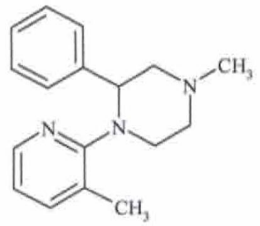
TLC PHARMACHEM

Certificate of Analysis

Certificate No.: **20120130C**

Date: January 30, 2012 Retest date: January 2015

Compound Name:	**Mirtazapine Impurity E**	
Molecular Weight:	267.38	
Molecular Formula:	C17H21N3	
Source:	TLC PharmaChem., Inc.	
Source Lot No.:	[redacted]	
Storage Conditions:	Store at 0-5 °C.	

Test Description	**Specifications**	**Results**
Visual Description	White to off-white solid	**Conforms**
Identification **MS** **^{1}H NMR**	 Conforms to structure Conforms to structure	 **Conforms** **Conforms**
Purity (HPLC)	Not less than 98.0%	**99.1%**
Recommendation:	**Released.** The compound contains 0.6% dichloromethane and 0.6% n-hexane according to its proton NMR.	

Name	**Department**	**Signature**	**Date**
Reviewed and approved by:	Analytical Services	[redacted]	[redacted]
Approved by:	Quality Assurance	[redacted]	[redacted]

Attachments: HPLC, MS and NMR spectra.

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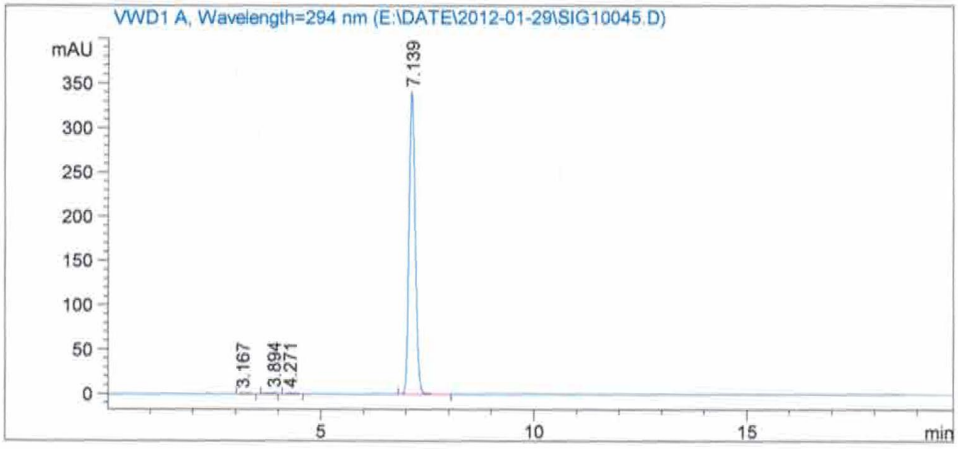
Data File E:[redacted]
Sample Name:[redacted]

```
Acq. Operator    : SYSTEM
Acq. Instrument  : LC1260                          Location : Vial 1
Injection Date   : 1/29/2012 1:55:26 PM
                                                   Inj Volume : 4.000 µl
Acq. Method      : C:\CHEM32\1\METHODS\1.M
Last changed     : 1/29/2012 1:54:42 PM by SYSTEM
                   (modified after loading)
Analysis Method  : C:\CHEM32\1\METHODS\1.M
Last changed     : 1/29/2012 2:39:02 PM by SYSTEM
                   (modified after loading)
Sample Info      : Plus-C18(4.6*250 mm,5 um); F=1 ml/min, T:30degree
                   CH3OH/10mmol/LCH3COONH4+0.03%TEA=73/27

Additional Info : Peak(s) manually integrated
```




```
                          Area Percent Report

Sorted By             :      Signal
Multiplier            :      1.0000
Dilution              :      1.0000
Do not use Multiplier & Dilution Factor with ISTDs
```

