

**CERTIFICADO DE ANÁLISIS**Certificado: **3996**

Fecha de emisión: 22/04/2014

**Producto**

NOMBRE DEL PRODUCTO:

2-Methyl-5,10-dihydro-4H-thieno[2,3-b][1,5]benzodiazepin-4-one

CÓDIGO DEL PRODUCTO:

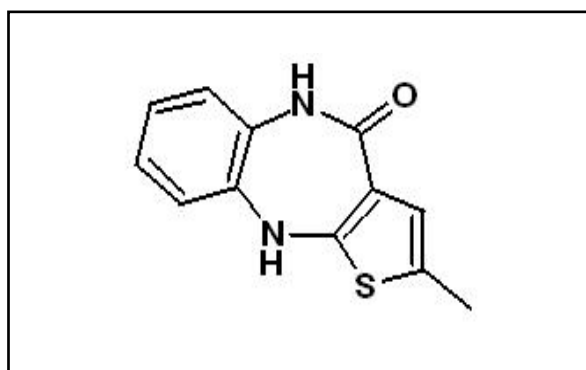
Olanzapina CRB (Olanzapina Imp B)

CAS RN: 221176-49-4

FÓRMULA: C<sub>12</sub>H<sub>10</sub>N<sub>2</sub>O<sub>2</sub>S

PESO MOLECULAR: 230.29

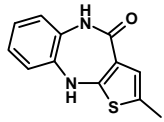
LOTE: ga0039063z

**Información técnica**Aspecto: **Sólido Castaño Claro**RMN-1H (DMSO-d<sub>6</sub>, 300 MHz): **Confirma estructura**Pureza por HPLC-MS: **97,73%**Espectrometría de Masas por ESI+: **Confirma masa**IR: **IR confirma identidad**TGA-volátiles (A): **0,314%**TGA-inorgánico (B): **0,755%****COMENTARIOS****Valoración= (100%-A-B)x(100-C)/100%= 96,68%****Mantener almacenado a +4 °C****Fecha recomendada de Re-Test: Abril 2015**

