

TCM BIOTECH INTERNATIONAL CORP.

泰宗生物科技股份有限公司

**BEST SOLUTION
FOR LIVER DISEASE**



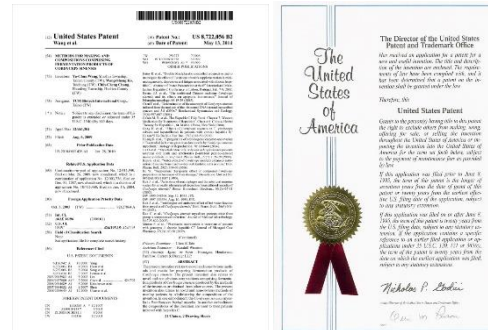
WHAT IS LivPhcD™?



LivPhcD™ is a mycelium cultured through patented fermentation technology



Strain:
Paecilomyces hepiali

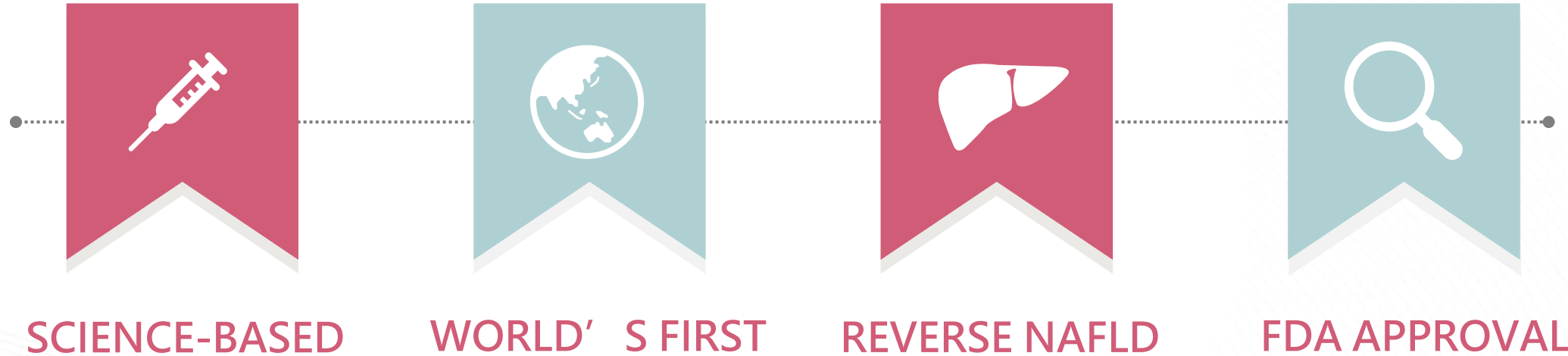


US Patent No. US8722056 B2



Main bioactive ingredients:
Adenosine(>2.2mg/g) · Polysaccharide (>40mg/g)

WHY LivPhcD™?




LivPhcD™ was shown to:

- ✓ BOOST IMMUNE
- ✓ ANTI-AGING
- ✓ REVERSE LIVER FIBROSIS
- ✓ LOWER AST/ALT
- ✓ ANTI-OXIDATION
- ✓ LOWER LIVER CHOLESTEROL

PATENTS

Tcmbio

TCM BIOTECH INTERNATIONAL CORP.


 US8658181B2

(12) **United States Patent**
Hsu et al.

(10) Patent No.: **US 8,658,181 B2**
(45) Date of Patent: **Feb. 25, 2014**

(54) **PHARMACEUTICAL COMPOSITION FOR PREVENTING AND TREATING LIVER FIBROSIS OR NONALCOHOLIC FATTY LIVER DISEASE**

(71) Applicant: **TCM Biotech International Corp., Taipei (TW)**

(72) Inventors: **Huan Ching Hsu, Taipei (TW); Ya Chuan Wang, Taipei (TW)**

(73) Assignee: **TCM Biotech International Corp., Taipei (TW)**

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **13464,559**

(22) Filed: **Oct. 31, 2012**

(65) **Prior Publication Data**
US 2013/025994 A1 Oct. 3, 2013

(30) **Foreign Application Priority Data**
Mar. 28, 2012 (TW) 10110713 A

(51) **Int. Cl.**
A61K 36/00 (2006.01)
A61K 36/06 (2006.01)
A61K 36/09 (2006.01)
A61K 36/06 (2006.01)


(52) **U.S. Cl.**
USPC 424/195.15; 424/725

(58) **Field of Classification Search**
None
See application file for complete search history.

Primary Examiner — Olwen M.
(14) **Attorney, Agent, or Firm** — Woodard, Emhardt, Moriarty, McNeer & Henry LLP

(57) **ABSTRACT**
The present invention provides a pharmaceutical composition for preventing and treating liver fibrosis or nonalcoholic fatty liver disease, comprising 50 to 90% by weight of Codonopsis sinensis mycelium powder, and 10 to 50% by weight of condensed astraagalus powder.

6 Claims, 6 Drawing Sheets



 The United States of America

The Director of the United States Patent and Trademark Office
Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this
United States Patent
Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America for the term set forth below, subject to the payment of maintenance fees as provided by law.

If this application was filed prior to June 8, 1995, the term of this patent is the longer of seventeen years from the date of grant of this patent or twenty years from the earliest effective U.S. filing date of the application, subject to any statutory extension.

If this application was filed on or after June 8, 1995, the term of this patent is twenty years from the U.S. filing date, subject to any statutory extension. If the application contains a specific reference to an earlier filed application or applications under 35 U.S.C. 120, 121 or 365(c), the term of the patent is twenty years from the date on which the earliest application was filed, subject to any statutory extensions.

Nicholas P. Ebdici
Acting Director of the United States Patent and Trademark Office

Qui M. Pison

Pharmaceutical composition for preventing and treating liver fibrosis or nonalcoholic fatty liver disease

- Taiwan
- USA
- Japan
- EU

TWI501771
TWI554277

US8,858,954
US8,658,181

JP6050099

EP2644201B1

FDA APPROVAL

Tcmbio


TCM BIOTECH INTERNATIONAL CORP.

FDA confirmed that LivPhcD™ was a natural botanical product with decent quality safe enough to be used as dietary supplements' new ingredient in the American market and therefore granted it a pre-market notification.

FDA agrees LivPhcD™ can :

- promote general health
- boost energy
- modulate physical functions



 **MARCO POLO TECHNOLOGIES, INC.**
A Green Pharmaceutical Company

PREMARKETING NOTIFICATION

TO: Division of Standards and Labeling Regulations
Office of Nutritional Products, Labeling,
and Dietary Supplement (HFS-820)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

DATE: March 31, 2002

Dear Sir/Madame:

HOMEGI BIOTECH INTERNATIONAL CORP., Taipei, Taiwan would like to notify FDA of its intent to market a dietary supplement, "Sustotrong" which contains new dietary ingredients, in the US market. It has authorized Dr. Yuan Lin of Marco Polo Technologies Inc. (Attachment 1) to be its representative who will handle matters regarding this notification. Sustotrong is a product of TCM Bio-Technology International. It is manufactured under contract by Sheng Chang Pharmaceutical Co. Ltd. and distributed by HOMEGI BIOTECH INTERNATIONAL CORP.

A. Name and complete address of Distributor


HOMEGI BIOTECH INTERNATIONAL CORP.
6th, Fl- 2, No. 560, Section 4, Chung-Hsiao E. Road
Shinyi Chiu, Taipei, Taiwan, 110
Republic of China

Authorized representative in the US
Dr. Yuan Lin
Marco Polo Technologies, Inc.
5900 Conway Road
Bethesda, MD 20817
301-897-5211 (phone), 301-530-5526 (fax)
e-mail: ylin60@yahoo.com

B. Name of product and dietary ingredients

Name of product: **Sustotrong**
Sustotrong is in capsule form. Each capsule contains 500 mg +/- 10%.
Each package contains 90 capsules. There is no structure/function claim on the label (Attachment 2—Package label).

