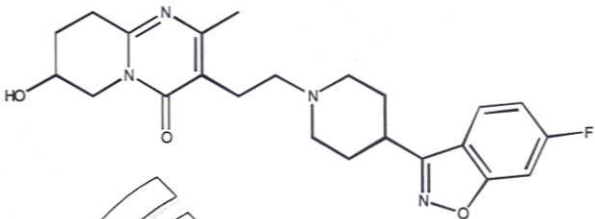


Certificate of Analysis

Certificate Number: 2699.A-01

Compound Name: 7-Hydroxy Risperidone	
Molecular Formula: C ₂₃ H ₂₇ FN ₄ O ₃	Structure: 
Molecular Weight: 426.48	
Supplier: Synthèse AptoChem Inc.	
Reference Standard Number: 2699.A	
Lot Number: AC0301159	
Appearance: Off-White Solid	
Storage Conditions: Room Temperature	

Test Description	Results	Comments
¹ H- NMR (DMSO-d ₆)	Conforms to structure	presence of dichloromethane (1.5%, w/w)
COSY-NMR (DMSO-d ₆)	Conforms to structure	none
¹ H- NMR (DMSO-d ₆ + D ₂ O)	Conforms to structure	none
Mass Spectrum (MS, MS/MS)	Conforms to structure	no presence of Risperidone
Chromatographic Purity (HPLC)	99.4%	none
Water Content (Karl Fischer)	0.9%	none


Use As Potency	97.0%	1 mg of Ref. Std. # 2699.A affords 970 µg of 7-Hydroxy Risperidone
-----------------------	-------	--

Date Tested: 10-Oct-2008	Date to be retested: before 10-Oct-2010
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Issued by:

Name	Title	Signature	Date
Robert Hambalek, Ph.D.	President and CEO		17-OCT-2008

Approved by

Name	Title	Signature	Date
Hadi Rezaei, Ph.D.	CSO and Head of Quality Assurance	 FOR	17-oct-2008

7-Hydroxy Risperidone,
Ref. Std. # 2699.A, Lot # AC0301159

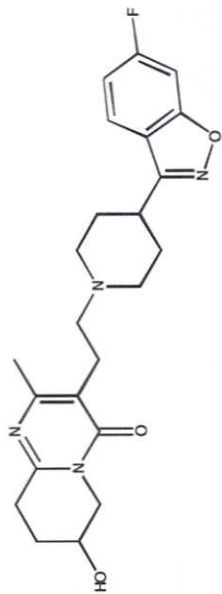
exp3 szpu1

date	Oct 17 2008	temp	not used
solvent	DMSO	gain	not used
file	/export/home/~	spin	0.008
ARD/vnmr	sys/data/2~	hst	14.500
599.A-01/HI_2699.A~	pw90	alpha	20.000
_dms0-d6.fid	alpha	alpha	20.000