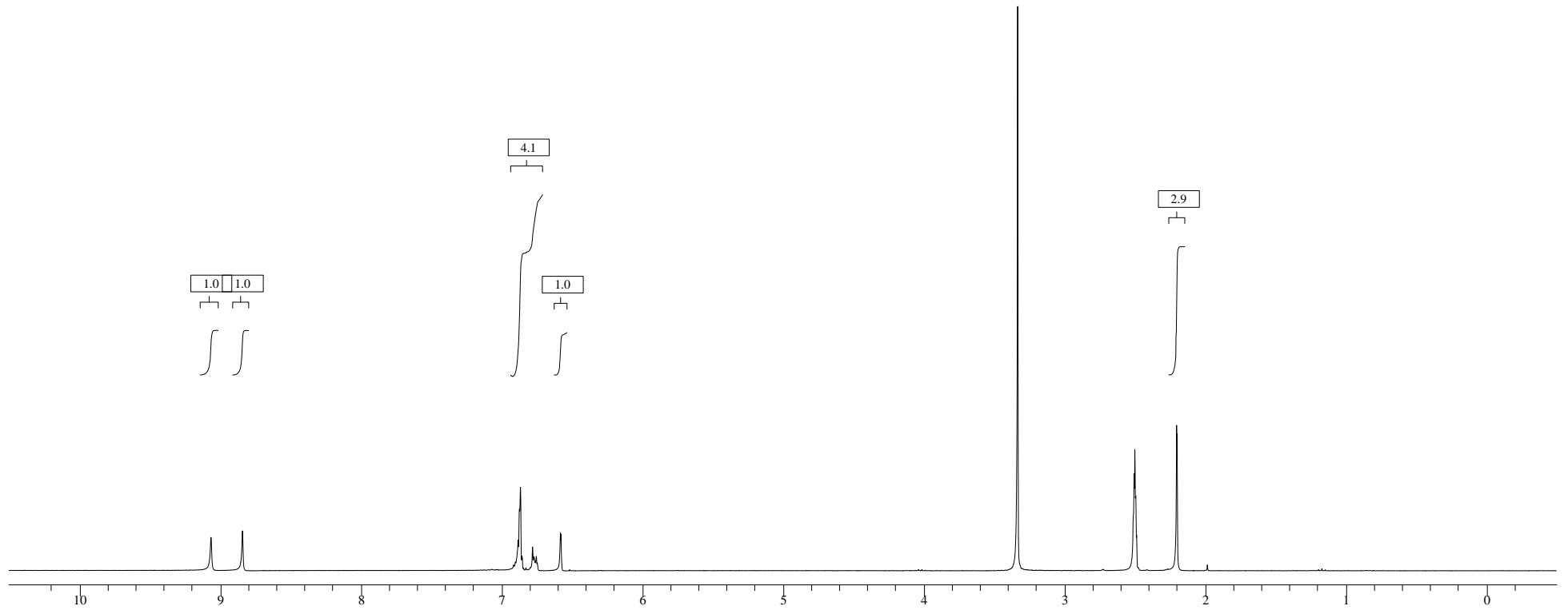
22/04/2014

Directora de Control de Calidad: Dra. Eva Codesido

08/04/2014

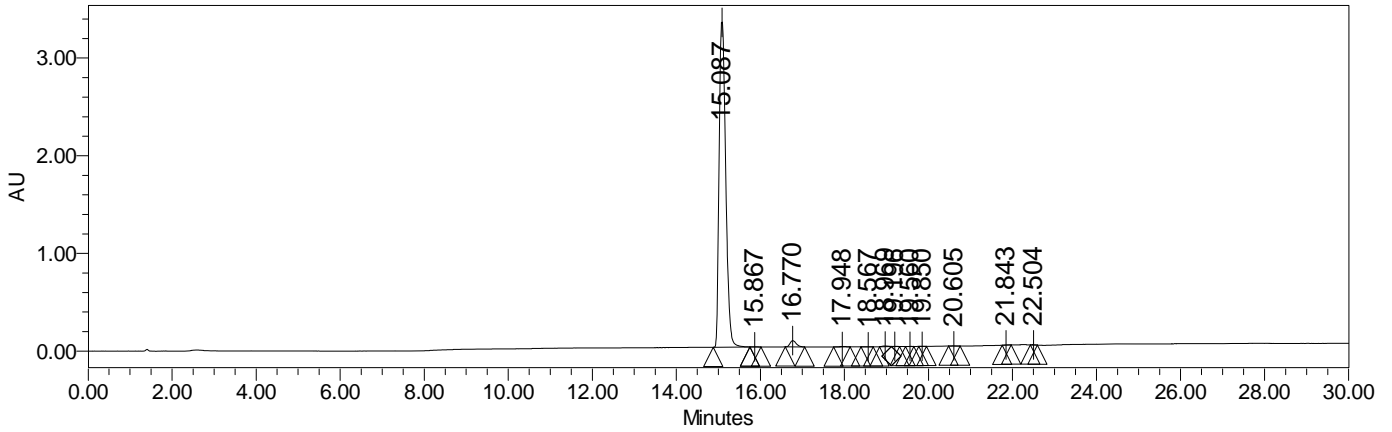


ga0039063z  
RMN-1H: DMSO-d<sub>6</sub>, 300 MHz



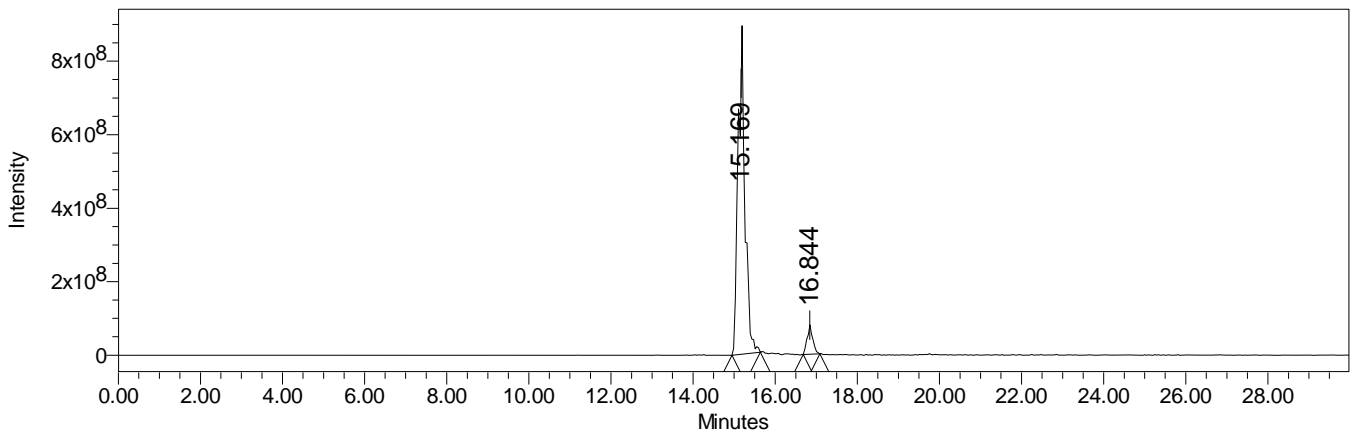
Column: Kinetex C18 5 um, 2.1 x 150 mm  
 Flow rate: 0.35 mL/min  
 Gradient: A:B:C 5 min in 5:90:5 + from 5:90:5 to 95:0:5  
 in 15 min + 10 min in 95:0:5.  
 A: CH3CN:MeOH (1:1)  
 B: Water; C: 100 mM ammonium acetate pH 7  
 Sample dissolved in methanol.