5900 Conway Road, Bethesda, Maryland 20817 Phone: (301) 897-5211; Fax: (301) 530-5526

 **DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service
Food and Drug Administration
Rockville, MD 20857

IND 65,222

TCM-Biotechnology International
Attention: Yuan Lin, Ph.D
U.S. Representative
5900 Conway Road
Bethesda, MD 20817

Dear Dr. Lin:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for TCM-700C.

We have completed our 30-day safety review of your application and as discussed with you in a telephone conversation with Jeff D. O'Neill of this Division on September 29, 2004 have concluded that you may proceed with your proposed clinical investigation.

If you have any questions, call Jeff O'Neill, Regulatory Health Project Manager, at 301-827-2335.

Sincerely,

[See appended electronic signature page]

Debra Birnkrant, M.D.
Director
Division of Antiviral Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

..... In Vivo

Experimental Results

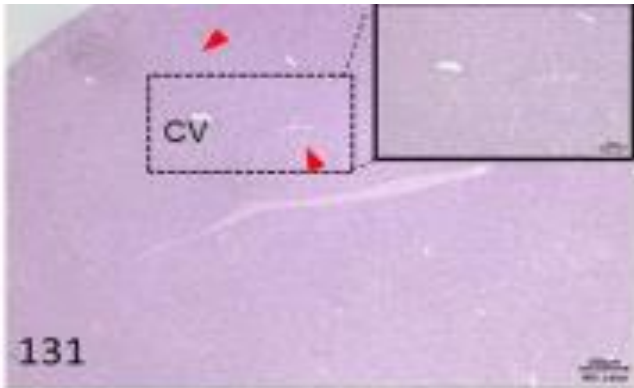
Effects of LivPhcD™ on High-Fat Diet-Induced
Non Alcoholic Fatty Liver Disease

SCIENTIFIC EVIDENCE FOR LivPhcD™

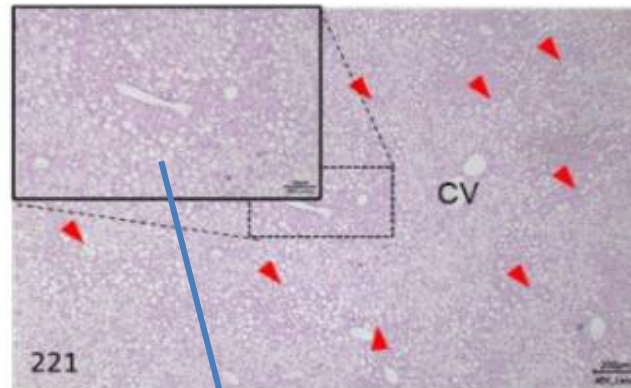
based on the study results of animal model (High-fat diet)

■ PATHOLOGIC OBSERVATION OF LIVER

Control

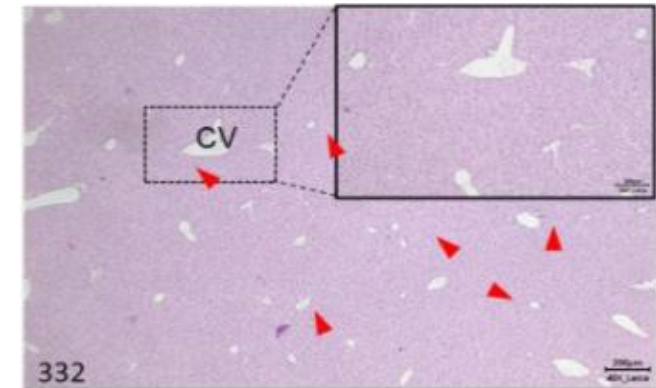


High-fat Diet-Induced
Non-alcoholic Fatty Liver (NAFL)



Hepatic steatosis
(lipid accumulation)

High-fat Diet + LivPhcD™



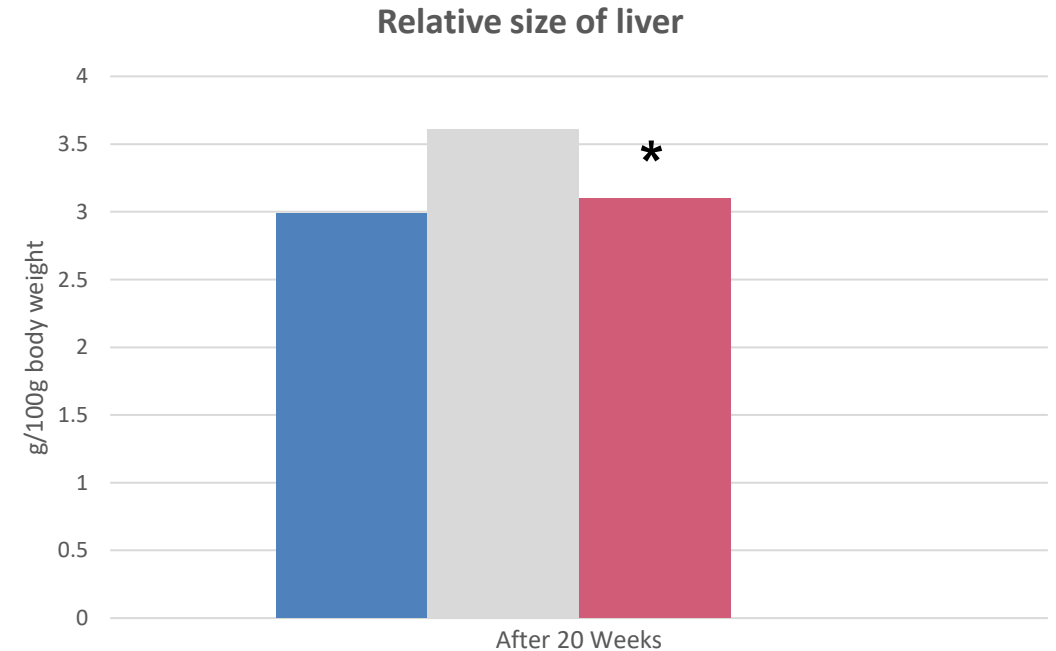
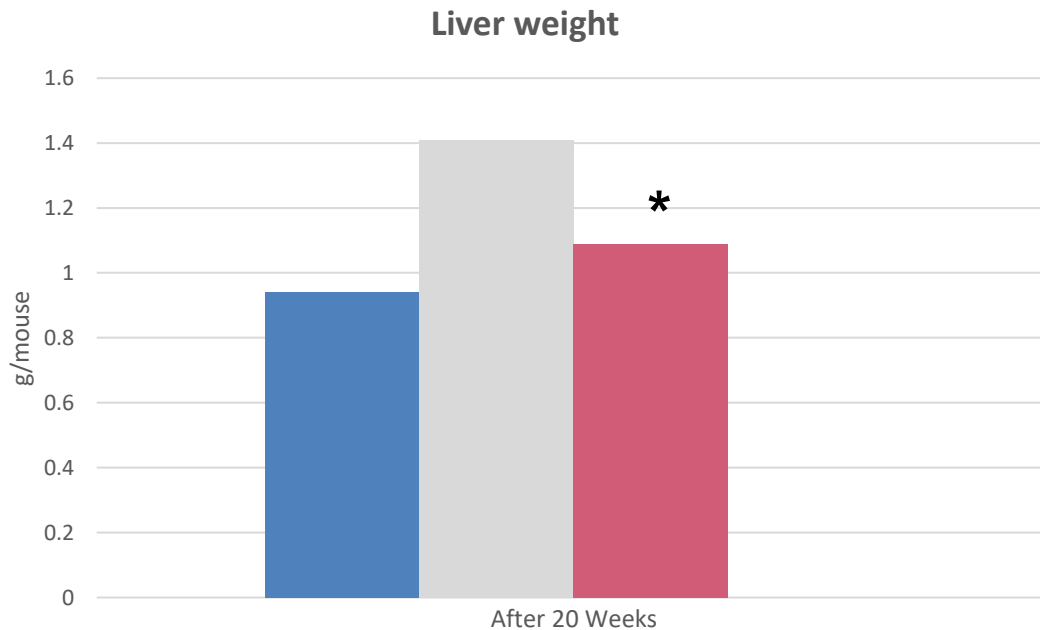
■ LivPhcD™ can reverse NAFL

