



Report Number: 1347356-1

Report Date: 03-Nov-2015

Report Status: Final

Supersedes : 1347356-0

Certificate of Analysis

Amino Cell, Inc.

3221 NW 10th Terrace

STE 505

Oakland Park Florida 33309 United States

Sample Name:	Chondroitin sulfate-A	Covance Sample:	4391191
Project ID	AMINO_CELL-20151014-0002	Receipt Date	14-Oct-2015
PO Number	15-002	Receipt Condition	Ambient temperature
Lot Number	230913CSA	Login Date	14-Oct-2015
Sample Serving Size		Storage Condition	Ambient temperature
Description	Injectable grade Raw Material	Online Order	10

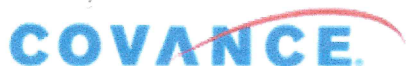
Analysis	Result
Chondroitin Sulfate *	
Chondroitin Sulfate	996 mg/g
Aerobic Plate Count *	
Aerobic Plate Count	<10 CFU/g
E. coli *	
Escherichia Coli	Absent /10 g
Salmonella USP *	
Salmonella	Absent /10 g
Staphylococcus *	
Staphylococcus Aureus	Absent /10 g
Yeast and Mold Count *	
Yeast Count	<10 CFU/g
Mold Count	<10 CFU/g
Preparatory Testing of Nutritional and Dietary Supplements *	
Staphylococcus Suitability Result	Pass**
Aerobic Plate Suitability Result	Pass**
E. coli Suitability Result	Pass**
Yeast and Mold Suitability	Pass**
Salmonella Suitability Result	Pass**
Elements by ICP Mass Spectrometry	
Arsenic	88.1 ppb
Cadmium	<25.0 ppb
Lead	<25.0 ppb
Mercury	<25.0 ppb
Identification by IR *	
Result	Conforms
Spectral Report	See Attachment 1347356-1_0003143773.pdf

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a, 2b and 3 *				
Benzene	2 ppm	2 ppm	<2.0 ppm	Pass
Carbon Tetrachloride	4 ppm	4 ppm	<4.0 ppm	Pass
1,2-Dichloroethane	5 ppm	5 ppm	<5.0 ppm	Pass
1,1-Dichloroethene	8 ppm	8 ppm	<8.0 ppm	Pass
1,1,1-Trichloroethane	10 ppm	1500 ppm	<10.0 ppm	Pass
Acetonitrile	410 ppm	410 ppm	<410 ppm	Pass
Chlorobenzene	360 ppm	360 ppm	<360 ppm	Pass

* This analysis is not ISO accredited.

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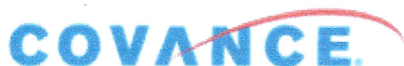
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Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a, 2b and 3 *				
Chloroform	60 ppm	60 ppm	<60.0 ppm	Pass
Cyclohexane	3880 ppm	3880 ppm	<3880 ppm	Pass
1,2-Dichloroethene	1870 ppm	1870 ppm	<1870 ppm	Pass
1,2-Dimethoxyethane	100 ppm	100 ppm	<100 ppm	Pass
1,4-Dioxane	380 ppm	380 ppm	<380 ppm	Pass
Hexane	290 ppm	290 ppm	<290 ppm	Pass
Methanol	3000 ppm	3000 ppm	<3000 ppm	Pass
Methylbutylketone	50 ppm	50 ppm	<50.0 ppm	Pass
Methylcyclohexane	1180 ppm	1180 ppm	<1180 ppm	Pass
Methylene Chloride	600 ppm	600 ppm	<600 ppm	Pass
Nitromethane	50 ppm	50 ppm	<50.0 ppm	Pass
Pyridine	200 ppm	200 ppm	<200 ppm	Pass
Tetrahydrofuran	720 ppm	720 ppm	<720 ppm	Pass
Tetralin	100 ppm	100 ppm	<100 ppm	Pass
Toluene	890 ppm	890 ppm	<890 ppm	Pass
Trichloroethylene	80 ppm	80 ppm	<80.0 ppm	Pass
Xylenes(O,M,P + EB)	2170 ppm	2170 ppm	<2170 ppm	Pass
Acetone	200 ppm	5000 ppm	<200 ppm	Pass
Anisole	200 ppm	5000 ppm	<200 ppm	Pass
1-Butanol	200 ppm	5000 ppm	<200 ppm	Pass
2-Butanol	200 ppm	5000 ppm	<200 ppm	Pass
Acetic Acid Butyl Ester	200 ppm	5000 ppm	<200 ppm	Pass
tert-Butylmethyl Ether	200 ppm	5000 ppm	<200 ppm	Pass
Cumene	70 ppm	70 ppm	<70.0 ppm	Pass
Ethanol	200 ppm	5000 ppm	1590 ppm	Pass
Ethyl Acetate	200 ppm	5000 ppm	<200 ppm	Pass
Diethyl Ether	200 ppm	5000 ppm	<200 ppm	Pass
Ethyl Formate	200 ppm	5000 ppm	<200 ppm	Pass
Heptane	200 ppm	5000 ppm	<200 ppm	Pass
Isobutyl Acetate	200 ppm	5000 ppm	<200 ppm	Pass
Isopropyl Acetate	200 ppm	5000 ppm	<200 ppm	Pass
Methyl Acetate	200 ppm	5000 ppm	<200 ppm	Pass
3-Methyl-1-butanol	200 ppm	5000 ppm	<200 ppm	Pass

