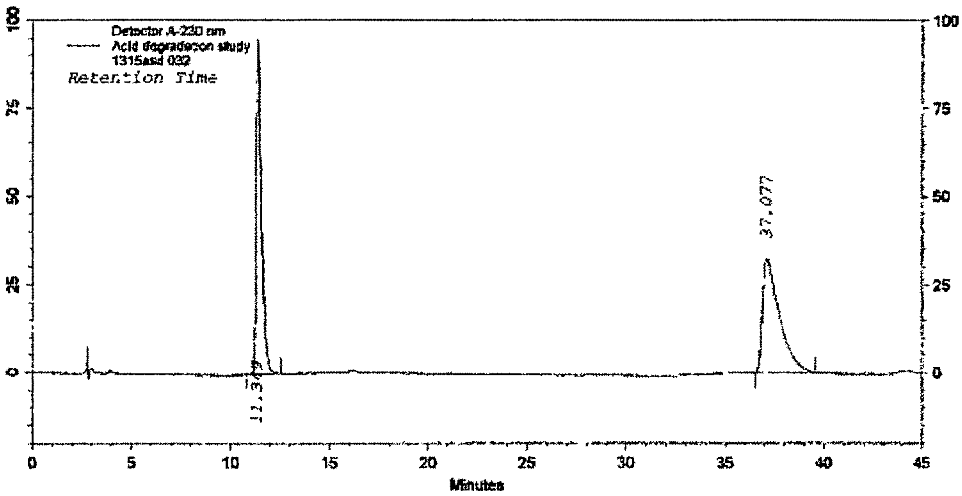
Totals		3519066	100.000	

Figure-178

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\1315asdeg.met
Data Name: C:\CLASS-VP\DATA\1315deg\1315asd.032
Acquired: 07/24/2000 12:56:26 PM
Sample name: Acid degradation study

Pantoprazole acid degradation



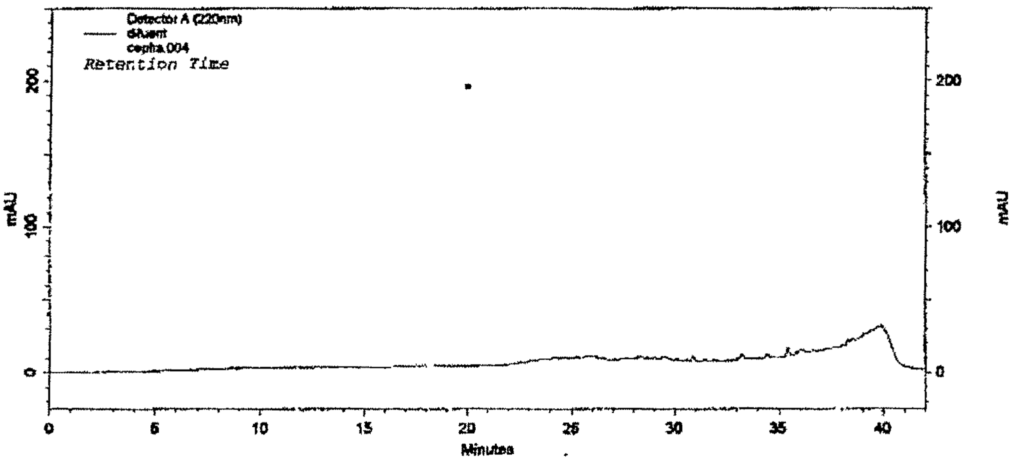
Detector A-230 nm

Pk #	Retention Time	Area	Area %	Total peak purity
1	11.349	1782656	47.810	99.71000
2	37.077	1945962	52.190	100.00000
Totals		3728618	100.000	

Figure-179

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.004
Acquired : 10/09/2000 7:10:35 PM
Sample name : diluent

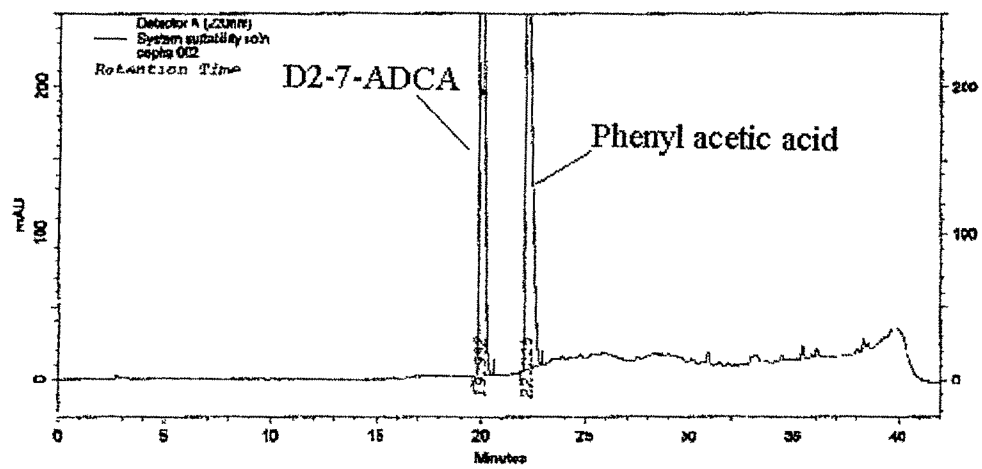


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
Totals			

Figure-180

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.002
Acquired : 10/09/2000 5:41:48 PM
Sample name : System suitability soln.