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (High-fat diet)

■ LIVER WEIGHT / RELATIVE SIZE OF LIVER

- Control
- High-fat diet
- High-fat diet + LivPhcD™



* indicate significant differences ($p < 0.05$)

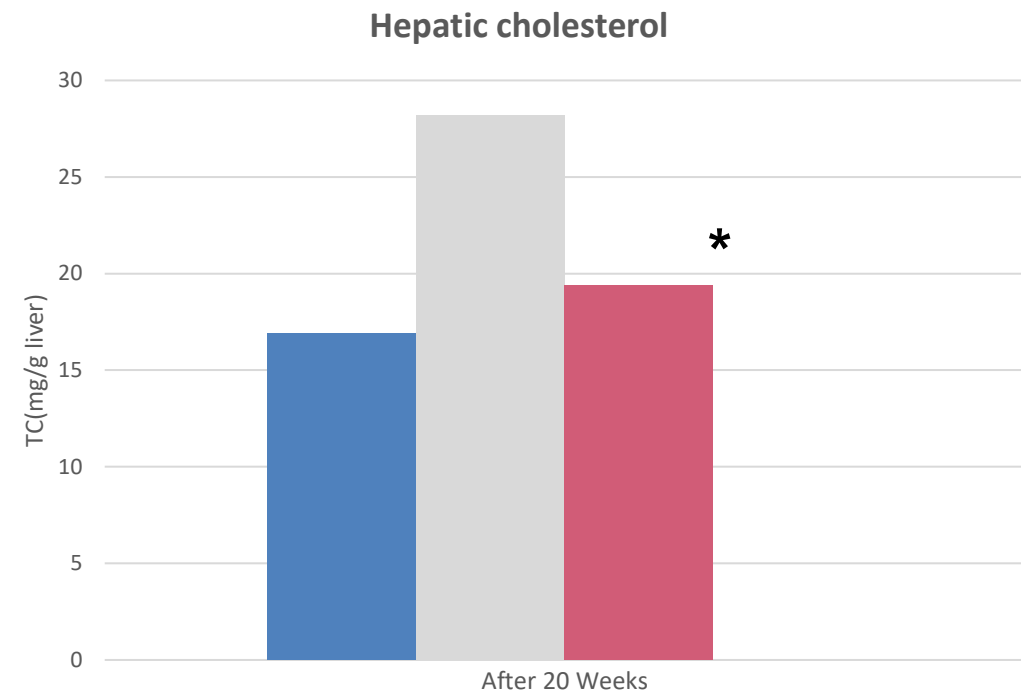
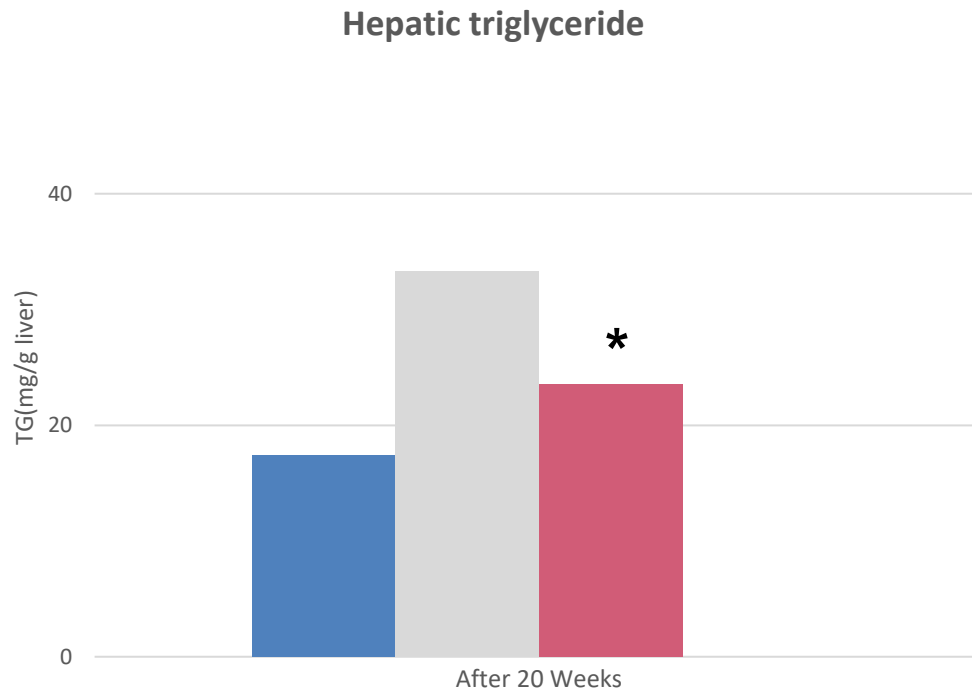
■ LivPhcD™ can reduce hepatic lipid accumulation

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (High-fat diet)

■ HEPATIC TRIGLYCERIDE/CHOLESTEROL

- Control
- High-fat diet
- High-fat die + LivPhcD™



* indicate significant differences (p<0.05)

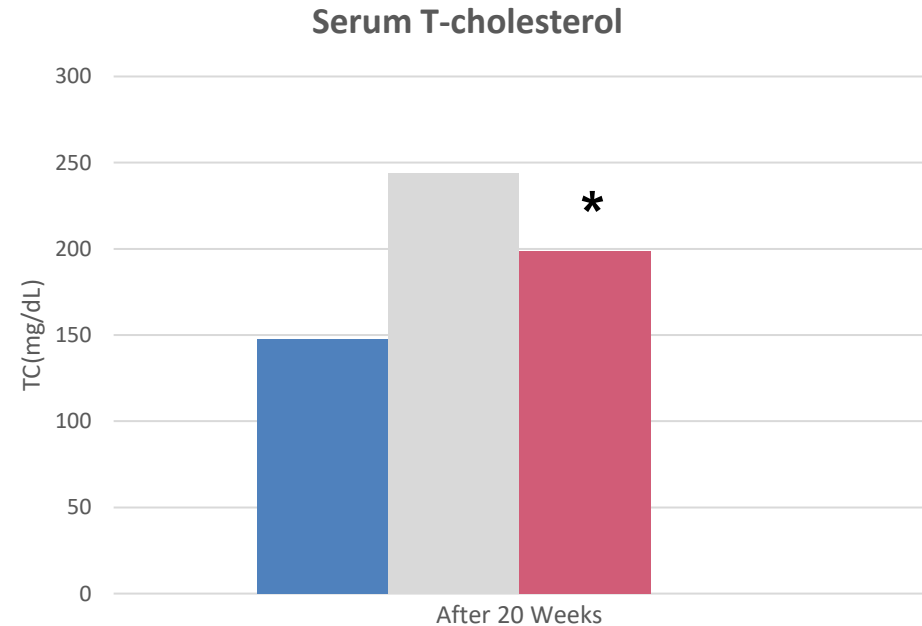
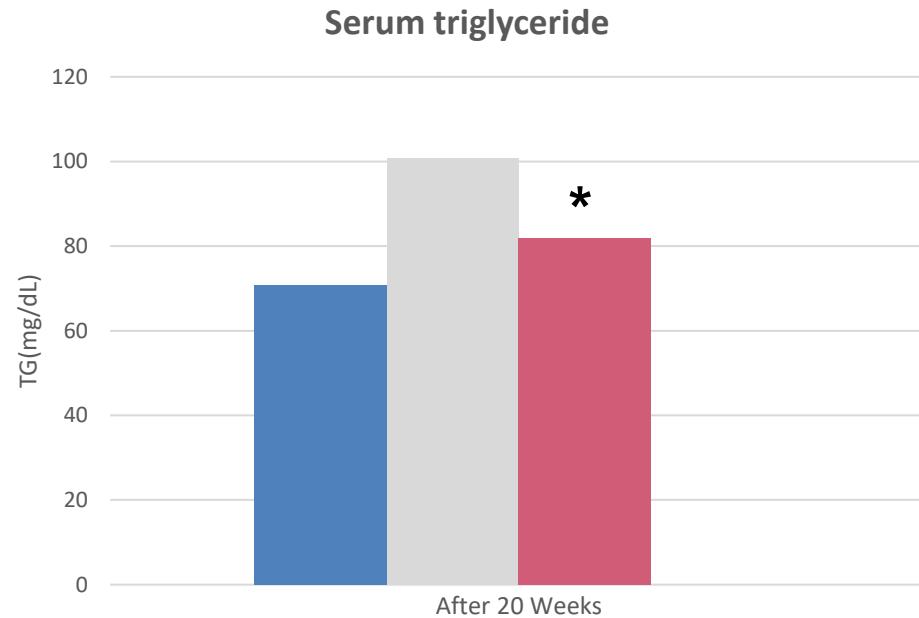
■ LivPhcD™ can lower hepatic triglyceride and cholesterol

