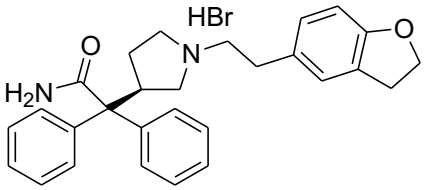
Certificate of Analysis

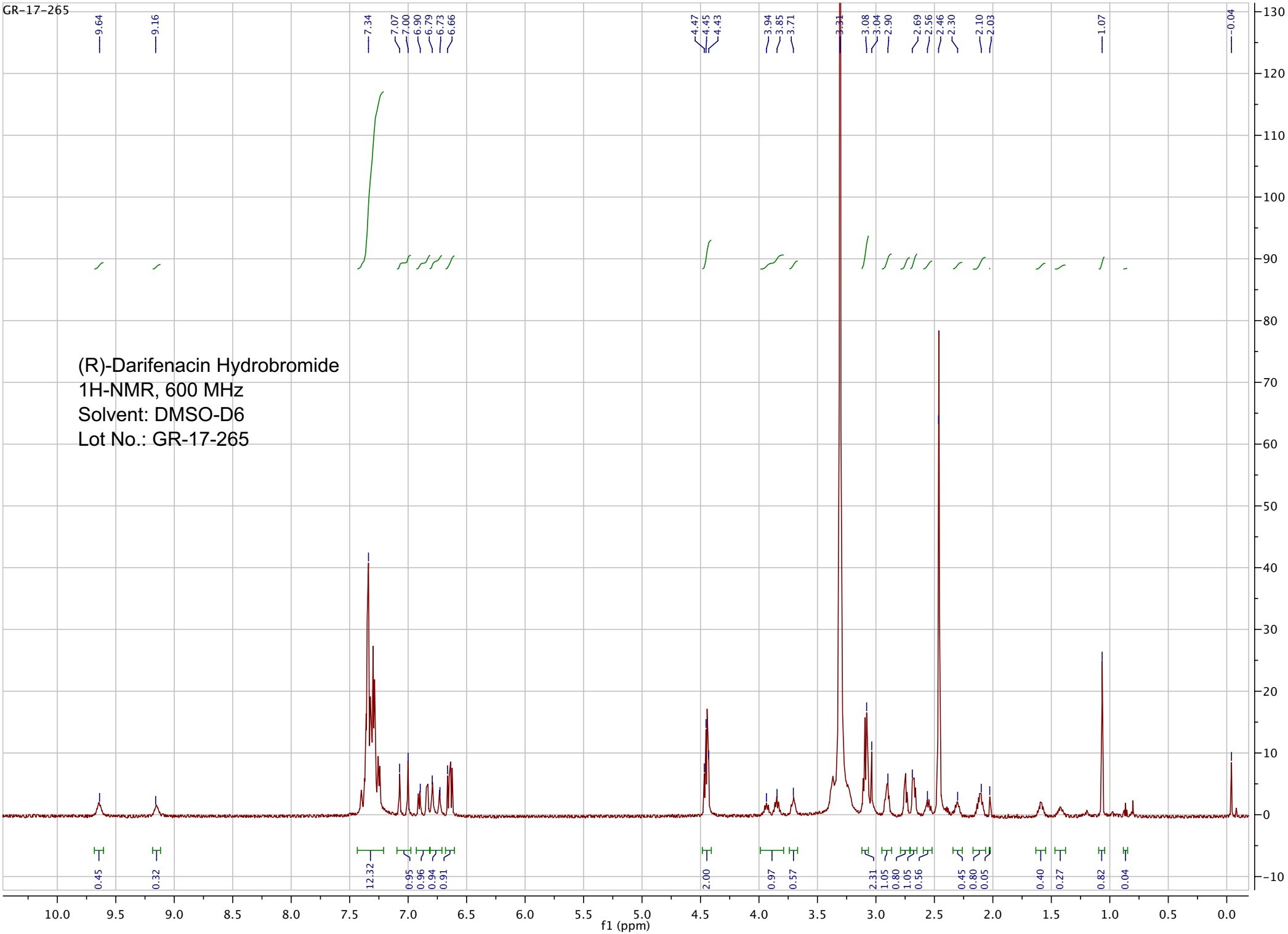


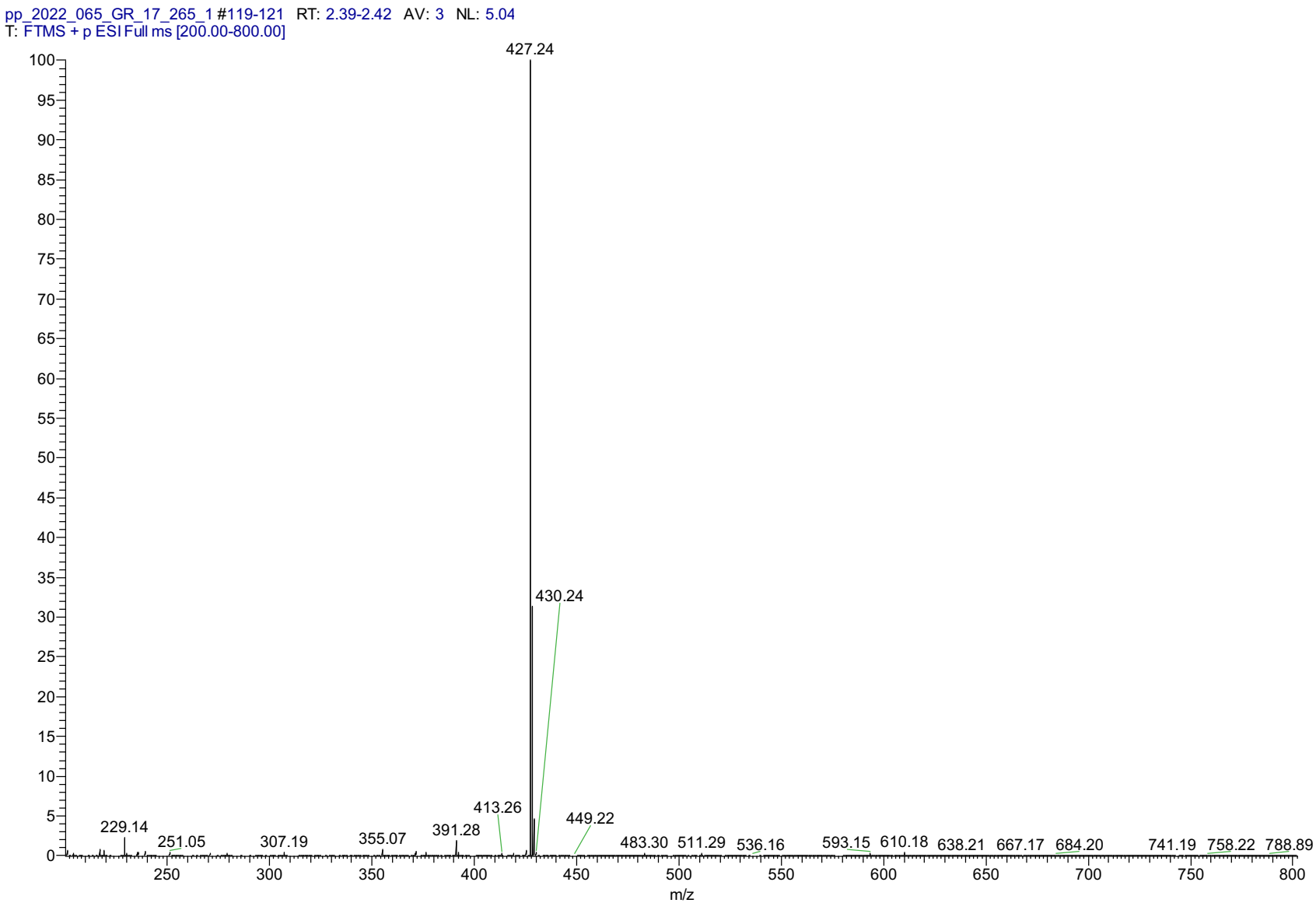
Name:	**(*R*)-Darifenacin Hydrobromide**
Lot#:	GR-17-265
Test Date:	10/27/2022 (re-test date: 10/27/2027)
CAS No.:	1092800-15-1
MF:	$C_{28}H_{31}BrN_2O_2$
MW:	507.46
Appearance:	Beige Solid
Purity:	97.9% by HPLC (average of two sample preparations); 100% ee by chiral HPLC