Auto-Scaled Chromatogram



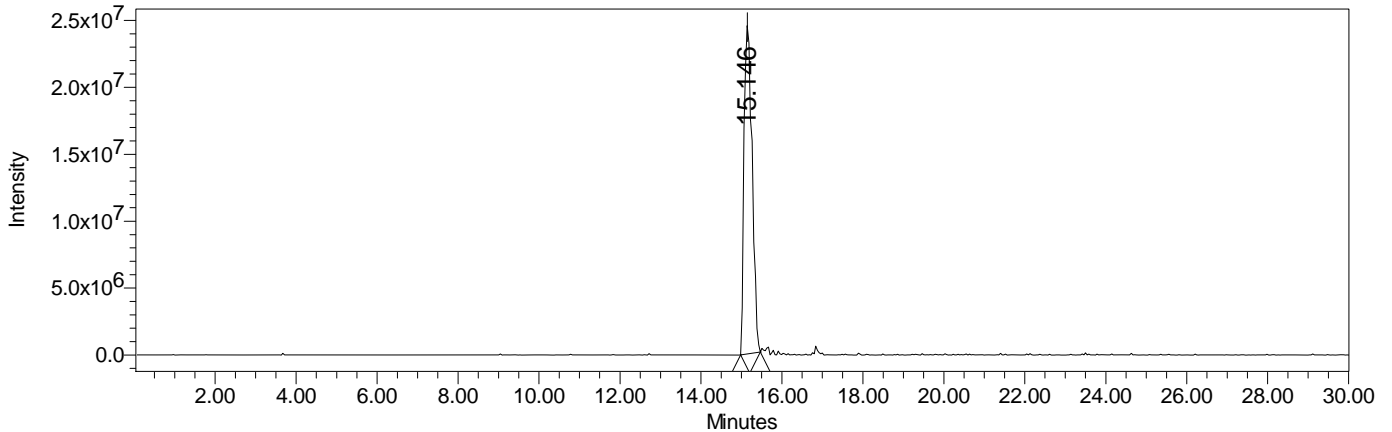
Channel Description PDA 210.0 to 400.0 nm at 1.2 nm; Channel Name PDA Max Plot 190.0 - 800.0