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (High-fat diet)

SERUM TRIGLYCERIDE/ CHOLESTEROL

- Control
- High-fat diet
- High-fat diet + LivPhcD™

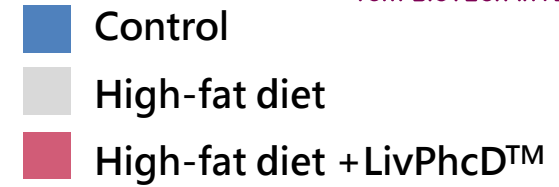


* indicate significant differences ($p < 0.05$)

■ LivPhcD™ can lower serum triglyceride and cholesterol

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (High-fat diet)

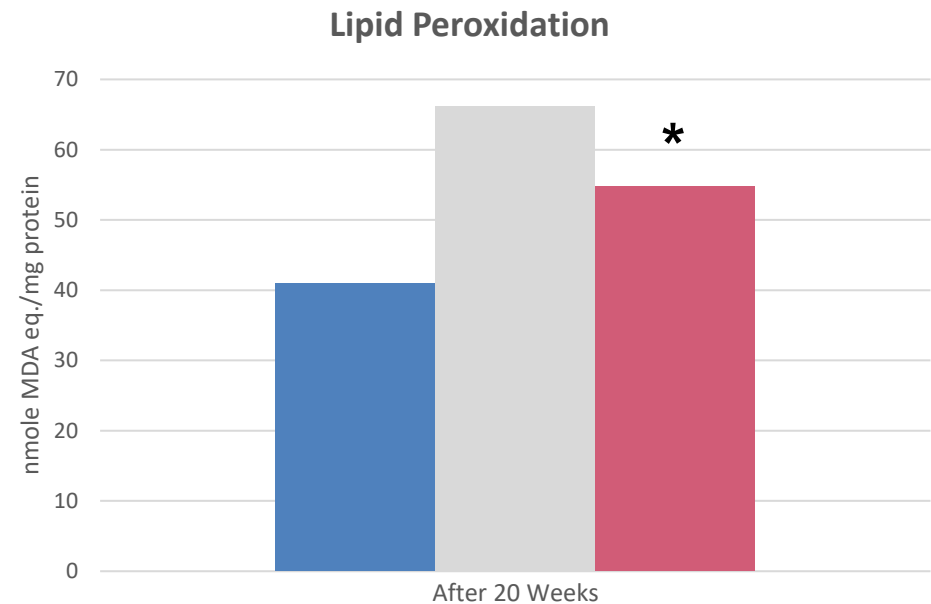


ACTIVITY OF LIVER ANTIOXIDANT ENZYME



■ LivPhcD™ can elevate the SOD enzyme values

LIVER LIPID PEROXIDATION



■ LivPhcD™ can lower lipid peroxidation

* indicate significant differences (p<0.05) 11

..... In Vivo

Experimental Results

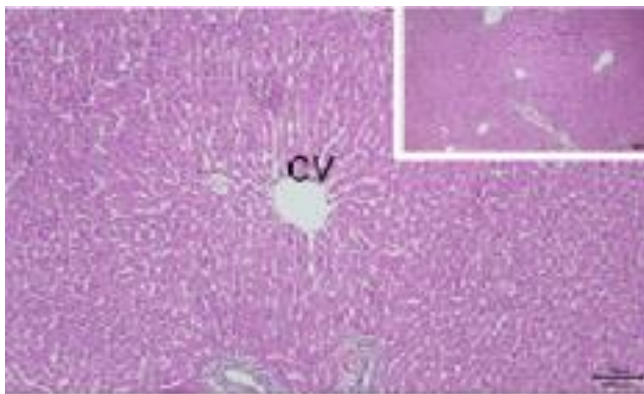
Effects of LivPhcD™ on Alcohol Liquid Diet–Induced
Alcoholic Fatty Liver Disease

SCIENTIFIC EVIDENCE FOR LivPhcD™

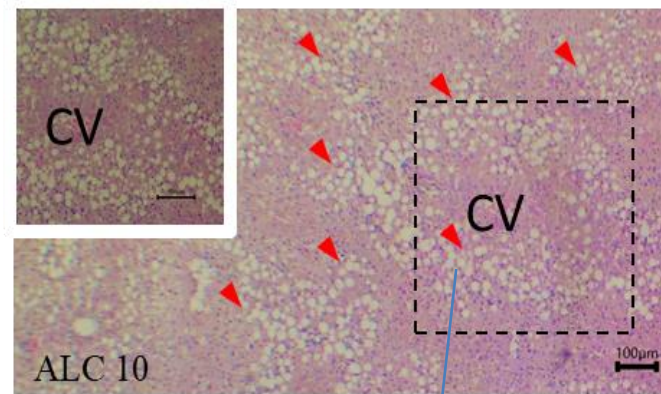
based on the study results of animal model (The Lieber–DeCarli alcohol liquid diet)

■ PATHOLOGIC OBSERVATION OF LIVER

Control

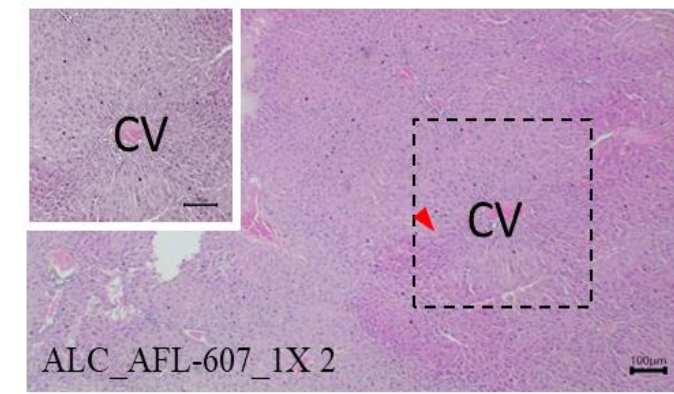


Alcohol Liquid Diet-Induced
Alcoholic Fatty Liver(AFL)



Hepatic steatosis
(lipid accumulation)

