

Amended Laboratory Report

Report prepared for:

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Analysis	Method	Result	Basis	Sample Amount Used	Date (Time)
Sample: Quote 7360-T Analysis of HCL GMP/ACS (1470-ML) LOT# 071317-122					
Lab ID: 2017-E-7549		Received: 2017-08-02			
<i>10M: ACS Heavy Metals</i>					
	Reagent Chemicals 11th Ed Supp 1	NMT 1 ppm	As Received	10.08227 g	2017-08-18
<i>408: Color</i>					
	Reagent Chemicals 11th Ed Supp 1	5	As Received	100 mL	2017-08-18
<i>454: Nonvolatile residue</i>					
	Reagent Chemicals 11th Ed Supp 1	< 0.0005 %	As Received	200 g	2017-08-16
<i>711: Ammonium by IC</i>					
	GLI Procedure ME-4D	< 2 ppm	As Received	554.01 mg	2017-08-09
	GLI Procedure ME-4D (matrix spike)	90.07 % Recovery	As Received	553.70 mg	2017-08-09
<i>774: Br/I, Free Br/Cl, SO4/SO3</i>					
	Reagent Chemicals 11th Ed Supp 1 ¹	< 1 ppm	As Received	85 mL	2017-08-15
	Reagent Chemicals 11th Ed Supp 1 ²	< 1 ppm	As Received	50 mL	2017-08-18
	Reagent Chemicals 11th Ed Supp 1 (matrix spike) ³	≥ 1 ppm	As Received	50 mL	2017-08-18
	Reagent Chemicals 11th Ed Supp 1 ⁴	< 1 ppm	As Received	42 mL	2017-08-18
	Reagent Chemicals 11th Ed Supp 1 (matrix spike) ⁵	≥ 1 ppm	As Received	42 mL	2017-08-18
	Reagent Chemicals 11th Ed Supp 1 ⁶	< 0.005 %	As Received	1 mL	2017-09-05
	Reagent Chemicals 11th Ed Supp 1 (matrix spike) ⁷	≥ 0.005 %	As Received	1 mL	2017-09-05
<i>788: Iron Method II</i>					
	Reagent Chemicals 11th Ed Supp 1	< 0.2 ppm	As Received	50.28748 g	2017-08-22
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	≥ 0.2 ppm	As Received	49.75370 g	2017-08-22
<i>Ag : Silver</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	96 % Recovery	As Received	50 mL	2017-08-18
<i>As : Arsenic</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	94 % Recovery	As Received	50 mL	2017-08-18

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Reported results are only applicable to the item tested.

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<i>Bi : Bismuth</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	107 % Recovery	As Received	50 mL	2017-08-18
<i>c33: Arsenic Color Method I</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	≥ 0.01 ppm	As Received	300.031 g	2017-08-15
	Reagent Chemicals 11th Ed Supp 1	< 0.01 ppm	As Received	300.037 g	2017-08-15
<i>Cd : Cadmium</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	100 % Recovery	As Received	50 mL	2017-08-18
<i>Cu : Copper</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	99 % Recovery	As Received	50 mL	2017-08-18
<i>Hg : Mercury</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	94 % Recovery	As Received	50 mL	2017-08-18
<i>j35: Hydrochloric Acid</i>					
	Reagent Chemicals 11th Ed Supp 1	36.83 %	As Received	3.36208 g	2017-08-23
<i>Mo : Molybdenum</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	102 % Recovery	As Received	50 mL	2017-08-18
<i>Pb : Lead</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	100 % Recovery	As Received	50 mL	2017-08-18
<i>Sb : Antimony</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	94 % Recovery	As Received	50 mL	2017-08-18
<i>Sn : Tin</i>					
	Reagent Chemicals 11th Ed Supp 1 (matrix spike)	93 % Recovery	As Received	50 mL	2017-08-18

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

For all samples on this report:

8. 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.
9. The matrix spike analysis was performed to satisfy method requirements. There is no additional charge for the matrix spike result.
10. Amended Report: This report amends data included in report 100567

Signatures:

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