^{1}H-NMR:	Conforms (contains a trace of 2-butanone and 1.5% of MTBE)
FTIR:	Attached
MS-ESI (+)	Conforms (shows peak at m/z = 427.24 $[M_{(free\ base)}+H]^+$)
Storage	Store at 0-5°C in a dry place away from direct sunlight

Approved by: Date: 11/01/2022

Viorica Rusu, QC/QA Manager

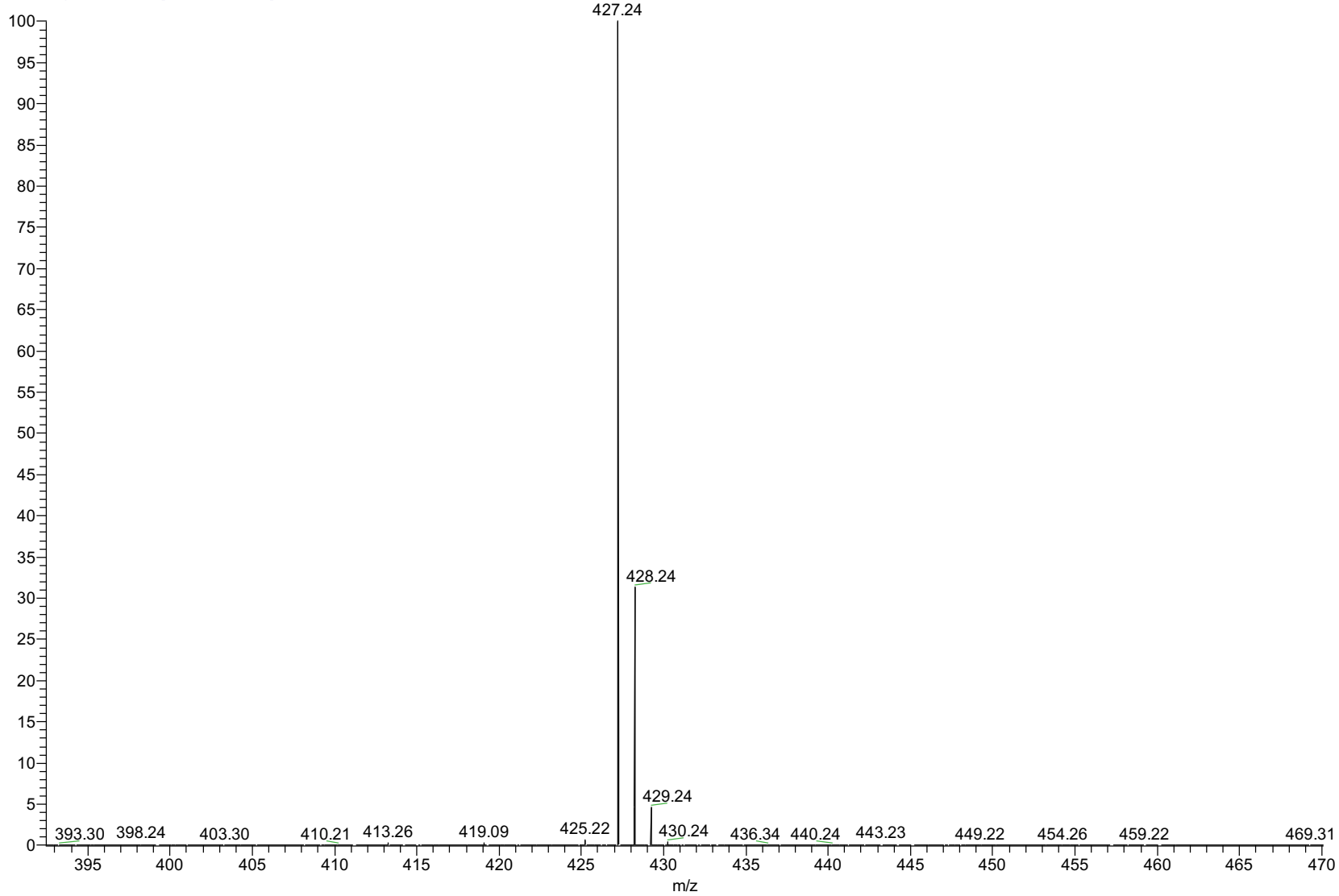
700, Collip Circle, The Research Park, London, ON, N6G 4X8
Ph: (647)4079078, e-mail: grusu@esschemco.com, www.esschemco.com

