

Title: LipoPhos EDTA, 2 oz	
Allergy Research Group® / NutriCology®	
Document No.: 75120CA	Revision: 012

Certificate of Analysis

Part Number	75120		
Lot Number	171111		
Product Count & Form	2 oz liquid		
Packaging, Closure	20/410 Black dispensing smooth flat disc-top, 0.270" ORIF Caps; Amber 20/410 2 oz. Pet Boston round bottles		
Storage Condition	Room Temperature, Refrigerate after opening		
Shelf Life	18 months	Expiration Date	08/2021
Label Number, Size	75120L, A		
Retain Sample	1 bottle total		

ANALYSIS

Physical

Attribute	Method / SOP	Specification	Test Result
Product Color	SOP 515	Yellow	Complies
Product Odor	SOP 515	Acceptable Odor	Complies

Purity/Strength per 2 Tablespoons (30 mL)

Active Ingredients	Label Claim	Release Limits	Test Result
Essential Phospholipids (sunflower lecithin)	2.5 g	100-150% LC by P-NMR	3.7g
Calcium Sodium EDTA	1 g	100-150% LC by ICP-OES	100-150% LC by ICP-OES*
Alpha Lipoic Acid	50 mg	100-150% LC by HPLC	100-150% LC by HPLC*
Magnesium (as Magnesium Chloride)	40 mg	100-150% LC by HPLC	100-150% LC by HPLC*
Other Ingredients			
Deionized water, organic cane alcohol, xanthan gum, potassium sorbate.			

*Production and Process Control

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Identification \ Chemical \ Heavy Metals


Attribute	Method / SOP	Specification	Test Result
Identity	Bulk Certificate of Analysis Review	Approved	Approved
Arsenic (inorganic)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	1.740 mcg/day
Cadmium	ICP-MS per USP <2232>	≤ 5 mcg/day Ψ	0.120 mcg/day
Mercury (total)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	BQL
Lead	ICP-MS per USP <2232>	≤ 10 mcg/day Ψ	0.510 mcg/day

*Production and Process Control, Ψ – Permitted Daily Exposure. BQL – Below Quantitative Level.

Microbiology

Attribute	Method / SOP	Specification	Test Result
Total Aerobic Count	USP/ AOAC/ FDA BAM	≤ 1 x 10 ⁴ CFU/g	<10 CFU/g
Total Yeast & Mold	USP/ AOAC/ FDA BAM	≤ 1 x 10 ³ CFU/g	<10 CFU/g
Coliform	USP/ AOAC/ FDA BAM	≤ 1 x 10 ² CFU/g	<10 CFU/g
Escherichia coli	USP/ AOAC/ FDA BAM	None Detected	None Detected
Staphylococcus aureus	USP/ AOAC/ FDA BAM	None Detected	None Detected
Salmonella	USP/ AOAC/ FDA BAM	None Detected	None Detected

*Production and Process Control

Approval: 	Digitally signed by Kimberly Vennebush Date: 2020.04.29 08:30:47 -06'00'	Date: 29APR2020
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If you liked our service, please tell a friend. If you didn't, please tell us!

Test Certificate

Description: LipoPhos EDTA
Sample ID: 85120/171111
Lot No:
Location:
Received: 2/27/2020
Completed: 3/4/2020Client: Allergy Research Group
2300 N Loop Rd.
Alameda, CA 94502

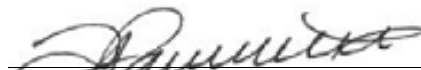
Lab No: 189793-01

Analysis	Result	Per Unit	Specifications	Method
Total Aerobic Microbial Count	<10	CFU/g	<= 10,000 CFU/g	USP <2021>
Coliform	<10	CFU/g	<= 100 CFU/g	AOAC 991.14
E Coli	Absent	per 10 grams	Absent	USP <2022>
Salmonella	Absent	per 10 grams	Absent	USP <2022>
Staphylococcus aureus	Absent	per 10 grams	Absent	USP <2022>
Total Yeast & Mold	<10	CFU/g	<= 1,000 CFU/g	USP <2021>
Yeast *	<10	CFU/g	<= 1,000 CFU/g	
Mold *	<10	CFU/g	<= 1,000 CFU/g	

THESE RESULTS APPLY ONLY TO THE SAMPLE SUBMITTED AND NOT TO THE PRODUCT FROM WHICH IT WAS TAKEN. THESE RESULTS ARE PROVIDED ONLY FOR THE BENEFIT OF CLIENT, WITHOUT REPRESENTATION OR WARRANTY OF ANY KIND, EXCEPT FOR THE EXPRESS LIMITED WARRANTY PROVIDED SOLELY TO CLIENT IN ADVANCED LABORATORIES' TERMS OF SERVICE.