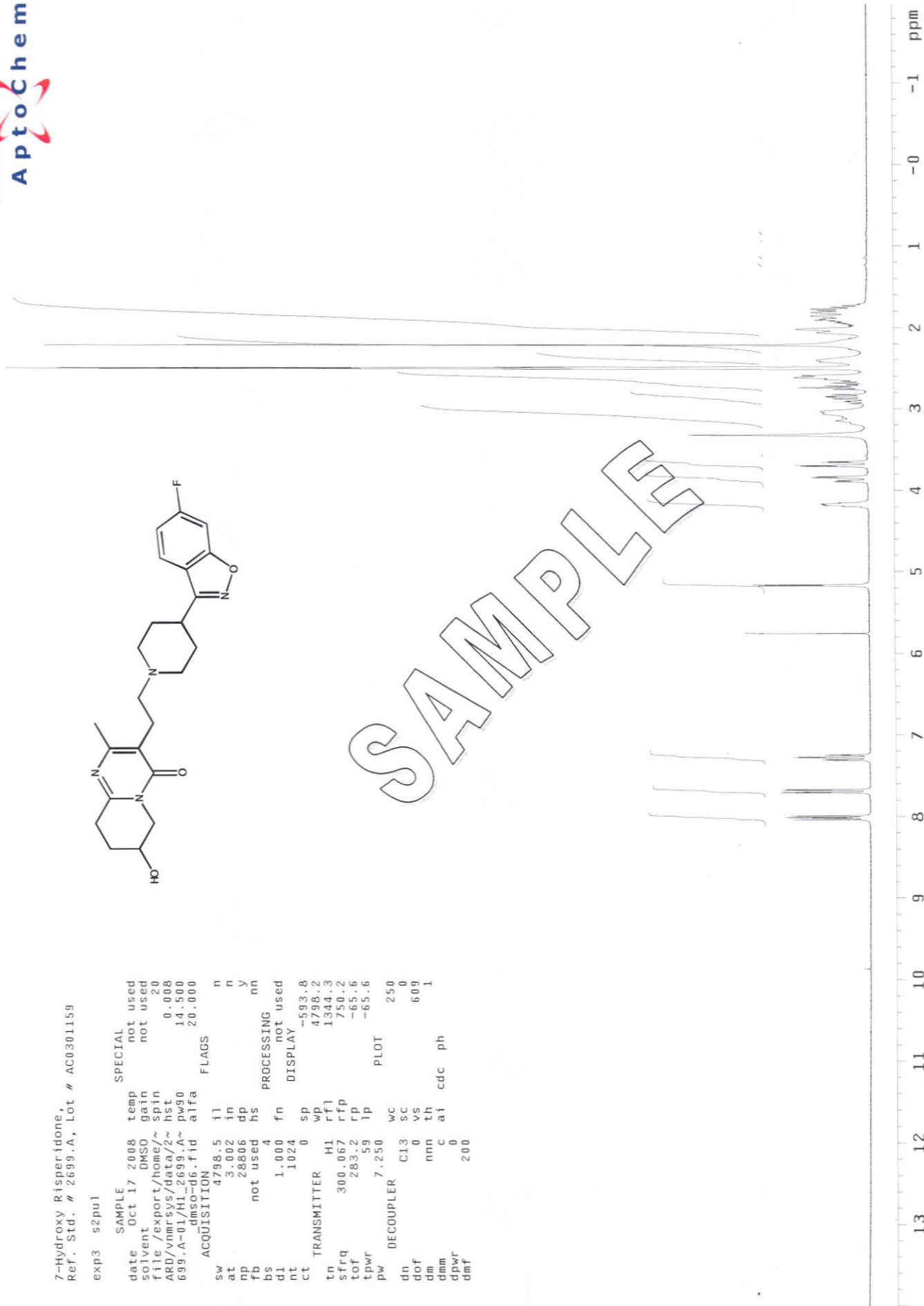
sw	4798.5	il	n
at	3.002	in	n
pp	28806	dp	v
fb	not used	hs	nn
bs	4	hs	nn
d1	1.000	fn	not used
nt	1024	fn	not used
ct	0	sp	-593.8

tn	4798.2	wp	1344.3
sfrq	300.067	rfl	750.2
tof	283.2	rfp	-65.6
tpwr	59	lp	-65.6
pw	7.250	lp	-65.6

DECOUPLER	C13	sc	250
dn	0	vs	0
dof	0	vs	609
dm	nnn	th	1
dmm	c	ai	cdc
dpwr	0	ph	
dmf	200		



SAMPLE



13 12 11 10 9 8 7 6 5 4 3 2 1 -1 -0 -1 ppm

[Signature]

Acquired by / Date: 17-0 CT-20-08

QA-PCIC:\Users\AptoChem\QA\ISOPFORMS\30710\3010-01

[Signature]

