

Laboratory Report

Report prepared for:

Ray D. Gardner, Jr.
The Elco Corporation
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Report prepared by:

Salvador Pastor

Purchase Order:

32464

For further assistance, contact:

Salvador Pastor
Technical Manager
PO Box 51610
Knoxville, TN 37950 -1610
(865) 546-1335
salpastor@galbraith.com

Sample: Lot: 071015-122 HCl by FCC

Lab ID: 2015-Z-7236

Received: 2015-07-22

Analysis	Method	Result	Basis	Sample Amount Used	Date (Time)
<i>100: Specific Gravity</i> ¹					
	FCC 9th Edition Supplement 2	1.190	As Received	100 mL	2015-08-24
	FCC 9th Edition Supplement 2	1.190	As Received	100 mL	2015-08-24
	FCC 9th Edition Supplement 2	1.190	As Received	100 mL	2015-08-24
<i>224: Reducing Substances</i>					
	FCC 9th Edition Supplement 2	< 0.007 %	As Received	1 mL	2015-08-03
	FCC 9th Edition Supplement 2	< 0.007 %	As Received	1 mL	2015-08-03
<i>408: Color</i>					
	FCC 9th Edition Supplement 2	Passes Test	As Received	10 mL	2015-08-03
	FCC 9th Edition Supplement 2	Passes Test	As Received	10 mL	2015-08-03
<i>454: Nonvolatile residue</i>					
	FCC 9th Edition Supplement 2	< 0.0995 %	As Received	1005.43 mg	2015-07-31
	FCC 9th Edition Supplement 2	< 0.0990 %	As Received	1010.53 mg	2015-07-31
<i>553: Oxidizing Substances</i>					
	FCC 9th Edition Supplement 2	< 0.003 %	As Received	1 mL	2015-08-03
	FCC 9th Edition Supplement 2 (matrix spike) ²	≥ 0.003 %	As Received	1 mL	2015-08-03
<i>662: Degrees Baume</i>					
	FCC 9th Edition Supplement 2	23.2 Degrees Baume	As Received	200 mL	2015-08-18
	FCC 9th Edition Supplement 2	23.2 Degrees Baume	As Received	200 mL	2015-08-18
<i>777: Identification</i>					
	FCC 9th Edition Supplement 2	Passes Test	As Received	1 mL	2015-07-27
	FCC 9th Edition Supplement 2	Passes Test	As Received	1 mL	2015-07-27
<i>788: Iron</i>					
	FCC 9th Edition Supplement 2	< 5 mg/kg	As Received	5.0114 g	2015-08-03
	FCC 9th Edition Supplement 2 (matrix spike) ³	≥ 5 mg/kg	As Received	5.0675 g	2015-08-03
<i>805: Sulfate</i>					
	FCC 9th Edition Supplement 2	< 0.5 %	As Received	506.70 mg	2015-08-03
	FCC 9th Edition Supplement 2 (matrix spike) ⁴	≥ 0.5 %	As Received	506.70 mg	2015-08-03

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Reported results are only applicable to the item tested.

This report shall not be reproduced, except in full, without the written approval of the laboratory.

j35: Hydrochloric Acid

FCC 9th Edition Supplement 2	37.38 %	As Received	3.01022 g	2015-07-24
FCC 9th Edition Supplement 2	37.29 %	As Received	2.74573 g	2015-07-24

u80: Mercury

FCC 9th Edition Supplement 2	< 0.10 mg/kg	As Received	1.01040 g	2015-08-03
FCC 9th Edition Supplement 2 (matrix spike) ⁵	≥ 0.10 mg/kg	As Received	1.02417 g	2015-08-03

- Please see the enclosed analytical investigation for your specific gravity analysis, AI-2015-060, for a complete discussion of these results. If you have any additional questions, please contact our Technical Services group at your convenience.
- Matrix spike analyses were performed as part of our internal Quality Control Program. There is no additional charge for matrix spike values.
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For all samples on this report:

- Duplicate analyses were performed as part of our internal Quality Control Program. There is no additional charge for duplicate values.
- 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.