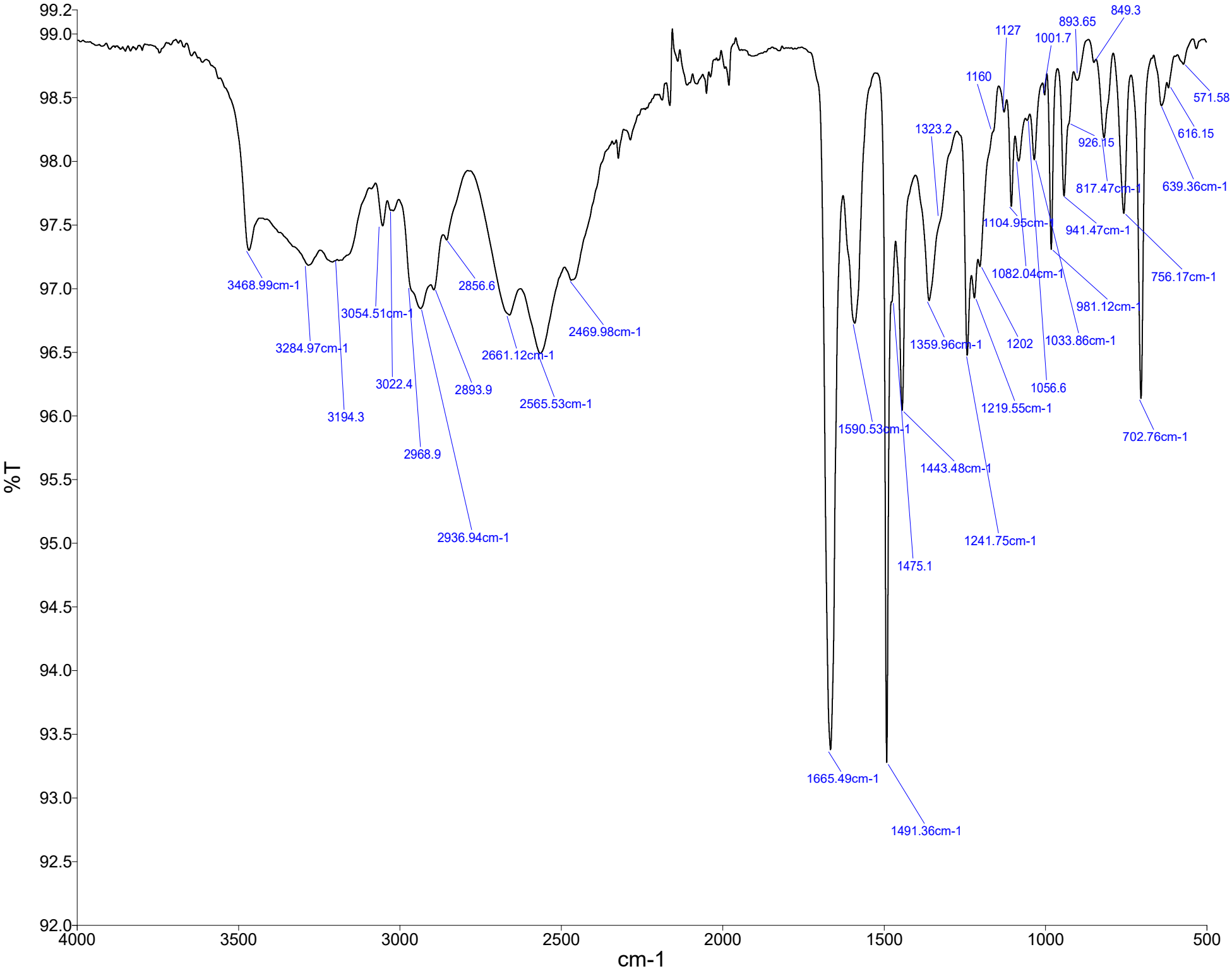

GR-17-265
(R)-Darifenacin Hydrobromide
1H-NMR, 600 MHz
Solvent: DMSO-D6
Lot No.: GR-17-265
9.64
9.16
7.34
7.07
7.00
6.90
6.79
6.73
6.66
4.47
4.45
4.43
3.94
3.85
3.71
3.31
3.08
3.04
2.90
2.69
2.56
2.46
2.30
2.10
2.03
1.07
-0.04
0.45
0.32
12.32
0.95
0.96
0.94
0.91
2.00
0.97
0.57
2.31
1.05
0.80
1.05
0.56
0.45
0.80
0.05
0.40
0.27
0.82
0.04
f1 (ppm)



