Katchem spol. s r. o.
Elišky Krásnohorské 123/6
110 00 Prague 1
Czech Republic

delivery address:
Minická 635
278 01 Kralupy nad Vltavou
Czech Republic

IČO: 00548162
DIČ: CZ00548162
Tel.: 736 529 644
Email: keder@katchem.cz
Registration: Registration court in Prague, section C, insert 624

Katchem

CERTIFICATE OF QUALITY

Name of compound:

Sodium mercaptododecaborate (10B), BSH **Cat. No.: 210**

$Na_2[^{10}B_{12}H_{11}SH]$ CAS No.: 12448-24-7

Declared chemical purity: >98%

Declared isotopic purity of 10B: >99,5%

THE RESULTS OF ANALYSES

Batch No.: 21/10	
Type of analysis	Results
10B NMR, D2O	-12.5(s,1B); -16.8(d,5B); -19,0(d,5B); -22.4(d,1B); [ppm]
1H NMR, D2O	1.33(H-B); 1.12(H-B); 0.92(H-B); [ppm]
Boron, acid-base titration	98.0% of Sodium mercaptododecaborate (10B), BSH
Bacterial endotoxins	<0.025 EU/mg
Liquid chromatography	4.75 min-->0.50%(dimer S-S);6.02-->99.50%(BSH)
Date of issuance: 02.11.2021	

There are no impurities detectable by NMR. Sensitivity of NMR device is 1%. For more details see the attached NMR spectrum.
For more details about isotopic purity of boron see the attached certificate of boric acid (the very first precursor).
The bacterial endotoxins are in accordance with limits (see attached report).
HPLC analyzing succesful (limits: BSH>98%, S-S dimer <2%). More in spectrum.

Output control: Ing. Roman Keder, PhD.
Supervised by: Ing. Zdeněk Duda

Certificate of Analysis

Project No:	**PRG11408**	Issue Date:	21/04/2022
		Laboratory:	ALS Czech Republic,s.r.o.|Pharmaceutical Na Harfe 336/9 - Prague 9 - Vysocany Czech Republic 190 00
Client: Address:	**- Zděnek Duda** **Katchem spol. s r.o., Kralupy nad Vltavou** **Areál Balak, Minická 365** **Kralupy nad Vltavou** **278 01** **Czech Republic**		
		Contact:	F&P Client Service
Contact:	Zděnek Duda	Email:	czsupport.pharma@alsglobal.com
Email:	duda@katchem.cz	Telephone:	+420 226 226 998
Telephone:		Page:	Page 1 of 2
Order No:	22059	Date of test:	11/04/2022 - 21/04/2022
Sampled By		Certificate No.:	TPRG011270-1 Final

General Comments:

This report shall not be reproduced except in full, without prior written approval from the laboratory.
The laboratory declares that the test results relate only to the listed samples.
The information about sample representativity is not mentioned.
The sample expiry date is not mentioned.

Responsible person:

Responsible for accuracy of reported results are persons listed below. The results were approved and authorized for reporting according to the procedures specified in the document CZ_SOP_D06_GMP_02 Processing of GMP Project which is in accordance with the procedures specified in FDA document CFR Title 21, Part 11.

Name/Position	Authorization Date
Barbora Hušeková, Microbiology Section Coordinator	21/04/22 13:53

GMP Control Laboratory approved by USKVBL
ALS Czech Republic, s.r.o.

GMP Control Laboratory approved by SÚKL
ALS Czech Republic, s.r.o.
•evidence no. 539•

Client Sample ID	Prod: A - NaBSH (10B merkaptobokat) Order No: 22059 Rcvd Dt: 05/04/2022 Sched Dt: 11/04/2022 Description: A; NaBSH (10B MERKAPTOBOKÁT); č.š. 22-03 Date / Time Sampled: 05/04/2022
Laboratory Sample ID	PRG17032
Client Sampling Date/Time	

Test	Method	Result	Units	Specification	Eval	Flag
Bac. Endo.	MIBI-BETOX03BG3-PRG	<0.025	EU/mg	<0.025 EU/mg	Pass	§2

Client Sample ID	Prod: B - NaBSH (10B merkaptobokat) Order No: 22059 Rcvd Dt: 05/04/2022 Sched Dt: 11/04/2022 Description: B; NaBSH (10B MERKAPTOBOKÁT); č.š. 22-03 Date / Time Sampled: 05/04/2022
Laboratory Sample ID	PRG17033
Client Sampling Date/Time	

Test	Method	Result	Units	Specification	Eval	Flag
Bac. Endo.	MIBI-BETOX03BG3-PRG	<0.025	EU/mg	<0.025 EU/mg	Pass	§2