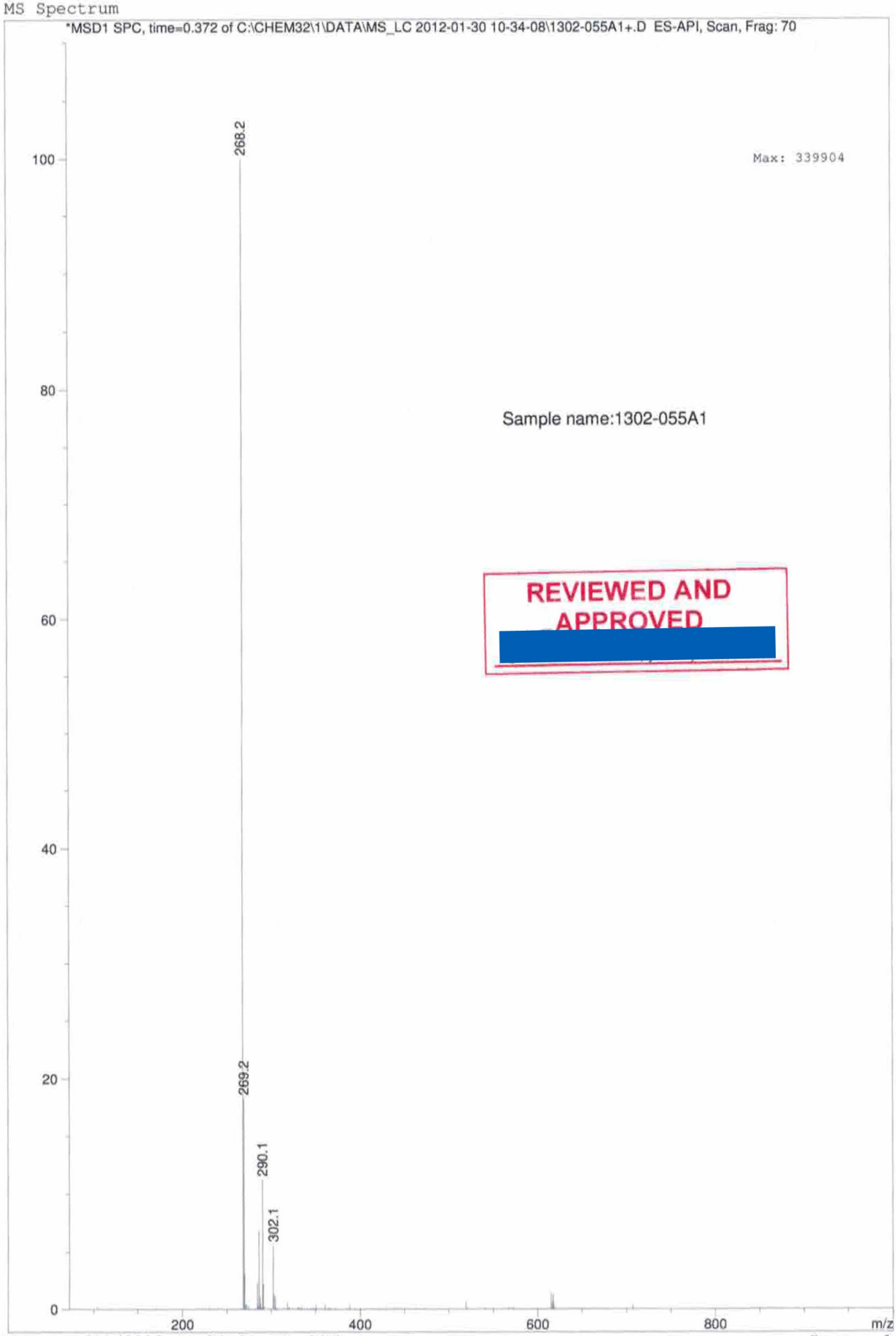
REVIEWED AND APPROVED
[redacted]

