



BSI Standards Publication

**Traditional Chinese medicine — Controlled
vocabulary on Japanese Kampo formulas
and the indication codes for the products**

National foreword

This Published Document is the UK implementation of ISO/TR 23022:2018.

The UK participation in its preparation was entrusted to Technical Committee CH/100/1, Traditional Chinese Medicine.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2018

Published by BSI Standards Limited 2018

ISBN 978 0 580 51179 0

ICS 11.120.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 May 2018.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------

Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products

*Médecine traditionnelle chinoise - Vocabulaire contrôlé relatif aux
formules Kampo japonaises et codes d'indication des produits*





COPYRIGHT PROTECTED DOCUMENT

© ISO 2018

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Abbreviated terms	5
5 Conformance	6
6 Coding system	6
Annex A (informative) Controlled vocabulary of Japanese Kampo formulas	8
Bibliography	87

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

Herbal medicines have been developed around the world by utilizing available vegetation to develop uses suitable for the physical constitution of the target population in each area.

Consequently, herbal prescriptions with the same name sometimes have different qualitative composition and quantitative composition strength in different parts of the world. In other words, there are plenty of polysemes (see ISO 1087-1) in the origin of crude drugs among some traditional medicines^[20]. The resulting confusion is further complicated by the use of similar letters^[12] in some countries.

These issues cannot be ignored in the process of standardizing contemporary terminology for medicinal products to keep with up-to-date drug information management policies, from clinical trials to post-market surveillance in the periodic safety update report (PSUR).

Furthermore, therapeutic indications are defined only for medicinal products, but not for formulas specified in some pharmacopoeias including Japan's^{[21][22]}. It is important to take this into account in international standardization though this has not yet been achieved in ISO/TC 249.

Therefore, this document describes the controlled vocabulary for formula names used in Japanese Kampo formulas with the respective indications and efficacies of each product to avoid market distortions and health hazards. The information provided in this document is expected to encourage international trade.

Formulas or traditional medicines that are not controlled by the Japanese Pharmacopoeia and the related official documents published by the Medicinal Regulatory Agency in Japan are beyond the scope of this document.

Traditional Chinese medicine — Controlled vocabulary on Japanese Kampo formulas and the indication codes for the products

1 Scope

This document specifies the controlled vocabulary for formulas used in Japanese Kampo medicine with the therapeutic indications of each product according to the subset of IDMPs (ISO 11238, ISO 11615, ISO 11616^[10], ISO 19844^[15], ISO/TS 20443^[16], ISO/TS 20451^[17]).

This document is intended to be used by:

- traders and distributors of medicinal products in Kampo formulas and crude drugs used in Kampo medicine;
- terminologists and developers of new terminological resources concerning herbal medicines in Kampo medicine, and maintenance officers of existing terminological resources concerning Kampo medicine to enable their conformance;
- informaticians, developers, or managers of HIS, EMR, or EHR systems concerning Kampo medicine;
- officers, analysts or maintenance personnel of national health statistics, and policy proposal staff of national health policies;
- officers of WHO, and WHO statistics.

This edition of this document describes only medicinal products in accordance with the Kampo formula in Japan. Both OTC Kampo formula medicinal products and in-pharmacy formula medicinal products are omitted, although they are permitted under Japanese jurisdiction.

Topics considered out of scope of this document are:

- any medicinal products manufactured in accordance with the formula of traditional medicines that are not permitted under the Japanese jurisdiction;
- whole information models of medicinal products, pharmaceutical products and substances (see ISO 11238) because those are already specified in IDMPs;
- any categorical structure(s) of herbal medicaments (see ISO/TS 18062, ISO 17115^[13] and EN 12264^[18]).

The controlled vocabulary for formulas used in Japanese Kampo medicine is given in [Annex A](#).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 1087-1, *Terminology work — Vocabulary — Part 1: Theory and application*

ISO 11238, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated information on substances*

ISO 11615, *Health informatics — Identification of medicinal products — Data elements and structures for the unique identification and exchange of regulated medicinal product information*