ISO 23723:2021 (E)

Traditional Chinese medicine — General requirements for herbal raw material and materia medica

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 General principle

5 Requirements for all Chinese materia medica

5.1 General
5.2 Identification
5.3 Quality requirements
5.3.1 Moisture and loss on drying
5.3.2 Foreign matter
5.4 Safety requirements
5.4.1 Heavy metals and arsenic
5.4.2 Pesticide residues

6 Requirements for specific Chinese materia medica

6.1 Quality requirements
6.1.1 Total ash and acid-insoluble ash
6.1.2 Assay
6.1.3 Extractives
6.1.4 Essential oil
6.1.5 Rancidity
6.1.6 Degree of colouration
6.2 Safety requirements
6.2.1 Sulfur dioxide residues
6.2.2 Aflatoxins
6.2.3 Aristolochic acids
6.2.4 Aconitum alkaloids
6.2.5 Microbial contamination

7 Methods

7.1 Identification
7.1.1 Macroscopic identification
7.1.2 Microscopic identification
7.1.3 TLC identification and HPLC identification
7.2 Quality tests
7.2.1 Moisture and loss on drying
7.2.2 Foreign matter
7.2.3 Total ash and acid-insoluble ash
7.2.4 Assay
7.2.5 Extractives
7.2.6 Essential oil
7.2.7 Rancidity
7.2.8 Degree of colouration
7.3 Safety test
7.3.1 Heavy metal and arsenic

7.3.2 Pesticide residues
7.3.3 Sulfur dioxide residues
7.3.4 Aflatoxins
7.3.5 Aristolochic acids
7.3.6 Aconitum alkaloids
7.3.7 Microbial contamination

8 Sampling

9 Test report

10 Packaging

11 Labelling

12 Storage and transportation

Annex A (informative) Test information of single herbs in national and regional pharmacopoeias

A.1 Test items
A.2 Herbal names

Page count: 100