Alcohol Liquid Diet + LivPhcD™



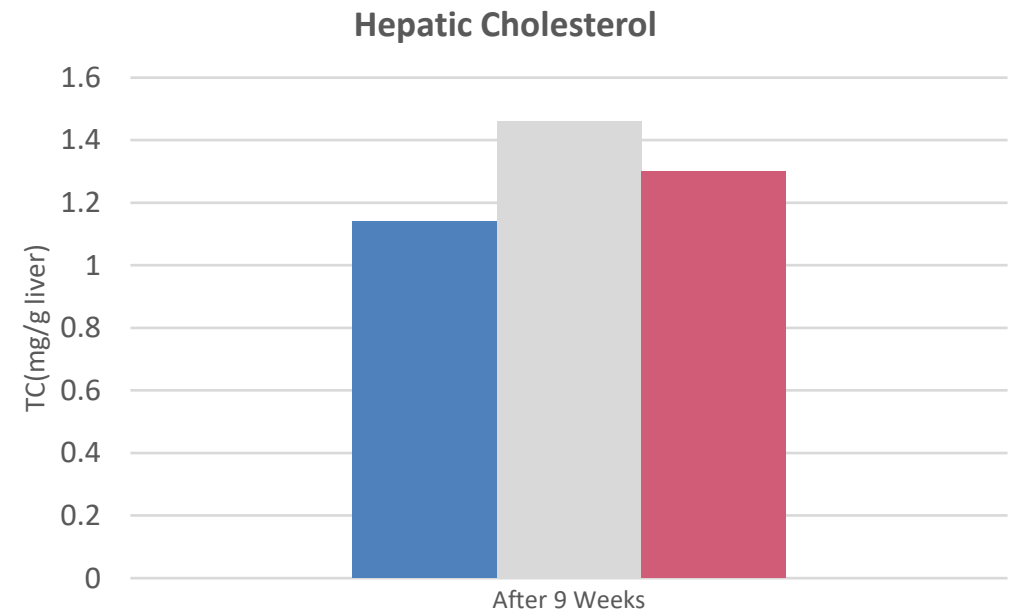
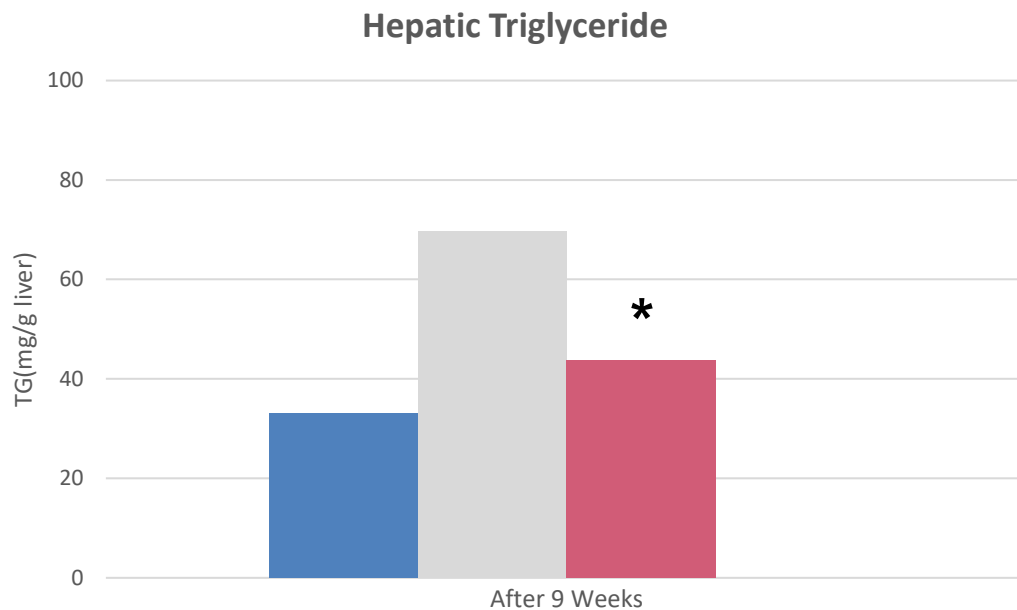
■ LivPhcD™ can reverse AFL

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (The Lieber–DeCarli alcohol liquid diet)

■ HEPATIC TRIGLYCERIDE/CHOLESTEROL

- Control
- Alcohol liquid diet
- Alcohol liquid diet + LivPhcD™



* indicate significant differences ($p < 0.05$)

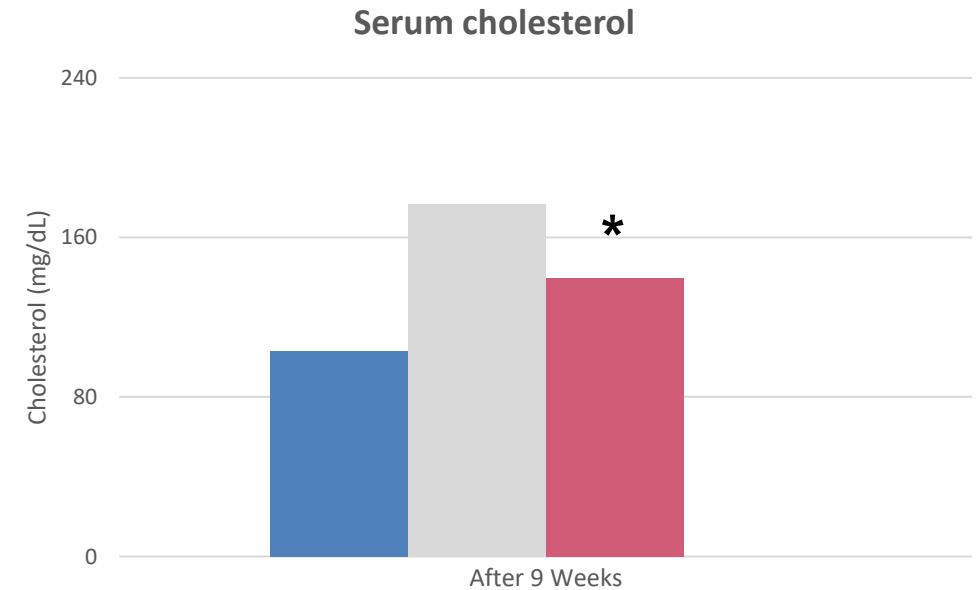
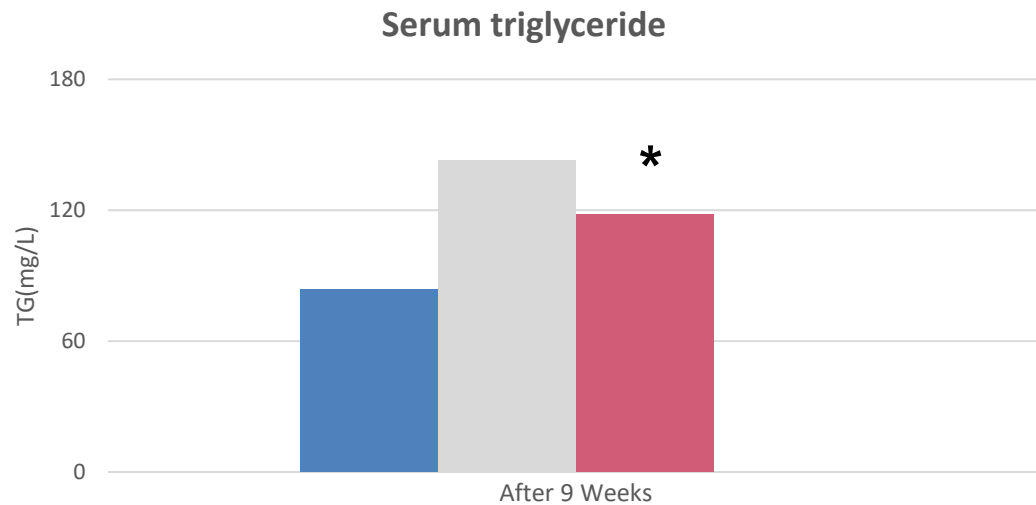
■ LivPhcD™ can lower hepatic triglyceride and cholesterol value