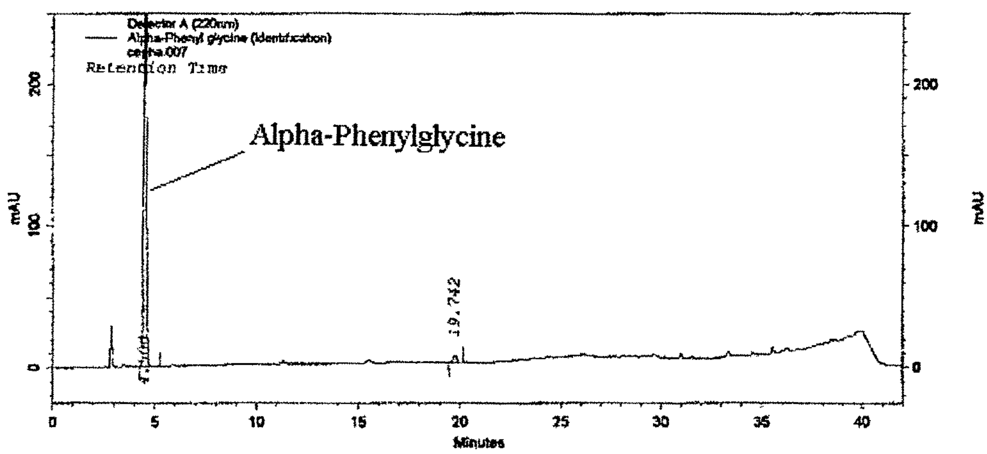
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	19.992	7040636	53.18
2	22.225	6199441	46.82

Totals		13240077	100.00

Figure-181

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VLdata\Cepha\cepha.007
Acquired : 10/09/2000 9:23:44 PM
Sample name : Alpha-Phenyl glycine (Identification)



Detector A (220nm)

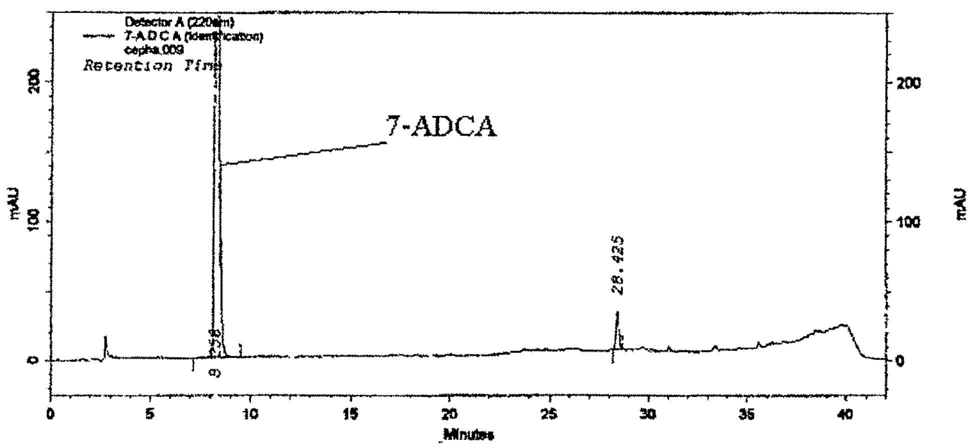
Pk #	Retention Time	Area	Area Percent
1	4.500	4016420	98.43
2	19.742	64022	1 57

Totals		4080442	100.00

Figure-182

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.009
Acquired : 10/09/2000 10:52:32 PM
Sample name : 7-A.D.C.A (Identification)

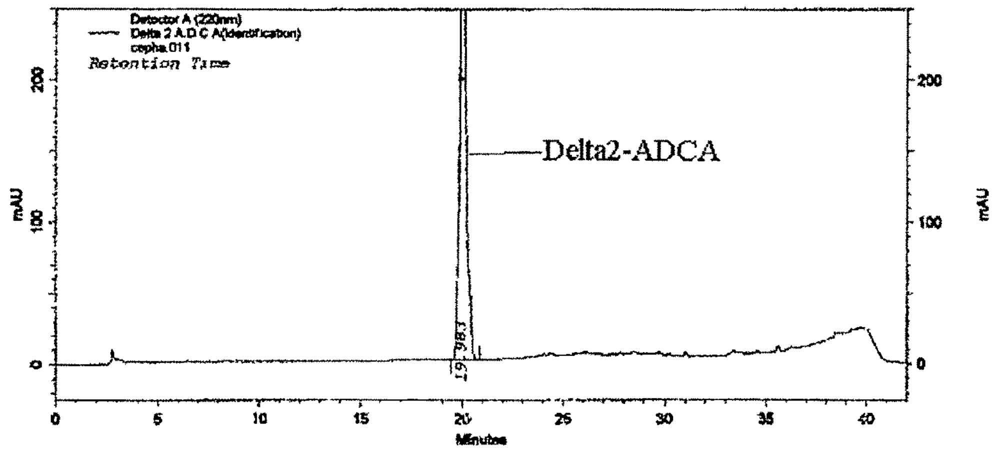


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	8.258	5034876	95.32
2	28.425	247154	4.68
Totals		5282030	100.00

Figure-183

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.011
Acquired : 10/10/2000 12:21:11 AM
Sample name : Delta 2 A.D.C.A(Identification)