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Description	Injectable grade Raw Material	Online Order	10

Analysis	LOQ	Limit	Result	Pass/Fail
Residual Solvents - Class 1, 2a, 2b and 3 *				
Methylethylketone	200 ppm	5000 ppm	<200 ppm	Pass
Methylisobutylketone	200 ppm	5000 ppm	<200 ppm	Pass
2-Methyl-1-propanol	200 ppm	5000 ppm	<200 ppm	Pass
n-Pentane	200 ppm	5000 ppm	<200 ppm	Pass
1-Pentanol	200 ppm	5000 ppm	<200 ppm	Pass
1-Propanol	200 ppm	5000 ppm	<200 ppm	Pass
2-Propanol	200 ppm	5000 ppm	<200 ppm	Pass
Propyl Acetate	200 ppm	5000 ppm	<200 ppm	Pass
Total Class 3 Residual Solvents	5000 ppm	5000 ppm	<5000 ppm	Pass

Method References

Testing Location

Aerobic Plate Count (USPC2021:6)

Covance Laboratories - Madison NE

USP Current revision, Chapter 2021.

To satisfy the requirements of the USP, the Preparatory Test must be completed on each matrix.

**Based on the results of the preparatory test, the detection limit stipulated is adequate for the enumeration of the specified microorganisms.

Chondroitin Sulfate (CHON_S:4)

Covance Laboratories - Madison

The United States Pharmacopeia, Thirty Fourth Revision, USP Convention, Inc.:
Rockville, MD (2011)(Modified).

E. coli (USPE2022:6)

Covance Laboratories - Madison NE

USP Current revision, Chapter 2022.

To satisfy the requirements of the USP, the Preparatory Test must be completed on each matrix.

**Based on the results of the preparatory test, conditions stipulated are adequate for detecting the presence of the specified microorganism.



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Method References	Testing Location
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Elements by ICP Mass Spectrometry (ICP_MS_S:21)

Covance Laboratories - Madison

Official Methods of Analysis, Method 2011.19 and 993.14, AOAC INTERNATIONAL, (Modified).

Identification by IR (ID_IR:13)

Covance Laboratories - Madison

United States Pharmacopeia, 38th Revision - National Formulary 33rd Edition, USP Convention, Rockville, MD 20852 (2014). (Modified)

Preparatory Testing of Nutritional and Dietary Supplements (USPA_PT:2)

Covance Laboratories - Madison NE

Preparatory Testing of Nutritional and Dietary Supplements (USPC_PT:4)

Covance Laboratories - Madison NE

Preparatory Testing of Nutritional and Dietary Supplements (USPE_PT:2)

Covance Laboratories - Madison NE

Preparatory Testing of Nutritional and Dietary Supplements (USPM_PT:4)

Covance Laboratories - Madison NE

Preparatory Testing of Nutritional and Dietary Supplements (USPS_PT:2)

Covance Laboratories - Madison NE

Residual Solvents - Class 1, 2a, 2b and 3 (USPR_S:14)

Covance Laboratories - Madison

United States Pharmacopeia, 38nd Rev. - National Formulary 33th Ed., Method <467>, USP Convention, Inc., Rockville, MD (2015). (Modified).

Salmonella USP (USPS2022:6)

Covance Laboratories - Madison NE

USP Current revision, Chapter 2022.

To satisfy the requirements of the USP, the Preparatory Test must be completed on each matrix.

**Based on the results of the preparatory test, conditions stipulated are adequate for detecting the presence of the specified microorganism.

Staphylococcus (USPA2022:7)

Covance Laboratories - Madison NE

USP Current revision, Chapter 2022.

To satisfy the requirements of the USP, the Preparatory Test must be completed on each matrix.

**Based on the results of the preparatory test, conditions stipulated are adequate for detecting the presence of the specified microorganism.

Certificate of Analysis

Amino Cell, Inc.

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 Oakland Park Florida 33309 United States

Method References

Testing Location

Yeast and Mold Count (USPM2021:7)

Covance Laboratories - Madison NE

USP Current revision, Chapter 2021.

To satisfy the requirements of the USP, the Preparatory Test must be completed on each matrix.

**Based on the results of the preparatory test, the detection limit stipulated is adequate for the enumeration of the specified microorganisms.

