

2026 Canada International Conference on TCM & Acupuncture
金木集团赞助-2026 加拿大国际中医药研讨会

FEDERAL REGULATIONS OF TRADITIONAL CHINESE MEDICINE AND MEDICAL DEVICES

DANIEL SIN
CYCTEK INC.



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Federal Regulations of Traditional Chinese Medicine and Medical Devices
中药和医疗器械的联邦法规

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DANIEL SIN P ENG

- PROFESSIONAL ENGINEER – P. ENG REGULATED PROFESSIONAL LIKE YOU
 - OVER 20 YEARS OF EXPERIENCE IN TCM AND ITS MANUFACTURING QUALITY MANAGEMENT
 - THANK YOU FOR THE 2025 NHP COST RECOVERY SUPPORT



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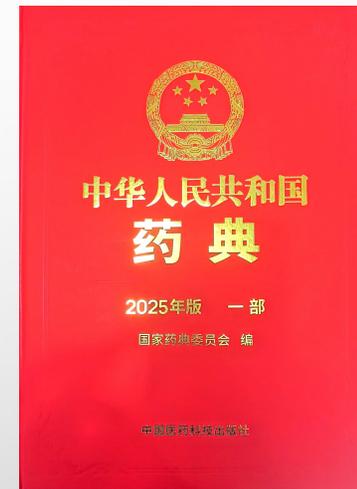


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TCM IN CANADA

- REGULATED BY THE NATURAL HEALTH PRODUCT REGULATION (NHPR)
 - 2003, IT IS THE LAW
 - TCM IS A SMALL PART OF NATURAL HEALTH PRODUCTS (15%)
- HEALTH CANADA USED THE CHINESE PHARMACOPOEIA AS THE SCIENTIFIC REFERENCE
 - CHINESE PHARMACOPOEIA IS THE KEY SCIENTIFIC EVIDENCE FOR TCM
 - TECHNICAL PROCESS IS GOOD MANUFACTURE PRACTICES - GMP



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TRADITIONAL CHINESE MEDICINE

- HEALTH CANADA DEVELOPED A TCM 专著
- FIRST IMPORTANT CONCEPT
 - TCM IS MEDICINE IS NOT SUPPLEMENT!

Government of Canada / Gouvernement du Canada

MENU

Canada.ca > Health Canada > Drugs & Health Products > Natural Health Products > Natural Health Products Ingredients Database

Traditional Chinese Medicine Ingredients (TCMI)

This monograph is intended to serve as a guide to industry for the preparation of Product Licence Applications (PLAs) and labels for natural health product market authorization. It is not intended to be a comprehensive review of the medicinal ingredients.

Natural Product Number (NPN):
80136404

Brand name(s):
Yubentang Fufang Danshen Hanpian ;
Fufang Danshen Hanpian ;
Fufang Danshen Tablet ;
Salvia Miltiorrhiza Tablet

Licence holder:
Beijing Yubentang Holding Group Co., Ltd.

Recommended use or purpose:
Traditional Chinese Medicine used to invigorate blood, dissolve stasis, regulate Qi and relieve pain due to Qi stagnation.
Traditional Chinese Medicines used for Qi stagnation and blood stasis.

to the Natural and Non-Prescription Health Products Directorate (NNHPD), the applicant is attesting that the e outlined in this monograph, including the conditions found in the Traditional Chinese Medicine (TCM) referenced ; restrictive and/or not specified in this monograph. The conditions of use include methods of preparations, source ons of medicinal ingredients, risk statements, and the theory of TCM.
its and all pharmacopoeial ingredients must be prepared in accordance with the most recent edition of an accepted ick of China). Ingredients not prepared according to pharmacopoeial standards are not supported by this

...name), describe the same common name and/or pharmacopoeial name, is considered fundamental change

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MANUFACTURER/IMPORTER COMMITMENTS

中国药典 2025 年版

桂 枝

Guizhi

CINNAMOMI RAMULUS

本品为樟科植物肉桂 *Cinnamomum cassia* Presl 的干燥嫩枝。春、夏二季采收，除去叶，晒干，或切片晒干。

【性状】 本品呈长圆柱形，多分枝，长 30~75cm，粗端直径 0.3~1cm。表面红棕色至棕色，有纵棱线、细皱纹及小疙瘩状的叶痕、枝痕和芽痕，皮孔点状。质硬而脆，易折断。切片厚 2~4mm，切面皮部红棕色，木部黄白色至浅黄棕色，髓部略呈方形。有特异香气，味甜、微辛，皮部味较浓。

【含量测定】 照高效液相色谱法(通则 0512)测定。

含桂皮醛(C₉H₈O)不得少于 1.0%

not less than 1.0 per cent of cinnamic aldehyde

Cinnamomi Ramulus

(桂枝, Guizhi)

Cassia Twig

Cassia Twig is the dried young branch of *Cinnamomum cassia* Presl (Fam. Lauraceae). The drug is collected in spring and summer, removed from leaf, dried in the sun, or dried in the sun after sliced.

Description Long cylindrical, much-branched, 30-75 cm long, thick end 0.3-1 cm in diameter. Externally brown to reddish-brown, with longitudinal ridges, fine wrinkles, dotted leaf-scars, branch-scars and bud-scars, lenticels dotted. Texture hard and fragile, easily broken.

