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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

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

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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.