Testing Location(s)

Released on Behalf of Covance by

Covance Laboratories - Madison

Lori Ross - Associate Director

Covance Laboratories Inc.
 3301 Kinsman Blvd
 Madison WI 53704
 800-675-8375 x4170



2918.01

Covance Laboratories - Madison NE

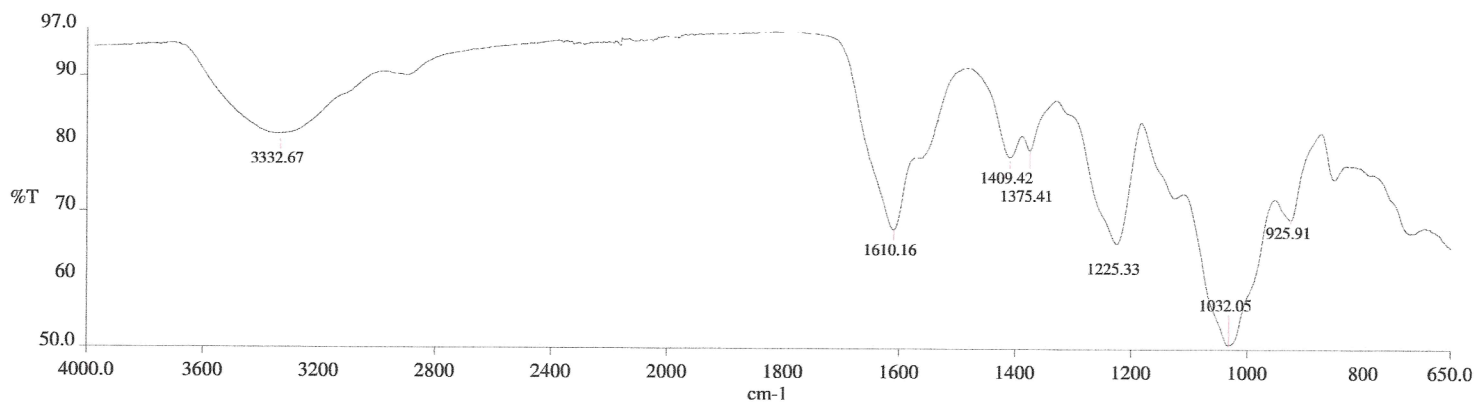
Lori Ross - Associate Director

Covance Laboratories Inc.
 2102 Wright Street
 Madison WI 53704
 855-83-MICRO

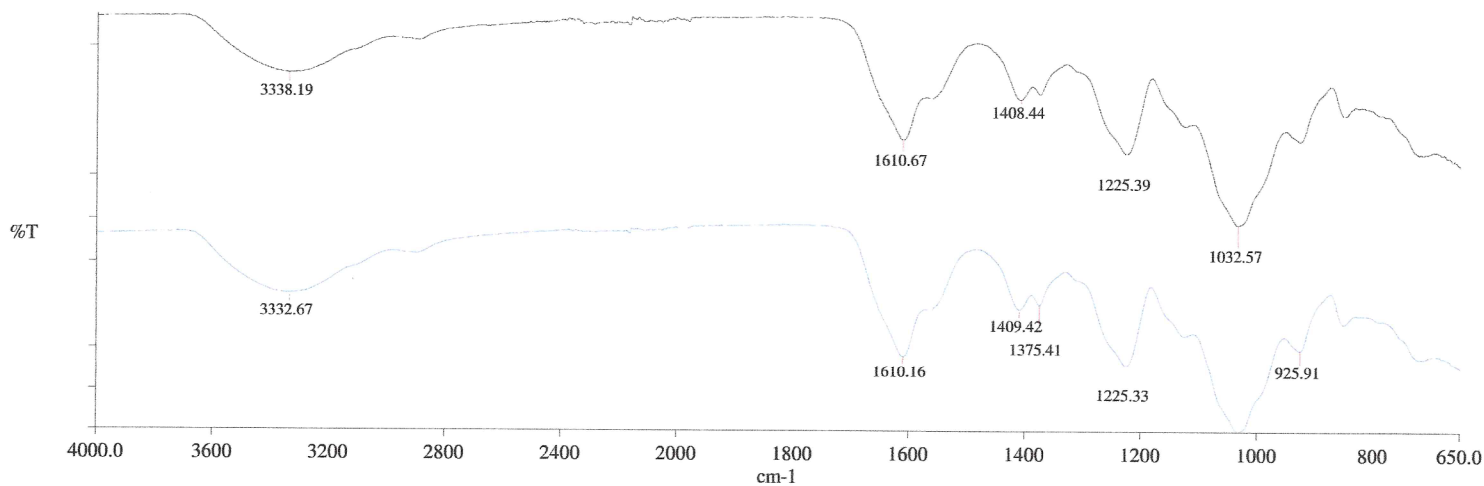
These results apply only to the items tested. This certificate of analysis shall not be reproduced, except in its entirety, without the written approval of Covance.

PerkinElmer Spectrum 100 Spectrometer SN: 79160
Spectrum ES v. 6.3.0.0126
ir accessory: Universal ATR
date created: Tuesday, November 03, 2015 12:00 PM Central Standard Time

Covance Laboratories, Inc.
Infrared Absorption Report
analyst: Ryan Rysewyk (ryrysewy)



—— NIMS# 4391200 (Chondroitin Sulfate).sp - 11/3/2015 - Chondroitin Sulfate



—— Chondroitin Sulfate Sodium_1.sp - 10/29/2008 - Sigma Lot 037K1061

—— NIMS# 4391200 (Chondroitin Sulfate).sp - 11/3/2015 - Chondroitin Sulfate