It contains not less than 1.0 per cent of cinnamic aldehyde (C₉H₈O), calculated with reference to the dried drug.



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MANUFACTURER/IMPORTER COMMITMENTS

中华人民共和国
国家药品监督管理局
标准

WS-10271 (ZD-0271)-2002-2011



Health Canada Santé Canada

Product Licence
Licence de mise en marché

二夏清心片

Erxia Qingxin Pian

【处方】

冬虫夏草 30g	半夏（麸炒） 120g	竹茹（麸炒） 120g
枳实（麸炒） 120g	陈皮 180g	茯苓 100g
炙甘草 60g	石菖蒲 120g	葛根 180g
干姜 50g		
滑石粉 6g	糊精 18g	硬脂酸镁 3g

制成 1000 片

【制法】 以上十味药材，冬虫夏草，茯苓粉碎成细粉，备用。其余半夏、竹茹等八味，加水煎煮二次，第一次 2 小时，第二次 1.5 小时，滤过，合并滤液；滤液浓缩至相对密度为 1.25~1.30 (50~60℃) 的清膏，加入上述细粉及滑石粉、糊精、硬脂酸镁，搅拌均匀，干燥，粉碎，制粒，压片，包糖衣，即得。

【含量测定】 照高效液相色谱法（中国药典 2000 年版一部附录 VI D）测定。
本品每片含葛根以葛根素（C₂₁H₂₀O₉）计，不得少于 0.09mg。

Product Number/Numéro de produit: 80144296

Brand Name/Marque nominative: Erxia Qingxin Pian

Other Brand Name(s)/Autre(s) marque(s) nominative(s):

Erxia Qingxin Tablet

UHerb Erxia Qingxin Tablet

Issued to/Émise à:

Name of licensee/Nom du titulaire:

Pharma Herb Inc.

19-60 West Wilmot Street



Health Canada Santé Canada

Quality of Natural Health Products Guide

Natural and Non-prescription Health Products Directorate



905-882-1083

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PRACTITIONER REQUIREMENTS

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Natural Health Product (NHP) Compounding Policy



The Natural Health Products Directorate (NHPD) has changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs). Please note that we are currently modifying documents to reflect this change.

Thank you for your patience and understanding.

Natural Health Products Directorate,
Health Products and Food Branch, Health Canada

October 10, 2006

• COMPOUNDING

- ALLOWS FLEXIBILITY
- MUST USE NHPS (TCM)
 - NPN
- LICENCED IMPORTERS
- LICENCED MANUFACTURERS



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COMPOUNDING

- CAPSULING OR PACKING OF NHPS IS ALLOWED
 - FOR A SPECIFIC PATIENT OR A PRACTICE REQUIREMENT
 - NOT MASS MANUFACTURING OR GENERAL SALE
 - UNAVAILABLE PRODUCT
 - NO CLEAR OPERATION GUIDANCE
 - SANITARY CONDITIONS



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GREY AREAS

- LOOSE HERBS WERE EXEMPTED FROM NHPR
 - FOOD IMPORTERS DO NOT TEST IF PRODUCTS MEET TECHNICAL STANDARDS
 - VOLUNTEER TESTING BY UNITED WINGS
 - COMPOUNDING REQUIRES NHPS
 - DOCTORS NEED MEDICINES
 - IS THERE LIABILITY?



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MEDICAL DEVICES REGULATIONS

 Government of Canada / Gouvernement du Canada

Search

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Medical Devices Regulations (SOR/98-282)
Full Document: [HTML](#) (Accessibility Buttons available) | [XML](#) [446 KB] | [PDF](#) [849 KB]
Regulations are current to 2026-02-18 and [last amended](#) on 2026-01-01. [Previous Versions](#)
Enabling Act: [FOOD AND DRUGS ACT](#)
Notes :

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

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Any instrument, apparatus, contrivance, material, or other article

- Diagnosis
- Treatment or Prevention
- Restoring or Modifying Body Functions
- Contraception



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[Canada.ca](#) > [Health Canada](#) > [Drugs & Health Products](#) > [Medical Devices](#) > Medical Devices Licence Listing

Active licence listing by company

From [Health Canada](#)

Manufacturer

APPLE INC.
*One Apple Park Way
Cupertino, CA, US, 95014*

Company ID: 145169

Licence No.: 102864

Type: Device Family
Device class: 2
Device first issue date: 2019-05-16
Licence name: ECG APP

Device details

Device first issue date:	Device name	Identifier first issue date	Device identifier
2019-05-16	ECG APP	2019-05-16	00190198909534
		2019-05-16	00190198909541



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EXAMPLES

- ACUPUNCTURE NEEDLES AND STIMULATORS
 - 130 PRODUCT GROUPS LICENSED PRODUCT LINES
- MOXIBUSTION
 - MEDICAL DEVICES AND NPNS
- [APPLE APPS AND DR-HO'S](#)
- INFRARED HEAT TREATMENT DEVICES
- MERIDIAN HEALTH DIAGNOSTIC MACHINE



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TYPICAL ENFORCEMENT

- COMPLIANCE LETTER OR WARNING
- STOP-SALE REQUEST
- PRODUCT RECALL
- LICENCE SUSPENSION
- PRODUCT SEIZURE
- PROSECUTION (RARE)
- MOST IMPORTANT FOR PROFESSIONALS IS LIABILITY



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QUESTIONS



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