FINAL STUDY REPORT

Work Order: HEA-0001-FSR-c60_oils_HPLC_quantification

Contract research analysis of C60 content in Oil Samples by HPLC

SPONSOR:

Heathy Action
499 Blue Knob Rd,
Blue Knob, NSW, Australia

TESTING FACILITY:

Ichor Therapeutics, Inc.
2521 US Route 11
LaFayette, NY 13084 United States

June 28th, 2018

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COMPLIANCE STATEMENT

This study was considered research grade and was not performed in accordance with the U.S. Department of Health and Human Services, Food and Drug Administration (FDA), United States Code of Federal Regulations, Title 21, Part 58: Good Laboratory Practice for Nonclinical Laboratory Studies.

This study was conducted in accordance with the procedures described herein. All deviations reported by the QAU and authorized/acknowledged by the Study Director are documented in the Study Records; and if there had been deviations, they would appear as CAPA investigation(s) in the study appendices. The report represents an accurate and complete record of the results obtained.

There were no deviations that affected the overall integrity of the study or the interpretation of the study results and conclusion

QUALITY ASSURANCE STATEMENT

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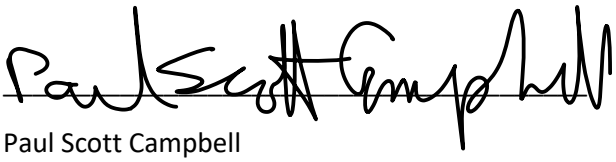
This study has been inspected by the Quality Assurance Unit (QAU) to assure conformance with the applicable Ichor Therapeutics requirements for research level (non-GLP) studies. Reports were submitted in accordance with SOPs and study methods.

There were no QAU inspections resulting in observations requiring investigations and resolution specific to this study. Any identified observations/deviations requiring investigations would have been performed as CAPA investigations, reported by the QAU to the Study Director and Management, and included in the appendices.

The Final Report has been reviewed to assure that it accurately describes the materials and methods, and that the reported results accurately reflect the raw data. Further, any investigations conducted by the QAU, specific to this study are documented as CAPA investigation(s) and are included in the study appendices.



6/28/2018

Paul Scott Campbell
Quality Assurance Director
Ichor Therapeutics, Inc.

Date

RESPONSIBLE PERSONNEL

Study Director		Aaron Wolfe
Testing Facility Management		Kelsey Moody Chief Executive Officer
Director of Operations		Aaron Wolfe Chief Operations Officer
Principal Investigators:		
Analytical Chemistry		Kris Grohn

SUMMARY

Samples were received on 6/26/18. On 6/27/18, 100 µL of each sample was diluted to 1mL in toluene in triplicate. Ten microliters of each sample were then injected into a Perkin Elmer LC Flexar system with an attached Waters Atlantis dC18 analytical column (4.6 * 150 mm, 3 µM particle size). The instrument was conditioned with a mobile phase composed of 70% toluene and 30% acetonitrile. The flow rate of the method was 0.5 mL/min, and detection was performed via absorbance at 330 nm. Data report was compiled 6/28/18.

A standard curve and 5 replicates of a 0.125 mg/mL standard solution of C60 were prepared and analyzed during the same instrument run as the primary samples to assess system suitability, repeatability, and system performance.

RESULTS

All samples showed detectable amounts of C60 with high precision within sample sets.

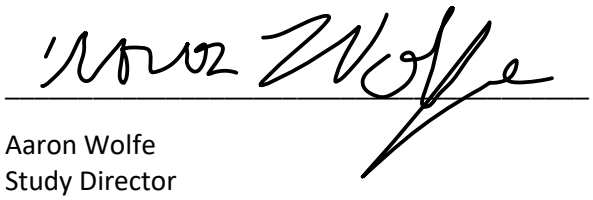
Standard curves were well within specifications and matched previous curves run on this instrument.

All system suitability and repeatability assessments passed.

Sample concentrations are as follows:

- Sample A (Coconut Oil): 0.884 mg/mL C60. Standard deviation of the sample set was 9 µg/mL
- Sample B (Olive Oil): 0.952 mg/mL C60. Standard deviation of the sample set was 4 µg/mL
- Sample C (Avocado Oil): 0.943 mg/mL C60. Standard deviation of the sample set was 28 µg/mL

REPORT APPROVAL



7/5/18

Aaron Wolfe
Study Director
Chief Operations Officer
Ichor Therapeutics, Inc.