ESI-MS spectrum for sample GR-17-265. Shows monoisotopic [M+H]+ mass.

pp_2022_065_GR_17_265_1 #119-121 RT: 2.39-2.42 AV: 3 NL: 5.04
T: FTMS + p ESI Full ms [200.00-800.00]

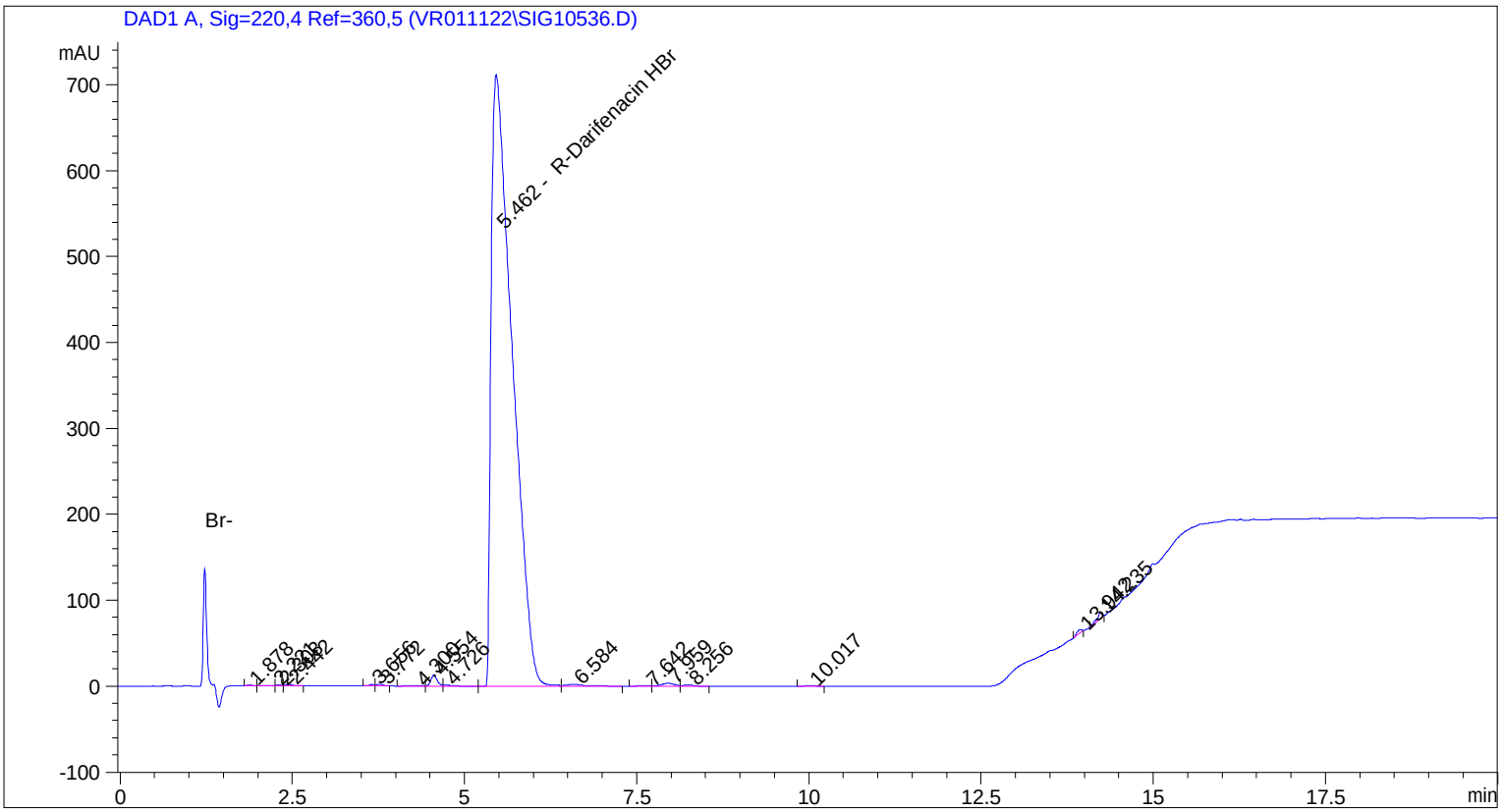




Name	Description
GR-17-265	Sample 045 By Analyst Date Monday, October 31 2022

Data File C:\CHEM32\1\DATA\VR011122\SIG10536.D
Sample Name: GR-17-265

==========
Acq. Operator : vrusu
Acq. Instrument : Instrument 1 Location : Vial 81
Injection Date : 10/27/2022 12:12:46 PM
Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\METHODS\VR102722_265.M
Last changed : 10/27/2022 12:08:43 PM by vrusu
Analysis Method : C:\CHEM32\1\METHODS\VR102722_265PM.M
Last changed : 10/27/2022 1:09:11 PM by vrusu



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Area Percent Report
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Sorted By : Signal
Calib. Data Modified : 10/27/2022 1:07:28 PM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=220,4 Ref=360,5

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.878	BB	0.0691	4.94728	0.0322	?
2	2.221	BV	0.0858	3.89037	0.0253	?
3	2.303	VV	0.0764	5.09846	0.0332	?
4	2.442	VB	0.0907	13.58703	0.0884	?
5	3.656	BV	0.0791	8.03354	0.0523	?
6	3.772	VB	0.0971	13.52016	0.0879	?
7	4.300	BV	0.1628	5.72119	0.0372	?
8	4.554	VV	0.1002	82.90334	0.5393	?

