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**Traditional Chinese medicine —  
Determination of ochratoxin A  
in natural products by liquid  
chromatography coupled with  
fluorescence detector**

*Médecine traditionnelle chinoise — Détermination de l'ochratoxine A  
dans les produits naturels par chromatographie liquide couplée à un  
détecteur de fluorescence*



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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.

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 (see [www.iso.org/directives](http://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 (see [www.iso.org/patents](http://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 of 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 [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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](http://www.iso.org/members.html).

## Introduction

Ochratoxins are naturally occurring mycotoxins produced by certain fungi, which can be found in a variety of agriculture products, contaminated foods and natural medicines, including natural products, decoction pieces and manufactured products. Ochratoxins are a class of compounds produced by a variety of *Aspergillus ochraceus*, *Aspergillus niger* and *Penicillium sp.* According to their discovery sequence, they are called ochratoxin A (OTA), ochratoxin B (OTB) and ochratoxin C (OTC). Among these, OTA is considered the most toxic. It has been well established that OTA is highly toxic and carcinogenic. The toxicity of OTA to animals and humans mainly includes kidney toxicity, liver toxicity, teratogenesis, carcinogenesis, mutation and immunosuppression. There are frequent reports of detection of toxic OTA in natural products. Therefore, there is a need to standardize the test method of OTA in natural products, which will bring benefits to the consumers, enterprises and companies in processing, management and trade of natural products. There are two main methods to detect OTA in natural products: the liquid chromatography tandem mass spectrometry (LC-MS/MS) method and the liquid chromatography coupled with fluorescence detector (LC-FLD) method. LC-FLD is preferred due to its high sensitivity, high accuracy and reasonable operating cost.

As national implementation can differ, examples of national, regional and organizational analytical methods and values are given in [Annex A](#) and [Annex C](#).



# Traditional Chinese medicine — Determination of ochratoxin A in natural products by liquid chromatography coupled with fluorescence detector

## 1 Scope

This document specifies the determination of ochratoxin A (OTA) in natural products by the liquid chromatography coupled with fluorescence detector (LC-FLD) method.

It is applicable to the analysis of OTA in raw materials and manufactured products, including decoction pieces derived from plants and animals. It is suitable for samples during the processes of harvesting, transportation and storage, as well as domestic and foreign trade for quality classification.

## 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

#### ochratoxin

mycotoxin produced mainly by *Aspergillus ochraceus*, *Aspergillus niger* and *Penicillium sp*

Note 1 to entry: At least seven different types of ochratoxins are produced naturally. Ochratoxin A is known to be highly toxic and carcinogenic.

Note 2 to entry: Ochratoxin A shall be tested and limited.

## 4 Abbreviated terms

HPLC	high-performance liquid chromatography
LC-FLD	liquid chromatography coupled with fluorescence detector
MRL	maximum residue limit
OTA	ochratoxin A

## 5 Reagents

The purity of the reagents used shall be checked by running a blank determination. The chromatogram obtained from the solvents shall have a baseline without noticeable peaks that would interfere with targeted OTA.