Auto-Scaled Chromatogram

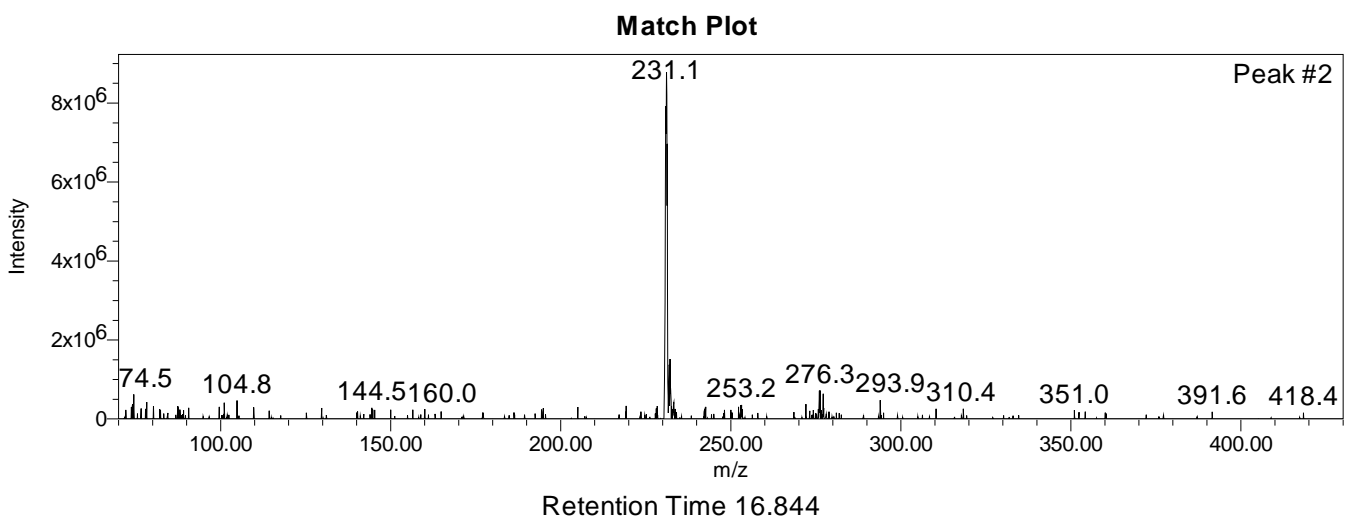
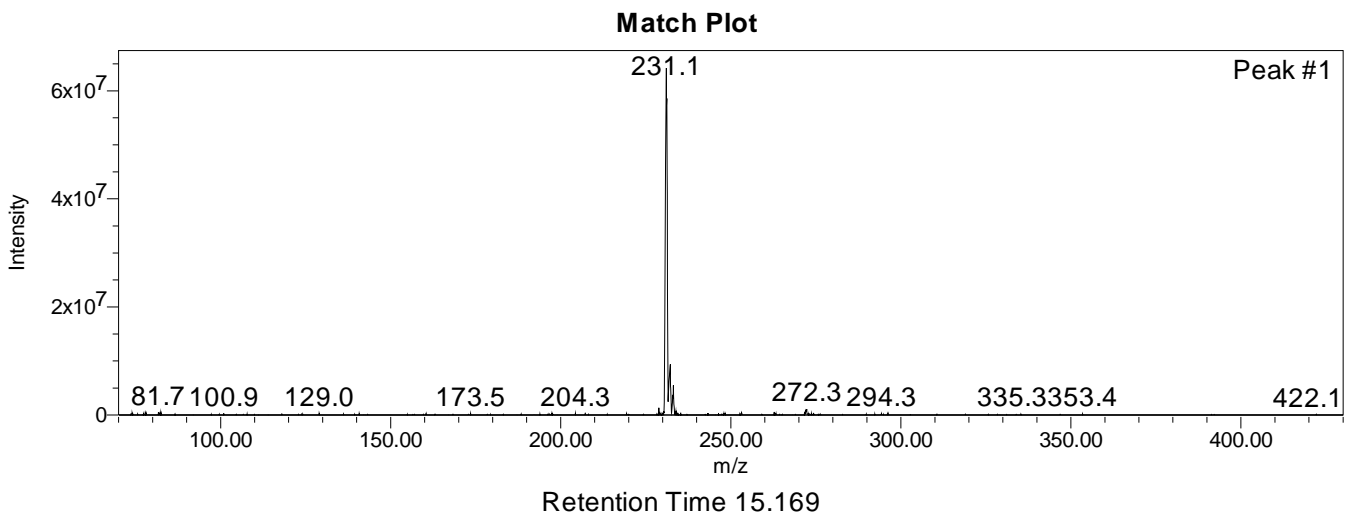
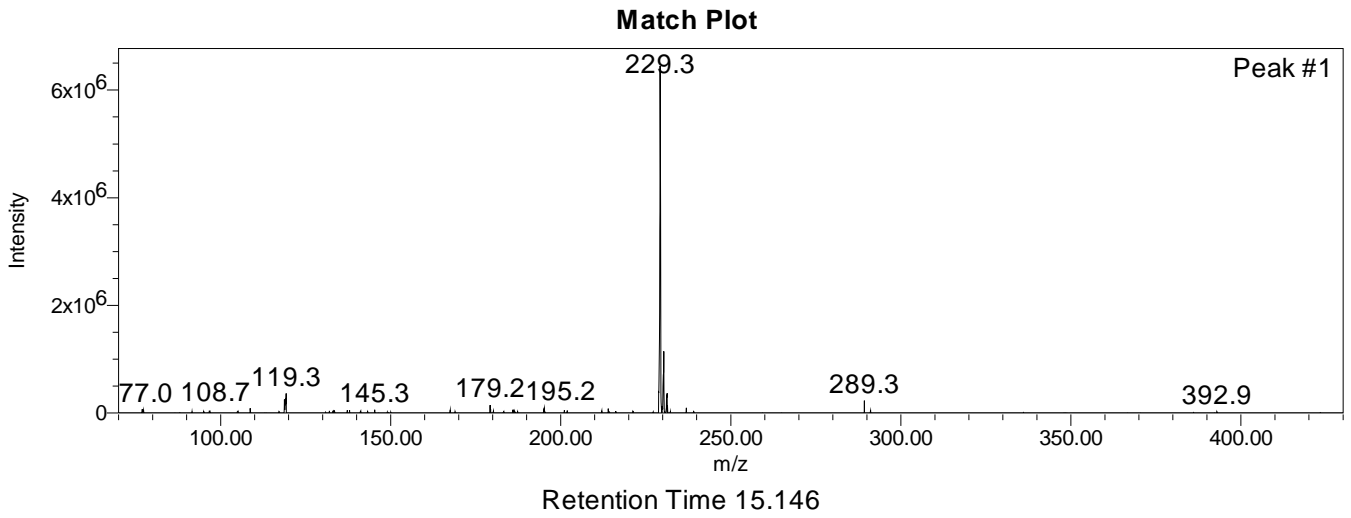