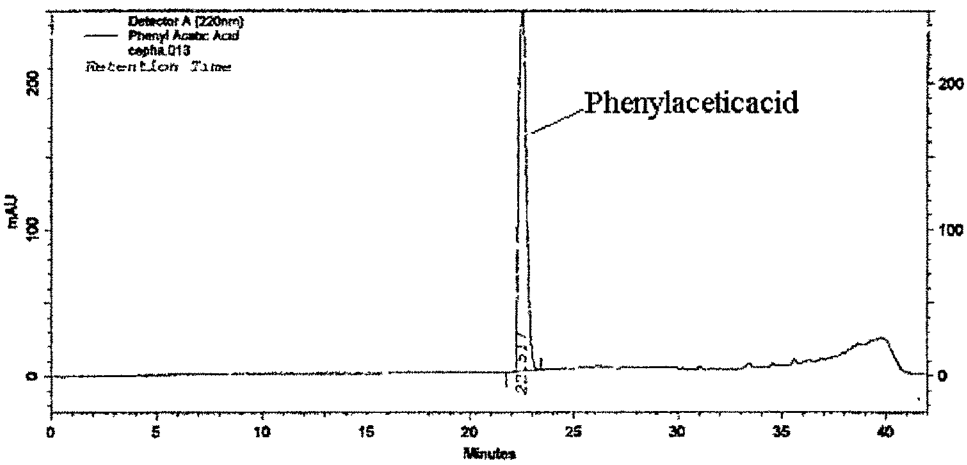


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	19.983	7234961	100.00
Totals		7234961	100.00

Figure-184

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.013
Acquired : 10/10/2000 1:50:01 AM
Sample name : Phenyl Acetic Acid



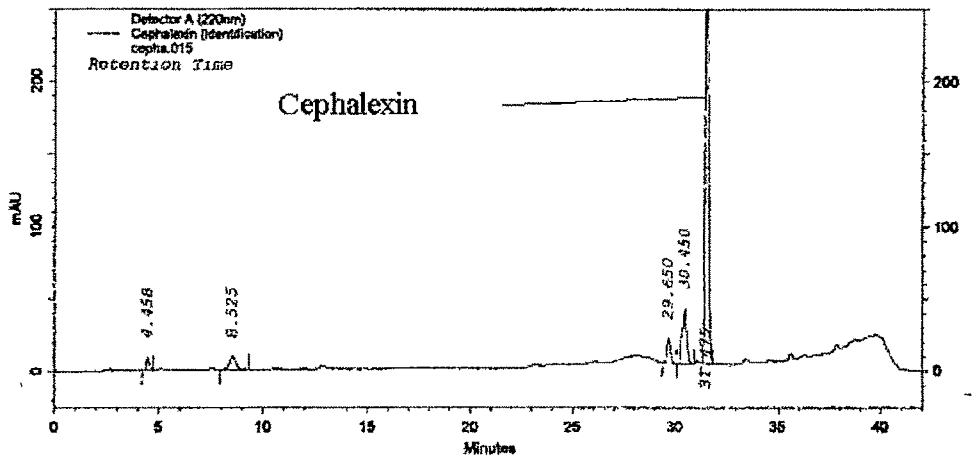
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	22.517	6391767	100.00

Totals		6391767	100.00

Figure-185

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.015
Acquired : 10/10/2000 3:18:45 AM
Sample name : Cephalexin (Identification)

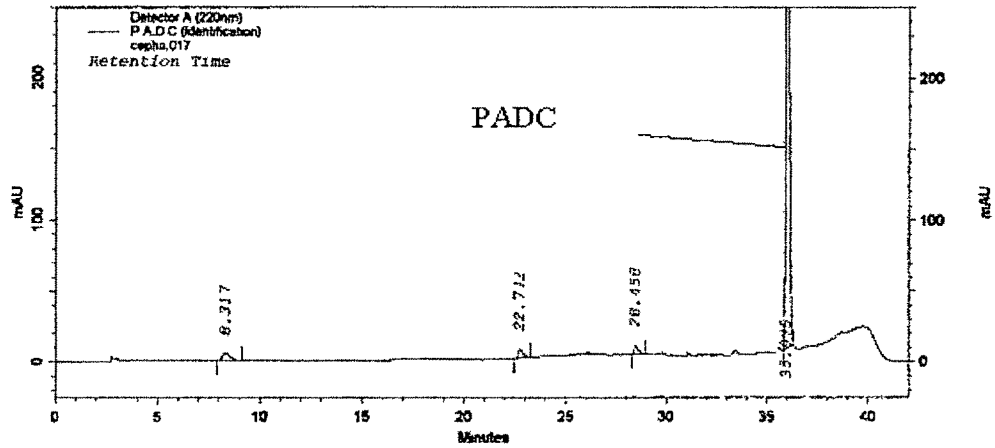


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4.458	75357	1.62
2	8.525	169584	3 64
3	29.650	190161	4.08
4	30.450	582966	12.52
5	31.475	3639475	78.14
Totals		4657543	100.00

Figure-186

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.017
Acquired : 10/10/2000 4:47:35 AM
Sample name : P.A.D.C (Identification)