Data File C:\CHEM32\1\DATA\VR011122\SIG10536.D
Sample Name: GR-17-265

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
9	4.726	VB	0.1151	12.90193	0.0839	?
10	5.462	BV	0.3066	1.50472e4	97.8782	R-Darifenacin HBr
11	6.584	VB	0.2721	42.38234	0.2757	?
12	7.642	BV	0.1399	7.42068	0.0483	?
13	7.959	VV	0.2006	45.91684	0.2987	?
14	8.256	VB	0.1791	16.82868	0.1095	?
15	10.017	BB	0.1464	6.79841	0.0442	?
16	13.942	BB	0.0808	21.92131	0.1426	?
17	14.235	BB	0.0754	34.32180	0.2233	?

Totals : 1.53734e4

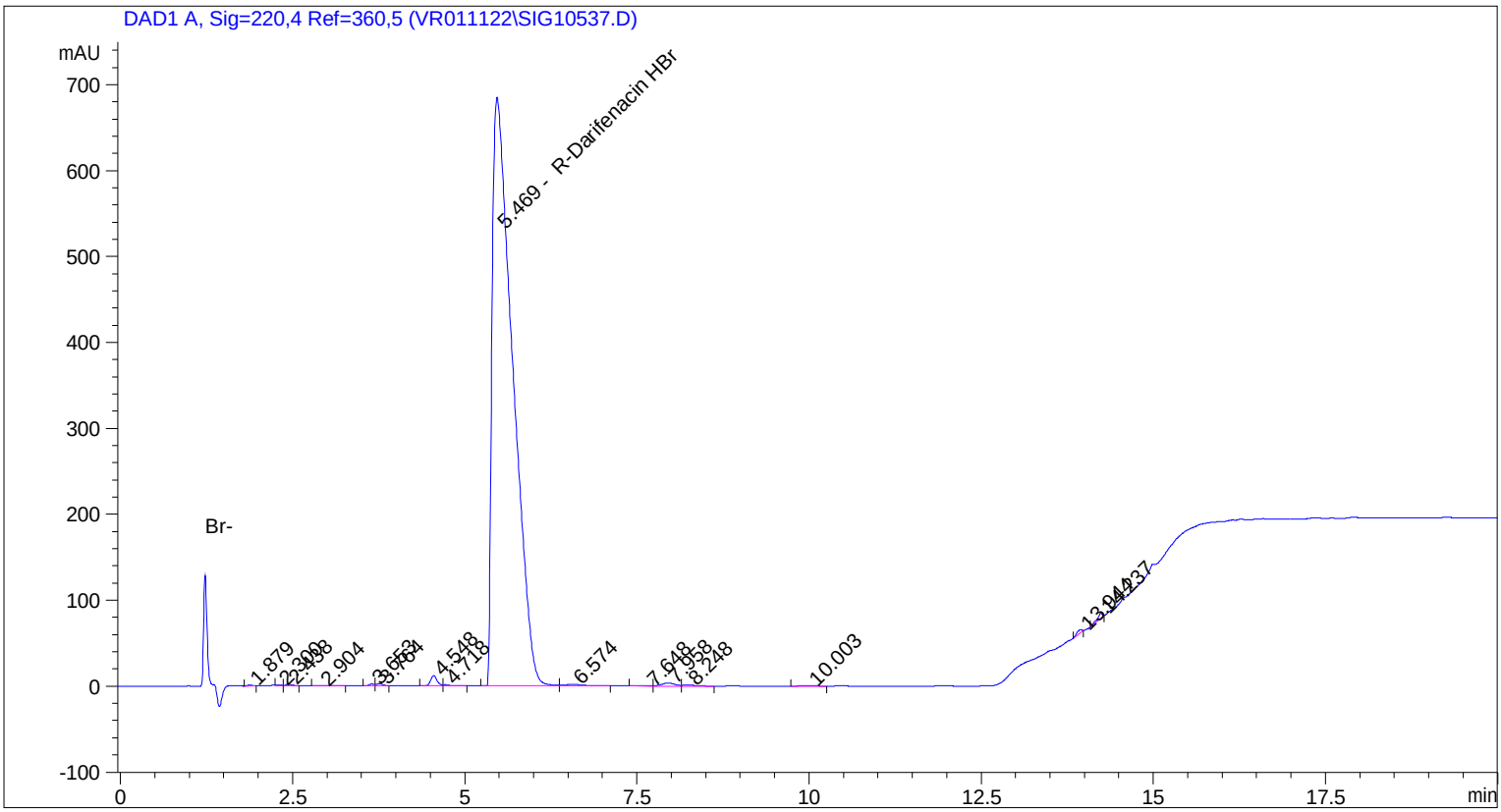
==========

*** End of Report ***

Data File C:\CHEM32\1\DATA\VR011122\SIG10537.D
Sample Name: GR-17-265 spl-2

==========

Acq. Operator : vrusu
Acq. Instrument : Instrument 1 Location : Vial 82
Injection Date : 10/27/2022 12:38:43 PM
Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\METHODS\VR102722_265.M
Last changed : 10/27/2022 12:37:31 PM by vrusu
Analysis Method : C:\CHEM32\1\METHODS\VR102722_265PM.M
Last changed : 10/27/2022 1:09:11 PM by vrusu