Approved by / Date: 17-0CT-20-08

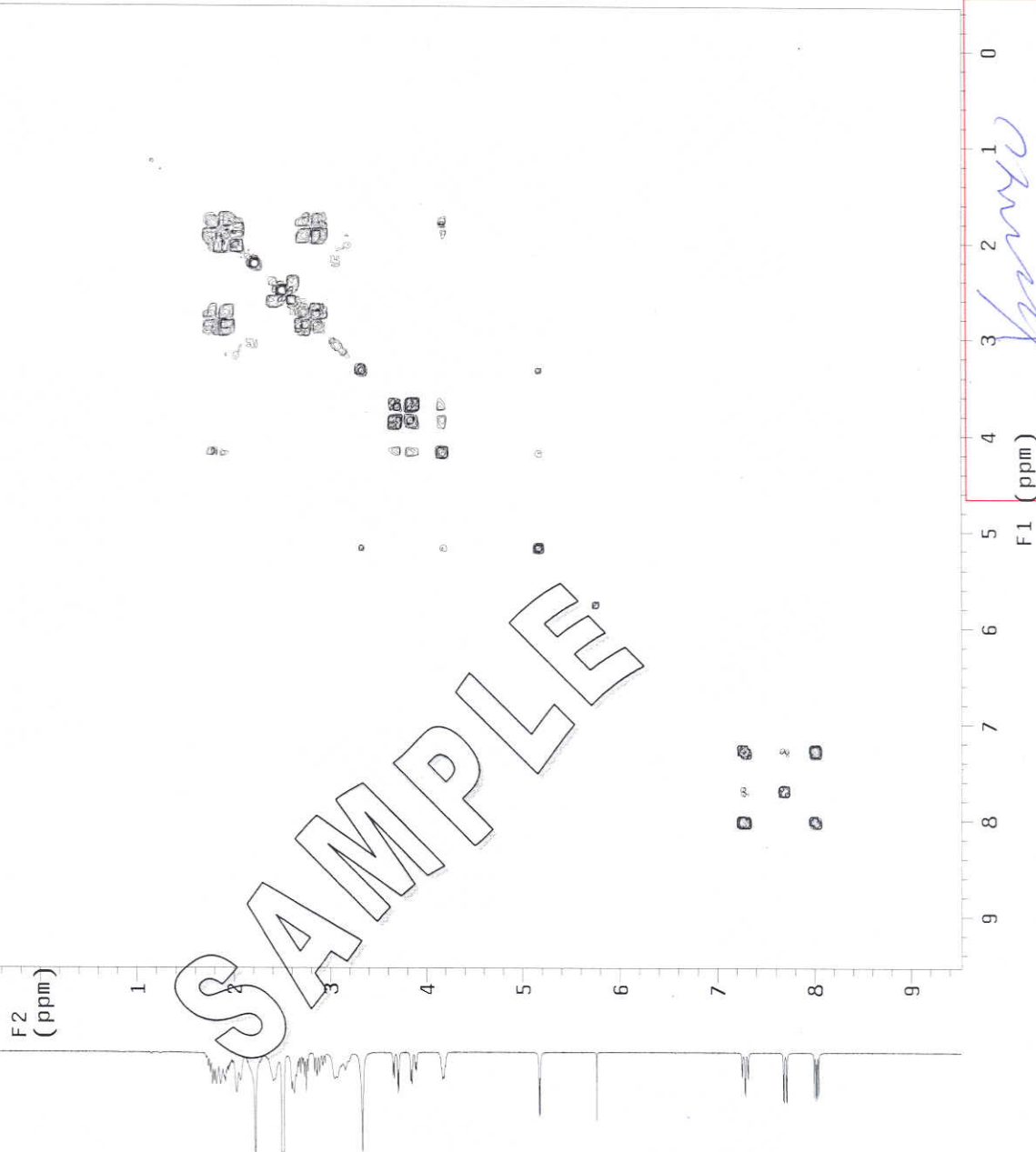
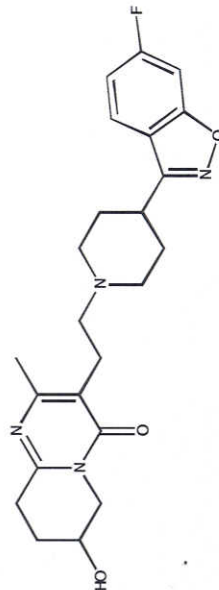
7-Hydroxy Risperidone, Ref. Std. # 2699.A, Lot # AC0301159

Archive directory: /export/home/ARD/vnmrSYS/data
Sample directory: ARD_17Oct2008

Pulse Sequence: gCOSY

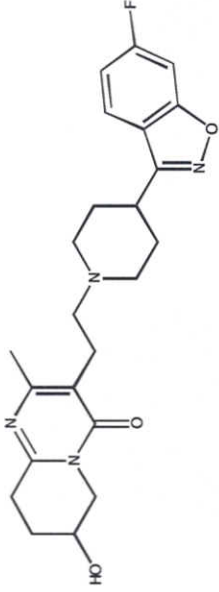
Solvent: DMSO
Ambient temperature
File: COSY_2699.A_dms0-d6
Mercury-300 "mustang"

Relax. delay 1.000 sec
Acq. time 0.170 sec
Width 3003.0 Hz
2D Width 3003.0 Hz
8 repetitions
512 increments
OBSERVE H1 300.0655303 MHz
DATA PROCESSING
Sq. sine bell 0.085 sec
F1 DATA PROCESSING
Sq. sine bell 0.043 sec
FT size 1024 x 1024
Total time 1 hr, 33 min, 37 sec



