

Mexico: Open for Business

U.S. Embassy Mexico City
March 2021



The U.S. Commercial Service: Who We Are

- **An agency of the U.S. Department of Commerce**
- **Mission**
 - Help U.S. exporters sell in Mexico
 - Attract investment to the United States
 - Protect U.S. business interests abroad
- **Offices**
 - Three in Mexico
 - In Mexico City we have a Standards Attaché, IP Attaché and Digital Attaché
 - 100+ offices in the U.S.
 - 75 world-wide



What We Do: Opening Markets for U.S. Business in Mexico

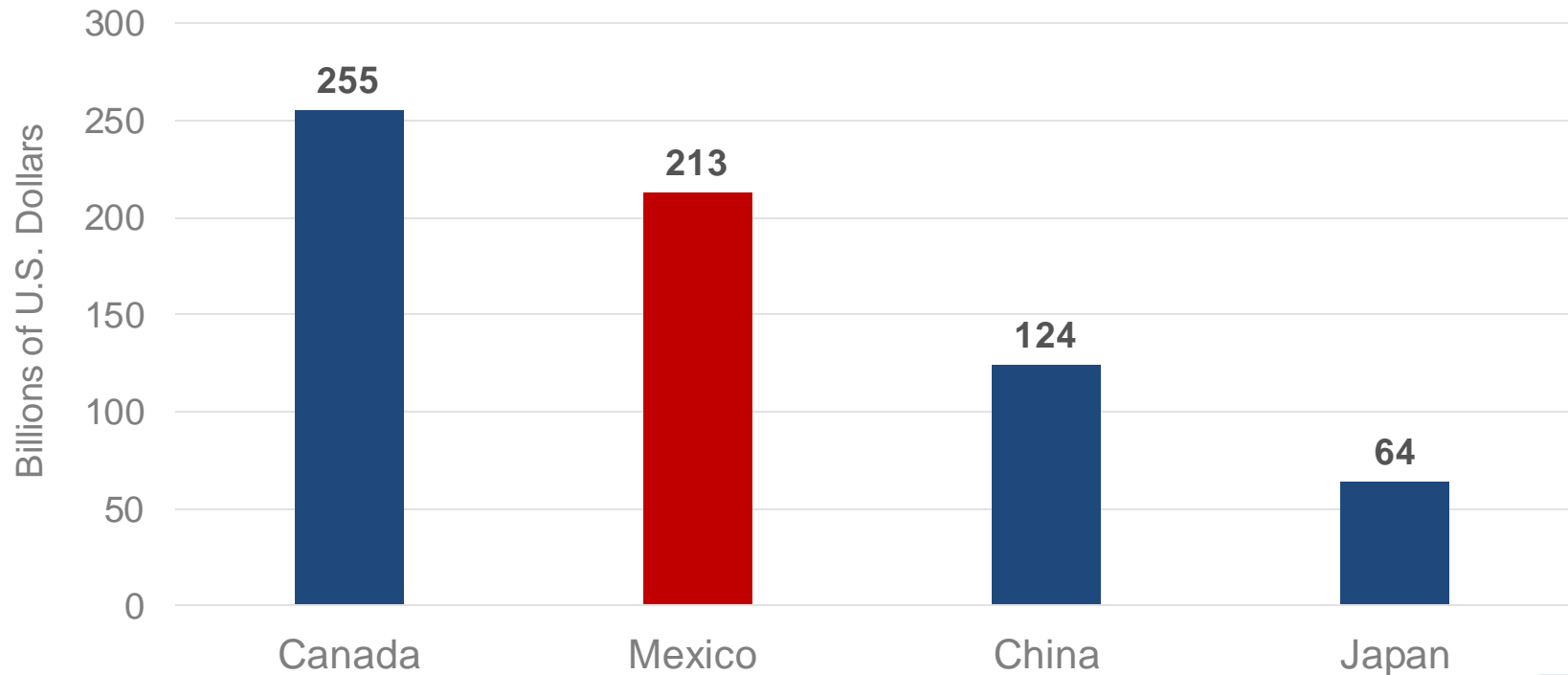


- **Trade and Investment Promotion**
Matching U.S. sellers and foreign buyers
- **Commercial Diplomacy**
Breaking down regulatory barriers
- **Advocacy**
Fighting for U.S. success in foreign government procurement
- **Market Access**
Keeping trade agreements working for U.S. business
- **Protecting Intellectual Property**
Enforcing trademarks, patents, copyrights, and more
- **Enforcement and Compliance**
Striking back at unfair dumping and subsidies
- **Safeguarding Technology**
Verifying proper end-use of sensitive technology