Client Sample ID	Prod: A - NaBSH (10B merkaptobokat) Order No: 22059 Rcvd Dt: 05/04/2022 Sched Dt: 11/04/2022 Description: A; NaBSH (10B MERKAPTOBOKÁT); č.š. 22-04 Date / Time Sampled: 05/04/2022
Laboratory Sample ID	PRG17034
Client Sampling Date/Time	

Test	Method	Result	Units	Specification	Eval	Flag
Bac. Endo.	MIBI-BETOX03BG3-PRG	<0.025	EU/mg	<0.025 EU/mg	Pass	§2

Client Sample ID	Prod: B - NaBSH (10B merkaptobokat) Order No: 22059 Rcvd Dt: 05/04/2022 Sched Dt: 11/04/2022 Description: B; NaBSH (10B MERKAPTOBOKÁT); č.š. 22-04 Date / Time Sampled: 05/04/2022
Laboratory Sample ID	PRG17035
Client Sampling Date/Time	

Test	Method	Result	Units	Specification	Eval	Flag
Bac. Endo.	MIBI-BETOX03BG3-PRG	<0.025	EU/mg	<0.025 EU/mg	Pass	§2

§2 Analysis was performed by ALS testing site Na Harfě 336/9, Prague 9, 190 00

If the client does not specify the date and time of sample collection, the laboratory will specify the date on sample delivery in parentheses, instead. If the time of sample collection is specified as 0:00 it means that the client did specify the date but not the time.

The end of result part of the certificate of analysis

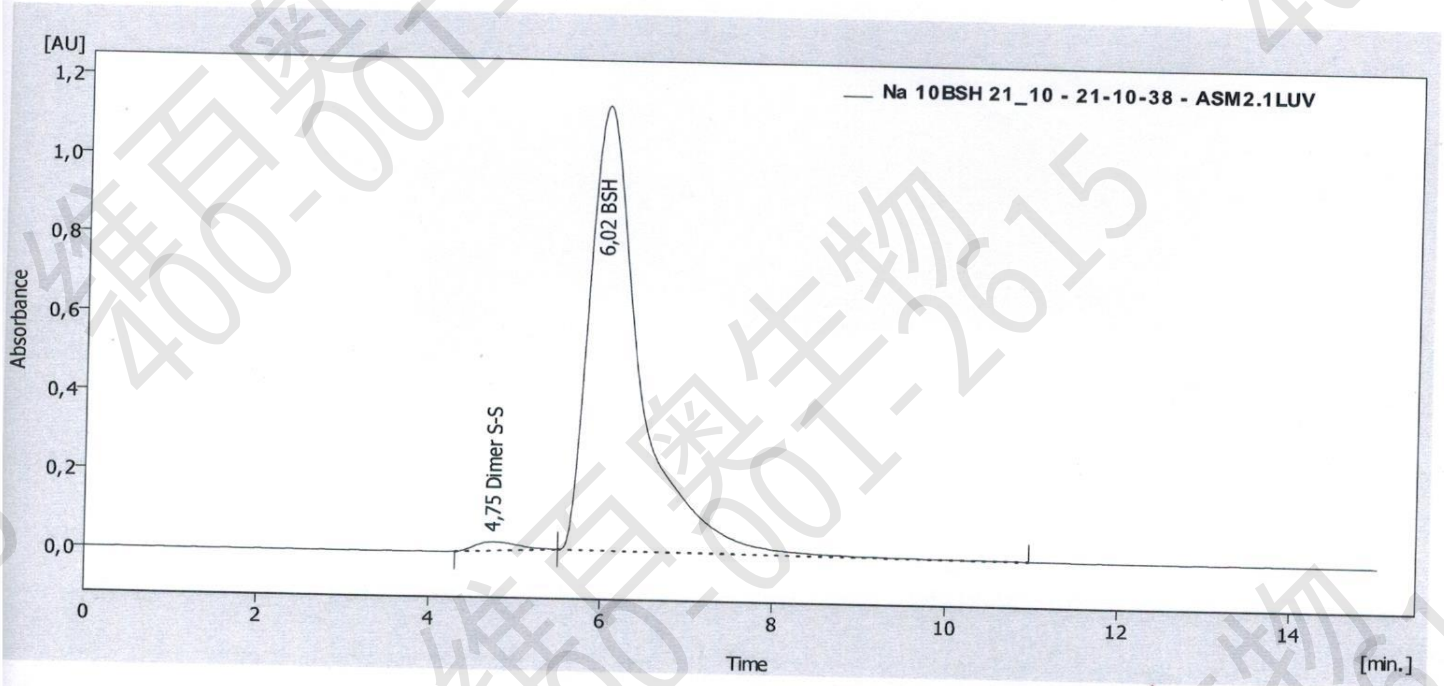
Brief Method Summaries

Analytical Methods	Method Descriptions
MIBI-BETOX03BG3-PRG	Bacterial endotoxins - Turbidimetric m.; G13

Katchem l.t.d.