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Area Percent Report

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Sorted By : Signal
Calib. Data Modified : 10/27/2022 1:07:28 PM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=220,4 Ref=360,5

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	1.879	BV	0.0768	5.34640	0.0370	?
2	2.300	VB	0.0678	3.13989	0.0217	?
3	2.438	BB	0.0782	9.07493	0.0628	?
4	2.904	BV	0.1541	3.64929	0.0253	?
5	3.653	BV	0.0842	11.18981	0.0775	?
6	3.764	VB	0.0993	15.67796	0.1085	?
7	4.548	BV	0.0995	76.47964	0.5294	?
8	4.718	VB	0.0874	7.69546	0.0533	?

Data File C:\CHEM32\1\DATA\VR011122\SIG10537.D
Sample Name: GR-17-265 spl-2

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
9	5.469	BV	0.2989	1.41489e4	97.9477	R-Darifenacin HBr
10	6.574	VV	0.2600	35.25882	0.2441	?
11	7.648	BV	0.1536	8.23085	0.0570	?
12	7.958	VV	0.1938	46.95141	0.3250	?
13	8.248	VB	0.1930	15.36961	0.1064	?
14	10.003	BB	0.1786	7.38228	0.0511	?
15	13.944	BB	0.0963	20.69317	0.1433	?
16	14.237	BB	0.0736	30.31607	0.2099	?

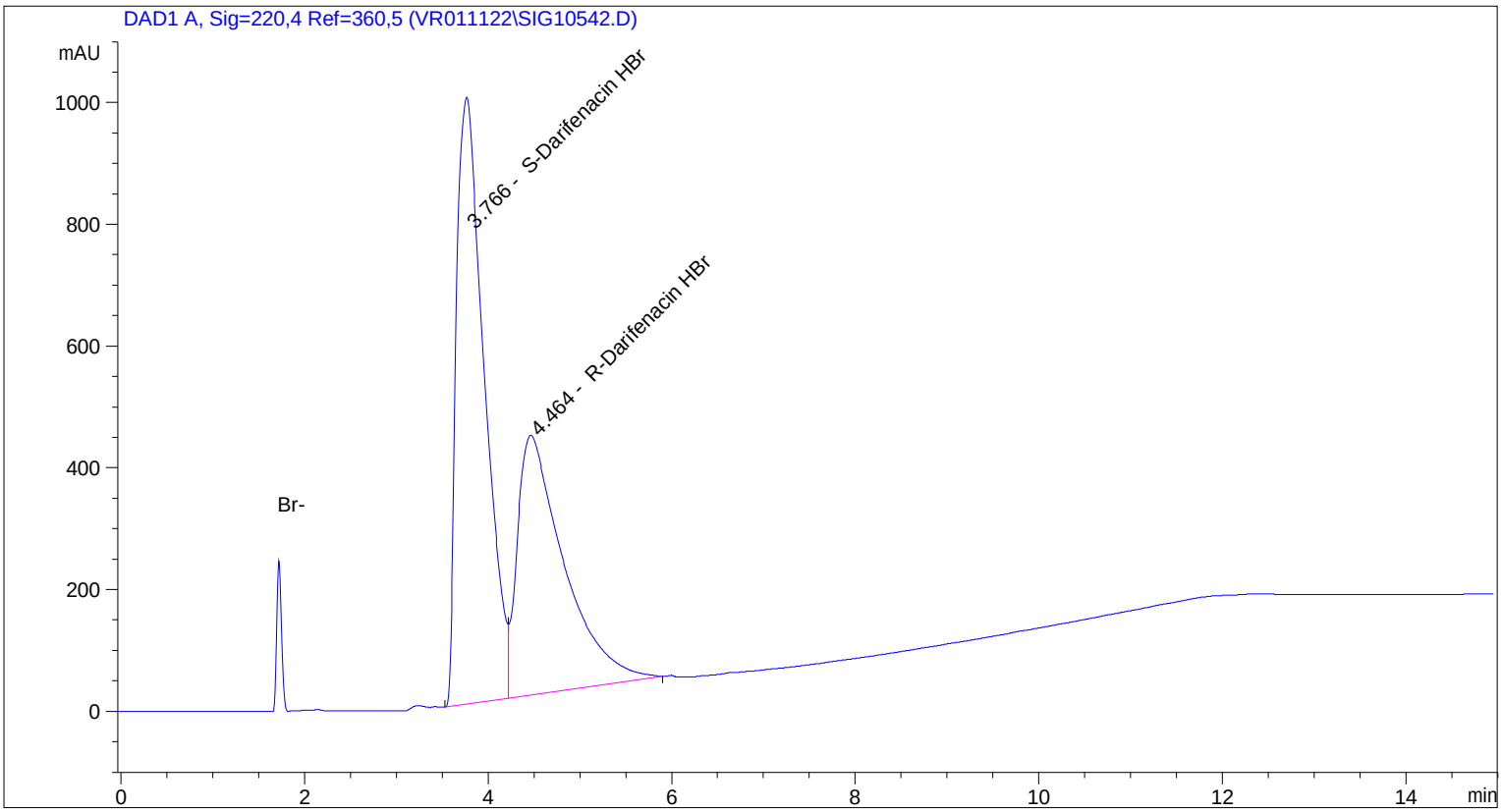
Totals : 1.44453e4

*** End of Report ***

Data File C:\CHEM32\1\DATA\VR011122\SIG10542.D
Sample Name: Resolution Solution

==========

Acq. Operator : vrusu
Acq. Instrument : Instrument 1 Location : Vial 84
Injection Date : 10/27/2022 2:44:09 PM
Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\METHODS\VR102722_265_2.M
Last changed : 10/27/2022 2:42:58 PM by vrusu
Analysis Method : C:\CHEM32\1\METHODS\VR102822_265PM2.M
Last changed : 10/28/2022 8:16:34 AM by vrusu