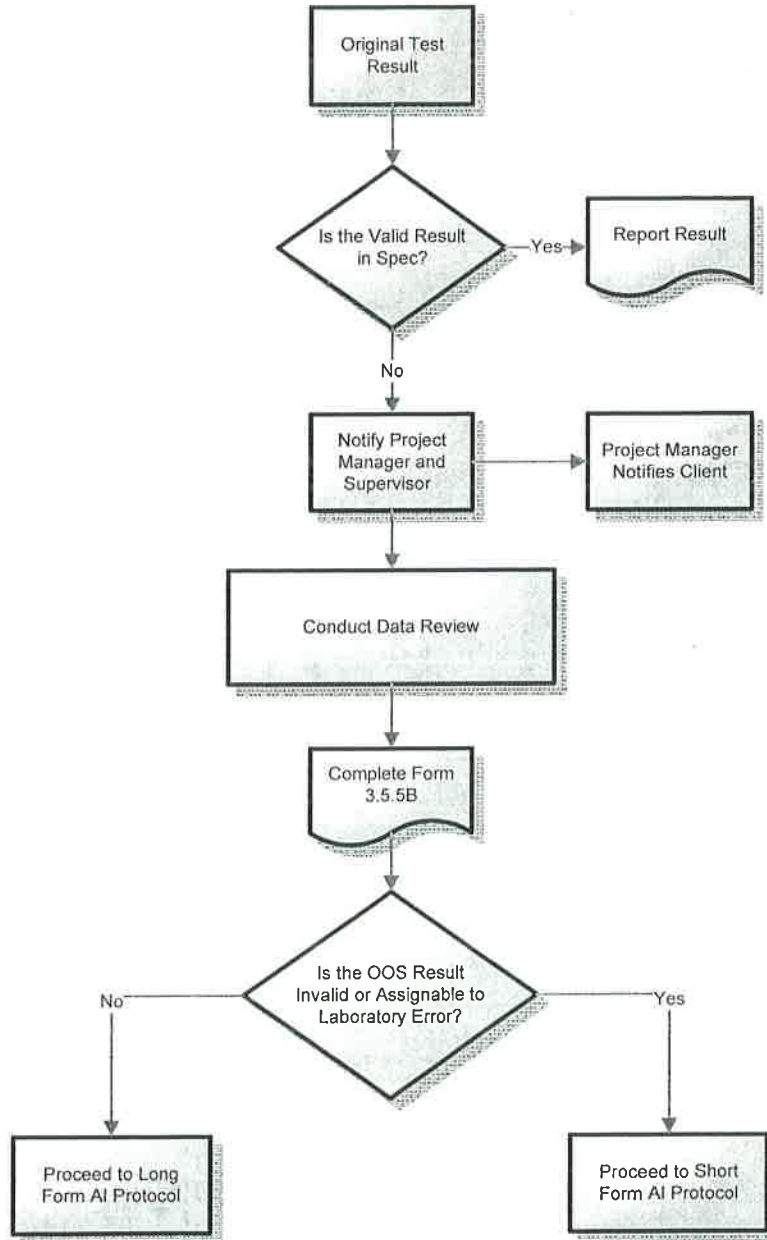
Signatures:

Inspected By: tammy.saylor
 Published By: tammy.saylor
 Created By: salvador.pastor

2015-09-02T15:42:17.317-04:00
 2015-09-02T15:42:30.67-04:00
 2015-09-02T13:49:23.053-04:00

- Physical signatures are on file.
- "Inspected By" signature indicates QA review and approval.
- "Published By" signature indicates authorized release of data.

