

Amended Laboratory Report

Report prepared for:

Ray D Gardner
The Elco Corporation
1000 Belt Line Ave
Cleveland, OH 44109
Phone: 216-749-2605 ext. 225
Fax: 216-749-7462
Email: rgardner@elcocorp.com

Report prepared by:

Michelle Smith

Purchase Order:

34120

For further assistance, contact:

Michelle Smith
Technical Manager
PO Box 51610
Knoxville, TN 37950 -1610
(865) 546-1335 ext. 1826
michellesmith@galbraith.com

Sample: Quote 7363-T Analysis of HCL GMP/NF (250 ML) LOT# 071317-122					
Lab ID: 2017-E-7548		Received: 2017-08-02			
Analysis	Method	Result	Basis	Sample Amount Used	Date (Time)
<i>118: Residue on Ignition (ROI)</i>					
	USP 40/NF 35 Supplement 1	< 0.006 %	As Received	20 mL	2017-08-16
<i>362: Heavy Metals Method II</i>					
	USP 40/NF 35 Supplement 1	< 5 ppm	As Received	3.8964 g	2017-08-15
	USP 40/NF 35 Supplement 1	≥ 5 ppm	As Received	3.8775 g	2017-08-15
<i>774: Br/I, Free Br/Cl, SO4/SO3</i>					
	USP 40/NF 35 Supplement 1 ¹	Passes Test	As Received	1 mL	2017-08-14
	USP 40/NF 35 Supplement 1 ²	Passes Test	As Received	Direct	2017-08-14
	USP 40/NF 35 Supplement 1 ³	Passes Test	As Received	10 mL	2017-08-14
	USP 40/NF 35 Supplement 1 ⁴	Passes Test	As Received	10 mL	2017-08-14
	USP 40/NF 35 Supplement 1 ⁵	Passes Test	As Received	10 mL	2017-08-22
	USP 40/NF 35 Supplement 1 ⁶	Passes Test	As Received	Direct	2017-08-22
<i>777: Identification</i>					
	USP 40/NF 35 Supplement 1	Passes Test	As Received	1 mL	2017-08-18
<i>j35: Hydrochloric Acid</i>					
	USP 40/NF 35 Supplement 1	37.05 %	As Received	3.52954 g	2017-08-23

1. Meets the requirements of the sulfate test.
2. Meets the requirements of the sulfite test.
3. Meets the requirements of the bromide test.
4. Meets the requirements of the iodide test.
5. Meets the requirements of the free chlorine test.
6. Meets the requirements of the free bromine test.

For all samples on this report:

- 7. 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.
- 8. Amended Report: This report amends data included in report 100567

Signatures:

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