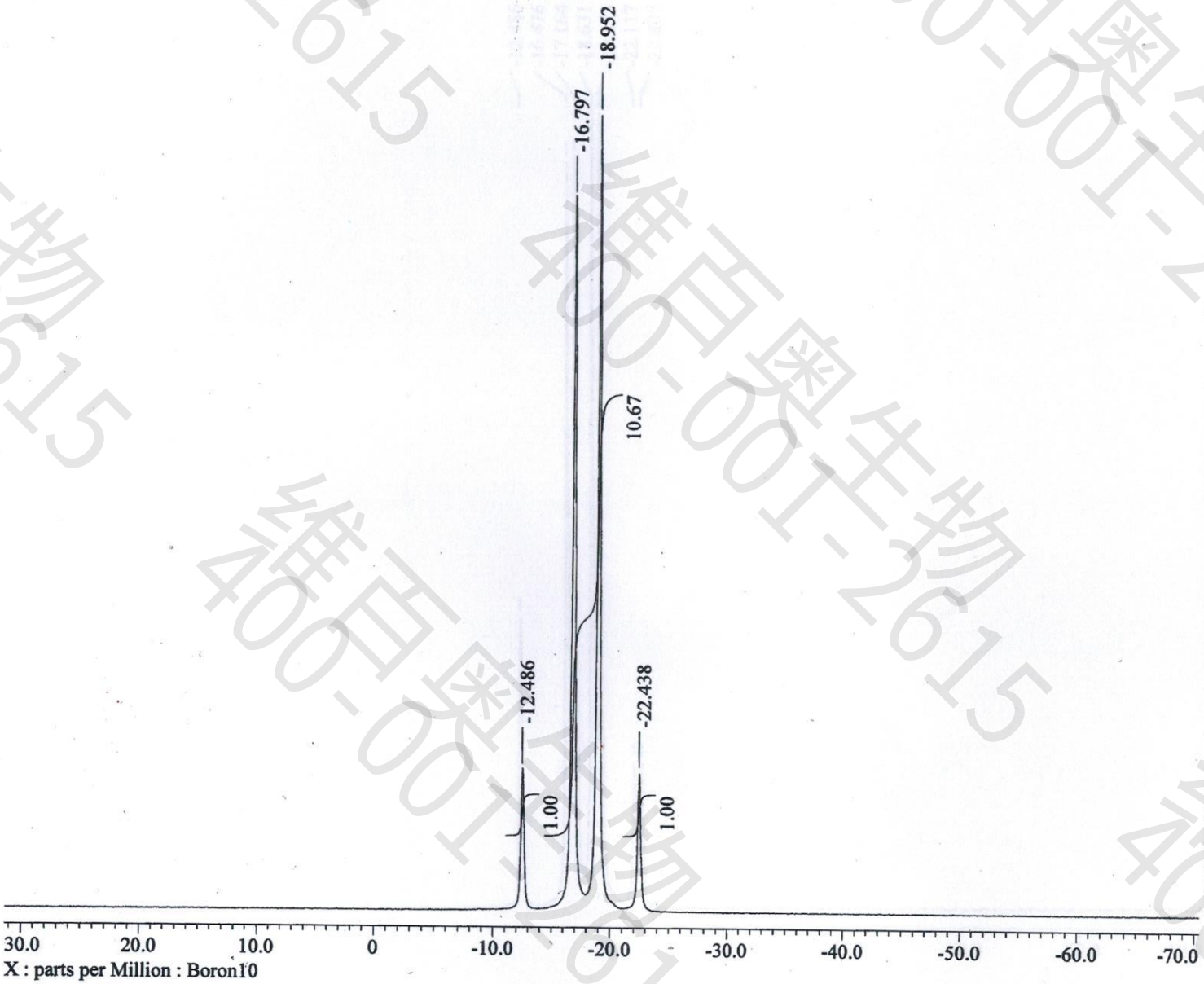
Sample Info:

Sample ID	: Na 10BSH 21/10
Sample	: Na 10BSH 21/10
Inj. Volume [mL]	: 0
Amount [mg]	: 0
ISTD Amount	: 0
Dilution	: 1
Method	: BSH
Description	: BSH
Created	: 1.3.2016 9:56
By	: zd
Modified	: 8.10.2021 13:49
Column	: YMC triart C18
Mobile Phase	: 0,05M NaClO4 in 0,01M Na2HPO4
Flow Rate	: 0,5ml/min
Note	:
Detection	: UV 204 nm
Temperature	:
Pressure	:
Autostop	: 15,00 min
Detector 1	: ASM2.1LUV
Subtraction Chromatogram	: (None)
External Start	: Start - Restart, Down
Range 1	: Bipolar, 10000 mAU, 1 Samp. per Sec.
Matching	: No Change

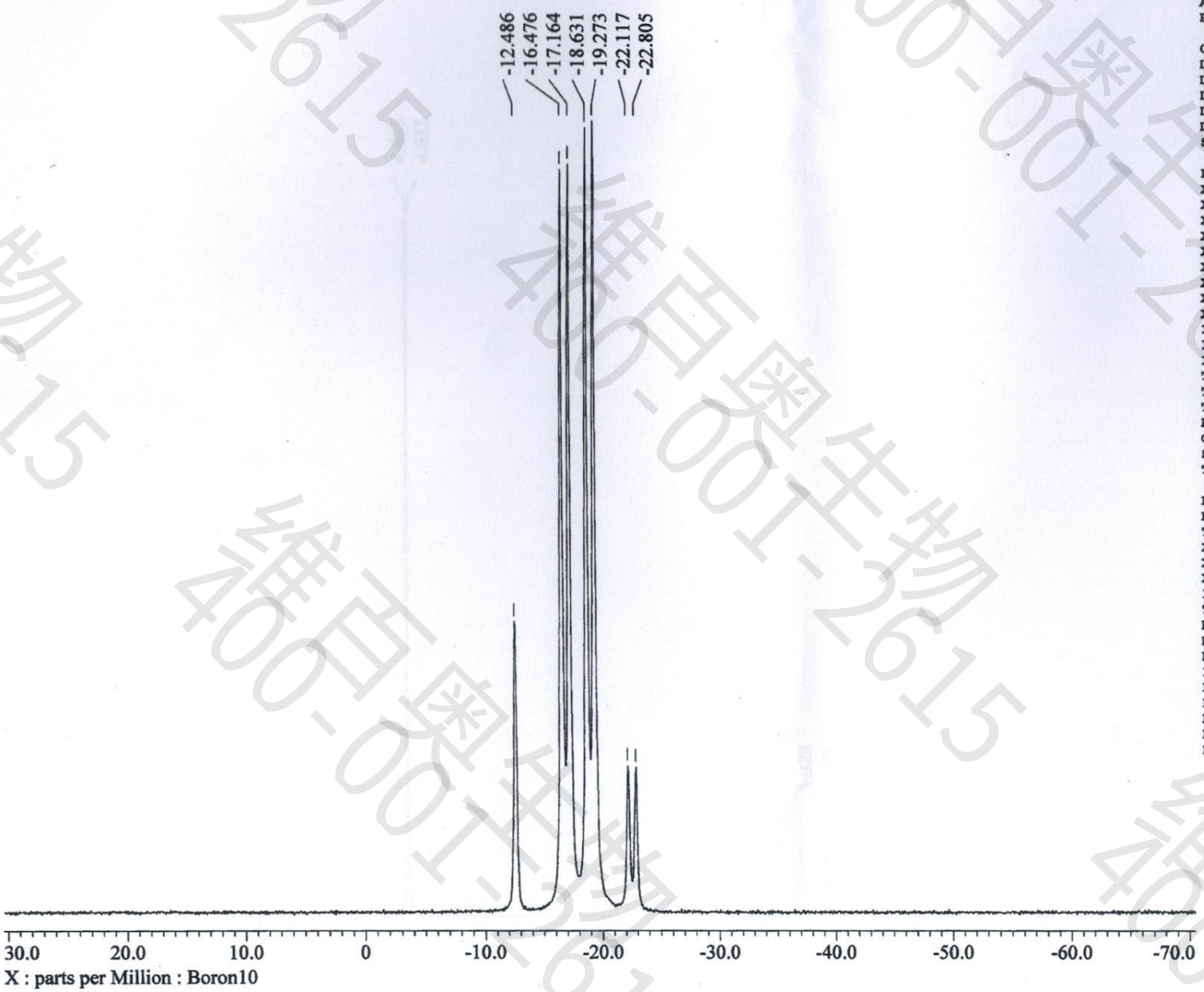


Result Table (ESTD - Na 10BSH 21_10 - 21-10-38 - ASM2.1LUV)

