

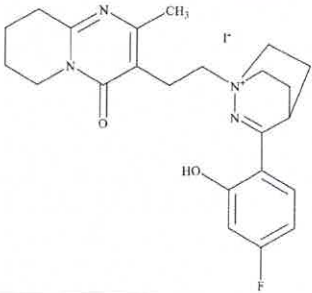
Certificate of Analysis

Certificate No.: 20211224010

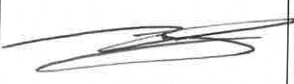

Date: December 24, 2021

Retest date: December 16, 2024

Compound Name: Bicyclo Risperidone Iodide	
Synonyms:	3-(4-fluoro-2-hydroxyphenyl)-1-(2-(2-methyl-4-oxo-6,7,8,9-tetrahydro-4H-pyrido[1,2-a]pyrimidin-3-yl)ethyl)-1,2-diazabicyclo[2.2.2]oct-2-en-1-ium, iodide (1:1)
TLC Catalogue Number:	R-0615
CAS Number:	2231638-02-9
Molecular Weight:	411.50 126.91
Molecular Formula:	C ₂₃ H ₂₈ FN ₄ O ₂ . I
Source:	TLC Pharmaceutical Standards
Source Lot No.:	4322-083A2
Storage Conditions:	Store at 2-8 °C
Solubility:	Methanol, DMSO, Water



Test Description	Specifications	Results
Visual Description	White to off-white solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Elemental Analysis	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.9%
Impurity (HPLC)	N/A	
Water Content (KF)	N/A	0.2%
Residual Solvents (NMR)	0.4% methanol and 0.3% acetone	
Assay (%)	Not less than 90.0%	99.0%
Recommendation:	Release.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		01 / 03 / 2022
Approved by:	Quality Assurance		01 / 03 / 2022

Attachments: HPLC, IR, MS and NMR spectra.

Sample Name: 4322-083A2

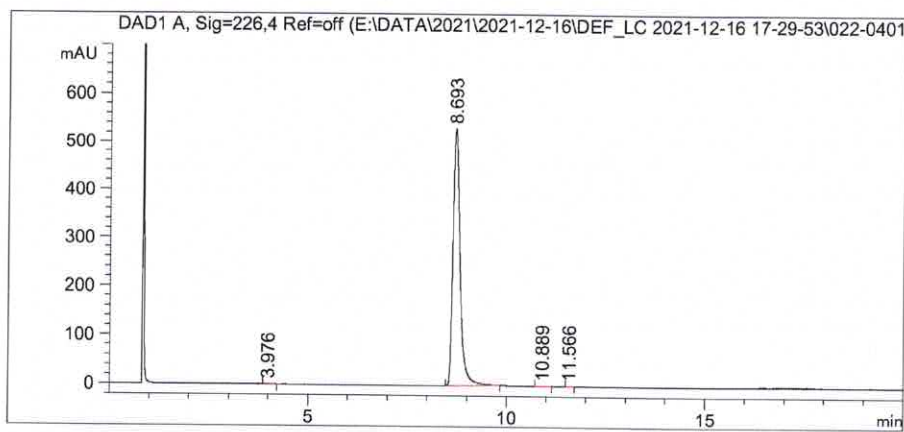
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Acq. Operator   : Mei Zhang                      Seq. Line :    4
Acq. Instrument : LC-1260_3                        Location  : Vial 22
Injection Date  : 12/16/2021 6:37:11 PM        Inj       :    1
                                                Inj Volume: 2.000 µl

Acq. Method    : E:\DATA\2021\2021-12-16\DEF_LC 2021-12-16 17-29-53\4.M
Last changed   : 12/16/2021 5:29:53 PM by Mei Zhang
Analysis Method: C:\CHEM32\1\METHODS\1.M
Last changed   : 12/17/2021 9:57:25 AM by Mei Zhang
                (modified after loading)