[Signature]
Acquired by / Date: 17-OCT-2008

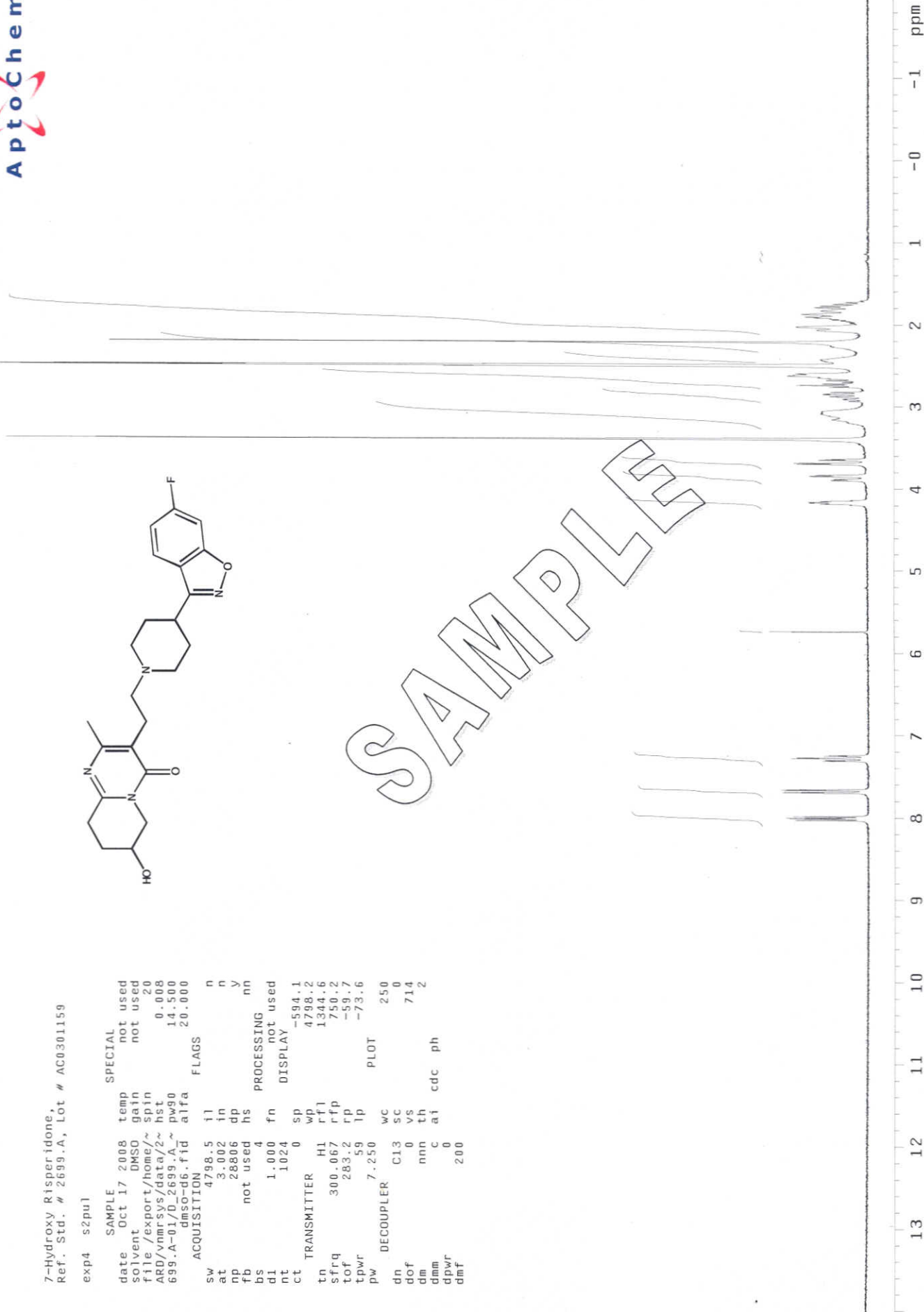
Approved by / Date: 17-OCT-2008
[Signature]



SAMPLE

7-Hydroxy Risperidone,
Ref. Std. # 2699.A, Lot # AC0301159

```
exp4 s2pu1
SAMPLE      date      DMSO      temp      SPECIAL
Oct 17 2008  not used
solvent     gain      not used
file        /export/home/~spin 20
ARD/vmr/sys/data/2~ hst 0.008
699.A-01/0_2699.A~ pw90 14.500
dms0-d6.fid aifa 20.000
ACQUISITION  sw 4798.5 11 n
at 3.002 1n n
np 28806 dp y
fb not used hs nn
bs 4
dl 1.000 fn not used
nt 1024 ct
ct TRANSMITTER H1
tn 4798.2
sfrq 300.067 rfp 1344.6
tof 283.2 rp 750.2
tpwr 59 lp -59.7
pw 7.250 wc -73.6
DECOUPLER C13 250
dn 0 sc 0
dm 0 vs 714
dmm nnn th 2
dmm c ai cdc ph
dpwr 0
dmf 200
```