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Area Percent Report

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Sorted By : Signal
Calib. Data Modified : 10/28/2022 8:15:30 AM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=220,4 Ref=360,5

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	3.766	BV	0.3183	2.10413e4	58.2062	S-Darifenacin HBr
2	4.464	VB	0.5033	1.51083e4	41.7938	R-Darifenacin HBr

Totals : 3.61496e4

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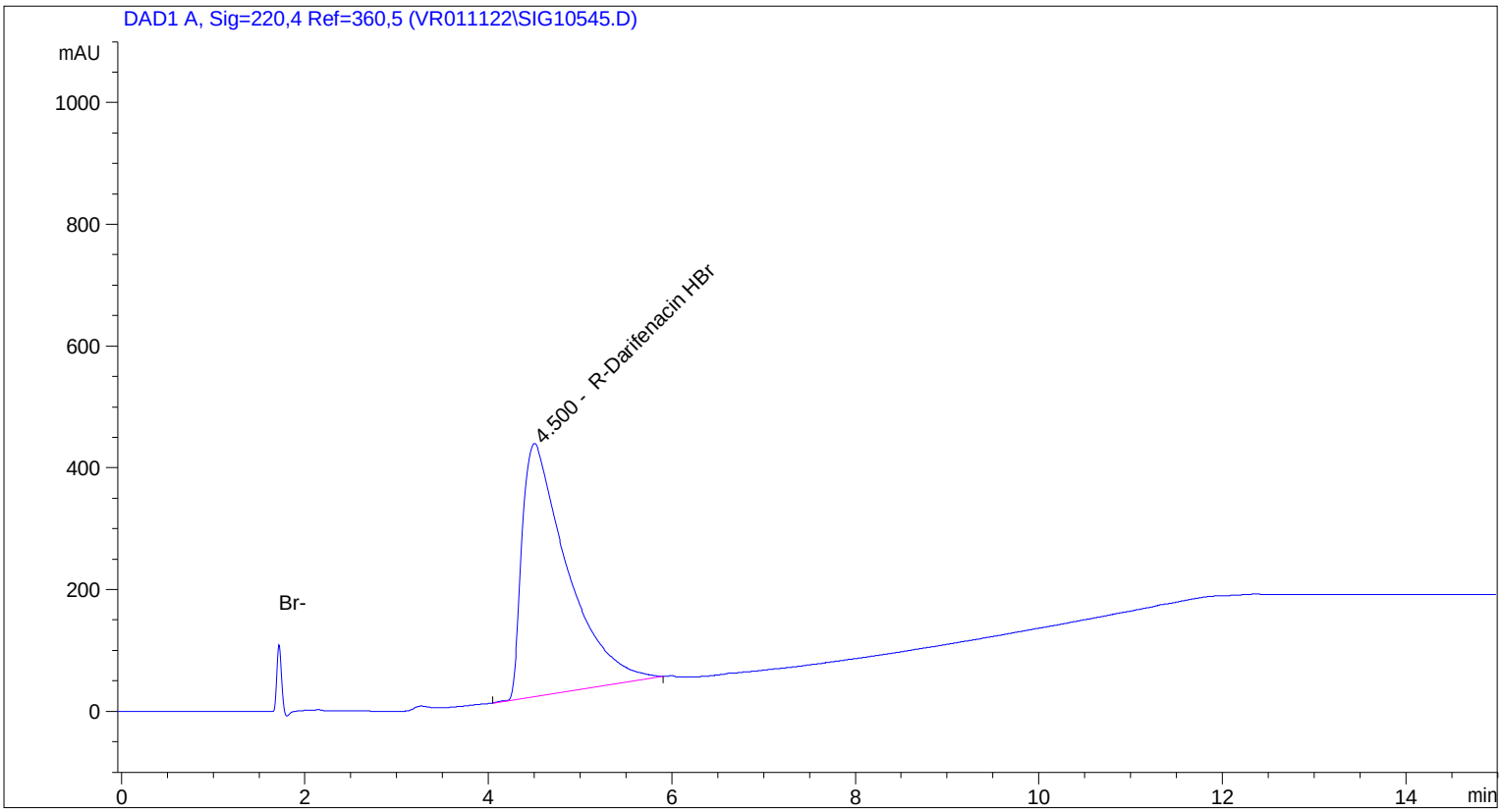
*** End of Report ***

Data File C:\CHEM32\1\DATA\VR011122\SIG10545.D
Sample Name: GR-17-265 En.Pur.