A Top Destination for U.S. Goods' Exports

U.S. Merchandise Exports, 2020



Source: Foreign Trade Division, U.S. Census Bureau

Contact us today
to connect with a world of opportunity.

export.gov/mexico

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Connecting You to Global Markets





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CERTIFIED REFERENCE STANDARDS



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Sobre Nosotros



CRS Laboratories es una empresa independiente especializada en el suministro de compuestos químicos de alta calidad con Estándares de Referencia Certificados, para industrias químicas y farmacéuticas.



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Objetivo

Nuestro objetivo es proveer una gama completa de Estándares de Referencia a fin de atender todas las necesidades de nuestros clientes y mantenernos como una empresa de referencia en este segmento.




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Equipo

Contamos con un equipo altamente calificado de profesionales trabajando siempre para ofrecer el mejor servicio a nuestros clientes.



Productos



Nosotros entendemos la importancia de proveer la mejor calidad a nuestros clientes, y es por eso que nos esforzamos para alcanzar la más alta pureza en nuestros estándares de referencia.



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Productos

Ofrecemos estándares de referencia para las siguientes categorías:

- ✓ Impurezas
- ✓ Intermediario
- ✓ Deuterados
- ✓ Fitoquímicos
- ✓ Nuevas Síntesis



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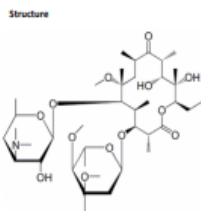
Análisis

- ✓ HPLC
- ✓ Massas Espectro
- ✓ NMR
- ✓ FT-IR
- ✓ TGA
- ✓ Solventes Residuales
- ✓ Perfil de Impurezas
- ✓ Informe de Elucidación



CERTIFICATE OF ANALYSIS

Name: N-Desmethyl Clarithromycin
Synonyms: Clarithromycin EP Impurity D; N-Desmethyl Clarithromycin; 3-N-Desmethyl-6-O-methylerythromycin A
Part Number: C1405
CAS Number: 101666-68-6
Mol. Formula: C₂₇H₄₅N₂O₇
Mol. Weight: 733.33
Lot Number: C1405-XH09V257
Expiration Date: September 13, 2022
Storage: Store at 2-8 °C.



TEST DESCRIPTION	RESULTS
APPEARANCE	Off White Solid
¹ H-NMR	Conforms to structure
MS	Conforms to structure
IR	Conforms to structure
SOLUBILITY	DMSO, Methanol
PURITY (HPLC)	99.174%
IMPURITIES (HPLC)	RT 12.612, 0.381%; RT 17.388, 0.404%
WATER CONTENT (TGA)	2.141%
ASH CONTENT/ ROI (TGA)	3.306%
RESIDUAL SOLVENTS (TGA, ¹ H-NMR)	Not Detected
POTENCY *	93.77%

Potency % based on (100-(water content)-(residual solvents-ash content)(HPLC purity))** ## ##%

% Potency = [(100 - 2.141(water content) - 3.306(ash content)) * (99.17)(HPLC Purity)] / 100 = 93.77%

Release Date: September 28, 2020

Reviewed and approved by: *Kelly Benner* Revised By: *Gargan Ma*

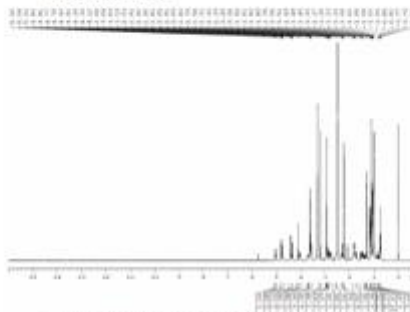
NOTE: THIS MATERIAL IS INTENDED FOR USE IN LABORATORY TESTS ONLY, NOT FOR HUMAN OR ANIMAL USE.

