

Laboratory Report

 Report prepared for:

 Daniel Pocci

 Elco Corp

 1100 State Road

 Ashtabula, OH 44004

 Phone:
 216-767-4001

 Email:
 d.pocci@italmatch.com, D.bias@italmatch.com, N.Massaro@Italmatch.com

Report prepared by: Michelle Mccurdy

Purchase Order: 70336766

For further assistance, contact: Michelle McCurdy Technical Manager PO Box 51610 Knoxville, TN 37950 -1610 (865) 546-1335 ext. 1826 michellemccurdy@galbraith.com

Lab ID: 2024-U-9	9096	Received:	2024-10-02		
Analysis Metho	od	Result	Basis	Sample Amount Used	Date (Time)
100: Specific Gravity					
FCC 1	4th Edition	1.1876	As Received	200 mL	2024-10-14
224: Reducing Substanc	es				
FCC 1	4th Edition	< 0.007 %	As Received	1 mL	2024-10-25
408: Color					
FCC 1	4th Edition	Passes Test	As Received	Direct	2024-10-10
454: Nonvolatile Residue					
FCC 1	4th Edition	0.33 mg	As Received	1008.44 mg	2024-10-16
553: Oxidizing Substance	es C/2				
FCC 1	4th Edition	< 0.003 %	As Received	1 mL	2024-10-25
FCC 1	4th Edition (matrix spike)	≥ 0.003 %	As Received	1 mL	2024-10-25
662: Degrees Baume					
FCC 1	4th Edition	22.9° Be	As Received	200 mL	2024-10-14
777: Identification					
FCC 1	4th Edition	Passes Test	As Received	1 mL	2024-10-22
782: Iron					
FCC 1	4th Edition	< 5 mg/kg	As Received	4.3 mL	2024-10-22
FCC 1	4th Edition (matrix spike)	≥ 5 mg/kg	As Received	4.3 mL	2024-10-22
785: Sulfate					
FCC 1	4th Edition	< 0.5 %	As Received	424 µL	2024-10-22
FCC 1	4th Edition (matrix spike)	≥ 0.5 %	As Received	424 μL	2024-10-22
j35: Hydrochloric Acid					
FCC 1	4th Edition	100.2 % Label Claim	As Received	3137.8 mg	2024-10-22
mPb: Lead					
FCC 1	4th Edition Supplement I	NMT 1 mg/kg	As Received	1.52712 g	2024-12-23
	4th Edition Supplement I (matrix spike)	85 % Recovery	As Received	1.51704 g	2024-12-23
u80: Mercury ¹					
FCC 1	4th Edition (mod.)	< 0.10 mg/kg	As Received	25.4 mL	2024-10-31
FCC 1	4th Edition (mod.) (matrix spike)	≥ 0.10 mg/kg	As Received	25.4 mL	2024-10-31

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Reported results are only applicable to the item tested.

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1. Dev 7579 - Use 30 g of sample in order to reach the 0.10 mg/kg DL.

For all samples on this report:

- 2. These analyses were performed in general compliance with the Laboratory sections of Current Good Manufacturing Practices for bulk pharmaceuticals as defined in 21 CFR 210 and 211.
- 3. The matrix spike analysis was performed to satisfy method requirements. There is no additional charge for the matrix spike result.

Signatures:

Created By:	michelle.mccurdy		
Published By:	tammy.saylor		
Modified By:	michelle.mccurdy		
Inspected By:	tammy.saylor		

2024-12-23T20:23:29.063-05:00 2024-12-23T20:46:13.807-05:00 2024-12-23T20:44:33.37-05:00 2024-12-23T20:46:10.873-05:00

ⁿ Physical signatures are on file.

- ⁿ "Published By" signature indicates authorized release of data.
- n "Inspected By" signature indicates QA review and approval.