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Canada Traditional Chinese Medicine and Acupuncture International Academic conference

NATURAL HEALTH PRODUCT REGULATION AND TRADITIONAL CHINESE MEDICINE IN CANADA

加拿大天然健康产品法规与中药的规管

冼伟昌, DANIEL SIN P. ENG. – 北美健康产品, CYCTEK INC.

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AGENDA

- ALTERNATIVE MEDICINES IN CANADA
- MARKET SIZE AND REGULATORY COMPONENTS
- CANADIAN NATURAL HEALTH PRODUCT REGULATORY FRAMEWORK
- TRADITIONAL CHINESE MEDICINE (TCM) IN CANADA
- PRODUCT, SITE LICENCING AND REGULATORY RESPONSIBILITIES
- TOP STRATEGIC ADVANTAGES, RISKS/OPPORTUNITIES OF TCM



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ALTERNATIVE MEDICINES IN CANADA

- WILDLY ADOPTED (79% OF THE POPULATION USES SOME FORM OF ALTERNATIVE MEDICINE) WITH CLEAR BENEFITS¹.
- TRADITIONAL CHINESE MEDICINE IS PART OF ALTERNATIVE MEDICINE AND IS REGULATED BY THE NATURAL HEALTH PRODUCT REGULATIONS (NHPR).
- OVER 6000 TCM REGISTERED PROFESSIONALS IN BC, AB, ON
- NHP MARKET SIZE IS ESTIMATED TO BE ABOUT 2 BILLION DOLLARS CANADIAN ANNUALLY IN 1999²
- CONTRARY TO THE PUBLIC HEALTHCARE SYSTEM, TCM IS A USER-PAY SYSTEM WITH SOME SERVICES COVERED BY JOB BENEFITS
- THE GOVERNMENT HAS RECOGNIZED THAT ALTERNATIVE MEDICINES SAVE THEM MONEY^{1,3}
- NHPR CAME INTO FORCE IN 2004

¹ <https://www.fraserinstitute.org/sites/default/files/complementary-and-alternative-medicine-2017.pdf>

² Lloyd Sicban, The Status of Traditional Chinese Medicine in Canada, CES Volume 46, Number 1 (2014), 181-196

³ [Heal Committee Report](#)





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TRADITIONAL CHINESE MEDICINE MARKET SIZE

- FRASER INSTITUTE-
MEDICAL SERVICES AND
MEDICINE
- CHFA (CANADIAN HEALTH
FOOD ASSOCIATION -
HEALTH FOOD AND
NATURAL HEALTH
PRODUCTS

➡ **Table 17c: Estimates of the National Expenditure on Complementary and Alternative Medicines and Therapies, 2016**

Alternative therapy	Number of users who spent money on alternative therapies in past year	Proportion of total respondent sample (users and non-users)	Mean annual expenditure (\$)*	Canadian population (2016)*	Projected Canadian expenditure (col. 3 x col. 4 x col. 5)
Chiropractic care	197	9.8	\$342	36,155,487	\$1,211,078,655
Massage	294	14.7	\$268	36,155,487	\$1,424,381,566
Relaxation techniques	51	2.6	\$359	36,155,487	\$337,569,320
Prayer/spiritual practice	19	1.0	\$77	36,155,487	\$27,803,570
Acupuncture	54	2.7	\$388	36,155,487	\$378,667,262
Yoga	147	7.3	\$302	36,155,487	\$797,083,866
Herbal therapies	75	3.8	\$209	36,155,487	\$287,696,441
Special diet programs	42	2.1	\$801	36,155,487	\$607,791,814
Energy healing	19	0.9	\$408	36,155,487	\$132,795,488
Naturopathy	37	1.9	\$395	36,155,487	\$271,346,930
Homeopathy	22	1.1	\$489	36,155,487	\$194,639,449
Folk remedies	21	1.1	\$166	36,155,487	\$65,821,064
Herbs and vitamins	129	6.5	\$295	36,155,487	\$692,811,442
Aromatherapy	27	1.3	\$142	36,155,487	\$66,790,031



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Constitutional Documents

Canadian Charter of Rights and Freedoms

Consolidation of Constitution Acts, 1867 to 1982

Consolidation of Constitution Acts, 1867 to 1982 (1990 Report version)

French Constitutional Drafting Committee (1990)

