

Title: PhosSerine Complex, 90 vegetarian capsules	
Allergy Research Group* / NutriCology*	
Document No.: 72571CA	Revision: 003

Certificate of Analysis

Part Number	72571		
Lot Number	9734		
Product Count & Form	90 vegetarian capsules		
Packaging, Closure	150 cc bottle, desiccant, cotton		
Storage Condition	Room Temperature		
Shelf Life	24 months	Expiration Date	07/21
Label Number, Size	72571L, C		
Retain Sample	2 bottles total - unopened		

ANALYSIS

Physical

Attribute	Method / SOP	Specification	Test Result
Product Color, Size	SOP 515	Tan- beige, clear Veg Cap Size "0"	Complies
Product Weight	SOP 514	Meets USP <2091> 470- 590 mg	Pass, 547 mg†
Disintegration Time	SOP 522	Meet USP <2040>	Pass, 26 minutes†

† Per FTI's CofA

Purity/Strength per Capsule

Active Ingredients	Label Claim	Release Limits/ Test Method	Test Result
Phosphatidylserine (PS) (sunflower)	100 mg	100-150% LC by ³¹ P-NMR	120.7 mg
Phosphatidic acid (PA) (sunflower)	90 mg	100-150% LC by ³¹ P-NMR	92.4 mg
Other Phospholipids (sunflower)	35 mg	100-150% LC by ³¹ P-NMR	41.1 mg
Other ingredients			
Hydroxypropyl Methylcellulose, Silicon Dioxide, L- Leucine			

¹ ³¹P-NMR Spectroscopy.

Title: PhosSerine Complex, 90 vegetarian capsules	
Allergy Research Group* / NutriCology*	
Document No.: 72571CA	Revision: 003

Identification \ Chemical \ Heavy Metals

Attribute	Method / SOP	Specification	Test Result
Identity	Bulk Certificate of Analysis Review	Approved	Complies
Identity	Near Infrared Spectroscopy	Matches Reference	Complies
Arsenic (inorganic)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	BQL
Cadmium	ICP-MS per USP <2232>	≤ 5 mcg/day Ψ	BQL
Mercury (total)	ICP-MS per USP <2232>	≤ 15 mcg/day Ψ	BQL
Lead	ICP-MS per USP <2232>	≤ 10 mcg/day Ψ	0.3795 mcg/day

*Production and Process Control, Ψ – Permitted Daily Exposure, BQL= Below quantitation limit

Microbiology

Attribute	Method / SOP	Specification	Test Result
Total Aerobic Count	USP/ AOAC/ FDA BAM	≤ 1 x 10 ⁴ CFU/g	750 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
Escherichi 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: 	Date: 10/16/19
---	----------------

September 4, 2019

Jing Lu
Allergy Research Group
2300 North Loop Road
Alameda, CA 94502
510.263.2000
QCgroup@allergyresearchgroup.com

Quantitative ³¹P-NMR Analysis of Phosserine Complex Capsule

Sample ID: Phosserine Complex, Item: 42571, Lot: G9734

Reference: SO-000795

Sample Received: August 14, 2019

Sample Storage Conditions: Ambient

Method:

Approximately 30 mg sample was extracted with 2.0mL chloroform-d:methanol(1:1) and 1.0mL Cesium-EDTA solution. The phospholipid solution in chloroform-d was analyzed at 32 scans on a Bruker AVANCE III 400 MHz NMR spectrometer with Prodigy cryoprobe. Phospholipid peaks in the sample spectrum were identified based on their chemical shifts as compared to known reference materials. The molar phosphorus response was calibrated with an internal standard, triphenyl phosphate. Recovery of a dioleoyl phosphatidylcholine (PC) control solution was required to meet the specification of 98.0%-102.0% to ensure method suitability; recovery was 99.1%. The molecular weight of phospholipid species used in calculations was based on normalized soy molecular weights, and the molecular weight of PC (770) was used to calculate the amount of unknown component.

Results:

Phospholipid content of the sample in mg/capsule is given in Table 1. The ³¹P NMR spectrum is provided in Figure 1.