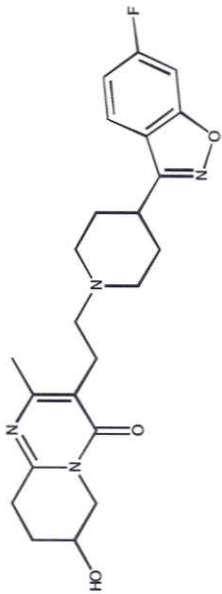
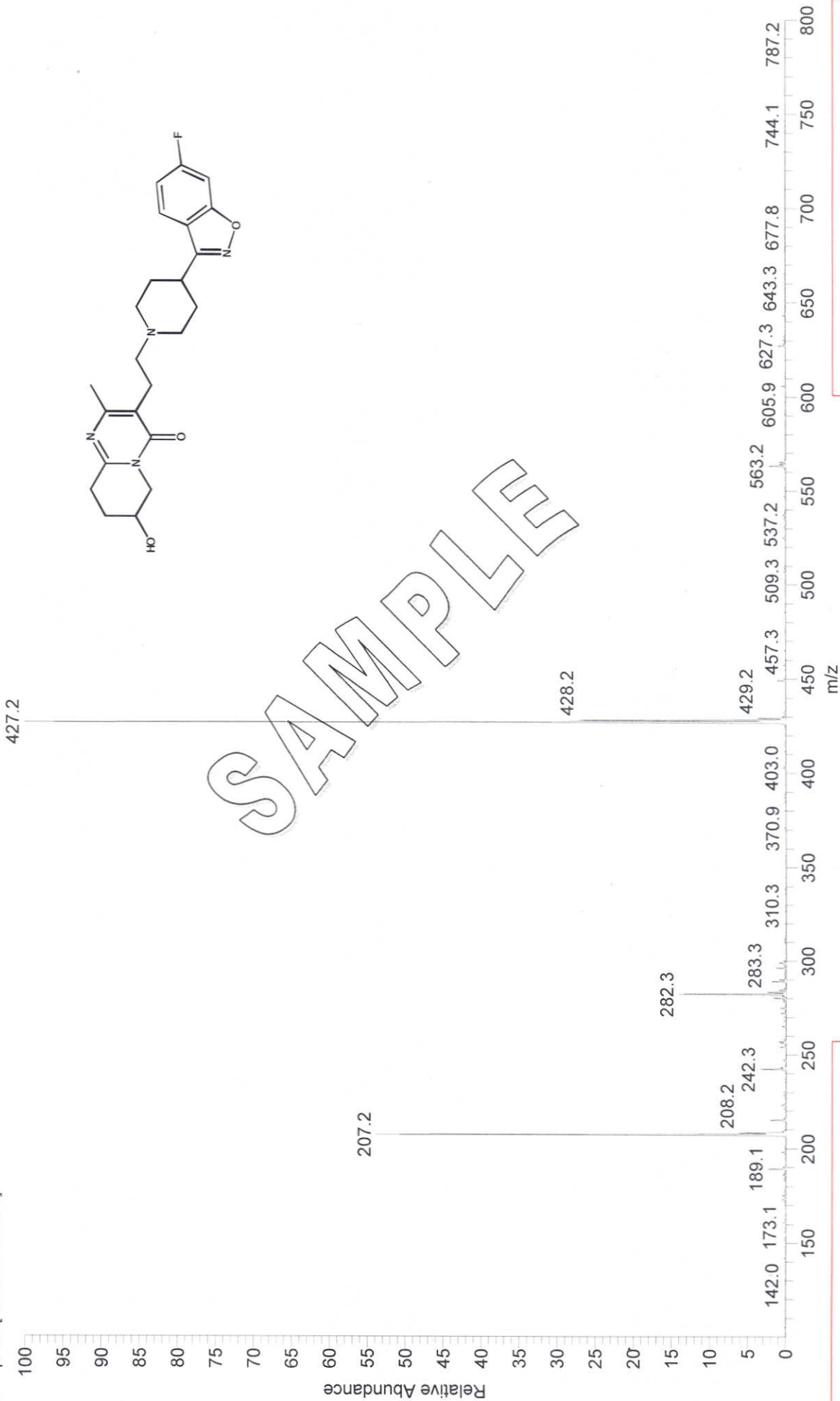
[Signature]
Acquired by / Date: 17-0CT-2008

[Signature]
Approved by / Date: 17-0CT-2008

C:\AptoChem-Data\...IMS_2699A_pos

10/16/2008 5:36:04 PM

MS_2699A_pos #1-101 RT: 0.02-2.04 AV: 101 NL: 1.35E5
T: + p ms [100.00-800.00]