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www.crs-labs.com



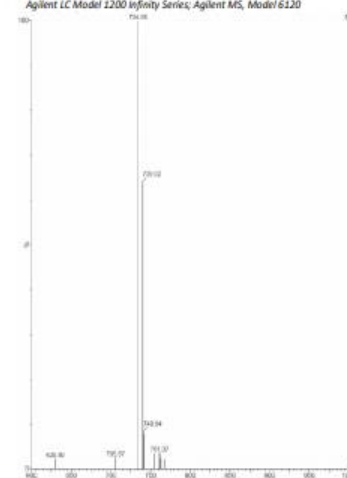
I. Identity
The identity of the reference substance was established by the following analyses:

A. ¹H-NMR Spectrum
Bruker 400 MHz, DMSO-d₆



Structure is confirmed by analysis of signals and their integration.

B. Mass Spectrum
Agilent LC Model 1200 Infinity Series; Agilent MS, Model 6120

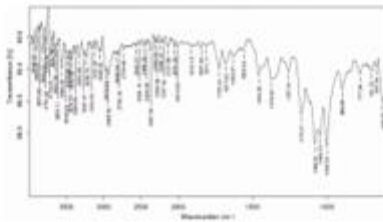


Theoretical value: 733.93
Observed value: 734.95 [M+1]

The signal of the MS/HRMS spectrum is consistent with the theoretical value. The interpretation of fragment peaks is consistent with the structure.



C. Infrared Spectrum ATR-FTIR, Bruker Model Alpha



Signals of the IR spectrum and their interpretation are consistent with the compound structure.

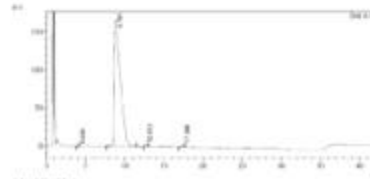


II. Purity

A. High Performance Liquid Chromatography (HPLC) SINAKOZU AC: 25KAP HPLC

HPLC Conditions:

Column: C18 L2 packing (Luna) 3.3 µm, 250 x 4.6 mm
Detection: UV, 205 nm
Injection: 10 µL, manual
Flow Rate: 1.1 mL/min
Solvent: ACN:water (2:1)
Solution A: 4.76 g/L Monobasic potassium phosphate (MOPK) Adjust pH with 6N Phosphoric acid or KOH to a pH 8.4. Pass the solution through C18 filtration
Solution B: Acetonitrile



