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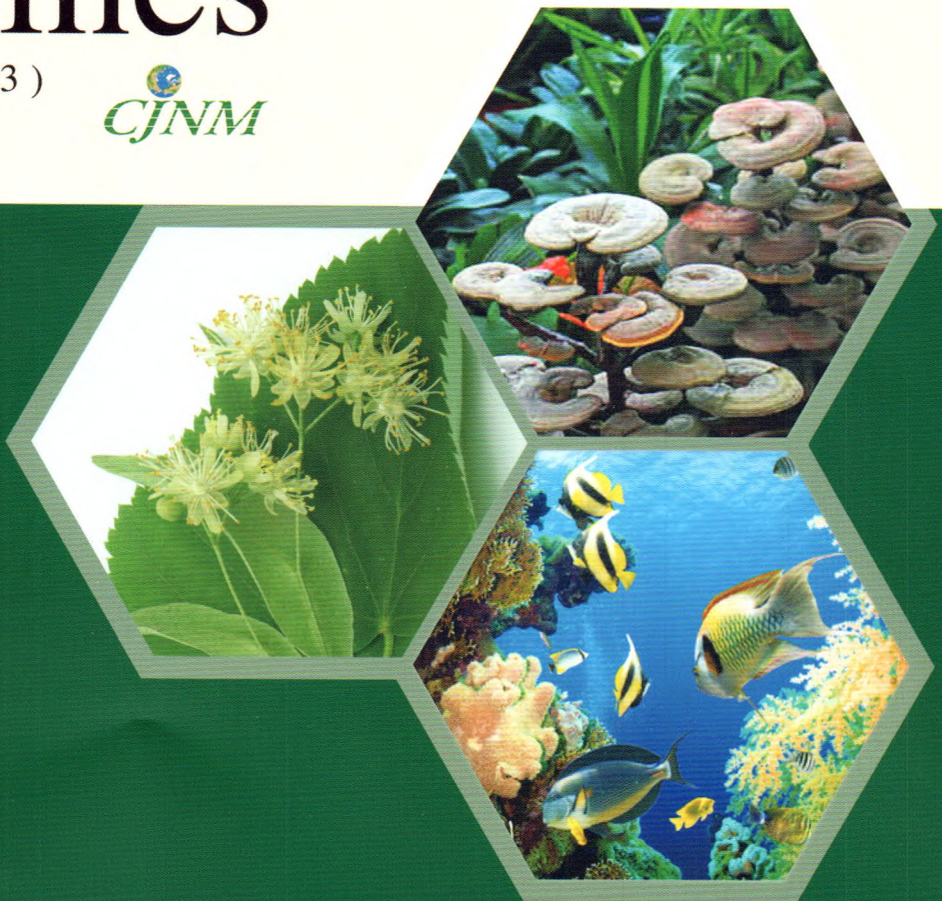
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Evolution of the registration regulations for proprietary Chinese medicines in China

YUAN Lin, MBA, Director-General, Department of International Cooperation, CFDA

Regulation of proprietary traditional Chinese medicines in Australia

Dr David Trevor GRAHAM, B Pharm, FPS, PhD, FAICD



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Contents

·Editorial·

Traditional Chinese medicine: research and development, globalization, and regulation

1-3

ZHANG Rui-Wen*

In this issue of *Chinese Journal of Natural Medicines (CJNM)*, we are pleased to publish two comprehensive and timely review articles addressing the registration regulation of traditional Chinese medicine (TCM), a critical issue in the development, regulation, and internationalization of TCM.



·Special topic·

Evolution of the registration regulations for proprietary Chinese medicines in China

4-11

YUAN Lin, WU Zhi-Ang*, SHAO Ming-Li*

In this review, we provide a comprehensive overview on the registration of proprietary Chinese medicines (PCMs) in China over the past century by examining published literature and historical data. We will examine this evolving administrative practice for PCMs registration in China, which is divided to the following five stages: (1) initial measures (1915–1948); (2) early development (1949–1965); (3) provincial approval and trial implementation of the “approval number” system (1966–1984); (4) legislation and cleanup (1985–1999); and (5) centralized national approval (2000 until now), offering a panoramic view on the characteristics of PCMs registration management in China.



Regulation of proprietary traditional Chinese medicines in Australia

12-14

David T. Graham*

This review article describes the regulation of proprietary Chinese medicines for the Australian market, which may permit many medicines used in Traditional Chinese Medicine to have a simplified process of market access provided that certain criteria for acceptable public safety are met.