Sample Info    : Poroshell HPH-C18 (4.6*100mm,2.7um); F=1.0mL/min; T=30 degree;
                CH3OH/10mmol/L NH4HCO3(adjusted to pH 9.0 with NH3·H2O)=37/63(0-6min),37/63
                -55/45(6-15min),55/45(after 15min)
                ~1.4mg in 0.7mL CH3OH
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Area Percent Report
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Sorted By      :      Signal
Multiplier     :      1.0000
Dilution       :      1.0000
Do not use Multiplier & Dilution Factor with ISTDs

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Signal 1: DAD1 A, Sig=226,4 Ref=off

Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	3.976	BBA	0.0946	1.52977	2.11032e-1	0.0236
2	8.693	BBA	0.1848	6484.13818	529.76404	99.9065
3	10.889	BBA	0.1566	3.64105	3.20365e-1	0.0561
4	11.566	BB	0.0929	8.94490e-1	1.25923e-1	0.0138

```
Totals :                6490.20350  530.42136
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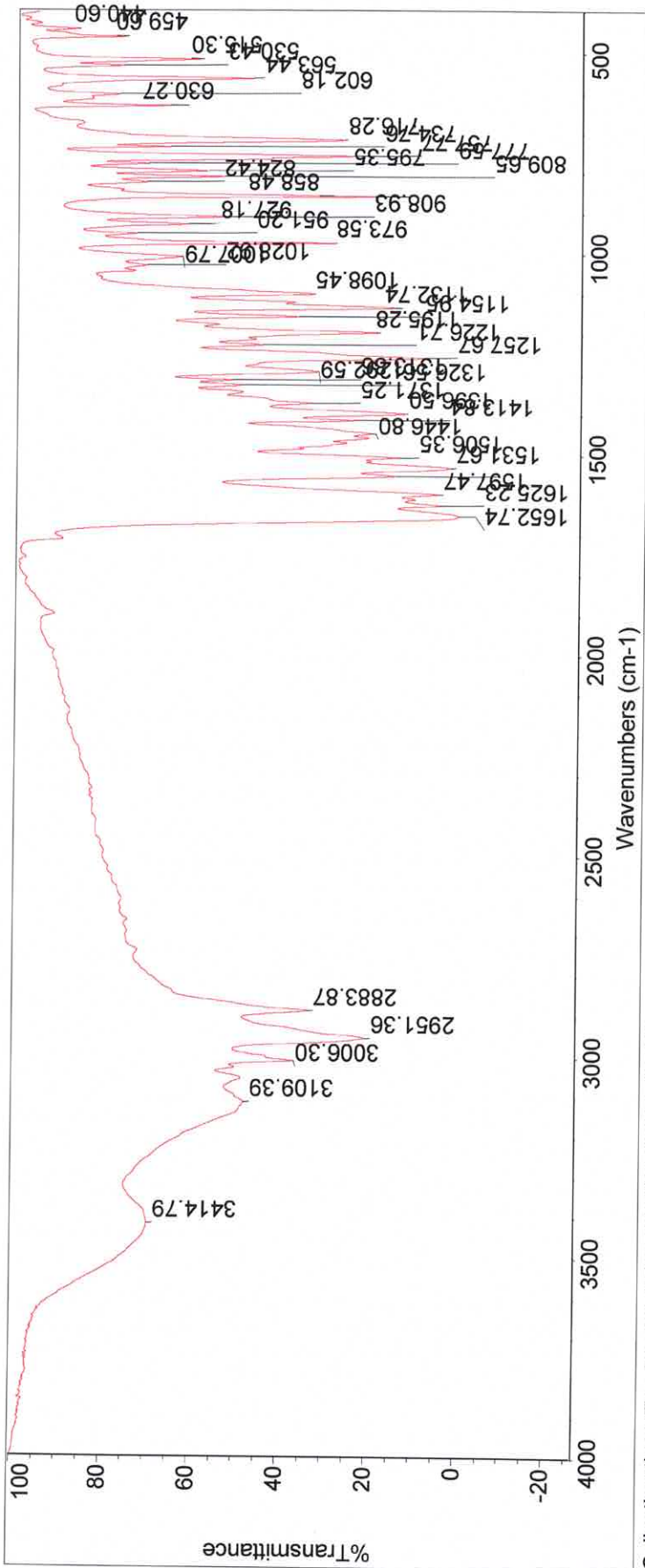


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*** End of Report ***
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4322-083A2



Collection time: Tue Dec 21 14:09:44 2021 (GMT+08:00)



Tue Dec 21 14:11:05 2021 (GMT+08:00)

FIND PEAKS:

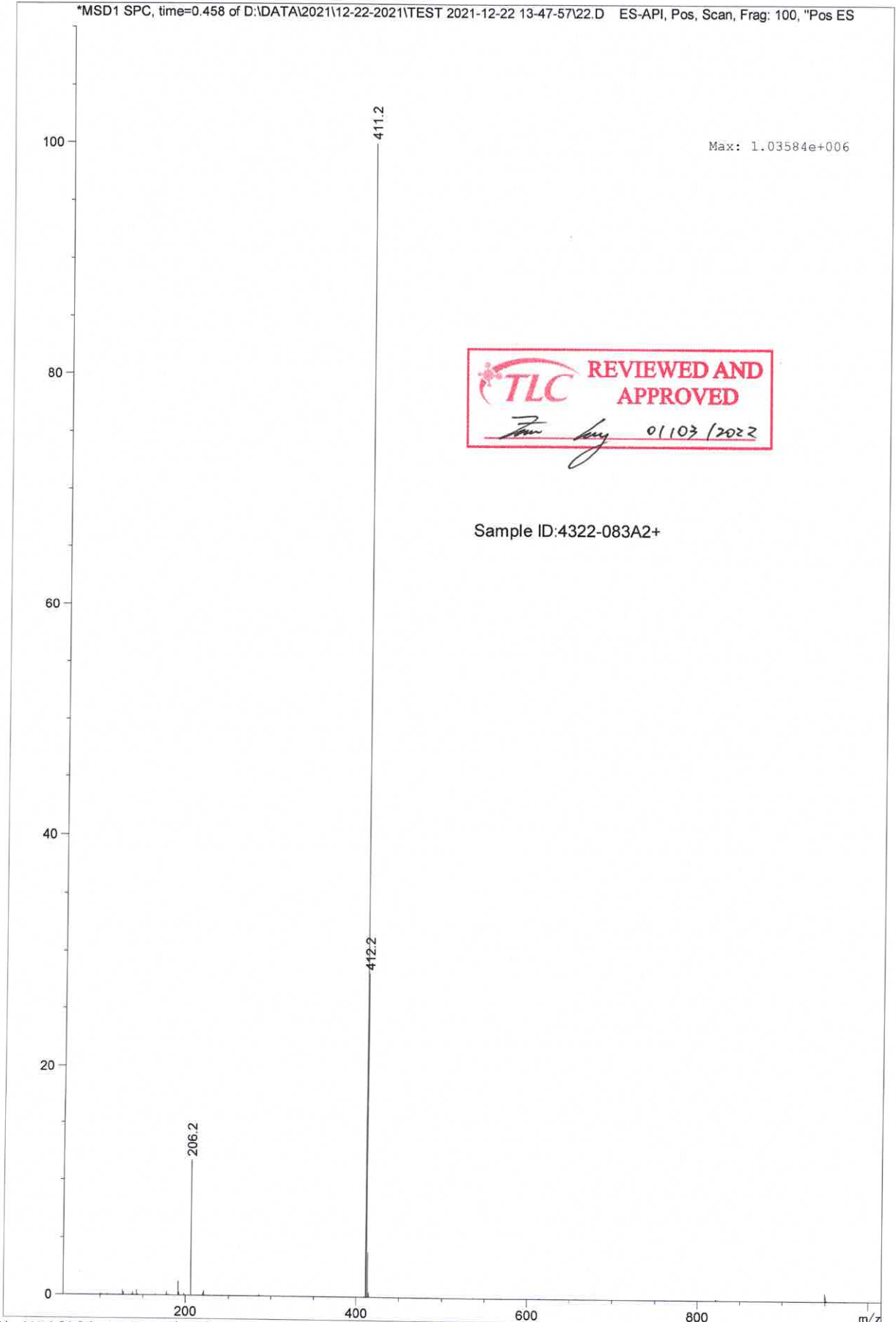
Spectrum: *4322-083A2
Region: 4000.00 400.00
Absolute threshold: 92.724
Sensitivity: 45
Peak list:

Position:	440.60	Intensity:	87.097
Position:	459.60	Intensity:	76.742
Position:	515.30	Intensity:	59.729
Position:	530.43	Intensity:	77.009
Position:	563.44	Intensity:	47.329
Position:	602.18	Intensity:	77.628
Position:	630.27	Intensity:	66.234
Position:	716.28	Intensity:	26.944
Position:	734.76	Intensity:	66.165
Position:	757.77	Intensity:	24.724
Position:	777.59	Intensity:	71.097
Position:	795.35	Intensity:	57.529
