

坚持守正创新 服务健康中国 上海和黄药业 传承岐黄薪火 拓展国粹价值

【现代研究成果】

麝香保心丸 引领中医药循证研究



作为“国家重大新药创制科技专项”产品，上海和黄药业独家产品麝香保心丸上市40年来，凭借扎实的丰富的现代研究成果，先后荣获“2011年度上海市科技进步一等奖”和“2018年度国家科技进步二等奖”，成为我国中药现代化研究、中药大品种二次开发的成功典范。

上市以来，麝香保心丸已累计发表现代研究成果论文2800余篇，其中SCI论文80余篇。2021年4月，麝香保心丸历时十年的MUST研究结果正式发布，这是首个以心脑血管事件为主要终点的冠心病中医药二级预防研究，通过循证医学的方法证实：长期服用麝香保心丸可以显

著改善心绞痛稳定性和发作频率评分，意味着麝香保心丸可以有效缓解患者症状、显著提升患者生活质量；长期服用麝香保心丸的患者肝肾功能及代谢相关不良事件发生率与对照组相当，体现出麝香保心丸长期应用的良好安全性。

在确切的循证研究数据面前，麝香保心丸赢得了临床专家一致的肯定和认可。截至目前，麝香保心丸已经获得《急性心肌梗死中西医结合诊疗指南（第2版）》《心力衰竭合理用药指南（第2版）》《中成药治疗冠心病临床应用指南（2020版）》《慢性心力衰竭中医诊疗专家共识》《动脉粥样硬化中西医结合诊疗专家共识》等多个指南与共识的推荐，为医生临床实践带来一定的指导意义。

凭借突出的临床疗效和市场表现，麝香保心丸已是载誉满满：连续两年上榜“中国家庭常备心脑血管药”榜单，唯一入选“十大医药影响力品牌”的中成药，荣获“‘十三五’中国医药科技标志性成果”荣誉称号。中国科学院院士陈可冀教授曾

2021 年
传承人文情怀
铸医学温度



上海和黄药业总裁 周俊杰

医师报讯（融媒体记者 王建生）胆宁片发明专利“Traditional Chinese medicine herb composition, making thereof, and application thereof”（一种中药组合物及其制备与应用）获加拿大知识产权局授权。

2022年1月18日，加拿大知识产权局发布的一条公告，不胫而走。这是上海和黄药业旗下中药产品获得授权的第一个PCT（国际专利体系）发明专利，标志着胆宁片加拿大知识产权保护体系完成构建。

2021，是上海和黄药业的又一个丰收年：核心产品麝香保心丸入选“2021中国医药品牌榜医院终端品牌榜”，获选“‘十三五’中国医药科技标志性成果”“中国医药最具成长力产品品牌”“十大医药影响力品牌”。



评价麝香保心丸是我国心血管治疗领域的著名中成药，始终坚持走循证发展之路，

注重学术研究及基础研究，是继承、发展、创新中国传统医药的典范。

传国粹 思创新

在传承经典中药产品的基础上，依托和记黄埔强大的研发实力，上海和黄药业应用国际先进的科学技术和方法，对传统中药产品进行二

次开发、不断创新，包括进一步阐明复方中药的药效物质基础、作用机理和临床疗效，建立了现代中药全面质量控制体系等，为我国中药

现代化和国际化树立了典范。如今，上海和黄药业正成长为海内外具有全球影响力及核心竞争力的中药企业之一。

上海和黄药业有限公司由和记黄埔（中国）有限公司与上海医药集团共同投资组建而成，是上海首家中药合资企业。2021年8月，上海和黄药业迎来成立20周年华诞。

作为一家卓越的创新药企，上海和黄药业力行“守正创新，追求卓越”的奋斗理念，取得了众多里程碑式的成绩，先后荣获“新中国成立70周年医药产业标杆企业”“2020年度十大医药创新企业”“2021年度中国医药工业最具投资价值企业”等荣誉称号，并多次荣登中国中药企业百强榜、中国医药制造业百强榜等，充分展现了上海和黄药业的创新力与品牌力。传承国粹，贵在创新。