Date

FIGURES

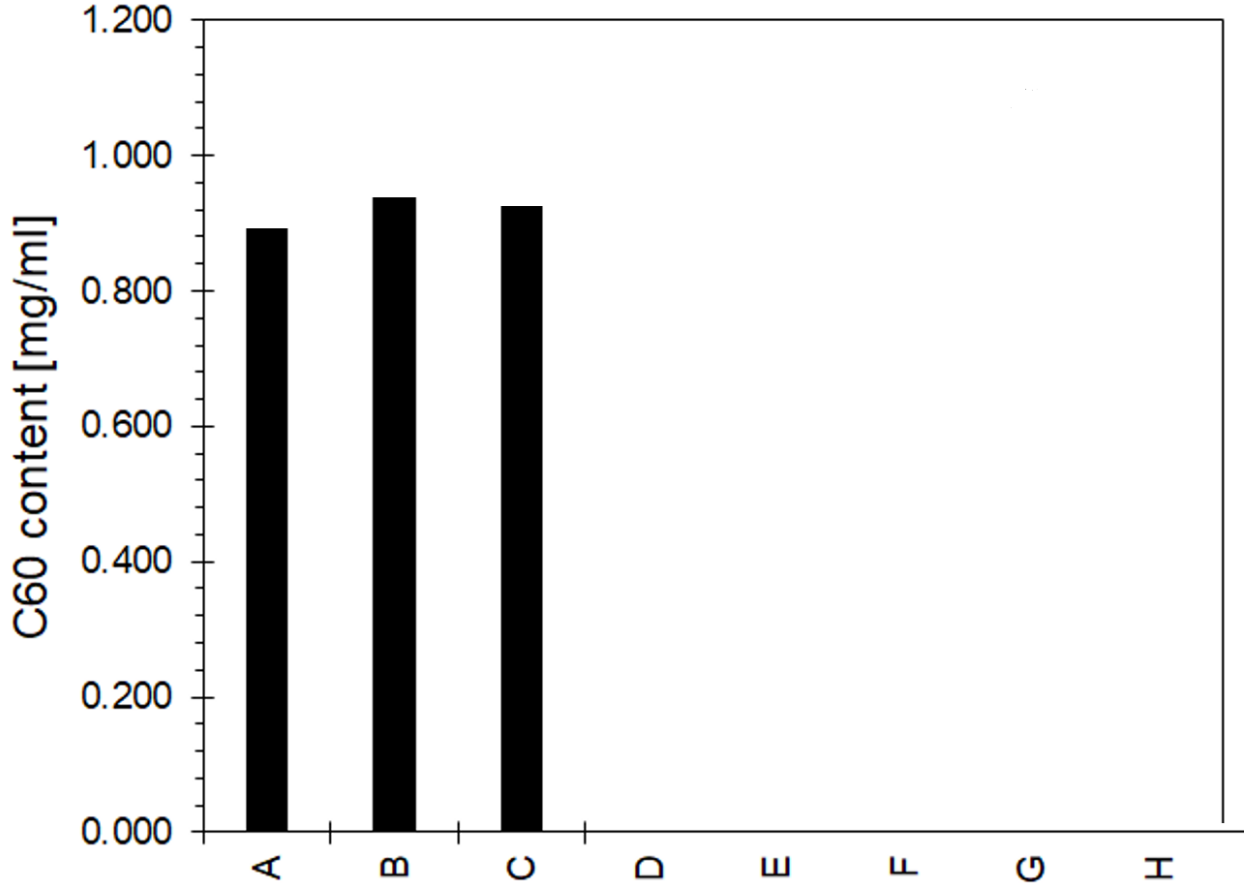


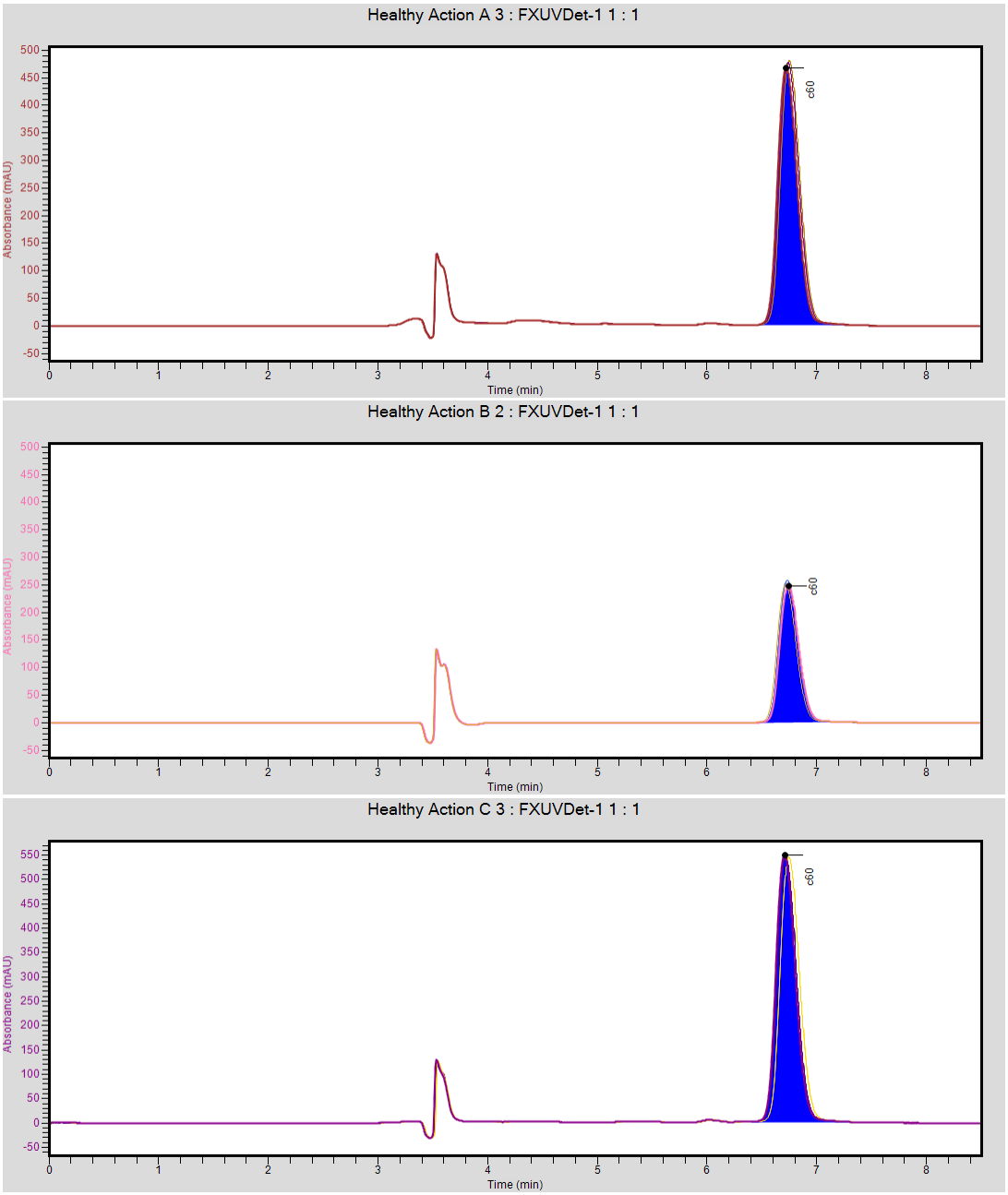
Figure 1 - Healthy Action Sample set, graphical summary.

Sample	Concentration (mg/ml)	±	Standard Deviation (mg/ml)
Standard	0.133	±	BLOQ(<0.001)
A	0.884	±	0.009
B	0.952	±	0.006
C	0.943	±	0.004

Notes: n = 3; Data are mean ± SD. BLOQ = Below limit of quantification (<0.001 mg/ml)

Table 1 - Healthy Action Sample set, analytical chemistry result summary.

APPENDIX – Sample Chromatography



APPENDIX – System suitability

0.91	Capacity Factor
4.25	Resolution
1.15	tailing factor
3149.96	Theoretical plate number

PASS	Plate count
PASS	Tailing factor
PASS	Resolution
PASS	Repeatability

System Suitability

Sample name	Analyte	Area count
C60 standard	C60	1075871
C60 standard	C60	1054766
C60 standard	C60	1066538
C60 standard	C60	1063652
C60 standard	C60	1048336
Average Area (uAU)		1061833
STDEV (uAU)		9535.436
STDEV (%)		0.898017
Pass/Fail		PASS