Laws

Consolidated Acts

Consolidated Regulations

Annual Statutes

Statutes Repeal Act: Reports, Deferrals and Repeals

Miscellaneous Statute Law Amendment Program

Typographical and Grammatical Corrections

Natural Health Products Regulations (SOR/2003-196)

Full Document: [HTML](#) (Accessibility Buttons available) | [XML](#) | [2](#)

Regulations are current to 2025-01-22 and last amended on 2025-01-22

Enabling Act: [FOOD AND DRUGS ACT](#)

Notes :

- See coming into force provision and notes, where applicable
- Shaded provisions are not in force. [Help](#)

Search within these regulations:

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4 - [Prohibition](#)

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9 - [Refusal to Issue or Amend](#)

11 - [Amendment](#)

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62 - [Recall Reporting](#)

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NHP REGULATION

- NATURAL HEALTH PRODUCTS REGULATION
- PART 1 – PRODUCT LICENSE, 20+ SUBITEMS
- PART 2 – SITE LICENSE , 10+ SUBITEMS
- ALL MUST MEET GMP STANDARDS

NATURALLYNORTH.CA



905-882-1083

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CANADIAN TCM REGULATORY FRAMEWORK

- REGULATED AS NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS (NNHPS) IN CANADA SINCE 2005
 - LED THE WESTERN WORLD IN TCM PRODUCT RECOGNITION – CLEAR TOXIC HEAT
 - UNLIKE THE UNITED STATES AND MEXICO WHICH CLASSIFY TCM MEDICATIONS AS FOOD SUPPLEMENTS
 - MANUFACTURER AND IMPORTER GMP SITE LICENCE
 - NATURAL HEALTH PRODUCT GMP – SPECIAL CONSIDERATION FOR HERBAL MEDICINES
 - REQUIRE RENEWALS – E.G. BEIJING YUBENTANG FOREIGN SITE UNDER PHARMA HERB INC.
 - PRODUCT LICENCES (NPNS) WITH FUNCTION AND INDICATION CLAIMS – FUFANG DANSHEN HANPIAN
 - RECOGNIZE CHINESE PHARMACOPOEIA STANDARDS - TANSINONE II_A
 - TCM MONOGRAPHS AVAILABLE TO MAKE LICENCING QUICKER AND EASIER
 - EQUAL TO OTC MEDICATION WITH HEALTH CLAIMS – LIKE PANADOL AND TYLENOL
 - PERMANENT LICENSES – NO RENEWAL



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CANADIAN TCM REGULATORY FRAMEWORK CONT'D

- 99% OF THE SINGLE HERBS IN THE 2020 CHINESE PHARMACOPOEIA ARE LICENSED
 - INCLUDING POTENTIALLY TOXIC INGREDIENTS XIXIN, CAOWU, CHUANWU AND FUZI ETC.
 - CLASS I II AND III WITH CLASS I AND II ARE MONOGRAPH BASED
 - THE SAME MEDICINE HAS DIFFERENT FORMULATION IN CANADA, AND PARTS OF CHINA (ANGONG NIUHUANG WAN)
- CANADA HAS STRICT STANDARDS ON PRODUCT IMPURITIES FOR NHP (TCM)
 - TOUGHEST IN HEAVY METAL, ALSO INCLUDES MICROBIAL, SOLVENTS, PESTICIDES AND MYCOTOXINS
 - MUST MEET CHINESE (PHARMACOPOEIA) AND [CANADIAN STANDARDS](#)
- REGULATION MOTIVATED MOSTLY BY FINANCIAL INTEREST
 - SAVE THE COST OF THE PUBLICLY FUNDED HEALTH CARE SYSTEM



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Licensing Schematic Diagram of TCM Import



NPN Product Licences

NPN 80136404
Fufang Danshen Hanpian
NPN 80122767
Luobuma Jiangya Pian
★
★
★

Canadian GMP site licence

Pharma Herb Inc.