Health Canada NATURAL AND NON-PRESCRIPTION HEALTH PRODUCTS DIRECTORATE	
FSRN NOTICE OF ACCEPTANCE	
TO: MAN CHO	FROM: BRUCE G. LI
COMPANY NAME: SHANGHAI HUTCHISON PHARMACEUTICALS LIMITED	DATE: JULY 12, 2019
RECEIVER'S FAX NUMBER:	PAGE(S): 2
RECEIVER'S TELEPHONE NUMBER:	SENDER'S CONTACT NUMBER:
APPLICATION TYPE: FSRN Issuance	COMPANY CODE: 39717
FILE NO.: 244513	SUBMISSION NO.: 244513
Re: Notice of Acceptance for Foreign Site Reference Number 5000525 Shanghai Hutchison Pharmaceuticals Limited 388, Xianye Road, Fengxian District, Shanghai, 201401, China	
Dear Mr. Man Cho, The Natural and Non-prescription Health Products Directorate (NNHPD) is pleased to inform you that the Good Manufacturing Practice (GMP) information submitted for the above Foreign Site Reference Number (FSRN) Application has been assessed and deemed adequate. Your reference number is 5000525 and is valid until 11 July 2020 for the following activities: manufacturer, packager, labeler. Following the assessment of this submission, the following observations were noted: 1. With regards to heavy metal contaminants, please update the finished product specification sheet with the updated limits, which are in agreement with Canadian regulations. 2. Upon renewal, please provide a copy of Certificate of Analysis for Biflow (Damping Tablets) release and stability testing results demonstrating that products meet their specifications at the expiry date for physical description, disintegration, microbiological contaminants, and medicinal ingredients quantity. It is important to note that the issuance of a FSRN is not an authorization for direct export of Natural Health Products (NHPs) into Canada, nor is it considered equivalent to a site licence. The issuance of a FSRN is not an exercise of a statutory power of decision under the Natural Health Products Regulations (the Regulations) as foreign manufacturers are not subject to	

Canadian regulations. Instead, the FSRN process is a service offered by Health Canada to permit Canadian importers to more efficiently demonstrate compliance with section 43(2) of the Regulations (http://www.hc-sc.gc.ca/canreg/regulations/RSR/2003/1363). It also reflects foreign sites from having to repeatedly provide the same GMP information to multiple importers.

With respect to the import for sale of products, it is pursuant to s. 43(2) and s. 100 of the Regulations, the responsibility of Canadian importers to demonstrate that products were manufactured, packaged, and labelled in accordance with requirements that are equivalent to those set out in the Regulations.

Please note, should Health Canada become aware of issues at a foreign site, the NNHPD will contact the relevant regulated parties (i.e. importers) in Canada to seek information to determine whether imported products comply with the Regulations.

Once a FSRN holder engages in a partnership with a licensed Canadian importer in order to export natural health products into Canada, the FSRN holder may authorize importers in Canada to access their information to support the importer's site licence application. Your authorization is to be given by completing the Foreign Site Reference Number Authorization Form found on the NNHPD website (http://www.hc-sc.gc.ca/https://prod/nhp/applications/licence-site/canadian-importer-form-site-ref-no-2019-01-23.pdf). A separate authorization form must be provided to each importer as the information captured in the form will be specific to the business arrangement between the two companies. The regulated party (importer) is then responsible for providing the completed form to the NNHPD as part of their application for a site licence.

In order to maintain the status of your FSRN, it is necessary that you update your GMP information by filing an application for FSRN renewal before the date of expiry mentioned above. If you have any questions regarding the application process or if you need information on how to maintain your reference number, please contact the NNHPD by email at: NNHPD_OPNSO@hc-sc.gc.ca.

Should you have any questions concerning this notice, please contact the Site Assessment Officer at the coordinates indicated at the top of this notice. Please note that the company code, file number, submission number, and foreign site reference number must be quoted on all correspondence regarding this submission.

Yours sincerely,
Heather Gilmer, Manager
Site Licence Assessment Unit
Natural and Non-prescription Health Products Directorate

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关键词一 个性签名

“守正创新，追求卓越” “创新传统中药，服务健康中国”

关键词二 企业名片

荣登“2020年度中国中药企业TOP100排行榜”；入选“新中国成立70周年医药产业标杆企业”；核心产品麝香保心丸入选“2021中国医药品牌榜医院终端品牌榜”，获选“‘十三五’中国医药科技标志性成果”“中国医药最具成长力产品品牌”“十大医药影响力品牌”