INITIAL ASSESSMENT PROTOCOL
AI-2015-060




Form 3.5.5A Rev 8

Initial Assessment Report

Investigation Number: AI-2015-060

SECTION I

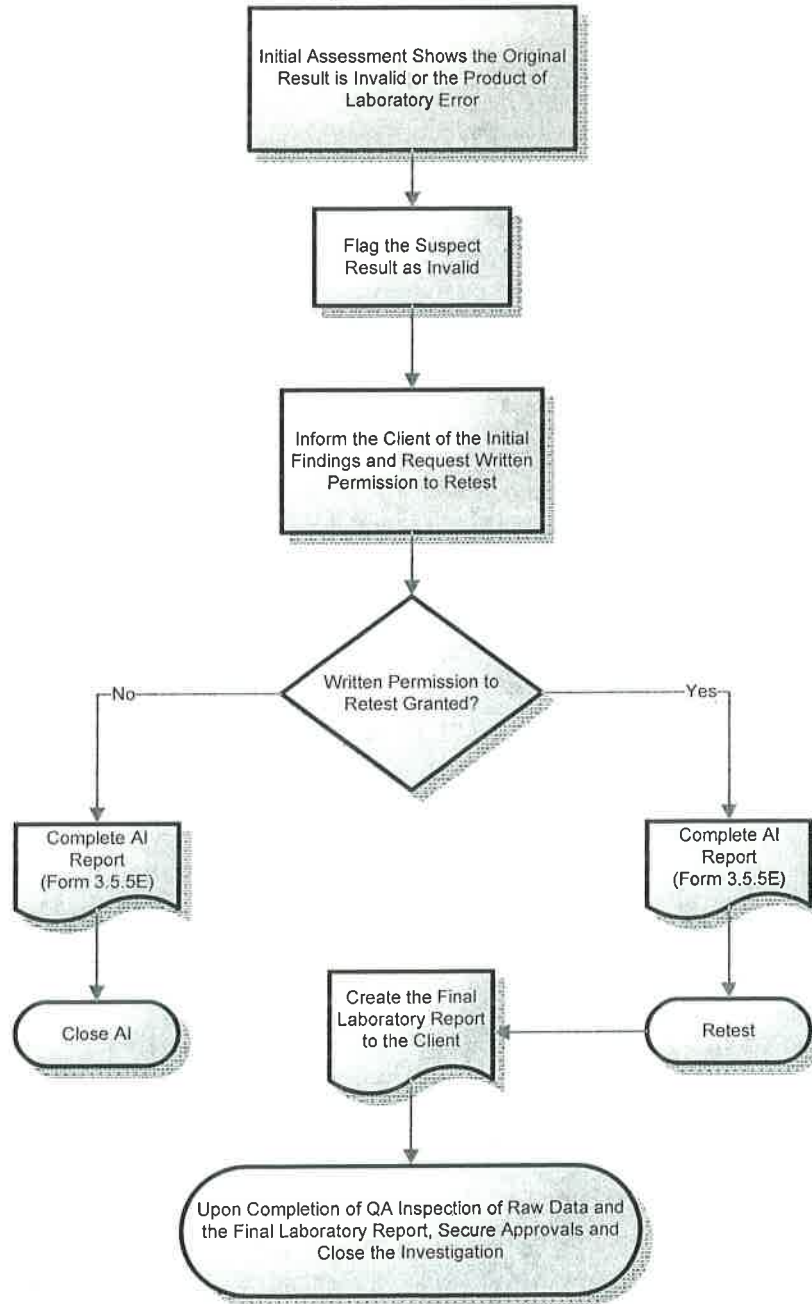
Date: <u>08/17/15</u>	Customer Acct No. <u>E0658</u>
Lab ID# <u>Z-7236</u>	Procedure: <u>FCC 9, Supplement 2</u>
Analyte: <u>Specific Gravity</u>	Test Code <u>100</u>
Project Manager: <u>Sal Pastor</u>	Date of Analysis: <u>08/11/15</u>
Datasheet#: <u>I-170</u>	Run/Inst.#: <u>1 and 2</u>
Result: <u>1.900 and 1.900</u>	Specification: <u>1.1852 – 1.1926</u>
Client notified of OOS by: <input type="checkbox"/> Phone <input checked="" type="checkbox"/> E-mail <input type="checkbox"/> Fax on Date: <u>08/17/15</u>	
15 Business Day Due Date: <u>09/04/15</u>	
Review each of the following elements:	
<input checked="" type="checkbox"/> Details of the procedure with the analyst	<input checked="" type="checkbox"/> Instrument condition
<input checked="" type="checkbox"/> Raw data	<input checked="" type="checkbox"/> Visual inspection of original sample
<input checked="" type="checkbox"/> Calculations	<u>N/A</u> Visual inspection of test solutions (if applicable)
Analyst Comments Initials/Date: <u>JV 8-18-15</u>	
<u>The procedure was followed as written. The maintenance was up-to-date on all instruments. Hydrometer calibrated at 60°F (15.56°C). Sample was liquid (HCl). No sediment in sample could be seen. There was nothing out of the ordinary seen with this sample.</u>	
Supervisor's Comments Initials/Date: <u>AP 8/18/15</u>	
<u>The procedure was followed as written. The raw data and calculations were free of errors. All instrument maintenance was up-to-date and a hydrometer calibrated at 60°F (15.56°C) was used. The sample container was intact. The sample was a clear colorless liquid. Nothing unusual was found.</u>	
Is the OOS result invalid or assignable to laboratory error?	
<input type="checkbox"/> Yes (Complete Section II below and proceed to Short Form Protocol)	
<input checked="" type="checkbox"/> Inconclusive (Proceed to Long Form Protocol)	
<input type="checkbox"/> Not applicable. The result is not OOS. (Note: Complete Form 3.5.5E and close the AI)	
Approved By:	
Technical Manager <u></u>	Date: <u>8/19/15</u>