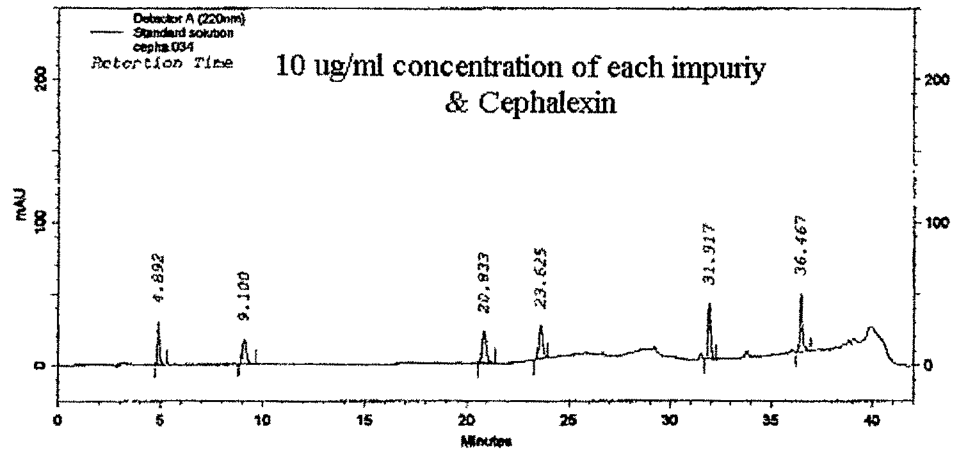
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	8.317	131612	2.42
2	22.742	103138	1.90
3	28.458	86417	1.59
4	35.975	5110137	94.09
Totals		5431304	100.00

Figure-187

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VLdata\Cepha\cepha.034
Acquired : 10/11/2000 6:34:02 PM
Sample name : Standard solution

Standard solution

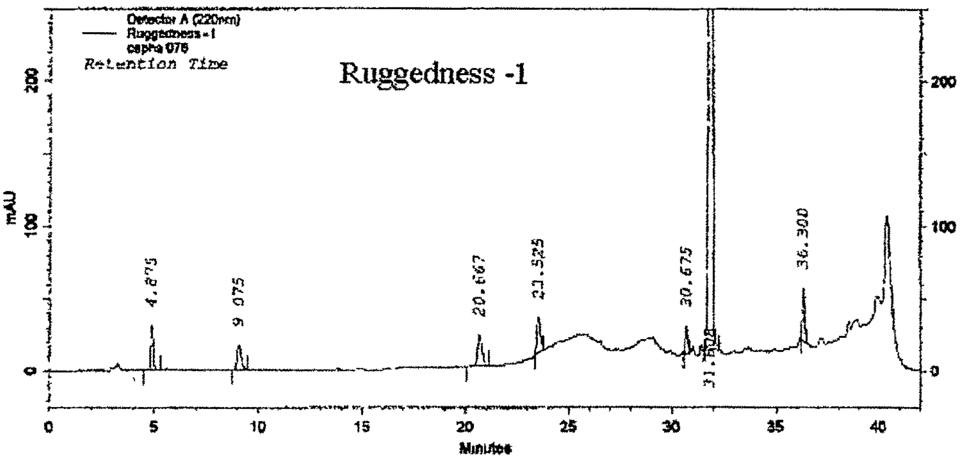


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4.892	220788	13.06
2	9.100	237346	14.04
3	20 833	300030	17 74
4	23.625	283407	16.76
5	31.917	312742	18.49
6	36.467	336743	19.91
Totals		1691056	100.00

Figure-188

Shimadzu CLASS-VP V5.03 *Area % Report*

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VLdata\Cepha\cepha.076
Acquired : 10/13/2000 12:14:24 PM
Sample name : Ruggedness - 1



Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4.875	226974	1.17
2	9 075	230216	1.19
3	20 667	309212	1.59
4	23.525	299001	1.54
5	30 675	142303	0.73
6	31.808	17947015	92.54
7	36.300	240045	1.24

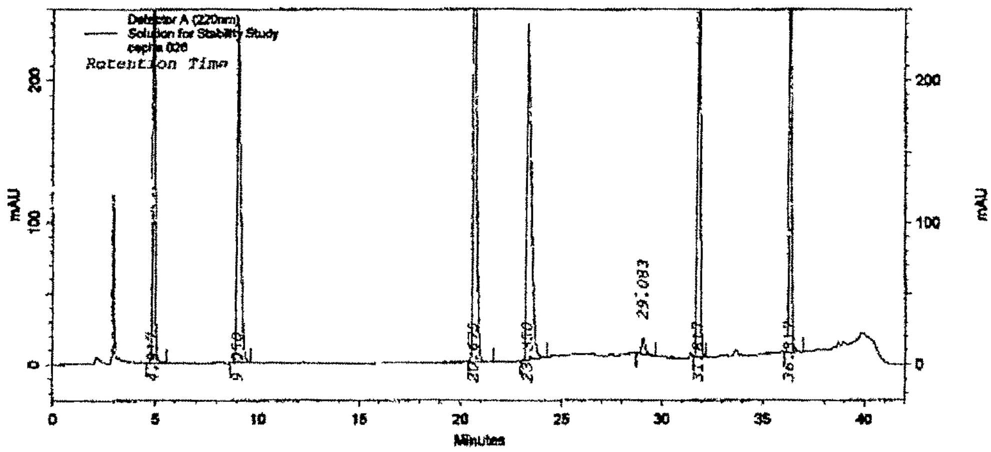
Totals		19394766	100.00

Figure-189

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.026
Acquired : 10/11/2000 12:39:19 PM
Sample name : Solution for Stability Study