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (The Lieber–DeCarli alcohol liquid diet)

■ SERUM TRIGLYCERIDE/ CHOLESTEROL

- Control
- Alcohol liquid diet
- Alcohol liquid diet + LivPhcD™



* indicate significant differences (p<0.05)

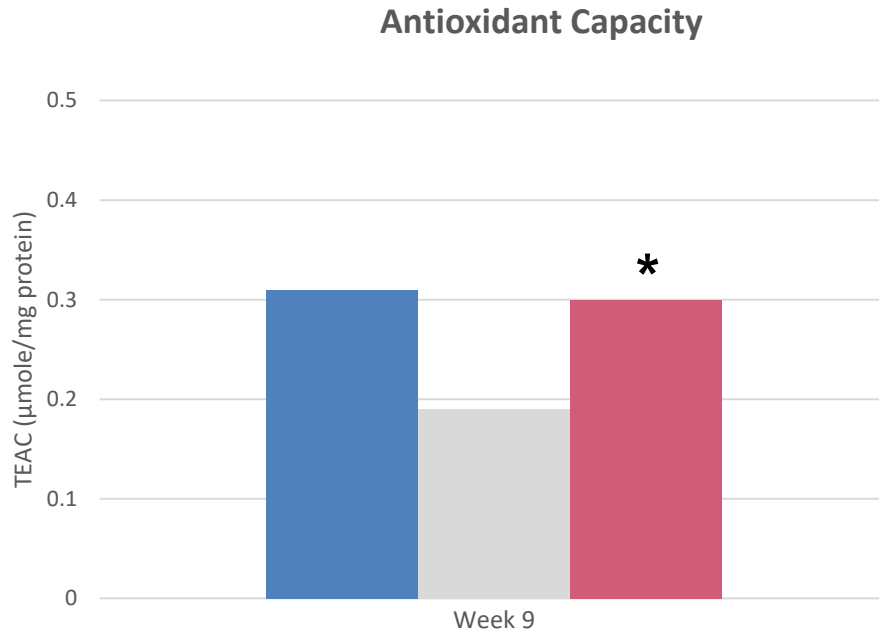
■ LivPhcD™ can lower serum triglyceride and cholesterol value

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (The Lieber–DeCarli alcohol liquid diet)

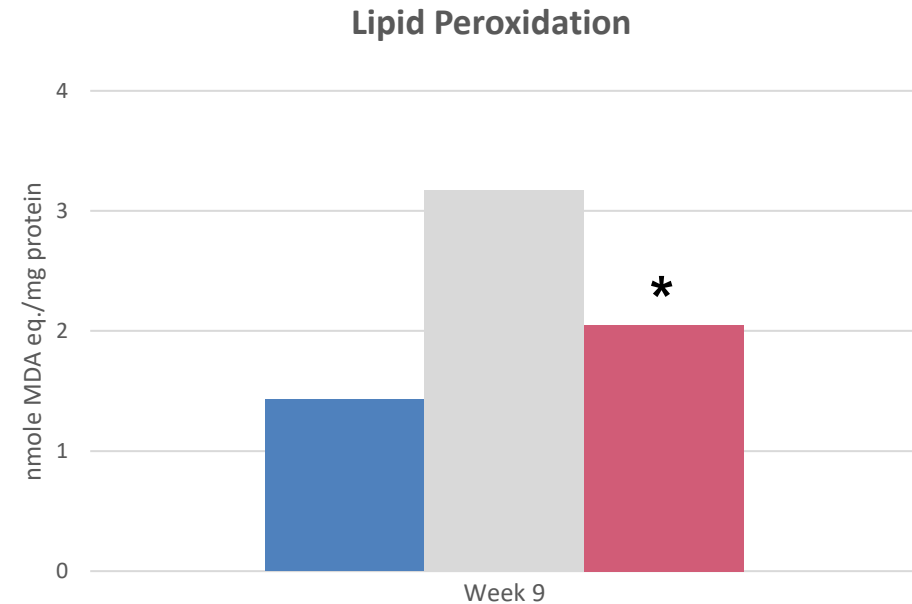
- Control
- Alcohol liquid diet
- Alcohol liquid diet + LivPhcD™

LIVER ANTIOXIDANT CAPACITY



■ LivPhcD™ can enhance liver antioxidant capacity

LIVER LIPID PEROXIDATION



■ LivPhcD™ can lower lipid peroxidation

* indicate significant differences (p<0.05)

..... In Vivo

Experimental Results

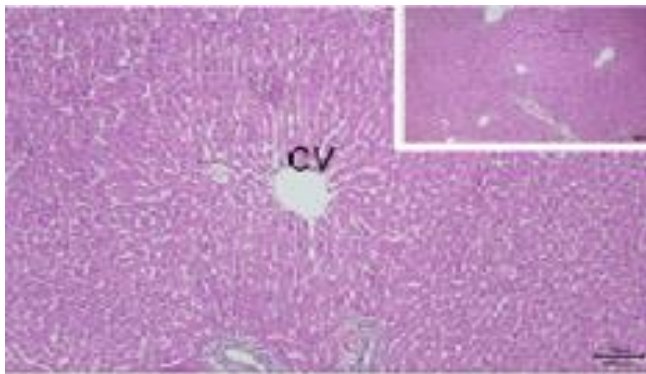
Effects of LivPhcD™ on Thioacetamide-induced Liver Fibrosis

SCIENTIFIC EVIDENCE FOR LivPhcD™

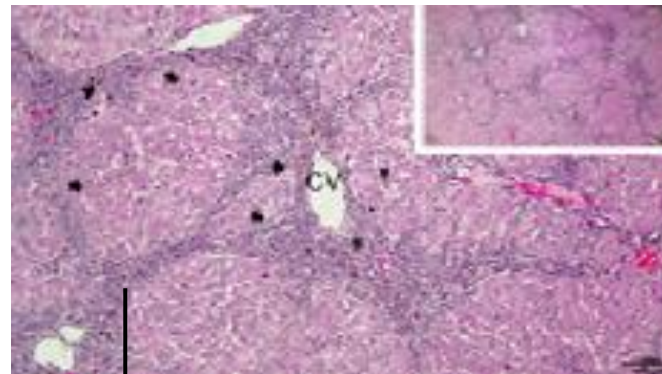
based on the study results of animal model (thioacetamide-induced liver fibrosis)