Legally responsible party



Chinese and Canadian GMP site licence(s)

Jinmon Group Site 1 and Site 2



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PRODUCT AND SITE LICENCING RESPONSIBILITIES

- MEET CHINESE AND CANADIAN SAFETY, QUALITY AND EFFICACY RESPONSIBILITIES
 - PRODUCTS MEET LICENCING REQUIREMENTS – GMP TO ENSURE SAFETY, EFFICACY AND QUALITY
 - LABELLING ACCORDING TO LICENSE AND BILINGUAL IN ENGLISH AND FRENCH
- DOCUMENTED OPERATION ACTIVITIES TO DEMONSTRATE COMPLIANCE
 - PRODUCT RELEASE, TESTING, STORAGE, TRACING, RECALL, STABILITY, CHANGE
 - SANITATION, PEST CONTROL, SHIPPING, TRAINING, CORRECTIVE AND PREVENTIVE ACTIONS AND OPERATION RECORDS
- SUPPORT TCM DOCTORS IN TCM MEDICATION DISPENSING



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KEY STRATEGIC ADVANTAGES, RISKS/OPPORTUNITIES OF TCM

- CANADIAN INFRASTRUCTURE IS READY FOR USERS – CURE DISEASES
 - GOOD CLINICAL EXPERIENCE MAKES BELIEVERS IN TCM, MAINSTREAM ADOPTION GROWING
- SELF-CARE FRAMEWORK AND TCM
 - CANNOT REGULATE NATURAL HEALTH PRODUCTS THE SAME AS NON-PRESCRIPTION DRUGS⁴
 - CAN WE TIGHTEN THE OVERSIGHT OF NHPS WHILE THEY ARE CONSIDERED FOOD IN THE US?
 - NO EXTRA COST IN LICENCING IN THE US, CANADIANS CAN BUY PRODUCTS ONLINE
 - NEED CONSTANT GUIDANCE AND FEEDBACK TO NNHPD ON OPERATIONAL CHALLENGES (2024 [MIRABILITUM PRAEPARATUM](#))
- MUCH WORK IS STILL AHEAD, FINE-TUNING THE REGULATING OF THE MEDICINE PART OF TCM

⁴ The Star - between 2000 and 2011, an average of 68 Canadians died each year because of acetaminophen





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複方丹參含片

Fufang Danshen Hanpian



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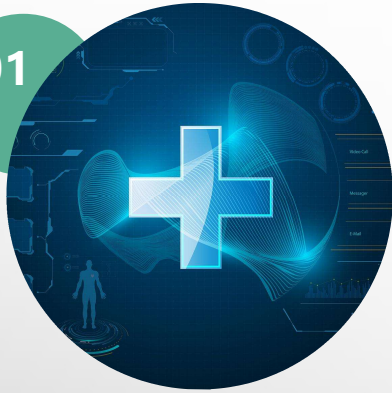
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Introduction to Fufang Danshen Hanpian

01



Composition



Traditional Chinese Medicine composed of Salvia miltiorrhiza, Panax notoginseng and Borneolum syntheticum

02



Function



Traditional Chinese Medicine used to invigorate blood, dissolve stasis, regulate Qi and relieve pain due to Qi stagnation.

03



Dosage



Adults 18 years and older:
2 tablets 3 times per day
Dissolve two tablets entirely in mouth. Avoid taking with food.

Effective compounds and pharmacology

Function

Antioxidant

Central
conditioning

Anti-
inflammatory

Protect
heart
muscles

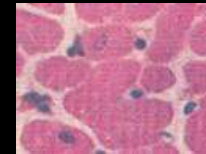
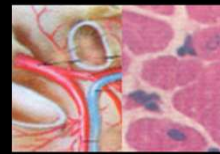
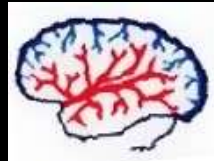
Blood vessel

Hypothalamus

Cells

Cells

Target

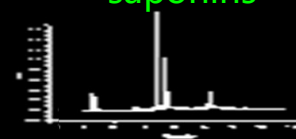
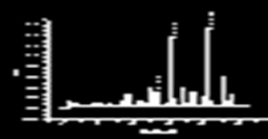
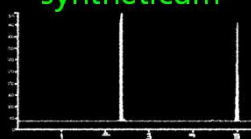
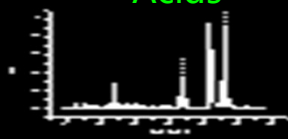