Channel Description 70.00-900.00 ES+, Continuum, CV=25; Channel Name 231.0Da

Auto-Scaled Chromatogram

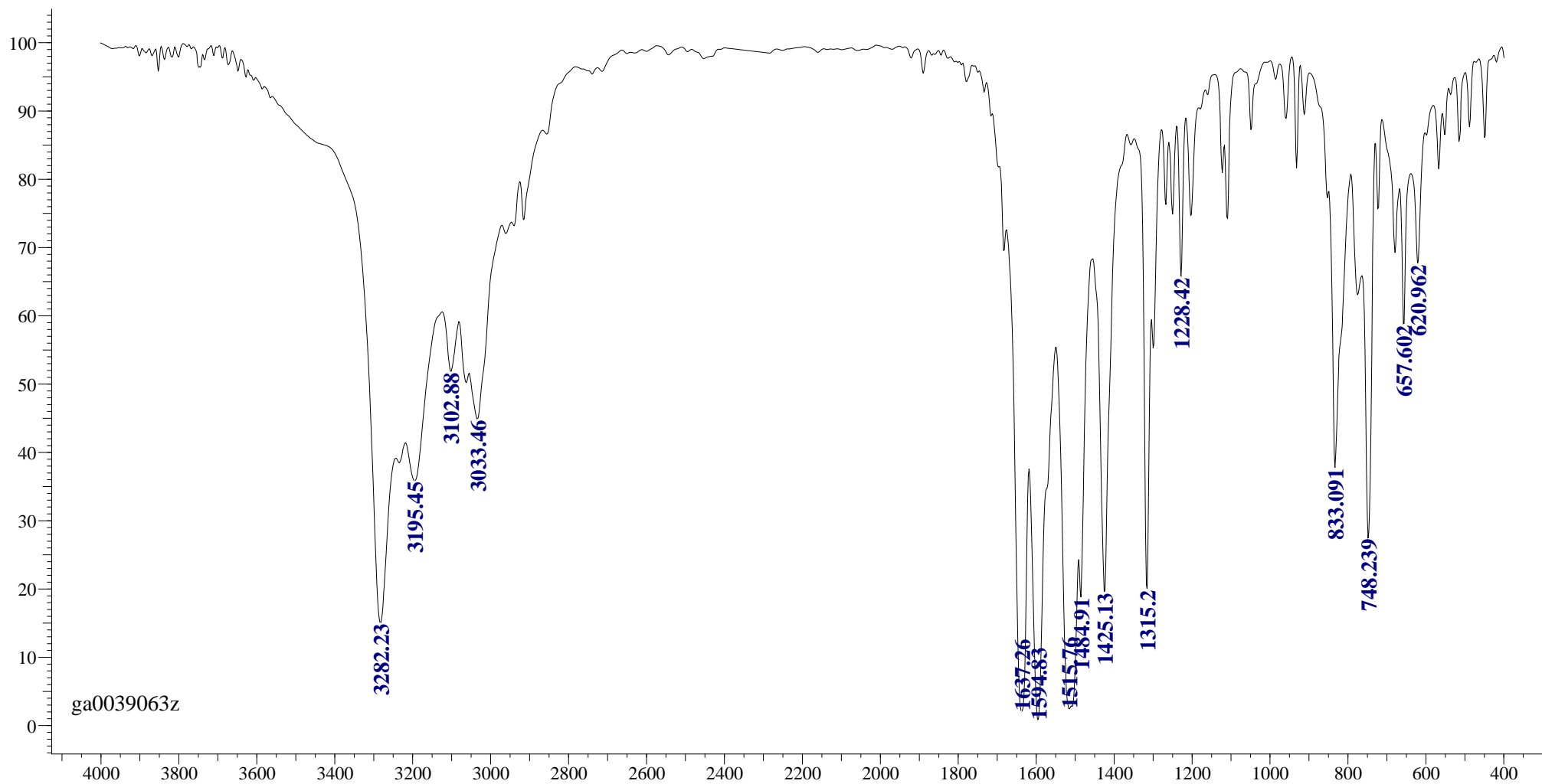


Channel Description 70.00-900.00 ES-, Continuum, CV=40; Channel Name 229.0Da



**Peak Results**

	<b>SampleName</b>	<b>RT</b>	<b>Area</b>	<b>% Area</b>
1	ga0039063z	15.087	36411466	97.73
2	ga0039063z	15.867	19742	0.05
3	ga0039063z	16.770	641535	1.72
4	ga0039063z	17.948	34957	0.09
5	ga0039063z	18.567	9806	0.03
6	ga0039063z	18.969	71602	0.19
7	ga0039063z	19.196	13272	0.04
8	ga0039063z	19.560	5542	0.01
9	ga0039063z	19.850	7662	0.02
10	ga0039063z	20.605	15455	0.04
11	ga0039063z	21.843	14508	0.04
12	ga0039063z	22.504	12658	0.03