SECTION II – Complete only if the result is invalid or due to laboratory error

Category of Laboratory Errors (Check)	
<input type="checkbox"/> Known sample mishandling	<input type="checkbox"/> Calculation error requiring re-testing
<input type="checkbox"/> Equipment malfunction	<input type="checkbox"/> Sample matrix problem
<input type="checkbox"/> Improper method	<input type="checkbox"/> Failure to follow method
<input type="checkbox"/> Other (describe): _____	

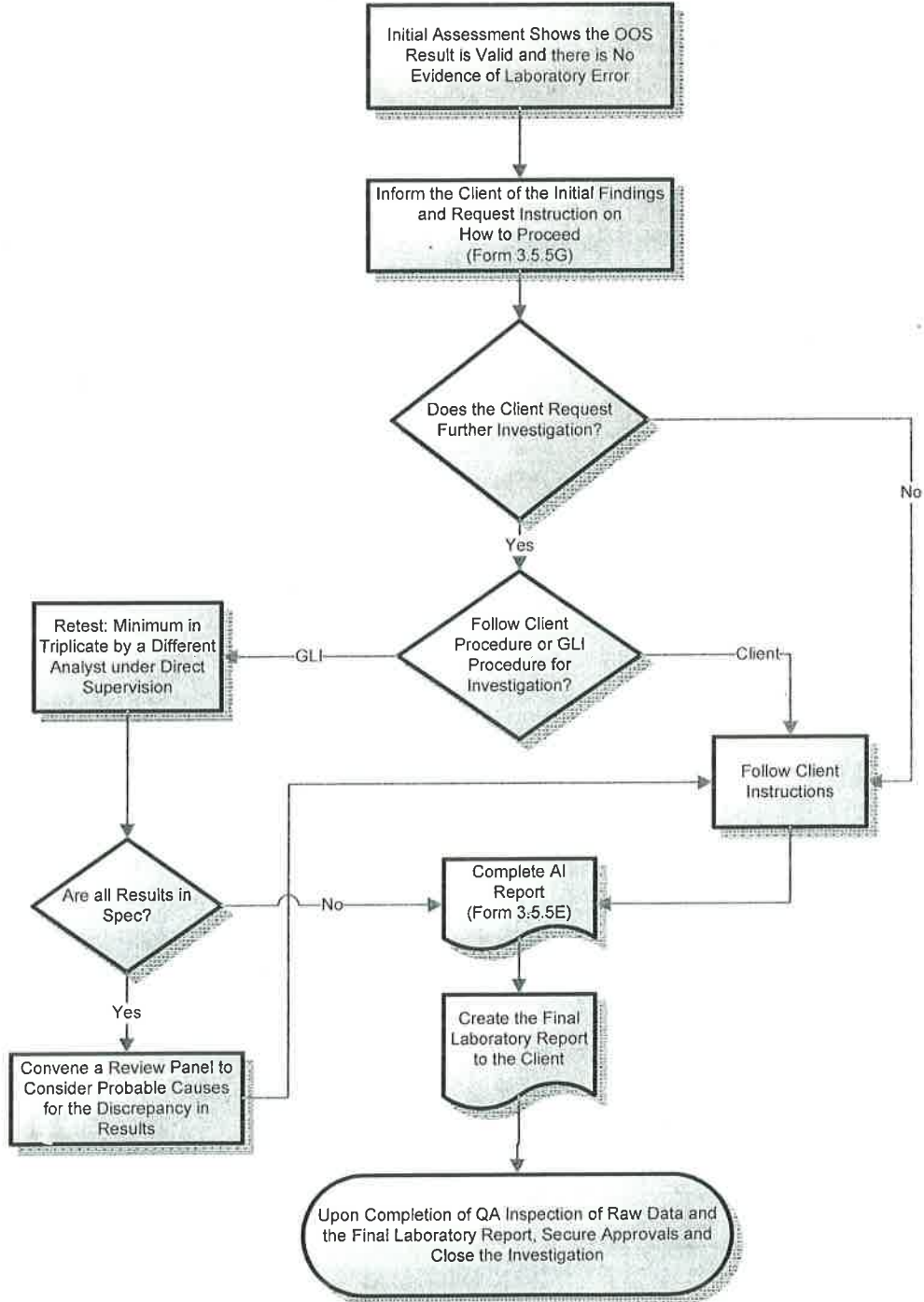
Form 3.5.5B Rev 10

**SHORT FORM PROTOCOL
AI-2015-060**



Form 3.5.5C Rev 5

Long Form Protocol (AI-2015-060)



Form 3.5.5D Rev. 6

ANALYTICAL INVESTIGATION REPORT (AIR)
AI-2015-060

Reason for the investigation:

Sample Z-7236 had failing specific gravity results of 1.900 and 1.900 (duplicate). The client provided specification is 1.1852 – 1.1926.