SAMPLE

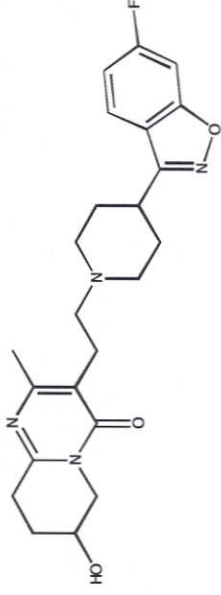
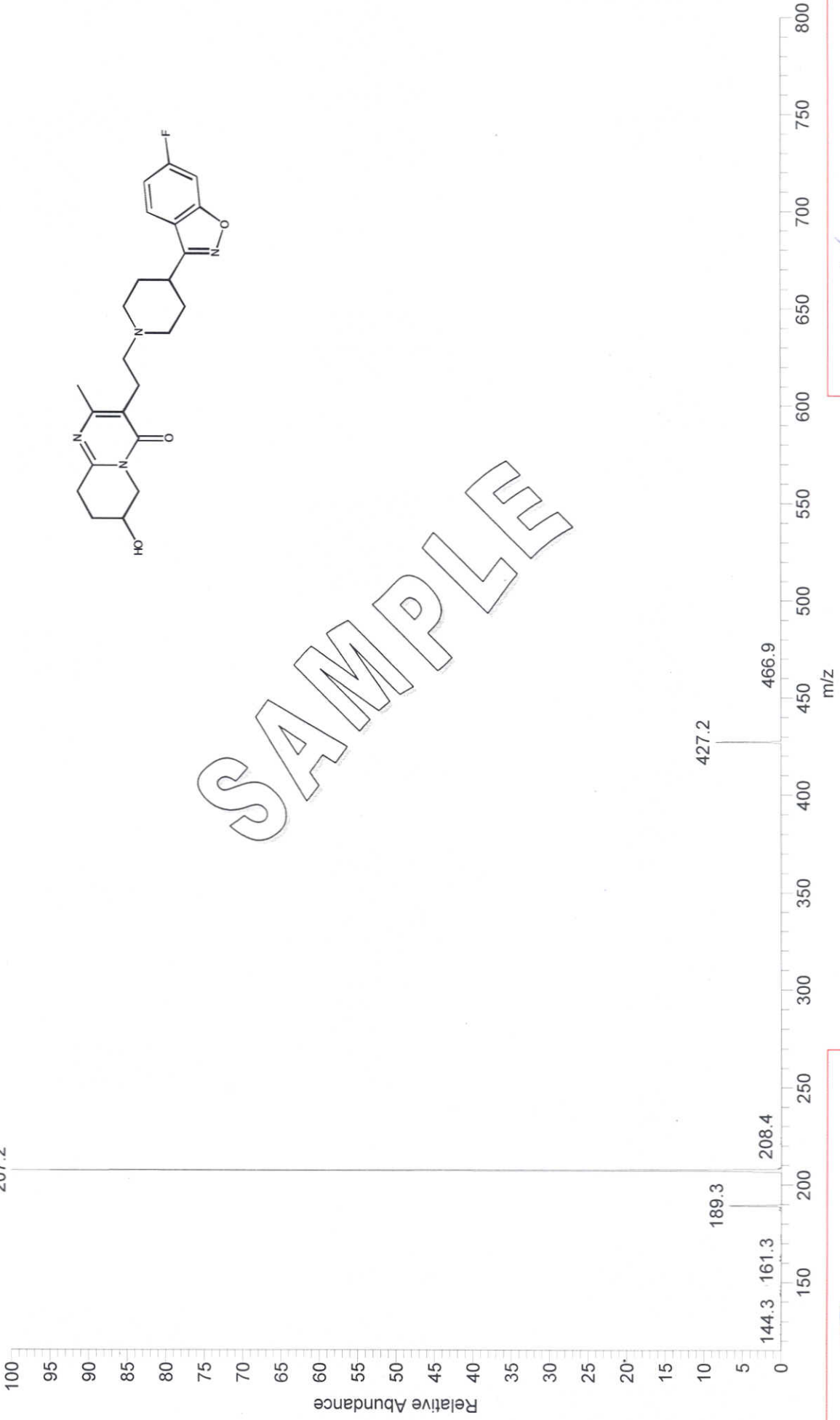
[Signature]
Acquired by / Date: 16-oct-2008

[Signature]
Approved by / Date: 16-oct-2008

C:\AptoChem-Data\...MS_MS_2699A_pos

10/16/2008 5:41:21 PM

MS_MS_2699A_pos
MS_MS_2699A_pos #1-11 RT: 0.01-0.28 AV: 11 NL: 1.78E5
T: + p Full ms2 427.10@29.00 [115.00-800.00]