Typical chromatogram showing solution stability study



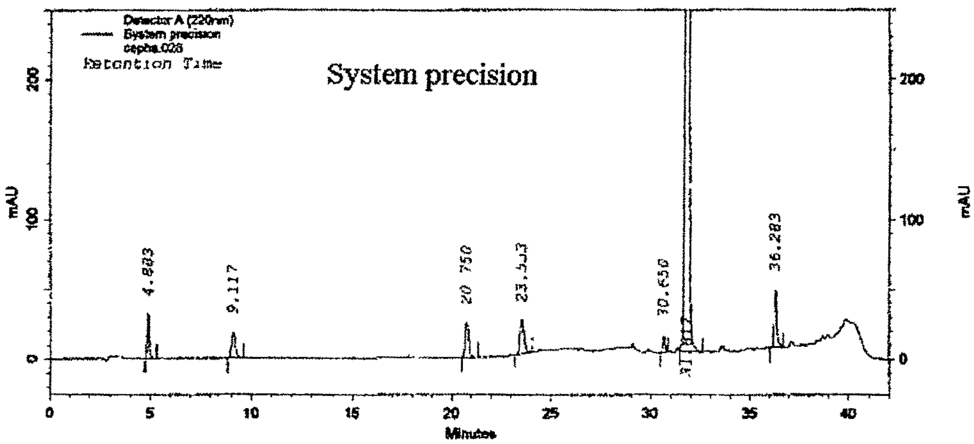
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4.917	2571330	12 78
2	9 050	3087482	15.34
3	20.675	3787151	18.82
4	23.350	3658724	18.18
5	29 083	154860	0.77
6	31.817	3641737	18 09
7	36.317	3225545	16.03

Totals		20126829	100.00

Figure-190

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.028
Acquired : 10/11/2000 2:08:02 PM
Sample name : System precision



Detector A (220nm)

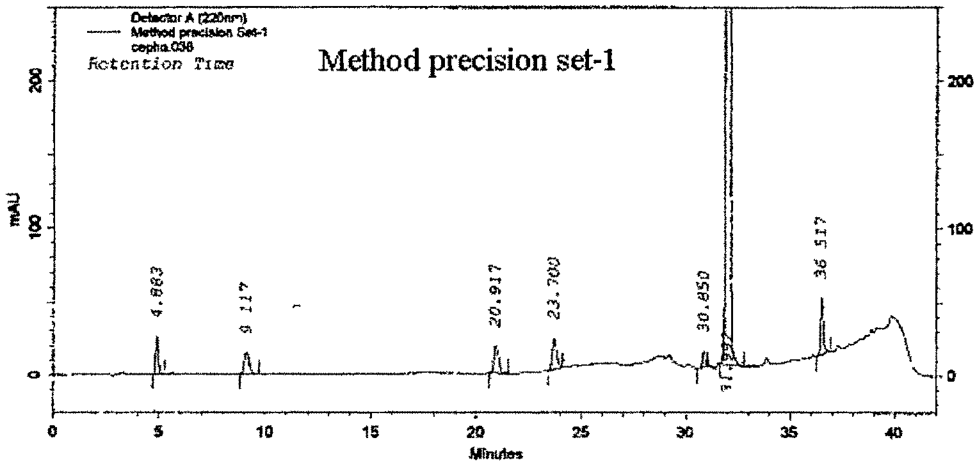
Pk #	Retention Time	Area	Area Percent
1	4.883	226633	1 13
2	9 117	244669	1.21
3	20.750	309276	1 54
4	23.533	320093	1 59
5	30.650	98342	0.49
6	31.817	18597662	92.33
7	36.283	345058	1 71

Totals			
		20141733	100 00

Figure-191

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VL.data\Cepha\cepha.038
Acquired : 10/11/2000 9:31:05 PM
Sample name : Method precision Set-1



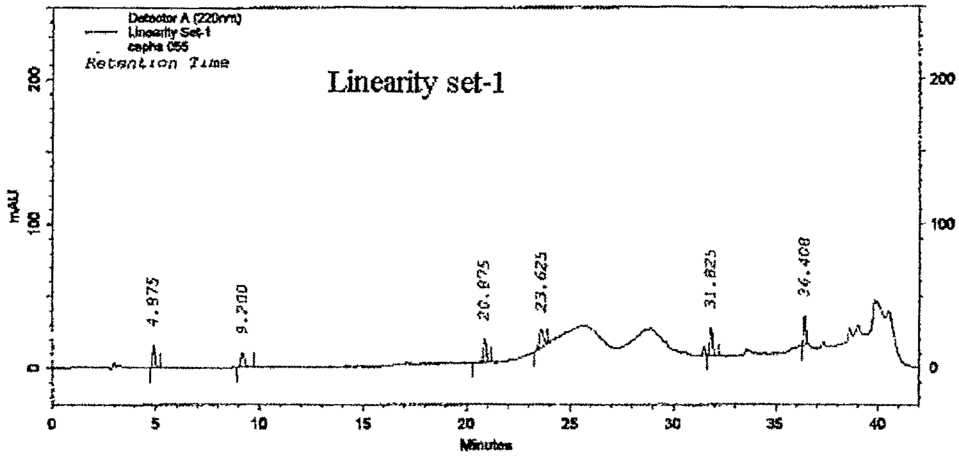
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4 883	217880	1.07
2	9.117	232841	1 15
3	20.917	298009	1 47
4	23.700	309067	1.52
5	30.850	103730	0 51
6	31.992	18832924	92.62
7	36.517	338059	1 66

Totals			
		20332510	100.00

Figure-192

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.055
Acquired : 10/12/2000 7:38:21 PM
Sample name : Linearity Set-1