Probable cause for the OOS result(s):

None identified.

Immediate corrective actions to prevent recurrence:

N/A

Other samples possibly affected:

N/A

Comments:

See attached document.

Report Prepared by: _____

Project Manager or designee

Date

8/31/15

Approved by:

Laboratory Manager

Date

8/31/15

Director of Technical Services

Date

(For Ref) 9/1/15

Quality Assurance Manager

Date

09/01/15

Corporate Review and Assessment:

Accepted with

No further action

CDPS#: 182333 Done 09/01/15

Training assignment to _____

Form 3.5.5E Rev 11

Review Panel Notes from August 26, 2015 Meeting

Investigation: **AI-2015-060**

Sample ID: Lot: 071015-122 HCl (Z-7236)

Participants: Janet Wilshire (Analyst)
Adelle Eberhardt (Dept. Supervisor)
Salvador Pastor (Project Manager)
David Venner (QA Manager)

Overview:

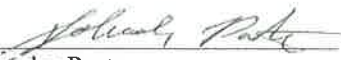
The Z-7236 sample was received on July 22, 2015 with regular turnaround. A mix of USP, FCC, and Reagent Chemicals testing was performed on this approx. 37% Hydrochloric Acid sample material. Of the 30+ tests that were performed on this material, the specific gravity was the only test that was out-of-specification. The client was notified of the out-of-specification results on August 17, 2015 after receiving clarification that the specification is 1.1852 – 1.1926. Repeat testing on 8/24/15 was performed in triplicate with a different analyst and yielded all results that were in specification. Repeat results for Z-7236 were 1.190, 1.190, and 1.190.

Activity Summary:

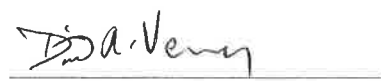
At the panel meeting discussion, the group went over the testing process to identify the issues that are seen. Although the testing process is easily performed, an analyst can sometimes misread numbers on a scale. This translation of the results from the measuring device to the data sheet is prone to errors if the analyst is in a rush or multi-tasking several tasks. We believe that the readings of 1.900 and 1.190 were confused. The Dept. Supervisor and P.M. confirmed that the results of 1.900 are beyond that which is possible with this material type based on known tables of specific gravity.

Conclusion:

The resolution to AI-2015-060 will be to invalidate the original 1.900 results collected for this sample Z-7236. The final report for FCC testing will contain the triplicate retest results of 1.190, 1.190, and 1.190.


Salvador Pastor
Technical Manager

8/31/15
Date


David Venner
Quality Assurance Manager

09/01/15
Date

**GALBRAITH LABORATORIES, INC.
CLIENT OOS NOTIFICATION
AND
RETEST APPROVAL FORM**
AI# AI-2015-060

Client Name Ray Gardner Date 08/19/15
Company The Elco Corporation
Address 1000 Belt Line St, Cleveland OH 44109
Phone 216-749-2605, ext 225
Email rgardner@elcocorp.com

As previously reported, this notice is to inform you that the sample(s) listed below failed to meet the given specification. Test data is as follows:

<u>Sample ID</u>	<u>Lab ID</u>	<u>Analyte</u>	<u>Result Found</u>	<u>Specification</u>
FCC-15-07-002 Lot: 071015-122	Z-7236	Specific Gravity	1.900, 1.900 (dup)	1.1852 – 1.1926

If you have any questions, please contact Sal Pastor, Technical Manager at 1-877-449-8797, ext. 1843 or by email at salpastor@galbraith.com.

The initial assessment of the OOS result(s) has been completed. There is no evidence of laboratory error and the OOS result(s) appear to be valid. Please indicate how you would like us to proceed:

- Retest and investigate according to Galbraith's internal analytical procedures *JK*
 Retest and proceed according to The Elco Corporation enclosed OOS procedure*.
 Do not perform any further testing. Send my laboratory report.
 Other _____

Ray D. Gardner
Client Approval Signature

8/19/15
Date

*Additional fees may apply

Form 3.5.5G Rev 4