Position:	809.65	Intensity:	53.920
Position:	824.42	Intensity:	71.430
Position:	858.48	Intensity:	19.832
Position:	908.93	Intensity:	54.712
Position:	927.18	Intensity:	62.128
Position:	951.20	Intensity:	73.687
Position:	973.58	Intensity:	28.460
Position:	1007.79	Intensity:	63.728
Position:	1028.92	Intensity:	71.324
Position:	1098.45	Intensity:	33.289
Position:	1132.74	Intensity:	15.156
Position:	1154.95	Intensity:	37.044
Position:	1195.28	Intensity:	18.877
Position:	1226.71	Intensity:	45.038
Position:	1257.67	Intensity:	8.562
Position:	1292.59	Intensity:	32.814
Position:	1313.86	Intensity:	52.194
Position:	1326.56	Intensity:	49.972
Position:	1371.25	Intensity:	34.018
Position:	1396.50	Intensity:	12.634
Position:	1413.84	Intensity:	24.275
Position:	1446.80	Intensity:	20.176
Position:	1506.35	Intensity:	14.551
Position:	1531.67	Intensity:	2.610
Position:	1552.32	Intensity:	15.018
Position:	1597.47	Intensity:	5.174
Position:	1625.23	Intensity:	4.885
Position:	1652.74	Intensity:	0.559
Position:	2883.87	Intensity:	33.759
Position:	2951.36	Intensity:	20.754
Position:	3006.30	Intensity:	37.210
Position:	3109.39	Intensity:	47.912
Position:	3414.79	Intensity:	69.554



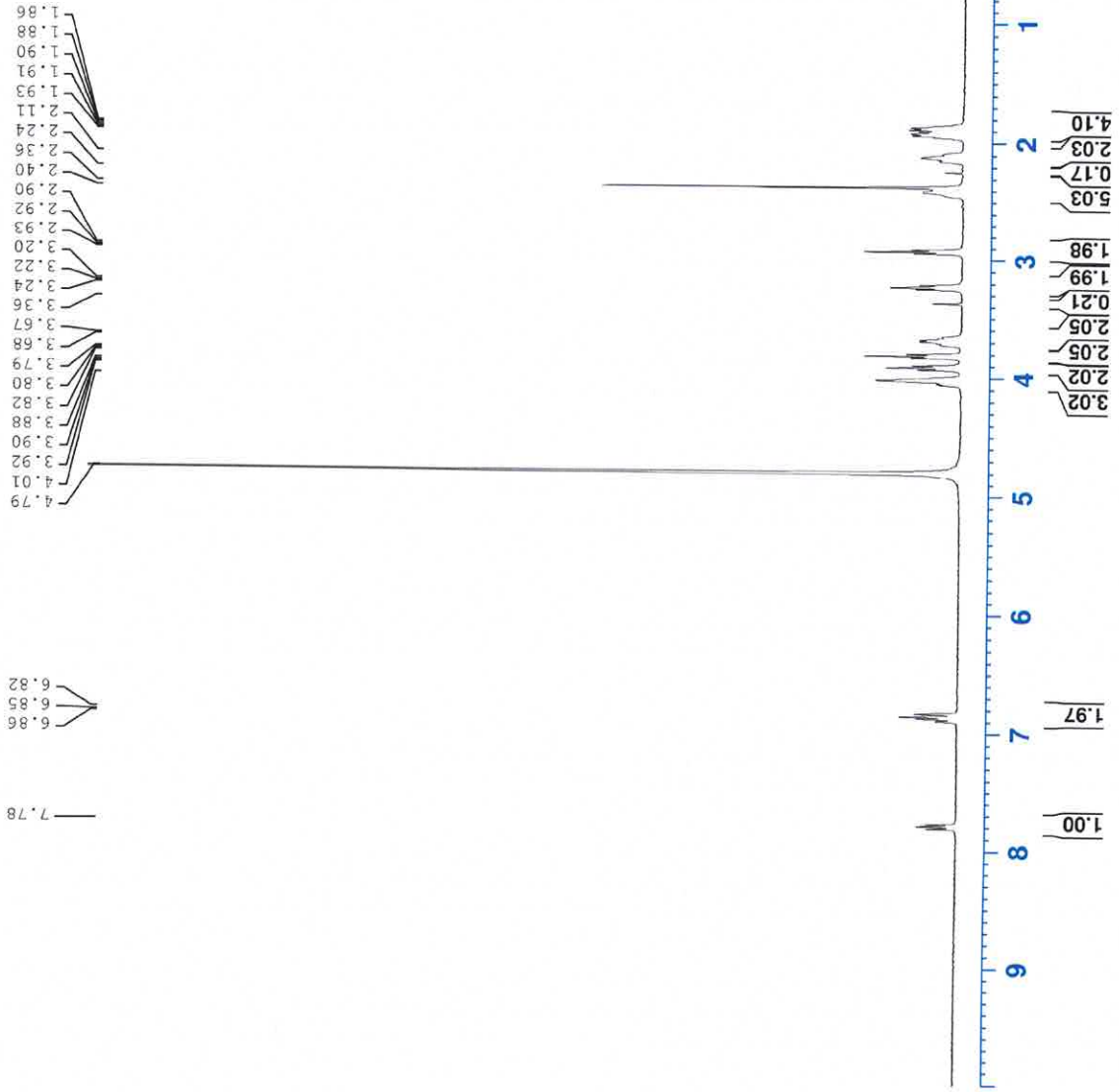
Signature: Jie Sun, 12-21-2021 14:11:16 (GMT+08:00), Authorship - signifies ownership
4322-083A2

MS Spectrum





4322-083A2 1H NMR in D2O



Current Data Parameters
NAME 2021-12-16 (NMR-400_2)
EXPNO 71
PROCNO 1

F2 - Acquisition Parameters
Date_ 20211216
Time 13.48 h
INSTRUM spect
PROBHD Z116098_0636 (z930
PULPROG 65536
SOLVENT D2O
NS 4
DS 0
SWH 9615.385 Hz
FIDRES 0.293438 Hz
AQ 3.4078720 sec
RG 109.98
DW 52.000 usec
DE 6.50 usec
TE 298.0 K
D1 1.00000000 sec
TD0 1
SF01 400.1836016 MHz
NUC1 1H
P1 10.00 usec
PLW1 19.54100037 W

F2 - Processing parameters
SI 65536
SF 400.1799643 MHz
WDW EM
SSB 0
LB 0
GB 0
PC 0.50