==========

Acq. Operator : vrusu
Acq. Instrument : Instrument 1 Location : Vial 81
Injection Date : 10/27/2022 3:26:12 PM
Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\METHODS\VR102722_265_2.M
Last changed : 10/27/2022 3:25:04 PM by vrusu
Analysis Method : C:\CHEM32\1\METHODS\VR102822_265PM2.M
Last changed : 10/28/2022 8:16:34 AM by vrusu



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Area Percent Report

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Sorted By : Signal
Calib. Data Modified : 10/28/2022 8:15:30 AM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=220,4 Ref=360,5

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	3.766		0.0000	0.00000	0.0000	S-Darifenacin HBr
2	4.500	BB	0.4956	1.42377e4	100.0000	R-Darifenacin HBr

Totals : 1.42377e4

1 Warnings or Errors :

Warning : Calibrated compound(s) not found

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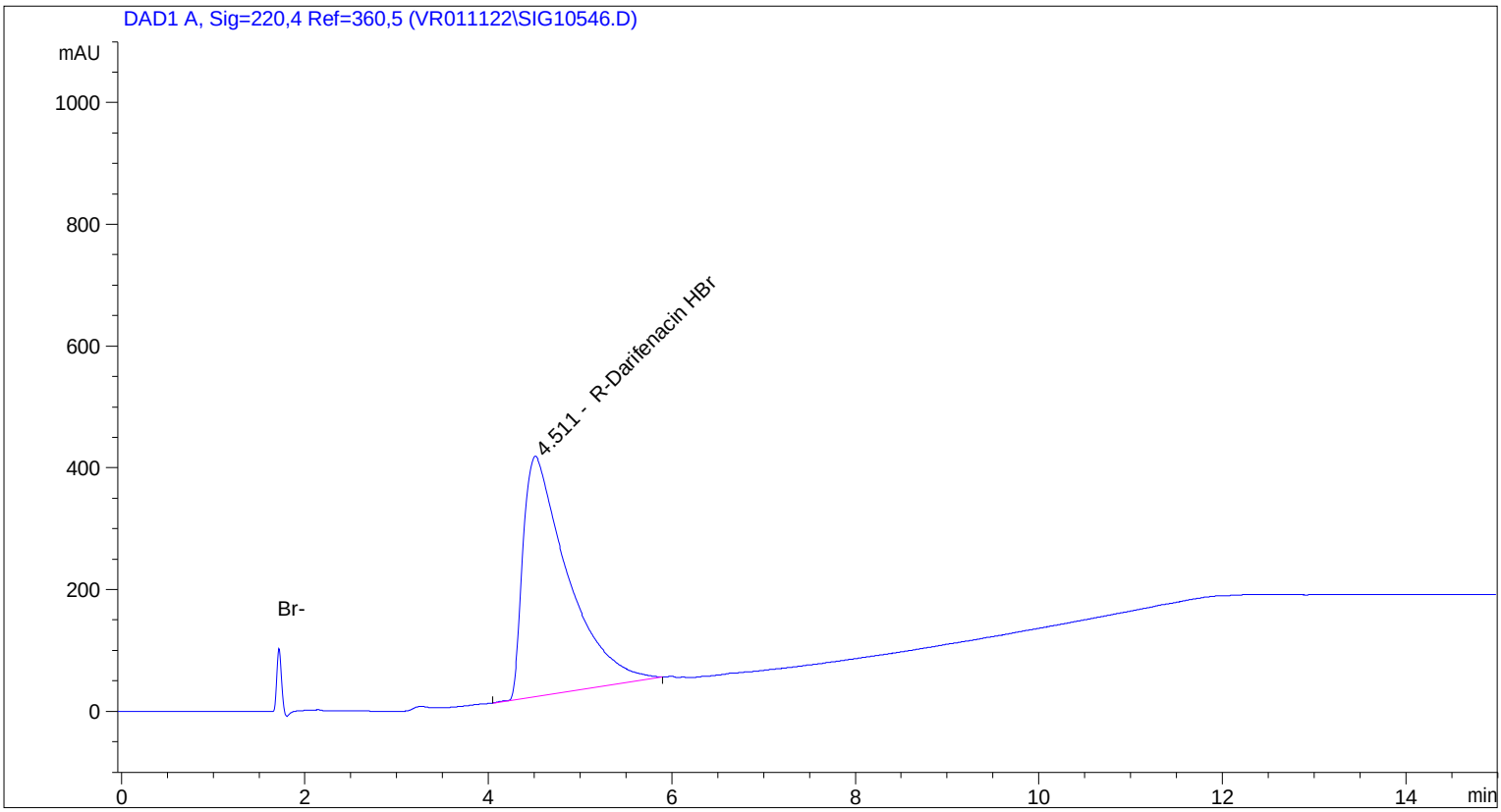
*** End of Report ***

Data File C:\CHEM32\1\DATA\VR011122\SIG10546.D
Sample Name: GR-17-265 spl-2, En.Pur.

==========

Acq. Operator : vrusu
Acq. Instrument : Instrument 1 Location : Vial 82
Injection Date : 10/27/2022 3:46:21 PM
Inj Volume : 10.0 µl
Acq. Method : C:\CHEM32\1\METHODS\VR102722_265_2.M
Last changed : 10/27/2022 3:45:09 PM by vrusu
Analysis Method : C:\CHEM32\1\METHODS\VR102822_265PM2.M
Last changed : 10/28/2022 8:16:34 AM by vrusu



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Area Percent Report

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Sorted By : Signal
Calib. Data Modified : 10/28/2022 8:15:30 AM
Multiplier: : 1.0000
Dilution: : 1.0000
Use Multiplier & Dilution Factor with ISTDs

Signal 1: DAD1 A, Sig=220,4 Ref=360,5

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Area %	Name
1	3.766		0.0000	0.00000	0.0000	S-Darifenacin HBr
2	4.511	BB	0.4825	1.33427e4	100.0000	R-Darifenacin HBr

Totals : 1.33427e4

1 Warnings or Errors :

Warning : Calibrated compound(s) not found

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*** End of Report ***