Salvianolic
Acids

Borneolum
syntheticum

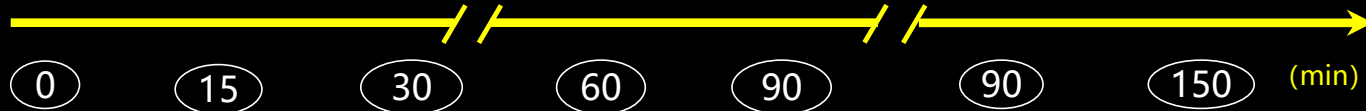
Tanshinone

Notoginseng
saponins



Compound

Time



973 Basic Research Project of China

Selected peer reviewed research articles

© Med Sci Monit, 2008; 14(1): RA1-7
PMID: 18160949

www.MEDSCI MONIT.COM
Review Article

Received: 2007.06.11
Accepted: 2007.11.26
Published: 2008.01.01

Authors' Contribution:

- A** Study Design
- B** Data Collection
- C** Statistical Analysis
- D** Data Interpretation
- E** Manuscript Preparation
- F** Literature Search
- G** Funds Collection

Compound *salvia* droplet pill, a traditional Chinese medicine, for the treatment of unstable angina pectoris: A systematic review

Zhang Junhua^{1,2A,B,C,E}, Shang Hongcai^{1,3A,B,D,G}, Gao Xiumei^{2A}, Zhang Boli^{2A,G},
Xiang Yaozu^{1B,F}, Cao Hongbo^{1B}, Ren Ming^{1B}, Wang Hui^{1B,F}

2007MEDLINE, EMBASE, Chinese Biomedical Database (CBM), and the Cochrane Center Controlled Trials Register – The paper searched randomized controlled trials databases of compound danshen preparation for the treatment of unstable angina published in any language, mainly comparing compound danshen preparation and western medicine with western medicine alone. A total of 17 randomized clinical trials were included, involving a total of 1462 patients.





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羅布麻降壓片

Luobuma Jiangya Pian

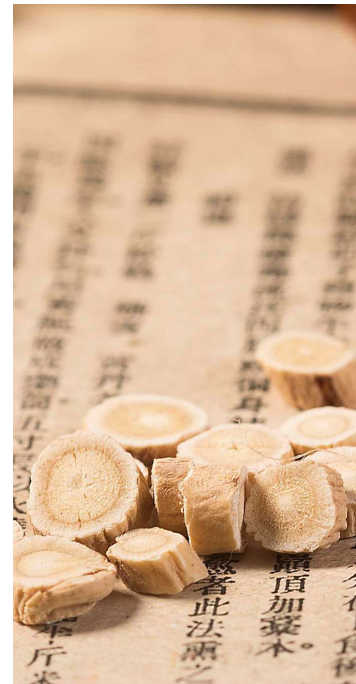


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The Characteristics and treatment methods of Liver Yang Ascension