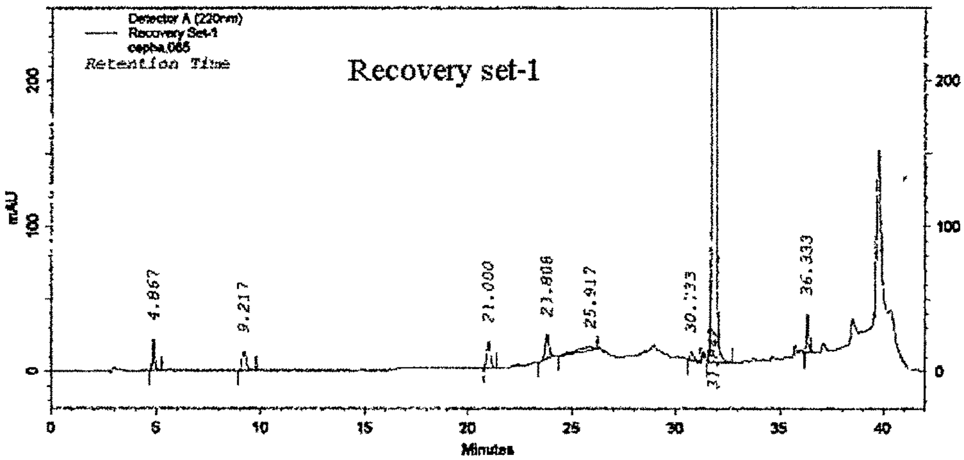


Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4 875	115309	13.57
2	9.200	123409	14.53
3	20.875	158755	18 69
4	23 625	153846	18.11
5	31.825	160526	18.90
6	36.408	137627	16 20
Totals		849472	100 00

Figure-193

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VLdata\Cepha\cepha.085
Acquired : 10/13/2000 11:15:48 PM
Sample name : Recovery Set-1



Detector A (220nm)

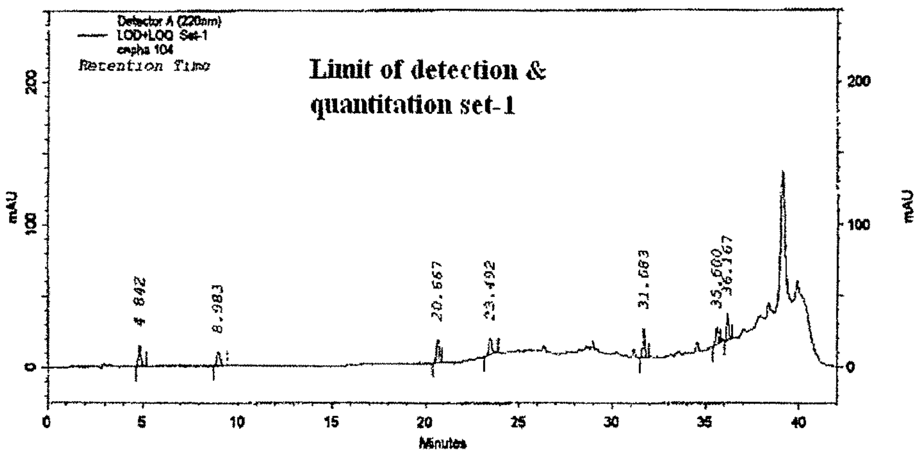
Pk #	Retention Time	Area	Area Percent
1	4 867	158534	0.81
2	9 217	174468	0 89
3	21.000	211910	1.09
4	23.808	194267	1.00
5	25 917	152638	0.78
6	30.733	77925	0 40
7	31 842	18355296	94 06
8	36.333	189148	0 97

Totals		19514186	100.00

Figure-194

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.104
Acquired : 10/14/2000 7:49:57 PM
Sample name : LOD+LOQ Set-1



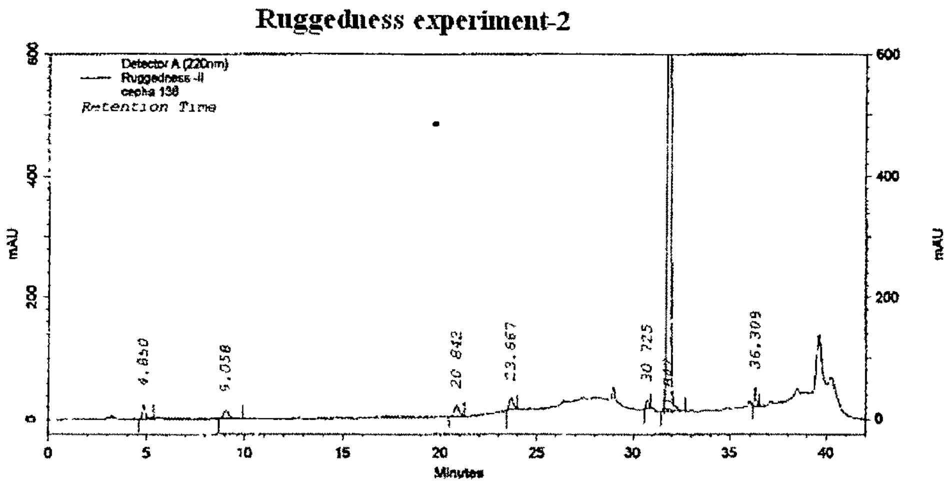
Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4 842	112169	12 30
2	8 983	123422	13.53
3	20.667	148572	16 29
4	23.492	143946	15.78
5	31.683	158005	17 33
6	35.600	95624	10 49
7	36 167	130243	14.28