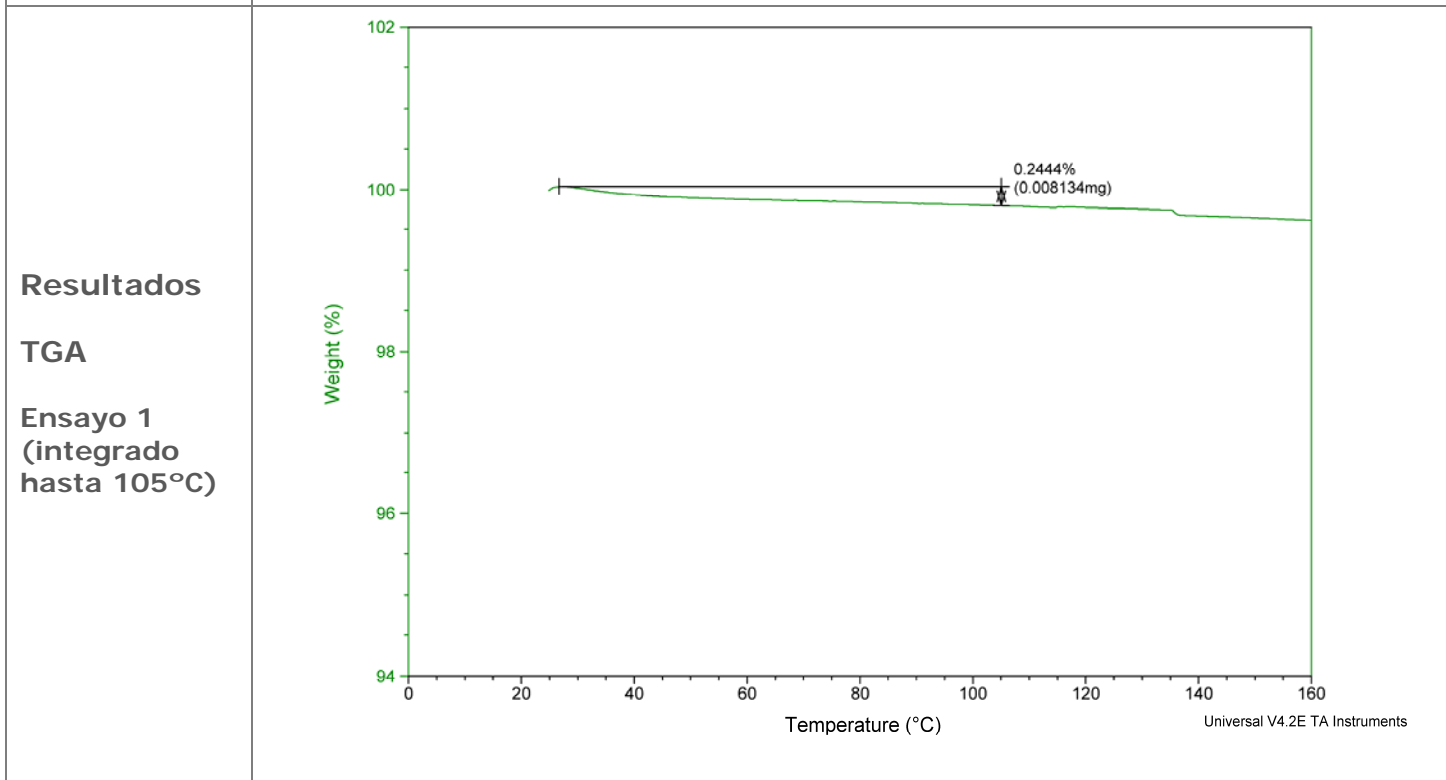
Peak Position:	Peak Height [%]:
3282.23	39.4062
3195.45	21.3137
3102.88	13.6573
3033.46	16.6605
1637.26	80.0486
1594.83	100
1515.76	77.5497
1484.91	34.7297
1425.13	33.9444
1315.2	33.5081
1228.42	8.72874
833.091	20.2471
748.239	26.8843
657.602	11.0514
620.962	8.12552