Characteristics

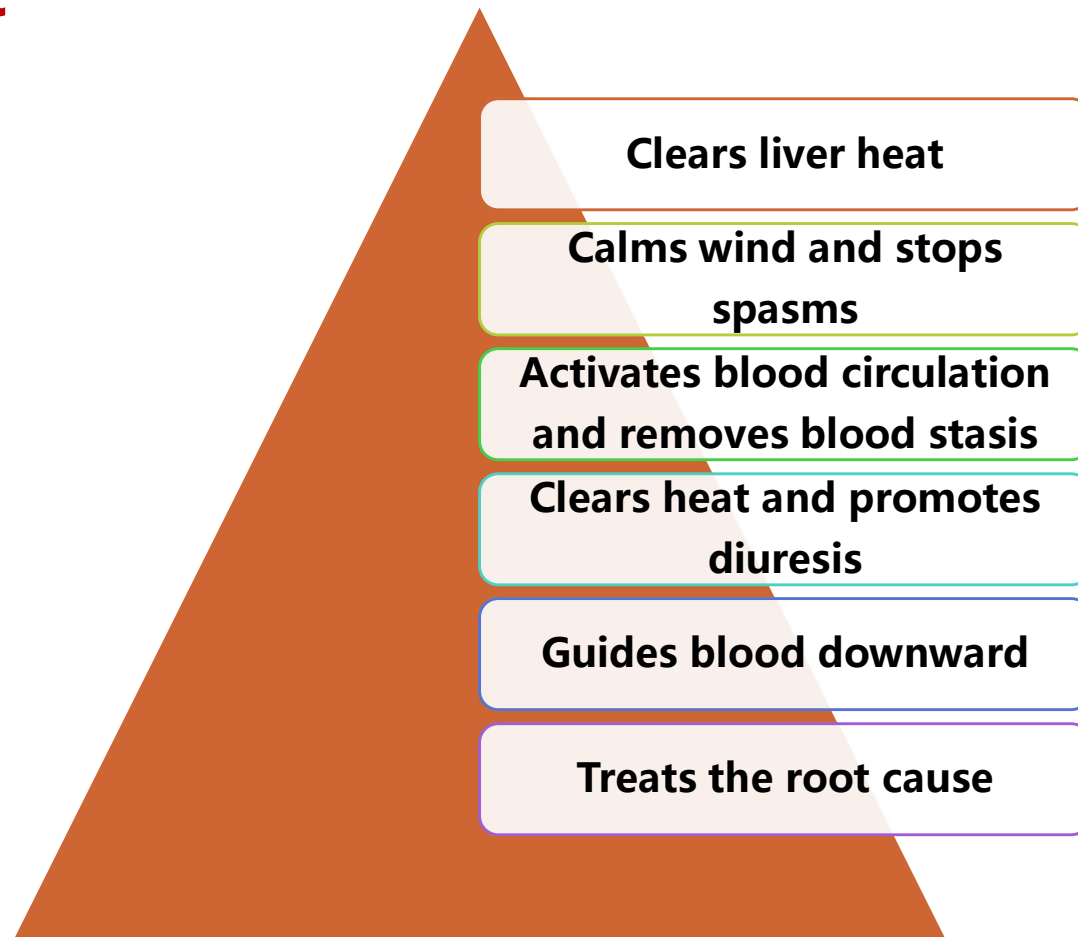
Headaches (often throbbing, located at the temples or vertex), Dizziness/Vertigo, constipation Tinnitus (ringing in ears), Irritability or quick temper, Red face/eyes, Dry mouth with bitter taste, Insomnia or restless sleep, Tongue: Red with yellow coating, Pulse: Wiry or rapid



Methods

Subdue Liver Yang and anchor hyperactivity, clear heat and extinguish wind. The commonly used formula is Tian Ma Gou Teng Yin with modifications, which includes herbs such as Rhizoma Gastrodiae and Ramulus Cum Uncis Uncariae etc.

TCM Theoretical Approach: Multi-Path Coordinated Treatment



Recommended Use

- **Subdue the liver and suppress Yang, remove wind, invigorate Blood and open collaterals.**
- **Specifically designed for: Liver Yang Ascension with blood stasis and blocked collaterals.**
- **Symptoms: It is effective for patients who have typical symptoms of Liver Yang Ascension, such as dizziness, headache, irritability and insomnia. It is also effective for lipids regulation due to the ingredients Fructus Crataegi and Rhizoma Alismatis.**

Luobuma Jiangya Pian: Product Advantages

All Natural Ingredients

Compose of pure herbs and minerals

Wholistic function

Targeting a specific TCM syndrome (liver yang hyperactivity), the aim is to improve the overall balance and associated symptoms, rather than simply lowering blood pressure..

Multi-targeted

- Subdue the liver and suppress Yang, remove wind, invigorate Blood and open collaterals.

Traditional Experience

Over 25 years of safe usage experience in Canada





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Q & A

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PRESENTER INTRODUCTION

- DANIEL SIN, BASC (U TORONTO), MASC (U TORONTO), MBA (IVEY), CISM, P. ENG.
 - PROFESSIONAL ENGINEER P. ENG
 - NHP REGULATORY SPECIALIST AND CERTIFIED QUALITY MANAGEMENT IN
 - CGMP, ISO9001, ISO13485, HACCP, GFSI, GAP
 - MEMBER OF HEALTH CANADA TCM ADVISORY COMMITTEE MEMBER 2010-12
 - 20 YEARS EXPERIENCE IN FOOD/NHP/TCM REGULATORY AFFAIRS, INTIMATE KNOWLEDGE OF QUALITY MANAGEMENT AND NORTH AMERICAN HEALTHCARE DELIVERY
 - TCM PRODUCT RESEARCH AND DEVELOPMENT
 - CANADIAN TCM (NATURAL HEALTH PRODUCT) LICENCING SERVICES



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