■ PATHOLOGIC OBSERVATION OF LIVER

Control

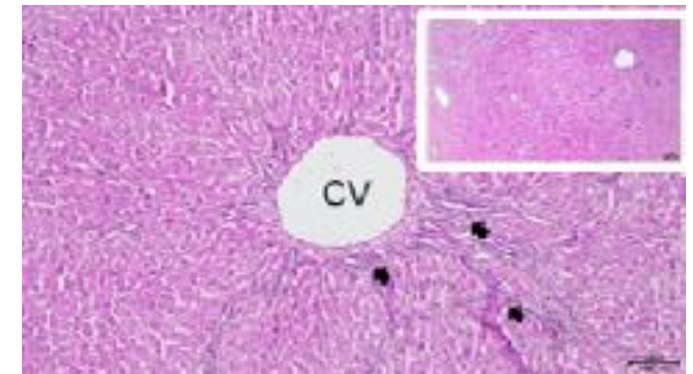


Thioacetamide(TAA)-induced
Liver Fibrosis



fibrosis

TAA + LivPhcD™



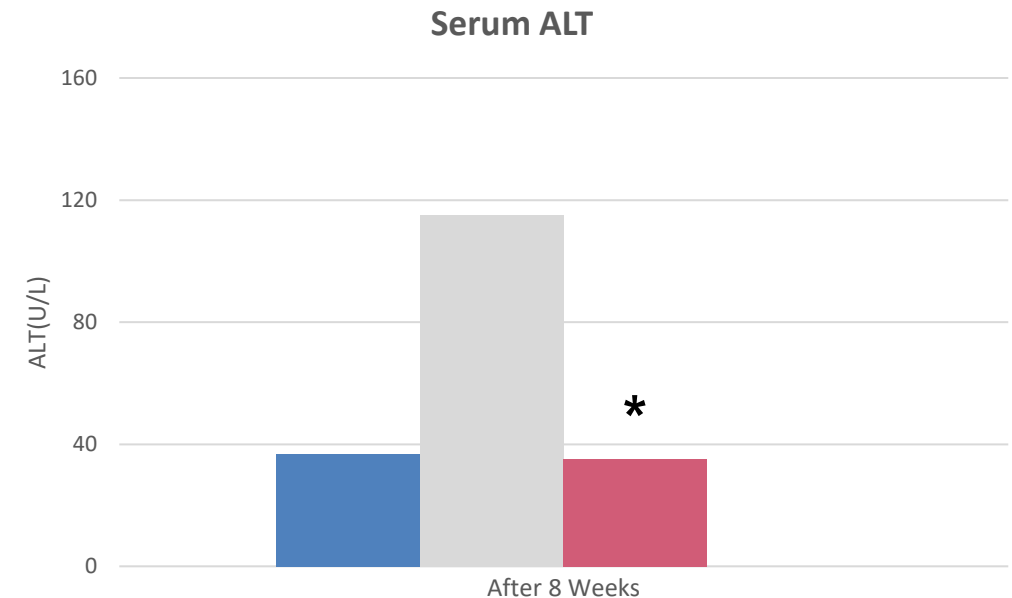
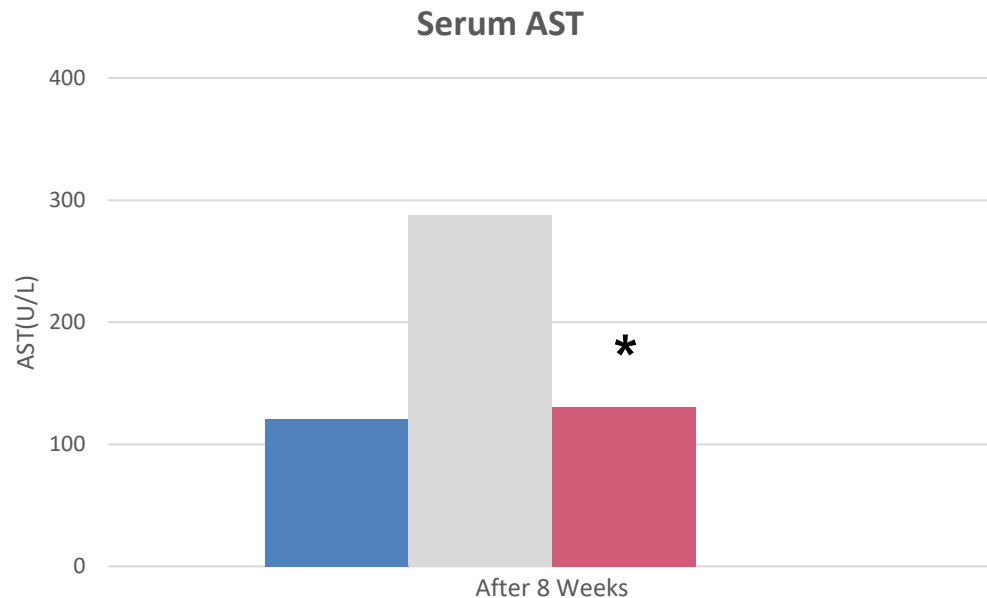
■ LivPhcD™ can reverse liver fibrosis

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (thioacetamide-induced liver fibrosis)

- Control
- Thioacetamide(TAA)
- TAA + LivPhcD™

SERUM BIOCHEMICAL PARAMETERS-AST(GOT), ALT(GPT)

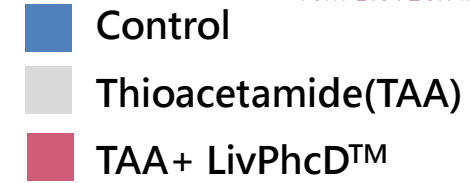


* indicate significant differences (p<0.05)

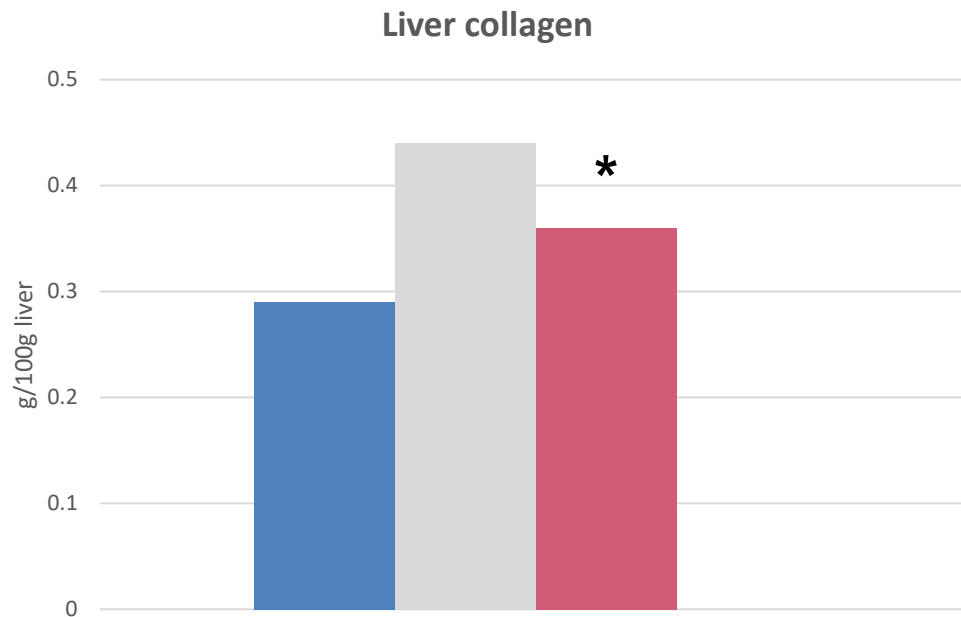
Results show LivPhcD™ can reduce AST(GOT) · ALT(GPT) values

SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (thioacetamide-induced liver fibrosis)

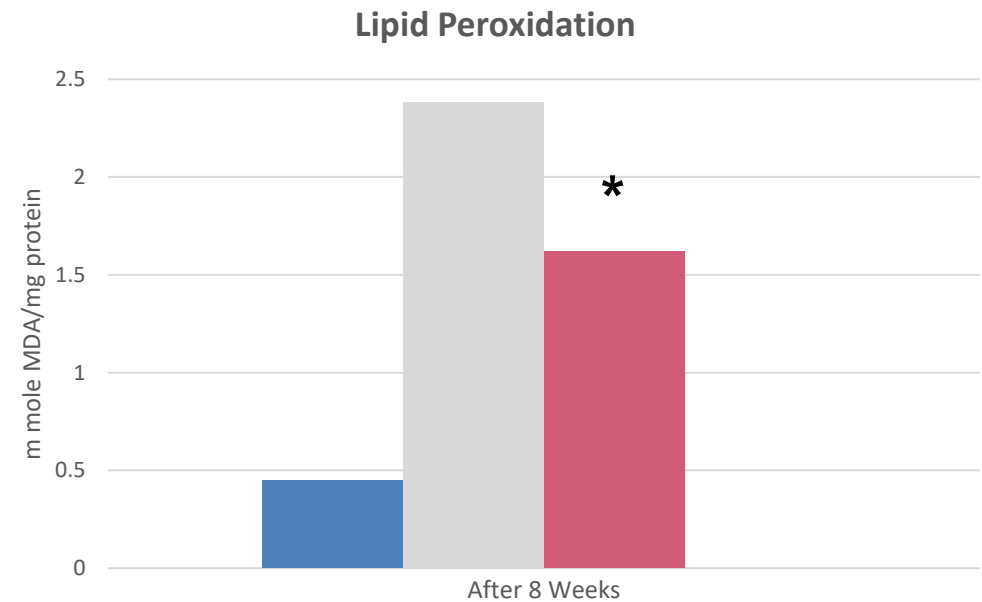


LIVER COLLAGEN CONTENT



■ LivPhcD™ can significantly reduce liver collagen content

LIVER LIPID PEROXIDATION



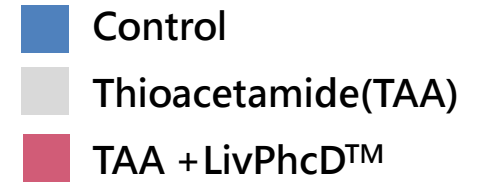
■ LivPhcD™ can reduce the level of liver lipid peroxidation