·Research articles·

Anti-tumor activity of wogonin, an extract from *Scutellaria baicalensis*, through regulating different signaling pathways

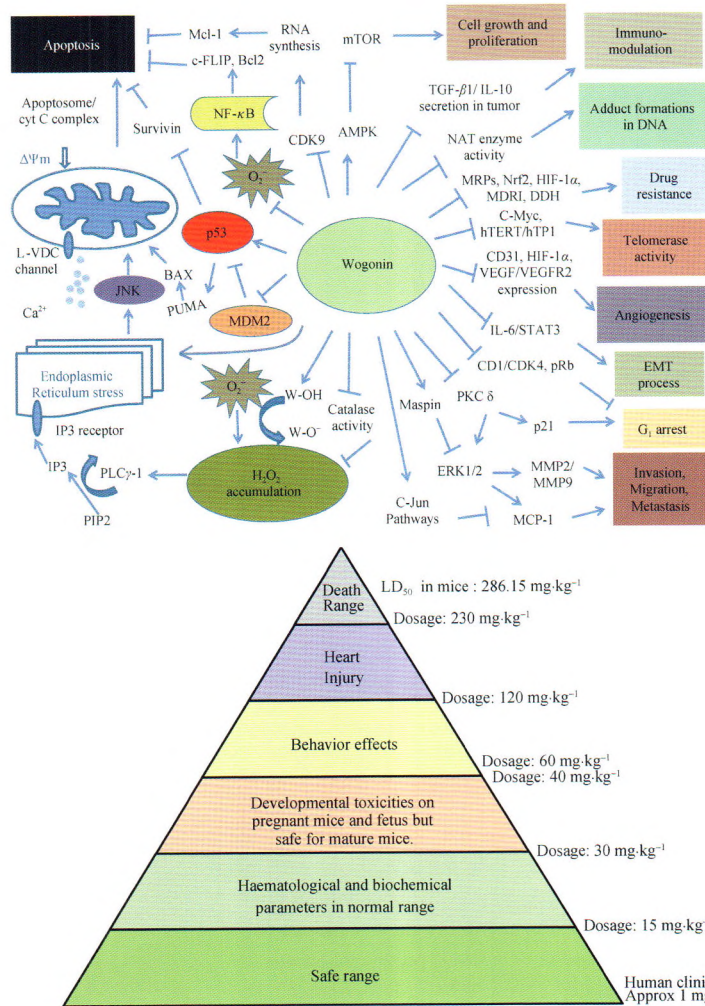
15-40

Do Luong Huynh, Neelesh Sharma, Amit Kumar Singh, Simrinder Singh Sodhi, ZHANG Jiao-Jiao, Raj Kumar Mongre, Mrinmoy Ghosh, Nameun Kim, Yang Ho Park, Dong Kee Jeong*

Wogonin, one of bioactive compounds extracted from the root of *Scutellaria baicalensis*, has been certified itself in anti-cancer activity via various signaling pathways *in vitro* and effectively inhibits tumor growth *in vivo* without side effects. Those impacts are including:

- Induction of apoptosis in both intrinsic and endoplasmic reticulum pathway
- Inhibition of cancer growth and cell cycle arrest
- Acts as angiogenesis inhibitor, effects on invasion and metastasis
- Telomerase inhibitor and anti-DNA adducts formation
- Anti-drug resistance in hypoxia and works as chemosensitizer
- Anti-inflammation related to carcinogenesis

Besides, wogonin derivatives are also developed to surmount its low bioavailability and to enhance its cytotoxicity to cancer cells. Wogonin pharmacokinetics and its side effects are also discussed in this review to figure out the metabolism of wogonin, the presence of this compound in animal models, and its safe range of applicable dose as well.

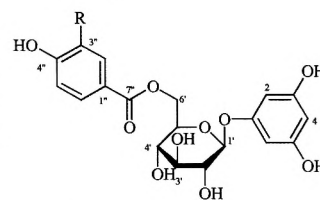


Two new phenolic glycosides isolated from the fruits of *Citrus aurantium*

41-44

ZHANG Xiao-Li, XU Wen-Feng^Δ, CHEN Gang, WANG Hai-Feng*, PEI Yue-Hu*

Two new phenolic glycosides, 1-*O*-3, 5-dihydroxyphenyl-(6-*O*-4-hydroxybenzoyl)- β -D-glucopyranoside (1) and 1-*O*-3, 5-dihydroxyphenyl-(6-*O*-3-methoxy-4-hydroxy benzoyl)- β -D-glucopyranoside (2), were isolated from the fruit of *Citrus aurantium*.



