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Traditional Chinese Medicine — General requirements for the ultrafine powder of herbs

ISO/TC 249

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Foreword

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Introduction

Ultrafine powder of herbs is an innovative development of the traditional powder form of decoction pieces that have been used commonly in traditional Chinese medicine for over 2 000 years. Ultrafine powder of herbs is prepared by pulverizing decoction pieces into ultrafine powder, followed by systematic quality analyses, which can increase the utilization efficiency, ensure consistency of quality and guarantee the safety of Chinese medicines. Ultrafine powder of herbs can be directly taken orally but is more commonly used as a raw material in the preparation of finished products. This is done by turning ultrafine powder of herbs into dosage form, such as granules, capsules or tablets, in order to achieve longer storage times and make its use more convenient.

Ultrafine powder of herbs and its products are becoming increasingly popular due to the obvious advantages in safety control, consistency of quality and high efficacy compared with traditional decoction pieces. Ultrafine powder of herbs and its products have been developed, registered and commercialized in areas including China, Hong Kong SAR, Taiwan Province of China, the Republic of Korea, Japan, Singapore, the United States of America and Canada. In 2018, China exported US\$ 3,91 billion of Chinese medicines. The sales volume of herbal supplements in the global market since 2015 is US\$ 93,15 billion. The sales volume of ultrafine powder of herbs products in China is over US\$ 137 million in 2020.

The lack of an International Standard for ultrafine powder of herbs could put consumers at risk when they take ultrafine powder of herbs and its products and thus jeopardize the market and reputation of Chinese medicines. Therefore, there is an urgent need to establish general requirements for ultrafine powder of herbs to ensure the safety and consistency of quality of ultrafine powder of herbs and related products and also enhance the international trade of ultrafine powder of herbs products.

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