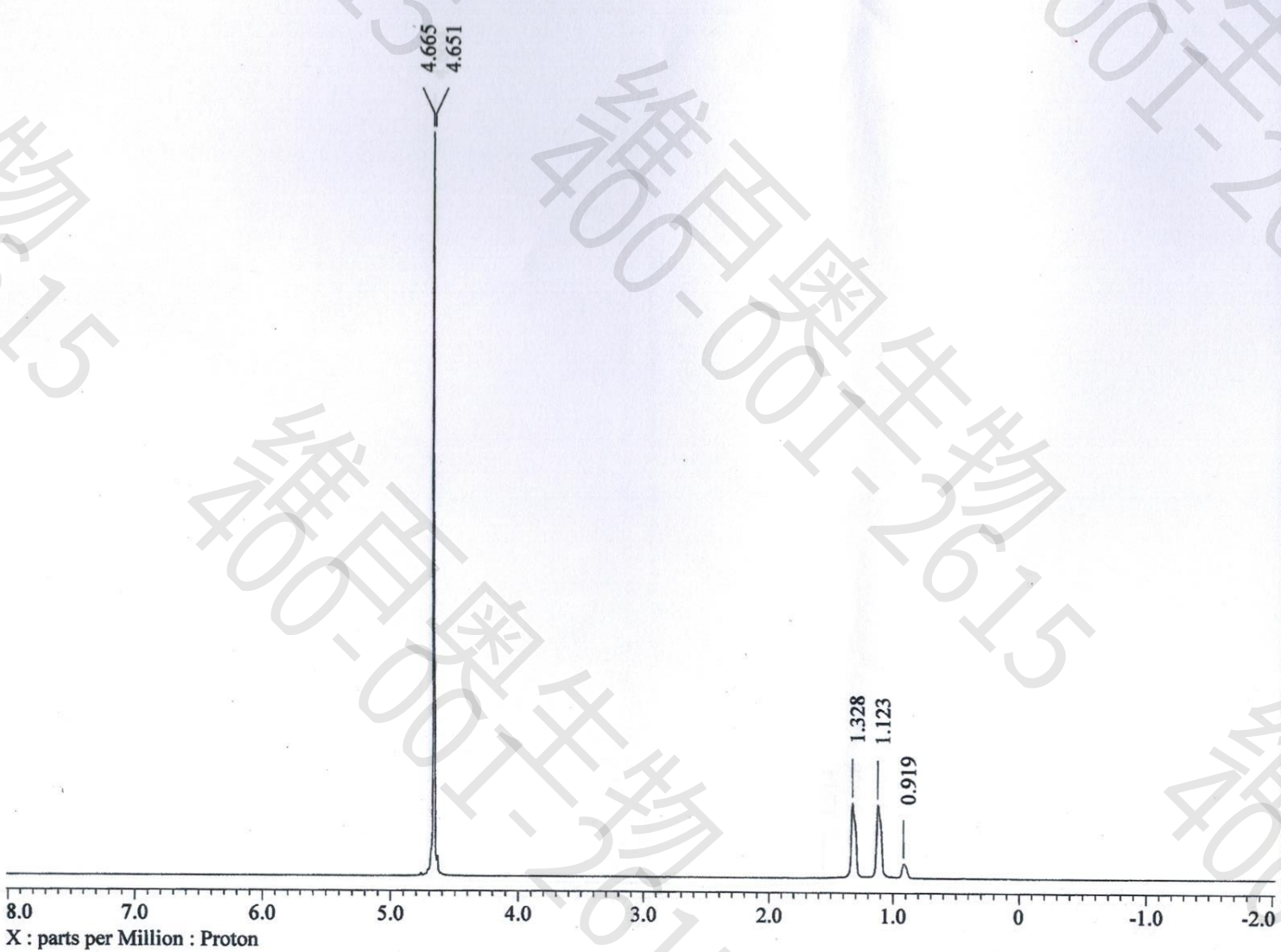
	Reten. Time [min]	Response	Amount [mg]	Amount [%]	Peak Type	Compound Name
1	4,750	751,889	0,522	0,5	Ordnr	Dimer S-S
2	6,017	46242,228	101,636	99,5	Ordnr	BSH
	Total		102,158	100,0		