Totals			
		911981	100.00

Figure-195

Shimadzu CLASS-VP V5.03 ***Area % Report***

Method Name: C:\CLASS-VP\METHODS\cephalexin.met
Data Name : C:\CLASS-VP\VI.data\Cepha\cepha.136
Acquired : 10/16/2000 7:12:50 PM
Sample name : Ruggedness -II



Detector A (220nm) Pk #	Retention Time	Area	Area Percent
1	4.850	225710	1.11
2	9 058	227191	1 11
3	20.842	289609	1 42
4	23.667	278802	1 37
5	30.725	122369	0 60
6	31.842	19038191	93.24
7	36 308	237656	1.16

Totals		20419528	100 00

Figure-196

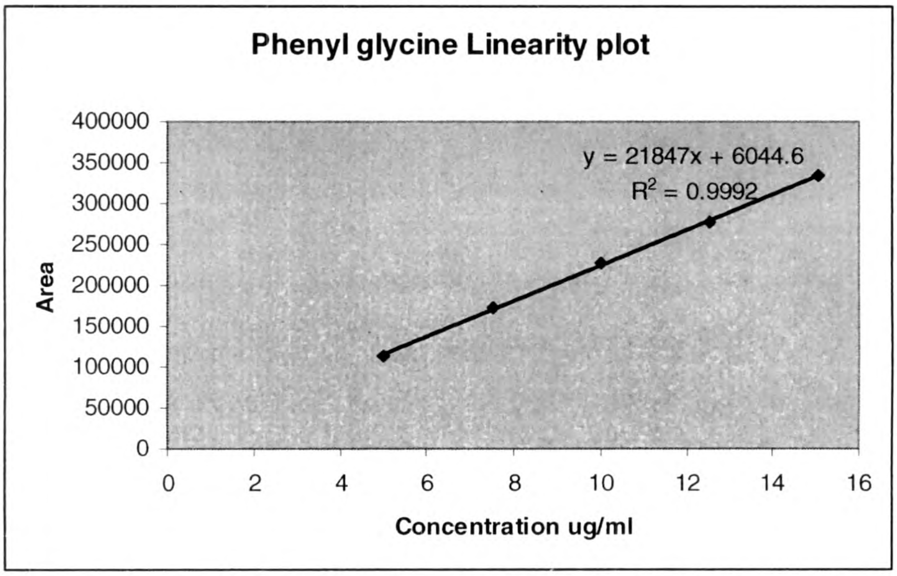


Figure-197

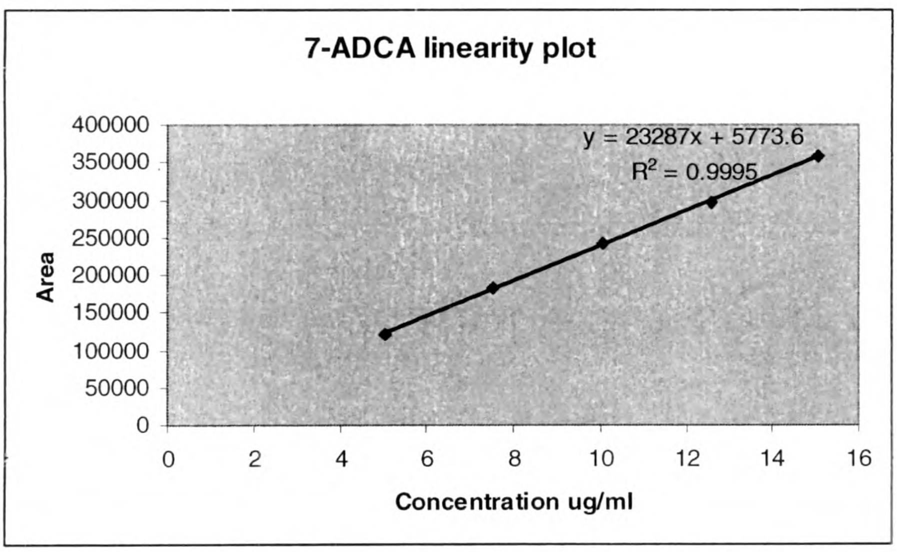


Figure-198

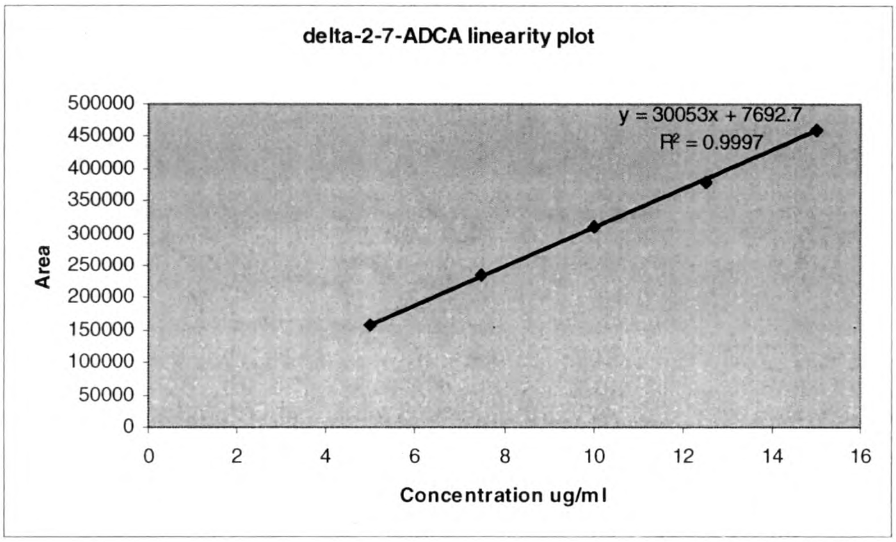


Figure-199

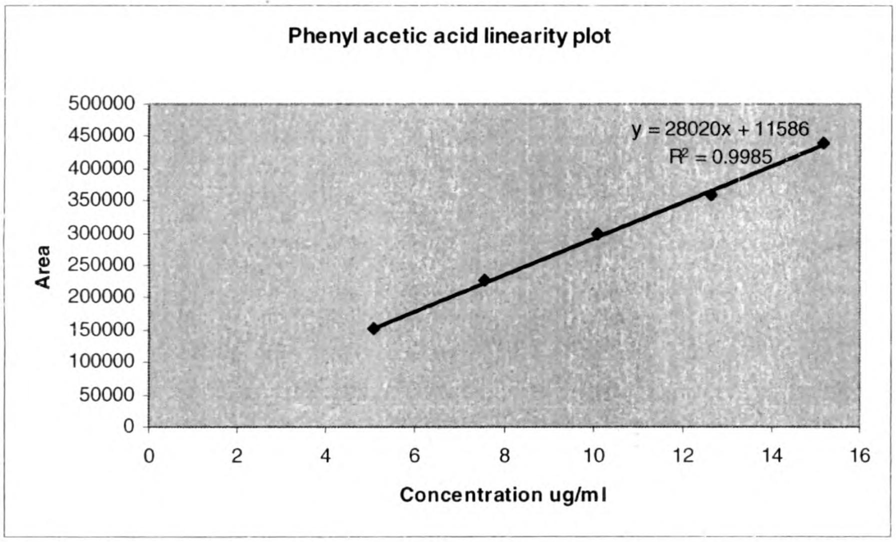


Figure-200

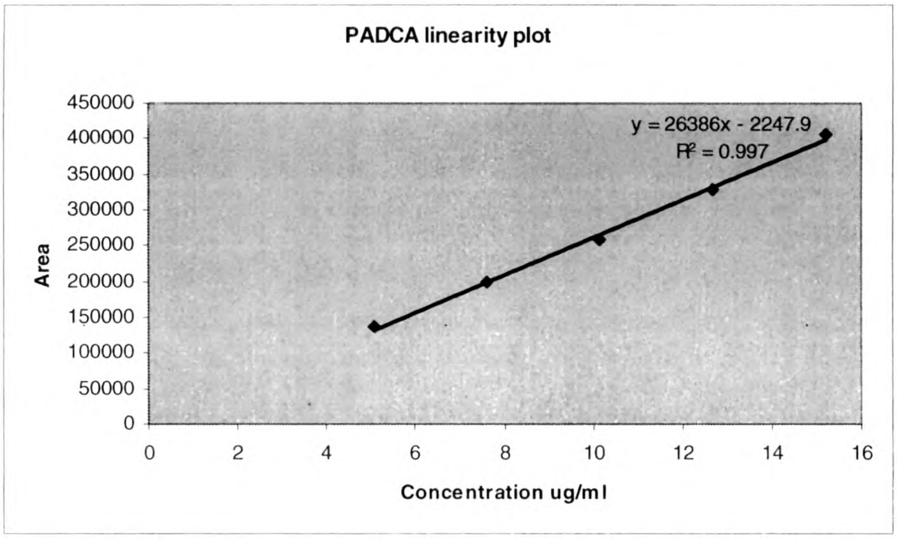


Figure-201

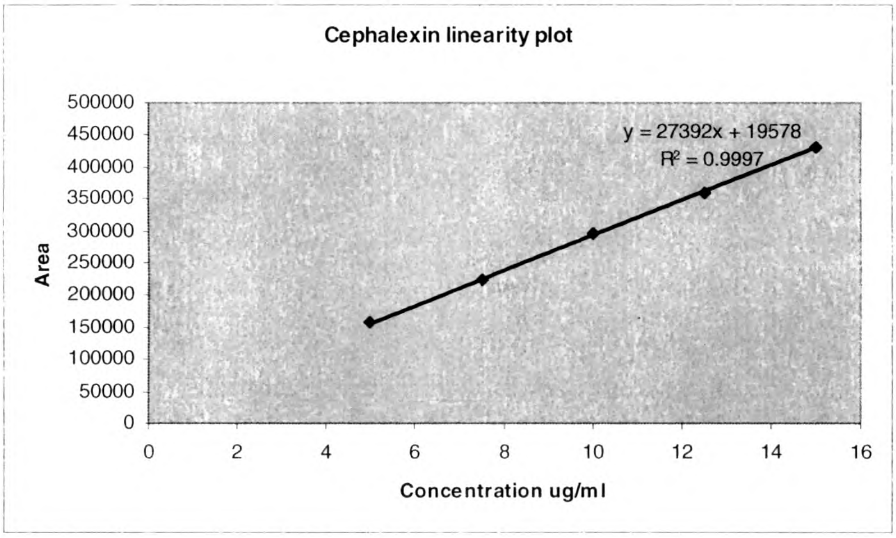


Figure-202