More Than Lipids

Solutions for the entire product cycle: Research to Commercialization

Avanti Polar Lipids, Inc., 700 Industrial Park Dr., Alabaster, Alabama 35007

Phone: 1-800-227-0651 | (205) 663-2494

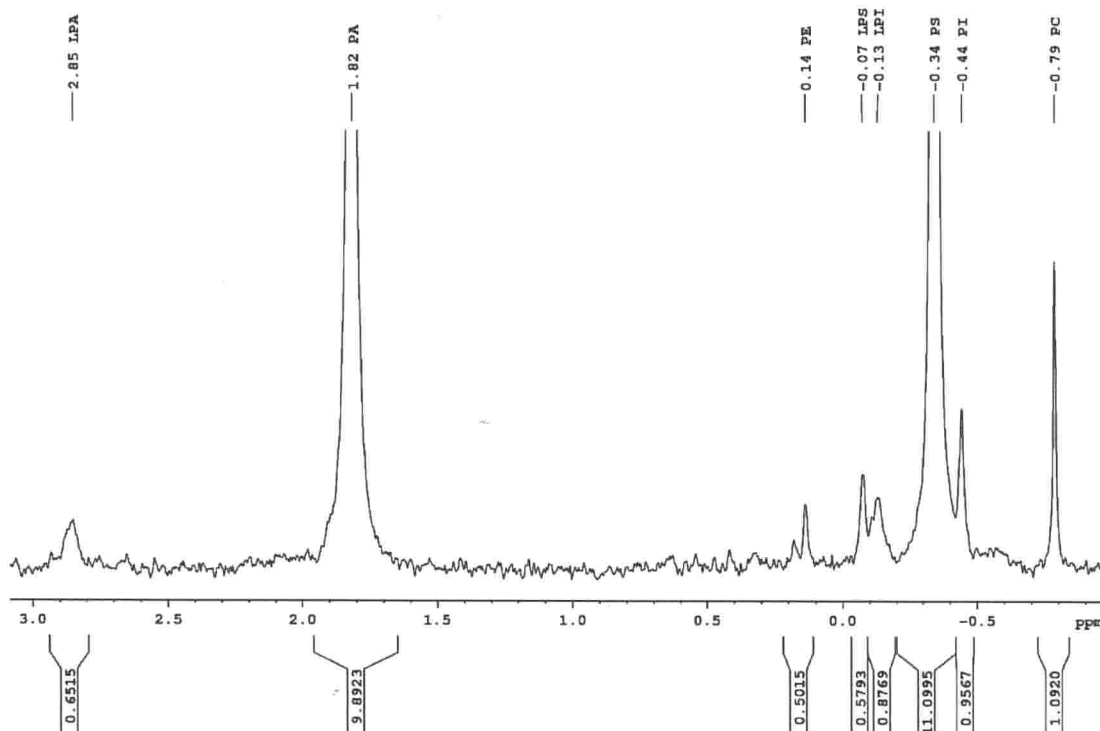
www.avantilipids.com

Table 1. Phospholipid Content of Phosserine Complex, Item: 42571, Lot: G9734 by QPNMR.

Compound	ppm	mM	MW	mg/capsule
Lysophosphatidic Acid (LPA (sn-1))	2.85	0.6515	430	3.8
Phosphatidic Acid (PA)	1.82	9.8923	685	92.4
Lysophosphatidylethanolamine (LPE (sn-1))	--	--	470	--
Phosphatidylethanolamine (PE)	0.14	0.5015	725	5.0
Lysophosphatidylserine (LPS (sn-1))	-0.07	0.58	470	3.7
Lysophosphatidyinositol (LPI (sn-1))	-0.13	0.8769	515	6.2
Phosphatidylserine (PS)	-0.34	11.0995	797	120.7
Phosphatidylinositol (PI)	-0.44	0.9567	835	10.9
Phosphatidylcholine (PC)	-0.79	1.0920	770	11.5
Total Phospholipid	N/A	25.6497	N/A	254.2

Figure 1. ³¹P NMR Spectrum of Phosserine Complex, Item: 42571, Lot: G9734 by QPNMR.

Phosserine Complex PS Capsules Item: 42571; Lot# G9734
 30.1mg of the composite fill material from 5 capsules + 10.0mg TPF in 1.0mL CDC
 Order SO-000795
 Quant_31P_biphasic CDC13 [C:\Bruker\Avanti_402} SG {4 H2 - 416}



More Than Lipids

Solutions for the entire product cycle: Research to Commercialization

Avanti Polar Lipids, Inc., 700 Industrial Park Dr., Alabaster, Alabama 35007

Phone: 1-800-227-0651 | (205) 663-2494

www.avantilipids.com

Specifications:

Phosphatidylserine: 100 mg/capsule
Phosphatidic acid: 100 mg/capsule

Conclusion:

The product meets the provided specification of 100 mg phosphatidylserine per capsule with a result of 120.7 mg/capsule phosphatidylserine, but fails to meet the provided specification of 100 mg per capsule phosphatidic acid with a result of 92.4 mg/capsule.