### Análisis Térmico ga0039063z

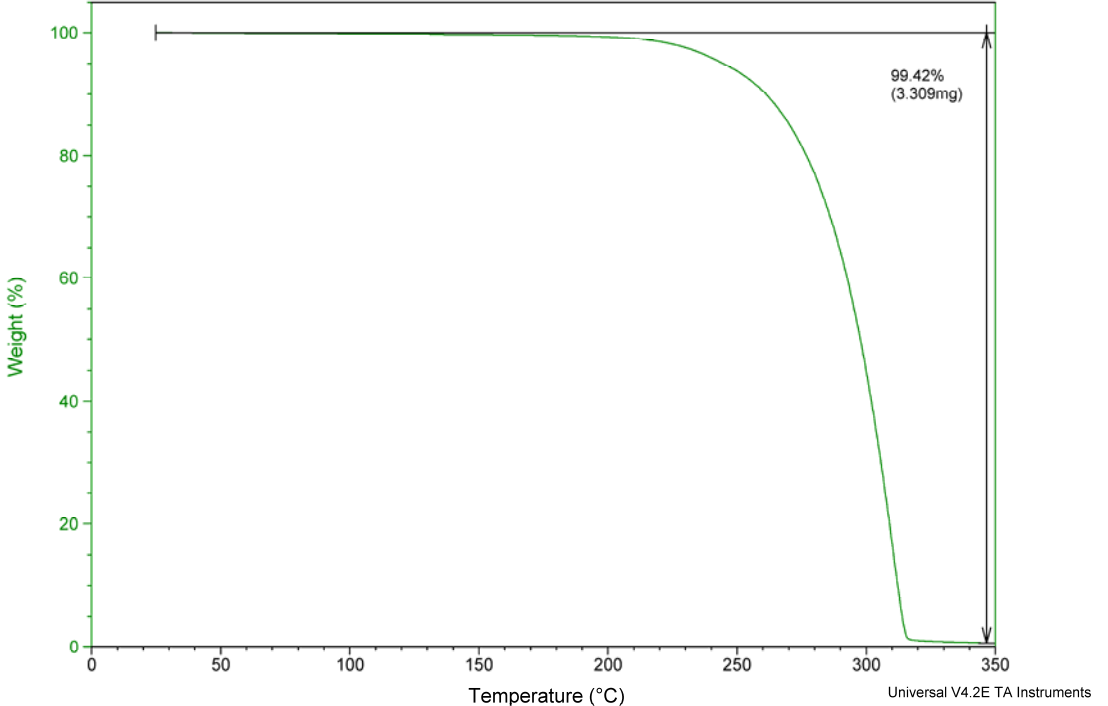
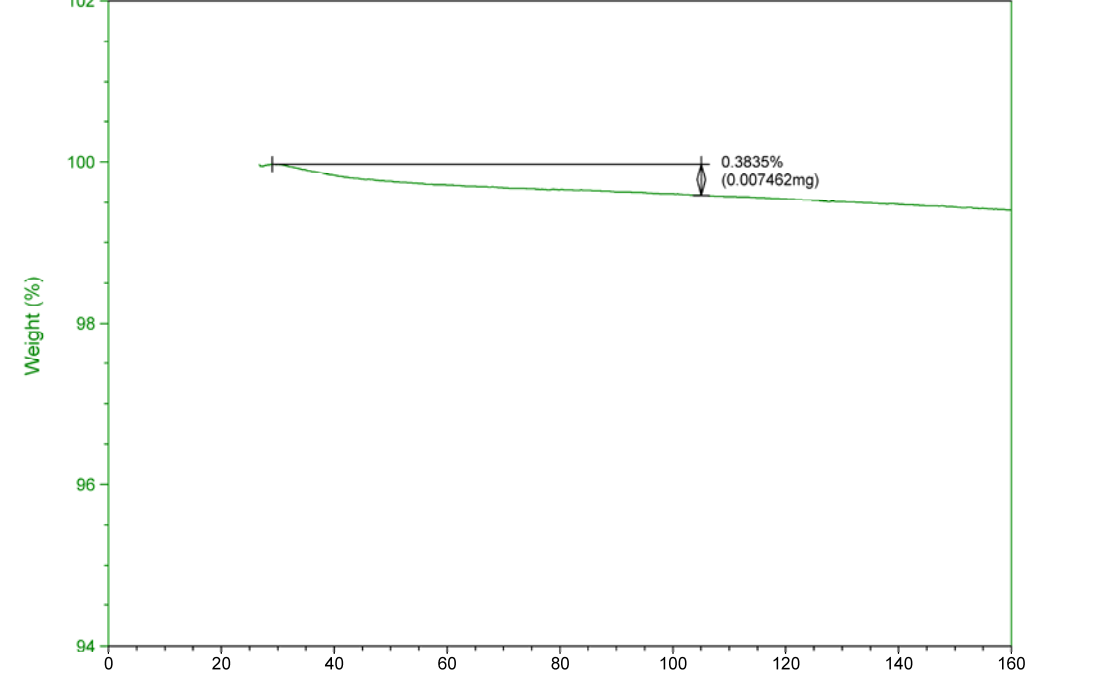
<b>Fecha ensayo</b>	09/04/2014
<b>Equipo</b>	TGA 2950 (TA Instruments)