Signal 1: VWD1 A, Wavelength=294 nm

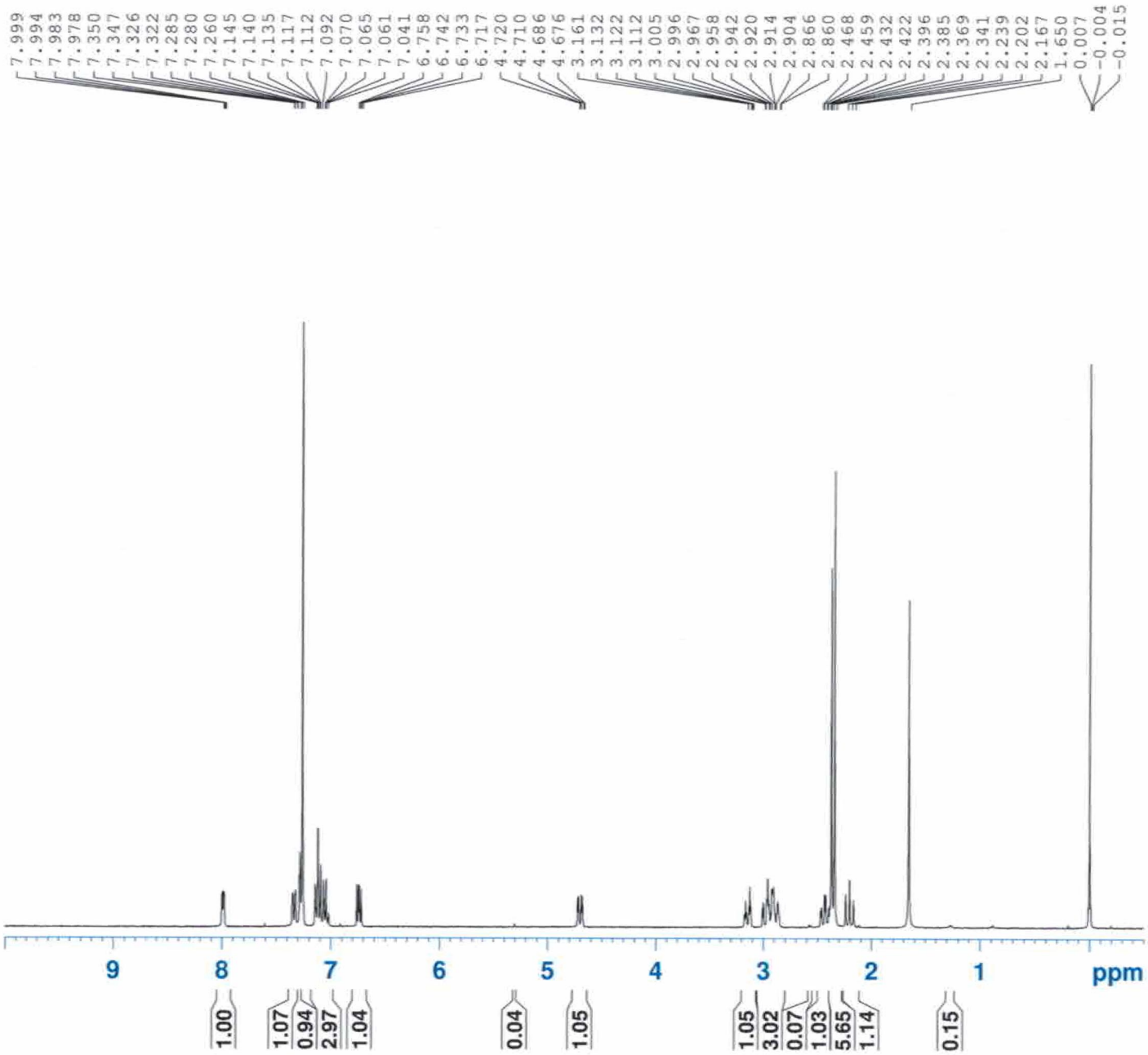
Peak #	RetTime [min]	Type	Width [min]	Area [mAU*s]	Height [mAU]	Area %
1	3.167	MM R	0.1871	4.79536	4.27112e-1	0.1386
2	3.894	MM R	0.1732	11.07190	1.06546	0.3200
3	4.271	MM R	0.1861	14.17035	1.26883	0.4095
4	7.139	BB	0.1566	3430.27539	340.34500	99.1319
Totals :				3460.31300	343.10641	

```
                        *** End of Report ***
```

MS Spectrum


*MSD1 SPC, time=0.372 of C:\CHEM32\1\DATA\MS_LC 2012-01-30 10-34-08\1302-055A1+.D ES-API, Scan, Frag: 70
Max: 339904
268.2
269.2
290.1
302.1
100
80
60
40
20
0
200
400
600
800
m/z
Sample name:1302-055A1
REVIEWED AND APPROVED
[redacted]

1302-055A1 1H NMR in CDCL3



NAME	20120130
EXPNO	5
PROCNO	1
Date_	20120130
Time	11.21
INSTRUM	spect
PROBHD	5 mm PABBO BB-
PULPROG	zg30
TD	65536
SOLVENT	CDC13
NS	11
DS	0
SWH	6188.119 Hz
FIDRES	0.094423 Hz
AQ	5.2953587 sec
RG	181
DW	80.800 usec
DE	6.50 usec
TE	673.2 K
D1	1.00000000 sec
TD0	1
======== CHANNEL f1 ========	
NUC1	1H
P1	12.30 usec
PL1	1.00 dB
PL1W	10.29555321 W
SFO1	300.1318534 MHz
SI	32768
SF	300.1300023 MHz
WDW	EM
SSB	0
LB	0.30 Hz
GB	0
PC	2.00

REVIEWED AND APPROVED