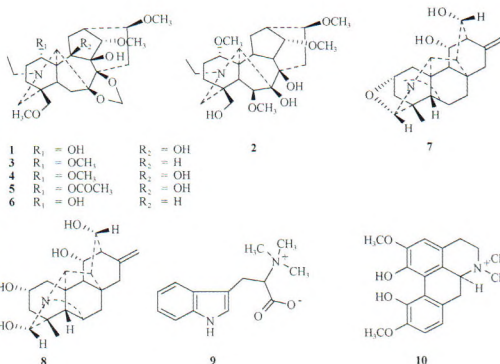
1, R = H

2, R = OCH₃

A new diterpenoid alkaloid isolated from *Delphinium caeruleum*

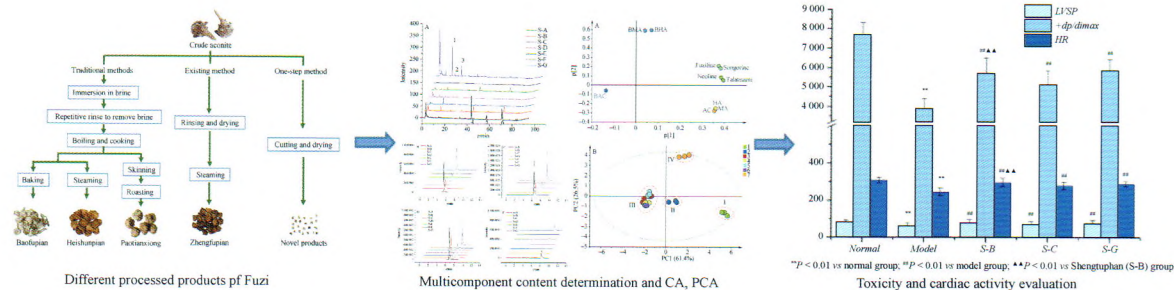
45-48

LIN Chao-Zhan, LIU Zhu-Jie, BAIRI Zeren-Dawa, ZHU Chen-Chen*



Compound 1 was a new licoctonine-type C19-diterpenoid alkaloid.

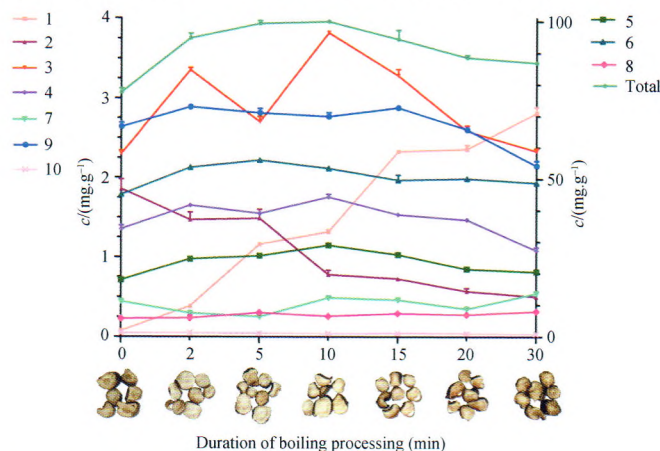
ZHANG Ding-Kun, HAN Xue, TAN Peng, LI Rui-Yu, NIU Ming, ZHANG Cong-En, WANG Jia-Bo*, YANG Ming*, XIAO Xiao-He



Effects of boiling duration in processing of White Paeony Root on its overall quality evaluated by ultra-high performance liquid chromatography quadrupole/time-of-flight mass spectrometry based metabolomics analysis and high performance liquid chromatography quantification

KONG Ming, XU Jun^Δ, LIU Huan-Huan, XU Jin-Di, LI Xiu-Yang, LU Min, WANG Chun-Ru, CHEN Hu-Biao*, LI Song-Lin*

Boiling processing conspicuously affected the holistic quality of White Paeony Root, and the duration of 2–10 min is recommended regarding both appearance and bioactive component contents.



Eurycoma Longifolia as a potential adoptogen of male sexual health: a systematic review on clinical studies

Hnin Ei Thu, Isa Naina Mohamed, Zahid Hussain, Putri Ayu Jayusman, Ahmad Nazrun Shuid*

The aim of the present review is to analyze and summarize the literature on human clinical trials which revealed the clinical significance and therapeutic feasibility of the *Eurycoma longifolia* (EL) in improving male sexual health. The findings of human clinical studies revealed a promising efficacy of EL to treat erectile dysfunction in sexually sluggish males by improving penile erection, erectile hardness and sexual performance. The clinical significance of EL in male infertility was also evidenced by significantly improving semen volume, concentration of sperms, and proportion of sperms having normal morphology, sperm motility, sexual libido, and overall sexual satisfaction. The critical analysis of the literature assessed that sex boosting effects of EL are due to its testosterone levels enhancing effects in males.

[Reference of *CJNM*] CN32-1845/R*2003*m*A4*80*en*P*¥50.00*1500*09*2017-1

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Aims and Scopes

The Chinese Journal of Natural Medicines (CJNM) is devoted to communications among pharmaceutical and medicinal plant scientists who are interested in the advancement of the botanical, chemical, and biological sciences in support of the use of natural medicines in health care, in particular, traditional Chinese medicines (TCM). CJNM aims to cover a broad spectrum of original research papers and review articles on natural medicines or their products from all over the world, including those from TCM.

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- Biological and Pharmacological Activity
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- DNA-based Botanical Authentication
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