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Traditional Chinese medicine — General requirements for the manufacturing process of natural products

Médecine traditionnelle chinoise — Exigences générales relatives au procédé de fabrication des produits naturels

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

Foreword

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

Introduction

Natural products used in traditional Chinese medicine (TCM) are manufactured from materials of natural origin, the quality of which is varied according to geographical, climatic and seasonal conditions. For quality assurance of final products, quality evaluation on starting materials for natural products used in TCM is essential. On the other hand, it is also important to handle these natural materials appropriately and to control manufacturing processes for natural products used in TCM.

The management of manufacturing processes under good manufacturing practice (GMP) is indispensable to ensure quality of medicinal products. International GMP was issued by World Health Organization (WHO) in 1967, and a number of regional and international GMPs have subsequently been established. Recently, Pharmaceutical Inspection Convention (PIC)/Pharmaceutical Inspection Cooperation Scheme (PIC/S) has been widely applied around the world. At present, two-thirds of the member bodies of ISO/TC 249 are affiliated with PIC/S and some other countries are waiting for review of their applications.

These general GMPs were extensively applied to different fields and complimented with special supplements for herbal medicines in some countries and organizations. However, these herbal GMPs are focusing on European herbal medicines, but not covering those in the East Asian regions such as China, Japan and Korea where traditional medicines are used.

The current herbal GMPs of WHO, EU or PIC/S are mainly based on single herbal products, and the products consisting of more than one herbs were stipulated as special cases. However, multi-herbal products are more common than single-herbal products in the East Asian regions. In addition, raw materials in herbal GMPs of WHO, EU or PIC/S are only exclusive for plant origin, while traditional medicines in East Asia also include animal and mineral materials. In order to use correct materials, it is important to identify the starting materials not only by physical/chemical examinations but also by perceptive identification by well-trained experts. However, the requirement for experts on natural materials are not described in these international herbal GMPs. For a better safety and quality control of TCM products, conventional GMPs for the manufacturing of herbal medicines are in need of improving by this proposed standard.

Therefore, based on Chinese, Japanese and Korean herbal GMPs, and with reference to international GMPs, this document specifies general requirements for manufacturing processes that are particularly applied to natural products used in TCM. Implementation of this document with conventional GMPs for general pharmaceutical products would make it possible for manufacturers to ensure the safety and quality of natural products used in TCM, and at the same time prevent people in countries where such products are used from health hazards caused by poor quality products as well as improving their health. It will allow people to enjoy the benefits of natural products used in TCM for treatments of diseases as well as promoting health. This document will also allow non-PIC/S member countries to request quality assurance of the products to manufacturers and manufacturing countries with reference to this document. Finally, this document will make it possible to complement and/or amend WHO, EU and PIC/S herbal GMPs.

Traditional Chinese medicine — General requirements for the manufacturing process of natural products

1 Scope

This document specifies the general requirements for manufacturing processes to ensure the quality of finished products used in traditional Chinese medicine (TCM). This document covers premises, documentation, personnel, training, manufacturing control and quality control. This document applies to the manufacturing of natural products used in and as TCM.

This document does not conflict with general pharmaceutical good manufacturing practices (GMPs).

This document applies to all materials of natural origin: medicinal plants, medicinal animals, medicinal minerals, crude drugs or crude drug preparations.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

NOTE Traditional Chinese medicines include various types of items. The same material can be classified in different categories (e.g. a powdered plant material can be both a crude herbal drug and a crude herbal drug preparation or, in a packed form, a traditional Chinese medicinal product).

3.1
active ingredient
crude drug(s) or the crude drug preparation(s) of a traditional Chinese medicine(s)

[SOURCE: WHO guidelines on good manufacturing practices (GMP) for herbal medicines, modified]

3.2
constituent of known therapeutic activity
substance or group of substances that is chemically defined and known to contribute to the therapeutic activity of a crude drug or of a preparation

[SOURCE: WHO guidelines on good manufacturing practices (GMP) for herbal medicines, modified]

3.3
marker substance
chemically defined constituent of a crude drug utilized for control purposes

Note 1 to entry: Marker substances contribute or not to the clinical efficacy. When they contribute to the clinical efficacy, however, evidence that they are solely responsible for the clinical efficacy can be available or not.

Note 2 to entry: Marker substances are generally employed when constituents of known therapeutic activity are not known or are not clearly identified, and are used to identify the crude drug or preparation or calculate their quantity in the finished product.