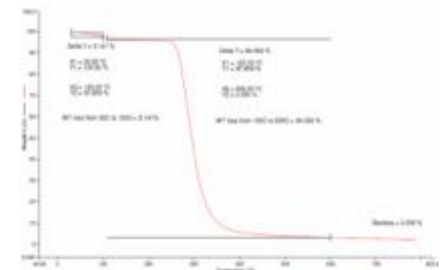
Retention Time (min)	Area	Height	Area%	Height%
10.5	1000000	100000	99.99	100.00
1.1	1000	100	0.01	0.00
1.2	1000	100	0.01	0.00
1.3	1000	100	0.01	0.00
1.4	1000	100	0.01	0.00
1.5	1000	100	0.01	0.00
1.6	1000	100	0.01	0.00
1.7	1000	100	0.01	0.00
1.8	1000	100	0.01	0.00
1.9	1000	100	0.01	0.00
2.0	1000	100	0.01	0.00
2.1	1000	100	0.01	0.00
2.2	1000	100	0.01	0.00
2.3	1000	100	0.01	0.00
2.4	1000	100	0.01	0.00
2.5	1000	100	0.01	0.00
2.6	1000	100	0.01	0.00
2.7	1000	100	0.01	0.00
2.8	1000	100	0.01	0.00
2.9	1000	100	0.01	0.00
3.0	1000	100	0.01	0.00
3.1	1000	100	0.01	0.00
3.2	1000	100	0.01	0.00
3.3	1000	100	0.01	0.00
3.4	1000	100	0.01	0.00
3.5	1000	100	0.01	0.00
3.6	1000	100	0.01	0.00
3.7	1000	100	0.01	0.00
3.8	1000	100	0.01	0.00
3.9	1000	100	0.01	0.00
4.0	1000	100	0.01	0.00
4.1	1000	100	0.01	0.00
4.2	1000	100	0.01	0.00
4.3	1000	100	0.01	0.00
4.4	1000	100	0.01	0.00
4.5	1000	100	0.01	0.00
4.6	1000	100	0.01	0.00
4.7	1000	100	0.01	0.00
4.8	1000	100	0.01	0.00
4.9	1000	100	0.01	0.00
5.0	1000	100	0.01	0.00
5.1	1000	100	0.01	0.00
5.2	1000	100	0.01	0.00
5.3	1000	100	0.01	0.00
5.4	1000	100	0.01	0.00
5.5	1000	100	0.01	0.00
5.6	1000	100	0.01	0.00
5.7	1000	100	0.01	0.00
5.8	1000	100	0.01	0.00
5.9	1000	100	0.01	0.00
6.0	1000	100	0.01	0.00
6.1	1000	100	0.01	0.00
6.2	1000	100	0.01	0.00
6.3	1000	100	0.01	0.00
6.4	1000	100	0.01	0.00
6.5	1000	100	0.01	0.00
6.6	1000	100	0.01	0.00
6.7	1000	100	0.01	0.00
6.8	1000	100	0.01	0.00
6.9	1000	100	0.01	0.00
7.0	1000	100	0.01	0.00
7.1	1000	100	0.01	0.00
7.2	1000	100	0.01	0.00
7.3	1000	100	0.01	0.00
7.4	1000	100	0.01	0.00
7.5	1000	100	0.01	0.00
7.6	1000	100	0.01	0.00
7.7	1000	100	0.01	0.00
7.8	1000	100	0.01	0.00
7.9	1000	100	0.01	0.00
8.0	1000	100	0.01	0.00
8.1	1000	100	0.01	0.00
8.2	1000	100	0.01	0.00
8.3	1000	100	0.01	0.00
8.4	1000	100	0.01	0.00
8.5	1000	100	0.01	0.00
8.6	1000	100	0.01	0.00
8.7	1000	100	0.01	0.00
8.8	1000	100	0.01	0.00
8.9	1000	100	0.01	0.00
9.0	1000	100	0.01	0.00
9.1	1000	100	0.01	0.00
9.2	1000	100	0.01	0.00
9.3	1000	100	0.01	0.00
9.4	1000	100	0.01	0.00
9.5	1000	100	0.01	0.00
9.6	1000	100	0.01	0.00
9.7	1000	100	0.01	0.00
9.8	1000	100	0.01	0.00
9.9	1000	100	0.01	0.00
10.0	1000	100	0.01	0.00

For the calculations, system peaks are ignored. The purity of the reference substance is determined as ratio of the peak area of the reference substance and the total areas of the all impurity peaks, summed to 100%.

Results:
Purity: 99.214%
Method: General Method



B. Thermogravimetric Analysis (TGA) Method: TGA Thermogram, % of weight loss 30-400 degrees C.



Residual Solvents
Method: percent of compound lost prior to water step, "W-AMF"
No residual solvents were detected.

Water Content
Method: percent of compound lost up to completion of water step (30-105 °C)
Water content was determined to be 0.214%.

Ash Content (Residue on Ignition)
Method: percent of compound remaining after completion of boiling point step (>600 °C)
Ash content was determined to be 0.214%.





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Estrategia

I - Proveer Estándares de Referencia, proporcionando a nuestros clientes las tres ventajas competitivas más importantes del mercado: precio, calidad, y entrega rápida.

Cientes

Empresas en los segmentos de:

- ✓ Farmacéutica y Diagnóstico
- ✓ Biotecnología
- ✓ Productos Químicos
- ✓ Investigación (Universidades).



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uno de nuestros
es!





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!Gracias!

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