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Traditional Chinese medicine — Determination of benzopyrene in processed natural products

Médecine traditionnelle chinoise — Dosage du benzopyrène dans les produits naturels transformés

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Foreword

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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

The International Agency for Research on Cancer (IARC) classified benzopyrene ($C_{20}H_{12}$) as a carcinogen (Group 1) in 2006.[1] Benzopyrene is produced by the incomplete combustion of carbohydrates, proteins and fats during high-temperature cooking and processing of raw materials. To prevent hazards induced by benzopyrene, it is important to determine the benzopyrene content in processed natural products used in traditional Chinese medicine (e.g. processed *Rehmannia* root, *Cyperus* rhizome and mume fruit), which are processed by the application of high temperatures (200 °C to 600 °C).

Some national pharmacopeias have technical guidelines for the determination of benzopyrene content[2,3]. This document describes an analytical method, including the device specifications, chemical reagents, operation procedures and formulae to determine benzopyrene content, considering each national pharmacopeia, as well as giving references to other standardized testing methods, maximum limits and risk assessment.

Traditional Chinese medicine — Determination of benzopyrene in processed natural products

1 Scope

This document specifies the method for the determination of benzopyrene content in processed natural products.

It is applicable to processed natural products such as processed *Rehmannia* root, processed *Cyperus* rhizome, processed ginseng and processed mume fruit. It is not applicable to the analysis of minerals used in traditional Chinese medicine.

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 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/

3.1
benzopyrene
$C_{20}H_{12}$
organic compound of pentacyclic hydrocarbons made of pyrene and phenylene group

Note 1 to entry: The chemical information of benzopyrene is described in Annex A. National regulations and limitations of benzopyrene are given in Annex B.

3.2
polycyclic aromatic hydrocarbon
PAH
compound that contains two or more fused aromatic rings made of only carbon and hydrogen atoms

[SOURCE: ISO 11338-1:2003, 3.3]

3.3
high-performance liquid chromatography
HPLC
technique in analytical chemistry used to separate, identify and quantify each component in a mixture

Note 1 to entry: High-performance liquid chromatography relies on pumps to pass a pressurized liquid solvent containing the sample mixture through a column filled with a solid adsorbent material. Each component in the sample interacts differently with the adsorbent material, resulting in different flow rates for different components, thereby leading to the separation of components as these flow out of the column.