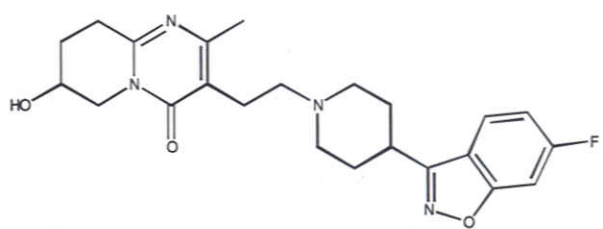


SAMPLE

[Signature]
Approved by / Date: 16-07-2008

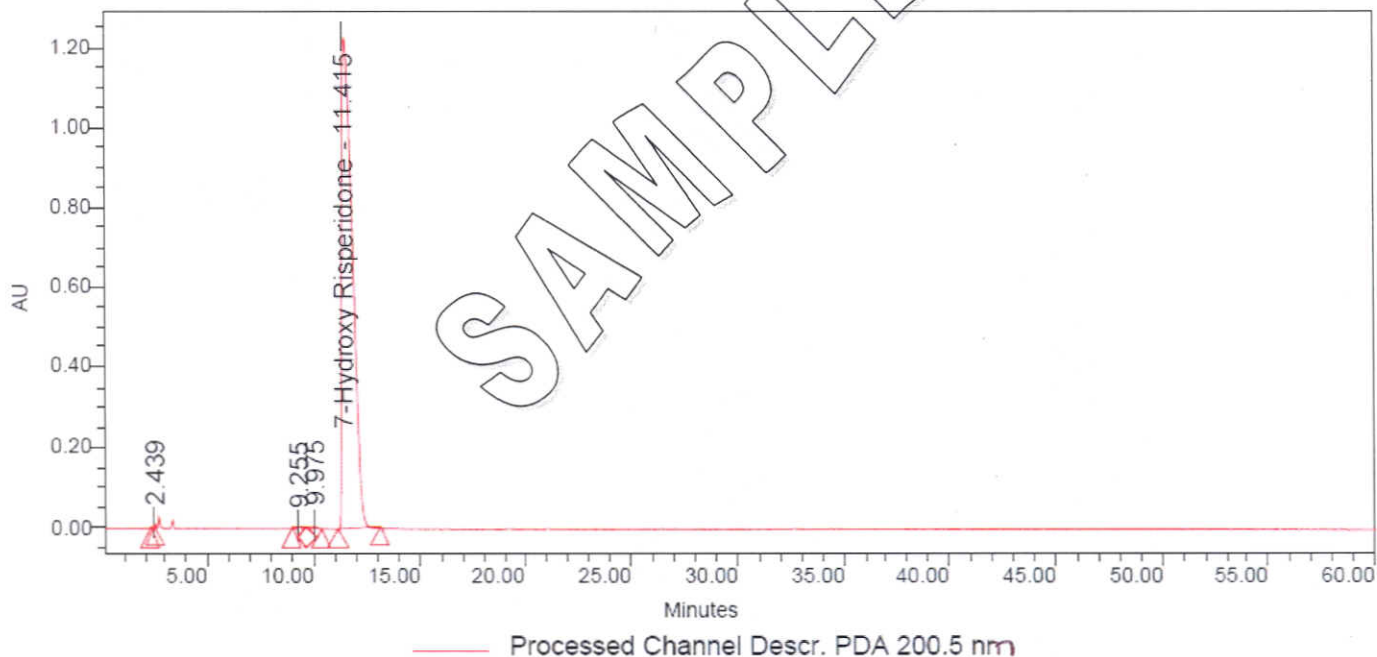
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Acquired by / Date: 16-07-2008

Chromatographic Purity by HPLC

Name: 7-Hydroxy Risperidone	
Reference Standard Number: 2699.A	Structure: 
Lot Number: AC0301159	
Instrument: HPLC 001	
Method-Revision: LC2699-00	
Date Acquired: 10/16/08 10:20:59 PM	


