
**Traditional Chinese medicine —
General requirements for
manufacturing procedures and quality
assurance of granules**

*Médecine traditionnelle chinoise — Exigences générales relatives aux
modes opératoires de fabrication et à l'assurance de la qualité des
granules*



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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.

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Herbal medicines used in traditional Chinese medicine have been used as decoctions for thousands of years. However, from the aspect of advantage and convenience in preparation, portability and sanitation, dry extract preparations such as granules or compactates, tablets and capsules have been developed as alternative forms of dosage for decoctions. Decoction is still the most common form of dosage in China, Korea, Australia and many other countries. However, exceptionally in Japan, nearly 100 % of the Kampo product market is taken up by dry extract preparations. Application of dry extract preparations in other countries has increased in recent years and this is expected to continue.

Among the dry extract preparations mentioned above, granules and compactates are the most cost-effective forms of dosage made by simple manufacturing procedures. Although granules are listed in many pharmacopoeias as a major form of dosage, there is no standard specializing in granules made from medicinal plants. In the manufacturing procedure of granules of medicinal plants, there are many critical points to be taken into account. To obtain granules and compactates with consistent good quality and without major processing troubles during manufacturing, these critical points must be clarified and optimized prior to commercial production.

Traditional Chinese medicine — General requirements for manufacturing procedures and quality assurance of granules

1 Scope

This document specifies general requirements for manufacturing procedures and quality and safety assurance of granules and compactates made from traditional Chinese medicine extracts or powder for oral use. This document excludes granules or compactates made from pure compounds (chemically defined) even if they are isolated as naturally occurring constituents of decoction pieces or crude herbal and mineral drugs.

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 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 19609-1, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 1: General requirements*

ISO 19609-2, *Traditional Chinese medicine — Quality and safety of raw materials and finished products made with raw materials — Part 2: Identity testing of constituents of herbal origin*

ISO 19617, *Traditional Chinese medicine — General requirements for the manufacturing process of natural products*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

ISO 22467, *Traditional Chinese medicine — Determination of microorganism in natural products*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

3 Terms and definitions

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

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>