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Results Approved By:


Alisa Farnsworth-Quality Technician

Dated:

3/4/2020

Printed: 3/4/2020 10:41:39 AM





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Phone: (801) 485-1800 Fax: (801) 484-9211
Email: utlab@advancedlabsinc.com
FDA Registration #14353128308

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Test Certificate

Description: LipoPhos EDTA
Sample ID: 85120/171111
Lot No:
Location:
Received: 2/27/2020
Completed: 3/4/2020

Client: Allergy Research Group
2300 N Loop Rd.
Alameda, CA 94502

Lab No: 189796-01

Analysis	Result	Per Unit	Specifications	Method
Mercury	< 0.001	µg / g	<= 0.5 µg / g	ICP-MS USP <730>
Lead	0.017	µg / g	<= 0.5 µg / g	ICP-MS USP <730>
Arsenic	0.058	µg / g	<= 0.5 µg / g	ICP-MS USP <730>
Cadmium	0.004	µg / g	<= 0.5 µg / g	ICP-MS USP <730>

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Results Approved By:
Alisa Farnsworth-Quality Technician

Dated: 3/4/2020

Printed: 3/4/2020 4:50:58 PM



March 20, 2020

Kimberly Vennebush
Allergy Research Group
2300 S Main St
South Salt Lake, UT 84115
510.263.2000
QCGroup@allergyresearchgroup.com

Quantitative ³¹P-NMR Analysis of LipoPhos EDTA Sample

Sample ID: LipoPhos EDTA, Part Number: 85120, Lot Number: 171111

Reference: SO-001056

Sample Received: March 5, 2020

Sample Storage Conditions: Ambient

Method:

Quantitative ³¹P-NMR analysis was performed on a solution prepared by adding 1 mL sample to 25 mL cholate detergent system. The solution was analyzed on a Bruker AVANCE III 400 MHz NMR spectrometer with Prodigy cryoprobe. Standard and sample solutions were assayed at 64 scans. Phospholipid peaks in the sample spectrum were identified based on their chemical shifts as compared to known reference materials. The molar response of a dioleoyl phosphatidylcholine solution of known concentration was used to calibrate the identified phospholipids in the sample, and a dioleoyl phosphatidylethanolamine solution of known concentration was used as a control. Recovery of the dioleoyl phosphatidylethanolamine (PE) control solution was required to meet the specification of 98.0%-102.0% to ensure method suitability; recovery was 98.8%. The molecular weight of phospholipid species used in calculations was based on normalized soy molecular weights.

Results:

Phospholipid content of the sample in mg/mL, g/30 mL, and wt/wt% is given in Table 1. The ³¹P NMR spectrum is provided in Figure 1.

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Table 1. Phospholipid Content of LipoPhos EDTA, Part Number: 85120, Lot Number: 171111 by QPNMR.

Compound	ppm	mM	MW	mg/mL	g/30 mL	wt/wt%
Lysophosphatidic Acid (LPA (sn-1))	--	--	430	--	--	--
Lysophosphatidic Acid (LPA (sn-2))	--	--	430	--	--	--
Phosphatidic Acid (PA)	--	--	685	--	--	--
Phosphate (PO ₄)	--	--	98	--	--	--
Lysophosphatidylglycerol (LPG (sn-1))	--	--	503	--	--	--
Lysophosphatidylglycerol (LPG (sn-2))	--	--	503	--	--	--
Glycerophosphoethanolamine	--	--	215.1	--	--	--
Phosphatidylglycerol (PG)	--	--	758	--	--	--
Lysophosphatidylethanolamine (LPE (sn-1))	--	--	470	--	--	--
Lysophosphatidylethanolamine (LPE (sn-2))	--	--	470	--	--	--
Lysophosphatidylserine (LPS (sn-1))	--	--	517	--	--	--
Glycerophosphocholine (GPC)	--	--	258.1	--	--	--
Lysophosphatidylserine (LPS (sn-2))	--	--	517	--	--	--
Lysophosphatidylinositol (LPI (sn-1))	--	--	570	--	--	--
Phosphatidylethanolamine (PE)	-0.28	0.7361	725	13.34	0.400	0.13
Lysophosphatidylcholine (LPC (sn-1))	-0.39	0.2952	515	3.80	0.114	0.04
Lysophosphatidylinositol (LPI (sn-2))	--	--	570	--	--	--
Phosphatidylserine (PS)	--	--	797	--	--	--
Lysophosphatidylcholine (LPC (sn-2))	--	--	515	--	--	--
Phosphatidylinositol (PI)	--	--	835	--	--	--
Phosphatidylcholine (PC)	-0.85	5.5292	770	106.44	3.193	1.07
Total	N/A	6.5605	N/A	123.6	3.7	1.2