Injection 1 of 2


Auto-Scaled Chromatogram



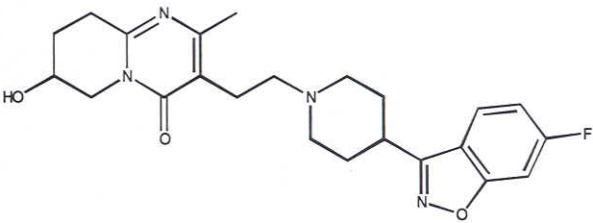
Peak Results

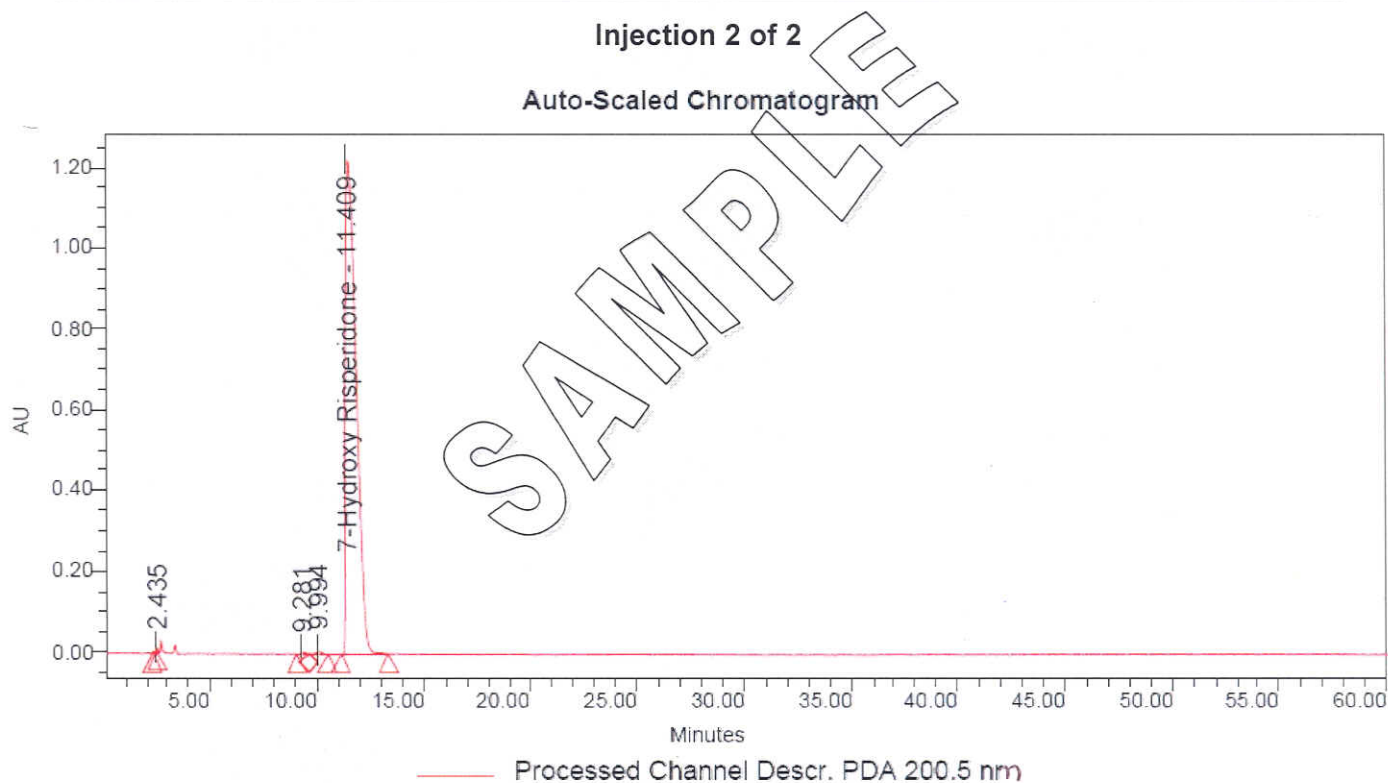
	Name	RT	% Height	Height	Area	% Area
1		2.439	0.71	8805	39006	0.09
2		9.255	0.34	4287	75492	0.18
3		9.975	0.52	6442	112365	0.26
4	7-Hydroxy Risperidone	11.415	98.43	1227863	42599414	99.47


Acquired by / Date: 17-01-2008


Approved by / Date: 17/oct/2008

Chromatographic Purity by HPLC

Name: 7-Hydroxy Risperidone	
Reference Standard Number: 2699.A	Structure: 
Lot Number: AC0301159	
Instrument: HPLC 001	
Method-Revision: LC2699-00	
Date Acquired: 10/16/08 11:22:17 PM	



Peak Results

	Name	RT	% Height	Height	Area	% Area
1		2.435	0.71	8804	37760	0.09
2		9.281	0.44	5427	83123	0.20
3		9.994	0.59	7292	143636	0.34
4	7-Hydroxy Risperidone	11.409	98.27	1223561	42171236	99.38



Acquired by / Date: 17-OCT-2008



Approved by / Date: 17/Oct/2008