* indicate significant differences (p<0.05)

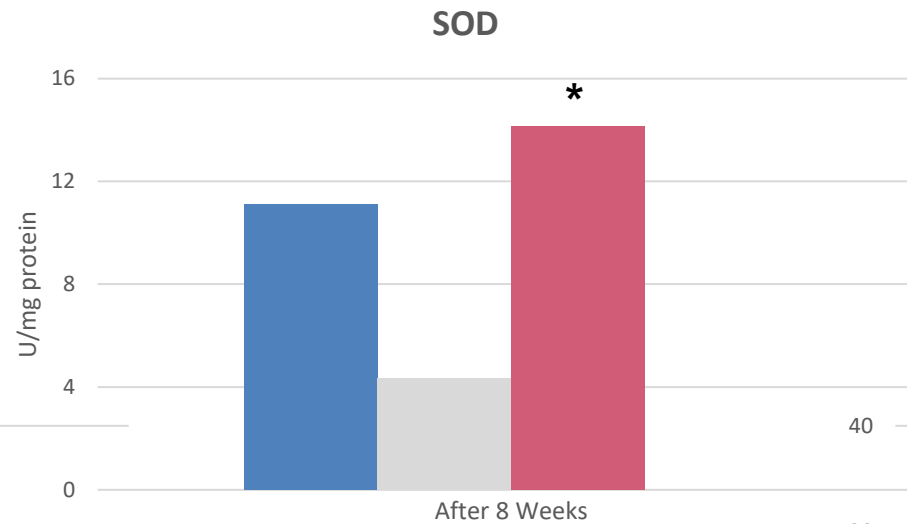
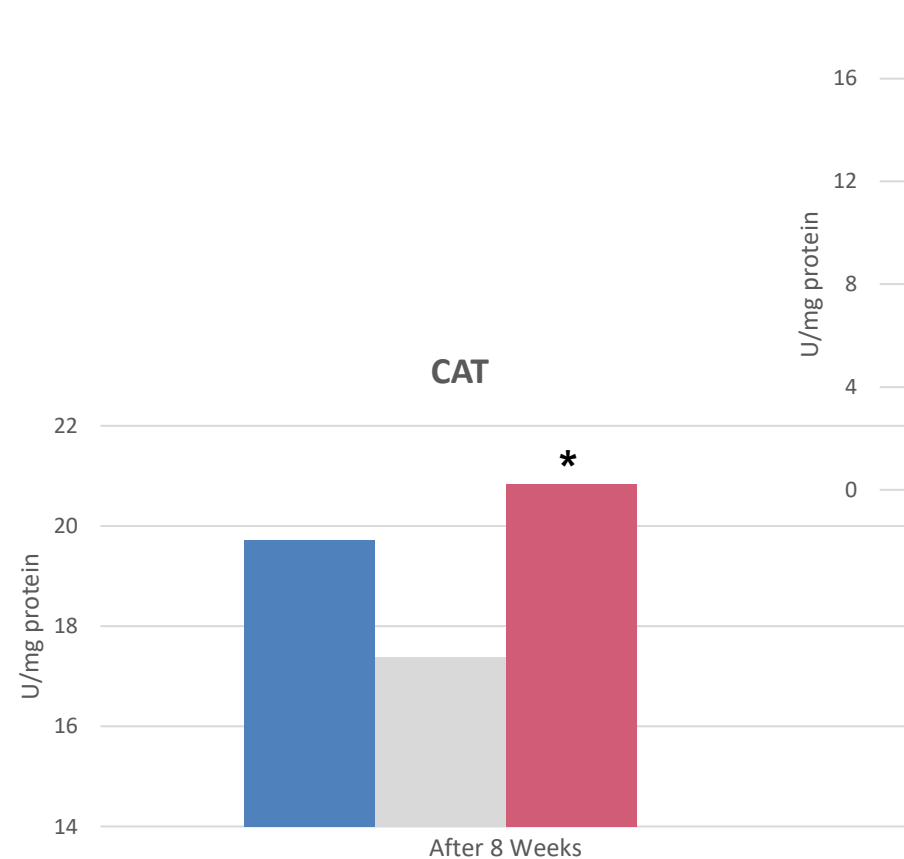
SCIENTIFIC EVIDENCE FOR LivPhcD™

based on the study results of animal model (thioacetamide-induced liver fibrosis)

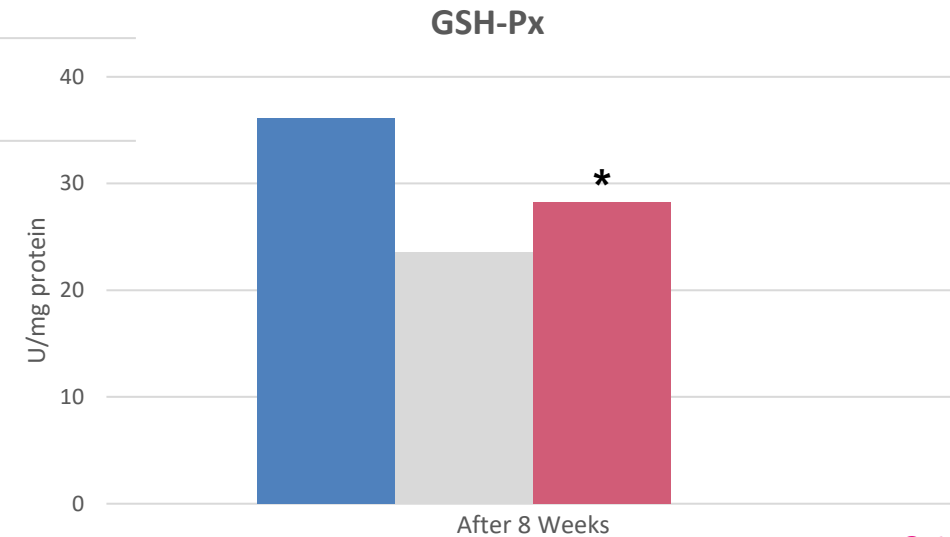
■ THE ACTIVITY OF LIVER ANTIOXIDANT ENZYME



* indicate significant differences ($p < 0.05$)



■ LivPhcD™ elevates liver antioxidant enzyme values



HOW TO USE LivPhcD™?



01 CAPSULES

02 TABLETS

03 SACHET

04 GUMMIES

05 LIQUIDS

06 COSMETIC

- For liver health maintenance: 500-750mg/day
- For NAFLD: 750mg/day
- For liver fibrosis: 2250mg/day



泰宗生物科技股份有限公司

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Fax +886-2-2697-2627

URL <http://www.tcmbio.com/en/>

Email kara@tcmbio.com

\ Thanks for Your Attention /