Filename	= 210-10B-NaBSH_dept
Author	= delta
Experiment	= depth_2_dec.jxp
Sample_Id	= 210-10B-NaBSH
Solvent	= D2O
Actual_Start_Time	= 13-OCT-2021 11:03:
Revision_Time	= 13-OCT-2021 09:55:
Comment	= single pulse decou
Data_Format	= 1D COMPLEX
Dim_Size	= 6554
Dim_Title	= Boron10
Dim_Units	= [ppm]
Dimensions	= X
Spectrometer	= DELTA2_NMR
Field_Strength	= 14.09636928[T] (60
X_Acq_Duration	= 0.33816576[s]
X_Domain	= 10B
X_Freq	= 64.48067664[MHz]
X_Offset	= -50[ppm]
X_Points	= 8192
X_Prescans	= 4
X_Resolution	= 2.95712966[Hz]
X_Sweep	= 24.2248062[kHz]
X_Sweep_Clipped	= 19.37984496[kHz]
Irr_Domain	= Proton
Irr_Freq	= 600.1723046[MHz]
Irr_Offset	= 5[ppm]
Blanking	= 5[us]
Clipped	= FALSE
Scans	= 128
Total_Scans	= 128
Relaxation_Delay	= 0.1[s]
Recvr_Gain	= 50
Temp_Get	= 18.7[dC]
X_Acq_Time	= 0.33816576[s]
X_Atn	= 7[dB]
X_Pulse	= 20.6[us]
Irr_Atn_Dec	= 27.338[dB]
Irr_Atn_Dec_Calc	= 27.338[dB]
Irr_Atn_Dec_Default_Calc	= 27.338[dB]
Irr_Atn_Noe	= 27.338[dB]
Irr_Dec_Bandwidth_Hz	= 7.23684211[kHz]
Irr_Dec_Bandwidth_Ppm	= 12.05794078[ppm]
Irr_Dec_Freq	= 600.1723046[MHz]
Irr_Dec_Merit_Factor	= 2.2
Irr_Decoupling	= TRUE
Irr_Noe	= TRUE
Irr_Noise	= WALTZ
Irr_Offset_Default	= 5[ppm]
Irr_Pwidth	= 76[us]
Irr_Pwidth_Default	= 76[us]
Irr_Pwidth_Default_Calc	= 76[us]
Irr_Pwidth_Temp1	= 76[us]
Irr_Wurst	= FALSE
Decimation_Rate	= 0
Initial_Wait	= 1[s]
Noe_Time	= 0.1[s]
Noe_Time_Flag	= FALSE
Relaxation_Delay_Calc	= 0[s]
Relaxation_Delay_Temp	= 0.1[s]
Repetition_Time	= 0.43816576[s]



Filename	= 210-10B-NaBSH_depth_2
Author	= delta
Experiment	= depth_2.jxp
Sample_Id	= 210-10B-NaBSH
Solvent	= D2O
Actual_Start_Time	= 13-OCT-2021 11:03:10
Revision_Time	= 13-OCT-2021 09:56:12
Comment	= single_pulse
Data_Format	= 1D COMPLEX
Dim_Size	= 6554
Dim_Title	= Boron10
Dim_Units	= [ppm]
Dimensions	= X
Spectrometer	= DELTA2_NMR
Field_Strength	= 14.09636928[T] (600[M
X_Acq_Duration	= 0.33816576[s]
X_Domain	= 10B
X_Freq	= 64.48067664[MHz]
X_Offset	= -50[ppm]
X_Points	= 8192
X_Prescans	= 4
X_Resolution	= 2.95712966[Hz]
X_Sweep	= 24.2248062[kHz]
X_Sweep_Clipped	= 19.37984496[kHz]
Irr_Domain	= Boron10
Irr_Freq	= 64.48067664[MHz]
Irr_Offset	= 5[ppm]
Tri_Domain	= Boron10
Tri_Freq	= 64.48067664[MHz]
Tri_Offset	= 5[ppm]
Blanking	= 5[us]
Clipped	= FALSE
Scans	= 64
Total_Scans	= 64
Relaxation_Delay	= 0.1[s]
Recvr_Gain	= 50
Temp_Get	= 18.6[dC]
X_Acq_Time	= 0.33816576[s]
X_Atn	= 7[dB]
X_Pulse	= 20.6[us]
Irr_Mode	= Off
Tri_Mode	= Off
Dante_Loop	= 10
Dante_Presat	= FALSE
Decimation_Rate	= 0
Initial_Wait	= 1[s]
Presat_Time	= 0.1[s]
Presat_Time_Flag	= FALSE
Relaxation_Delay_Calc	= 0[s]
Relaxation_Delay_Temp	= 0.1[s]
Repetition_Time	= 0.43816576[s]