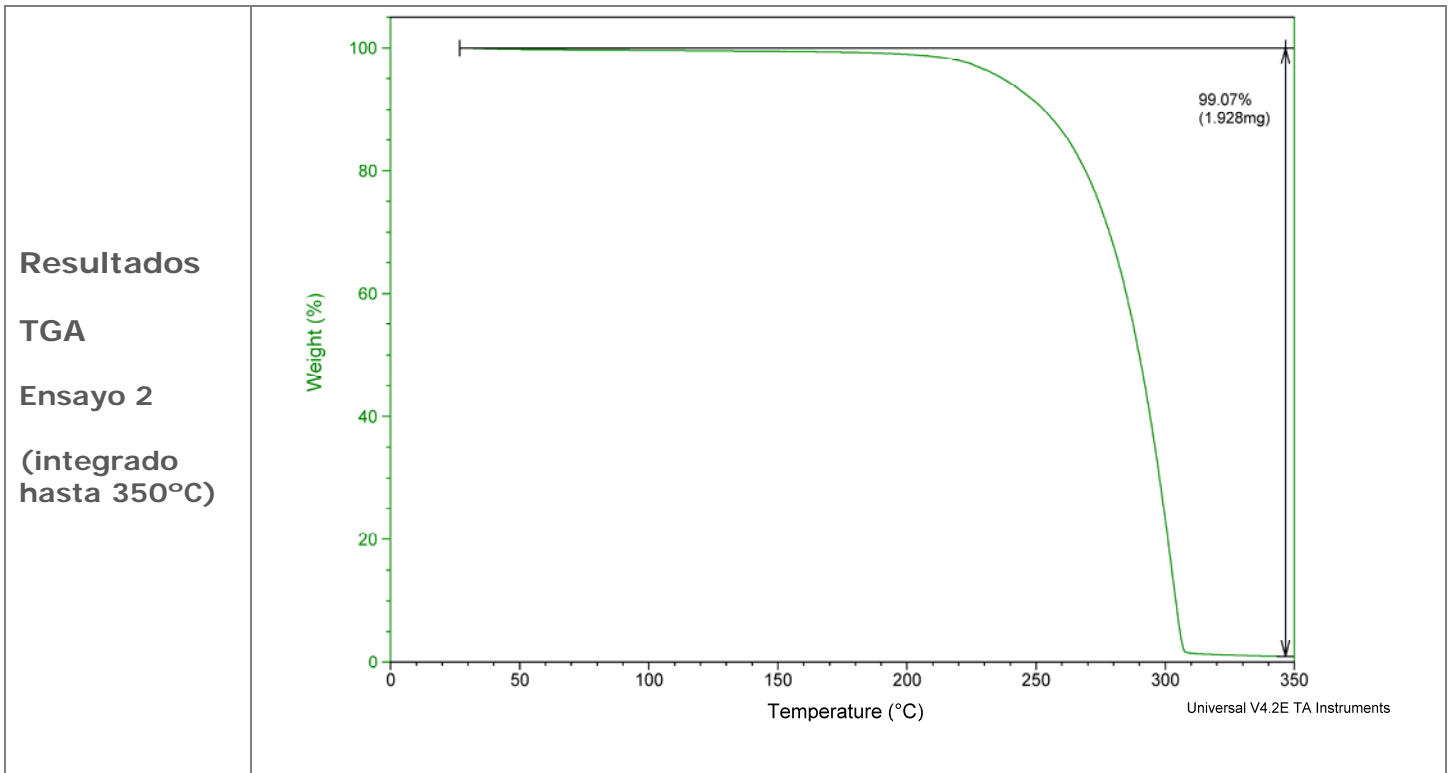
<b>Cliente</b>	<b>Galchimia</b>
<b>Contacto</b>	
<b>Tlf. /Ext.</b>	981814506
<b>E-mail</b>	

<b>Muestra</b>	<b>ga0039063z (1er replicado)</b>
<b>Protocolo</b>	Rampa a 10°C/min hasta 350°C
<b>Comentarios</b>	





<p><b>Resultados</b></p> <p><b>TGA</b></p> <p><b>Ensayo 1</b></p> <p><b>(integrado hasta 350°C)</b></p>	 <p>Weight (%)</p> <p>Temperature (°C)</p> <p>99.42% (3.309mg)</p> <p>Universal V4.2E TA Instruments</p>
<p><b>Muestra</b></p>	<p><b>ga0039063z (2° replicado)</b></p>
<p><b>Protocolo</b></p>	<p>Rampa a 10°C/min hasta 350°C</p>
<p><b>Comentarios</b></p>	
<p><b>Resultados</b></p> <p><b>TGA</b></p> <p><b>Ensayo 2</b></p> <p><b>(integrado hasta 105°C)</b></p>	 <p>Weight (%)</p> <p>Temperature (°C)</p> <p>0.3835% (0.007462mg)</p> <p>Universal V4.2E TA Instruments</p>



<b>Resultado (Determinación de volátiles)</b>	<b>0.314% ± 0.098%</b>
<b>Resultado (Residuo inorgánico)</b>	<b>0.755% ± 0.247%</b>

<b>Operador</b>	<b>Supervisor</b>
Lidia Pereiro Expósito	Carmen Álvarez Lorenzo