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: Shafesh Gandhi / 09-04-19.
Shafesh Gandhi, Ph.D.
Quality Control Analyst

Signature / Date: Lolli Meeks / 09-04-19
Lolli Meeks, M.S.
Analytical Manager of Research Release

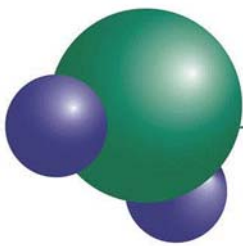
More Than Lipids

Solutions for the entire product cycle: Research to Commercialization

Avanti Polar Lipids, Inc., 700 Industrial Park Dr., Alabaster, Alabama 35007

Phone: 1-800-227-0651 | (205) 663-2494

www.avantilipids.com



Analytical Report

August 16, 2019

Tuyen Luong
Allergy Research Group/NutriCology
2300 North Loop Road
Alameda, CA 94502

Page 1 of 1
WO Number: W19H0475

Client: Allergy Research Group-QC
Client #: A5537-T
Sample Type: Capsule
Collector: Client

Customer PO: LJ08132019
Date Received: 8/14/2019
Date Completed: 08/16/2019
Discard Date: 08/30/2019

CSL#: 19H1092 Phosserine Complex - Lot#: 42571/ G9734

Parameter	Result	PQL	Method	Date	Analyst
Arsenic	<0.050 ug/g	0.050	ICP MS	08/15/19	JTP
Cadmium	<0.050 ug/g	0.050	ICP MS	08/15/19	JTP
Lead	0.23 ug/g	0.050	ICP MS	08/14/19	JTP
Mercury	<0.050 ug/g	0.050	ICP MS	08/15/19	JTP

CSL#: 19H1092

Parameter	Result	Serving Size	Unit Weight	Specification
Arsenic	<0.05 ug/g	1 Capsule	0.55 g	<0.50 ug/g
Cadmium	<0.05 ug/g	1 Capsule	0.55 g	<0.50 ug/g
Lead	0.23 ug/g	1 Capsule	0.55 g	<0.50 ug/g
Mercury	<0.05 ug/g	1 Capsule	0.55 g	<0.50 ug/g

Respectfully Submitted,
Chemical Solutions, Ltd.

QA Representative

Notes:

CONFIDENTIAL REPORT. This report is confidential and is for the sole use of the addressee.
This report can only be reproduced in full.
The units for the PQL are the same as those shown for the result.



466 Kato Terrace,
Fremont, CA 94539
Phone: 510-979-1979
Fax: 510-668-1980
E-mail: labdata@aemtek.com
Web: www.aemtek.com

Project Description: Product Testing (PO # LJ08132019)
Report Issued To: Allergy Research Group
2300 North Loop Rd.
Alameda, CA 94502
Contact: Janice Vu

Certificate of Analysis

AEMTEK #: 1908683

Sampling Date: 2019-08-13
Sample Received: 2019-08-14
Analysis Started: 2019-08-14
Analysis Performed By: JC, WY
Report Issue Date: 2019-08-17

Sample ID	Analyte	Aerobic Plate Count	Total Coliforms	Yeast	Mold	Escherichia coli	Salmonella	Staphylococcus aureus
5	Phosserine Complex	AOAC OMA 990.72 CFU/g 10	AOAC OMA 991.14 CFU/g 10	AOAC OMA 2014.05 CFU/g 10	AOAC OMA 2014.05 CFU/g 10	USP 37 <62> (mod.) per 10g P/A	USP 37 <62> (mod.) per 10g P/A	USP 37 <62> (mod.) per 10g P/A
RESULTS								
	Method Description	Lot #/Code						
	Phosserine Complex	42571/ G9734	<10	<10	<10	ND	ND	ND

Terminology:
 CFU = Colony Forming Units
 < Indicates less than the reporting limit as noted
 ND = Not Detected, negative, absent. Sensitivity is about 1 organism per test portion.
 BAM = FDA Bacteriological Analytical Manual
 AOAC OMA = Official Methods of Analysis of the AOAC International, 18th ed.

MPN = Most Probable Number
 P/A = Presence/Absence
 CP Staph = Coagulase Positive Staphylococci (Staphylococcus aureus)
 CMMEF = Compendium of Methods for the Microbiological Examination of Foods, 4th ed.
 AOAC RI = AOAC Research Institute Performance Tested.

ju 08115 119