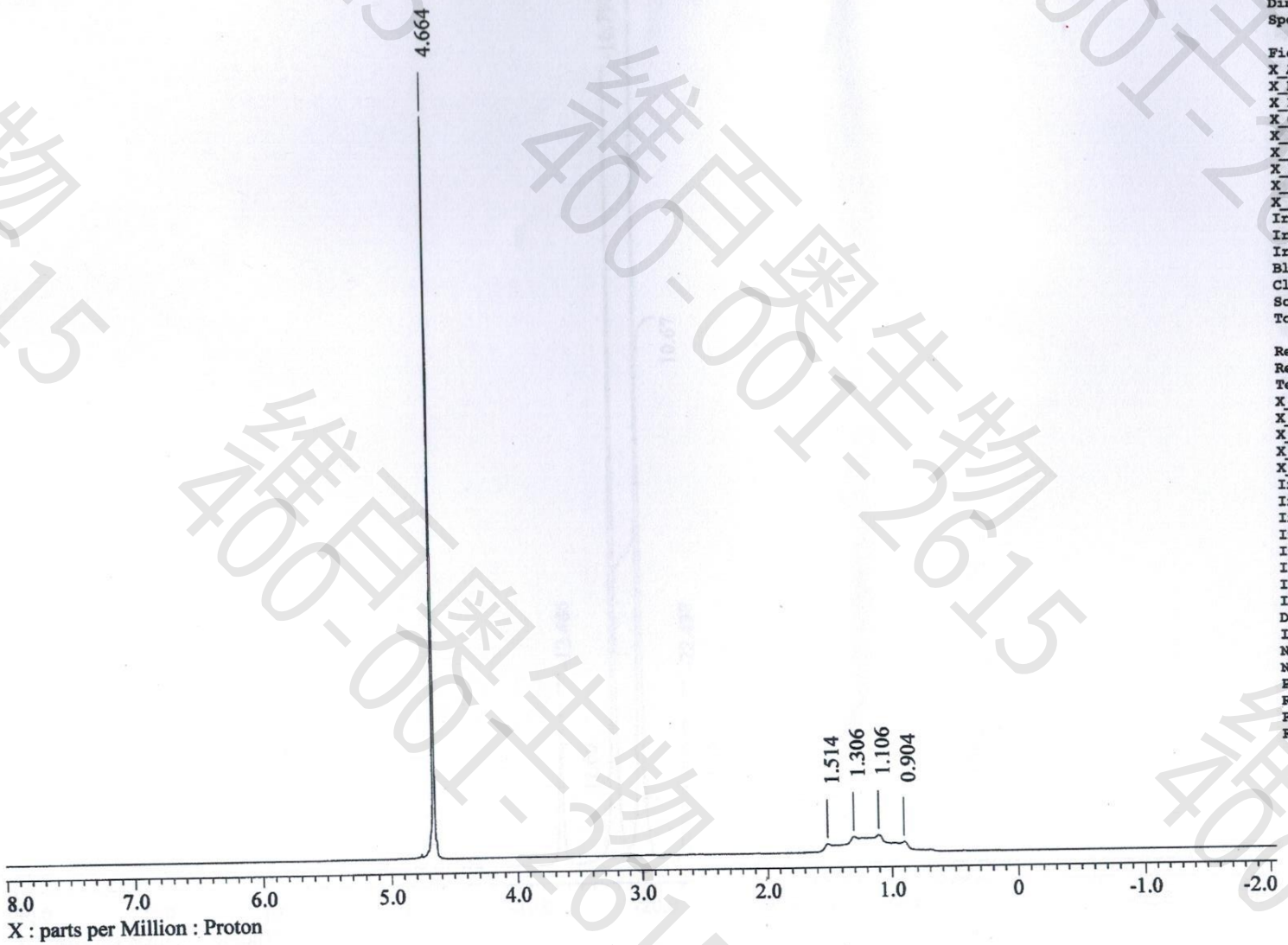



```
Filename                    = 210-10B-NaBSH_prot
Author                      = delta
Experiment                  = proton_dec.jxp
Sample_Id                   = 210-10B-NaBSH
Solvent                     = D2O
Actual_Start_Time           = 13-OCT-2021 11:05:
Revision_Time               = 13-OCT-2021 09:57:

Comment                     = single pulse decou
Data_Format                 = 1D COMPLEX
Dim_Size                    = 13107
Dim_Title                   = Proton
Dim_Units                   = [ppm]
Dimensions                  = X
Spectrometer                = DELTA2_NMR

Field_Strength              = 14.09636928[T] (60
X_Acq_Duration              = 1.3631488[s]
X_Domain                    = 1H
X_Freq                      = 600.1723046[MHz]
X_Offset                    = 4[ppm]
X_Points                    = 16384
X_Prescans                  = 0
X_Resolution                = 0.73359563[Hz]
X_Sweep                     = 12.01923077[kHz]
X_Sweep_Clipped             = 9.61538462[kHz]
Irr_Domain                  = Boron10
Irr_Freq                    = 64.48067664[MHz]
Irr_Offset                  = -18[ppm]
Blanking                    = 2[us]
Clipped                     = FALSE
Scans                       = 32
Total_Scans                 = 32

Relaxation_Delay            = 1[s]
Recvr_Gain                  = 46
Temp_Get                    = 19.6[dC]
X_90_Width                  = 6.08[us]
X_Acq_Time                  = 1.3631488[s]
X_Angle                     = 90[deg]
X_Atn                       = 5.4[dB]
X_Pulse                     = 6.08[us]
Irr_Atn_Dec                 = 20.66[dB]
Irr_Atn_Dec_Calc            = 20.66[dB]
Irr_Atn_Dec_Default_Calc    = 20.66[dB]
Irr_Dec_Bandwidth_Hz        = 12.0[kHz]
Irr_Dec_Bandwidth_Ppm       = 186.10226545[ppm]
Irr_Dec_Freq                = 64.48067664[MHz]
Irr_Dec_Merit_Factor        = 4.8
Irr_Decoupling              = TRUE
Irr_Noe                     = FALSE
Irr_Noise                   = GARP
Irr_Offset_Default          = 0[ppm]
Irr_Pwidth                  = 0.1[ms]
Irr_Pwidth_Default          = 0.1[ms]
Irr_Pwidth_Default_Calc     = 0.1[ms]
Irr_Pwidth_Templ            = 0.1[ms]
Irr_Wurst                   = FALSE
Decimation_Rate             = 0
Initial_Wait                = 1[s]
Noe_Time                    = 1[s]
Noe_Time_Flag               = FALSE