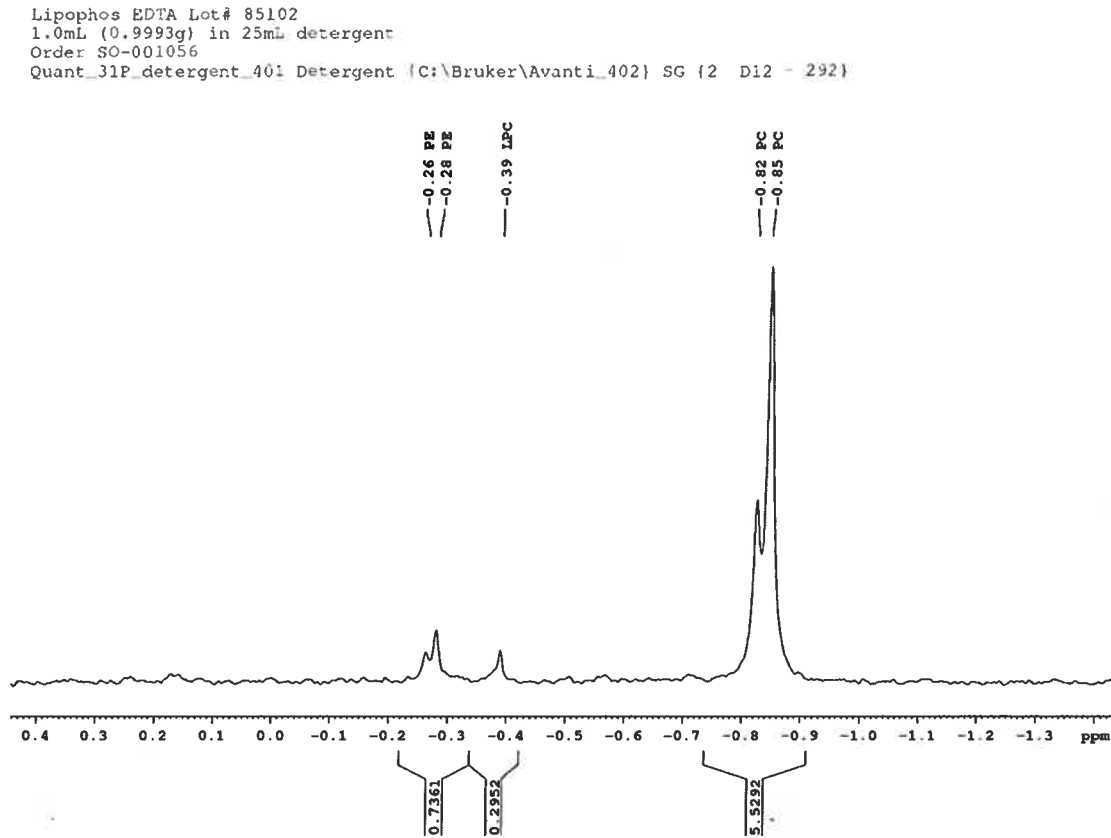
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Figure 1. ³¹P NMR Spectrum of LipoPhos EDTA, Part Number: 85120, Lot Number: 171111.



Specifications:

Report g/30 mL and % weight

Conclusion:

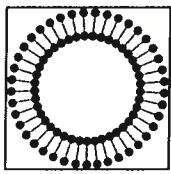
The product contains 3.7 g/30 mL and 1.2% (wt/wt) total phospholipids.

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Analytical Services

This analysis was conducted in a Quality Control Laboratory by a trained analyst and is intended for research use only. All work is documented and reviewed by a second trained analyst but does not involve the review of the cGMP Quality unit of Avanti. This analysis was conducted outside the scope of cGMP. Samples will be discarded 30 days after report has been issued unless additional testing has been requested.

Signature / Date: Shailish Gandhi / MARCH 20TH 2020
Shailish Gandhi, Ph.D.
Quality Control Analyst

Signature / Date: Lolli Meeks 03-23-20
Lolli Meeks, M.S.
Analytical Manager of Research Release

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