Phase                       = {0, 90, 270, 180,
Relaxation_Delay_Calc       = 0[s]
Relaxation_Delay_Temp       = 1[s]
Repetition_Time             = 2.3631488[s]
```




```
Filename                    = 210-10B-NaBSH_prot
Author                      = delta
Experiment                  = proton_dec.jxp
Sample_Id                   = 210-10B-NaBSH
Solvent                     = D2O
Actual_Start_Time           = 13-OCT-2021 11:07:
Revision_Time               = 13-OCT-2021 09:58:

Comment                     = single pulse decou
Data_Format                 = 1D COMPLEX
Dim_Size                    = 13107
Dim_Title                   = Proton
Dim_Units                   = [ppm]
Dimensions                  = X
Spectrometer                = DELTA2_NMR

Field_Strength              = 14.09636928[T] (60
X_Acq_Duration              = 1.3631488[s]
X_Domain                    = 1H
X_Freq                      = 600.1723046[MHz]
X_Offset                    = 4[ppm]
X_Points                    = 16384
X_Prescans                  = 0
X_Resolution                = 0.73359563[Hz]
X_Sweep                     = 12.01923077[kHz]
X_Sweep_Clipped             = 9.61538462[kHz]
Irr_Domain                  = Boron10
Irr_Freq                    = 64.48067664[MHz]
Irr_Offset                  = -18[ppm]
Blanking                    = 2[us]
Clipped                     = FALSE
Scans                       = 32
Total_Scans                 = 32

Relaxation_Delay            = 1[s]
Recvr_Gain                  = 46
Temp_Get                    = 19.2[dC]
X_90_Width                  = 6.08[us]
X_Acq_Time                  = 1.3631488[s]
X_Angle                     = 90[deg]
X_Atn                       = 5.4[dB]
X_Pulse                     = 6.08[us]
Irr_Atn_Dec_Default_Calc    = 79[dB]
Irr_Dec_Freq                = 64.48067664[MHz]
Irr_Dec_Merit_Factor        = 4.8
Irr_Decoupling              = FALSE
Irr_Noe                     = FALSE
Irr_Offset_Default          = 0[ppm]
Irr_Pwidth_Default          = 1[us]
Irr_Pwidth_Default_Calc     = 1[us]
Decimation_Rate             = 0
Initial_Wait                = 1[s]
Noe_Time                    = 1[s]
Noe_Time_Flag               = FALSE
Phase                       = {0, 90, 270, 180,
Relaxation_Delay_Calc       = 0[s]
Relaxation_Delay_Temp       = 1[s]
Repetition_Time             = 2.3631488[s]
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