



**International
Standard**

ISO 5471

**Traditional Chinese medicine —
Carthamus tinctorius flower**

*Médecine traditionnelle chinoise — Fleur de carthame des
teinturiers (Carthamus tinctorius)*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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 document 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).

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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.

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.

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Introduction

Carthamus tinctorius flower, the dried flower of *Carthamus tinctorius* Linné (Compositae), is a medicinal herb used to treat menstrual problems, cardiovascular disease, pain, and swelling associated with trauma in Asian countries and the Mediterranean region for thousands of years.

There are at least 60 countries worldwide using or producing *Carthamus tinctorius* flower and its products. Major users include India, China, the United States, Iran, Canada, Australia, Republic of Korea, etc. Due to its great demand in the global market, trade in *Carthamus tinctorius* flower has been complicated by adulteration and substitution issues. Dishonest vendors add sand, saline and syrup to increase the weight for sale. Stains such as golden orange II, lemon yellow, and carmine, are sometimes used to make its colour brighter, which can cause health risks. Factors including contamination, packaging and storage conditions also affect the quality of *Carthamus tinctorius* flower.

The establishment of an international standard for *Carthamus tinctorius* flower is therefore necessary to support its quality consistency, clinical effectiveness and safety in international trade.

As national implementation can differ, national standards bodies are invited to modify the values given in [5.4](#), [5.5](#), [5.6](#), [5.7](#) and [5.8](#) in their national standards. Examples of national and regional values are given in [Annex E](#).

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Traditional Chinese medicine — *Carthamus tinctorius* flower

1 Scope

This document specifies the minimum requirements and test methods for *Carthamus tinctorius* flower that is derived from *Carthamus tinctorius* Linné.

It is applicable to *Carthamus tinctorius* flower that is sold and used as Chinese materia medica.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 18664, *Traditional Chinese Medicine — Determination of heavy metals in herbal medicines used in Traditional Chinese Medicine*

ISO 21371, *Traditional Chinese medicine — Labelling requirements of products intended for oral or topical use*

ISO 22217, *Traditional Chinese medicine — Storage requirements for raw materials and decoction pieces*

ISO 22258, *Traditional Chinese medicine — Determination of pesticide residues in natural products by gas chromatography*

ISO 22283, *Traditional Chinese medicine — Determination of aflatoxins in natural products by LC-FLD*

ISO 22590, *Traditional Chinese medicine — Determination of sulfur dioxide in natural products by titration*

ISO 23723, *Traditional Chinese medicine — General requirements for herbal raw material and materia medica*

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

***Carthamus tinctorius* flower**

dried *tubulous flower* (3.2) of *Carthamus tinctorius* Linné (Compositae)

3.2

tubulous flower

flower with a long, thin, straight-sided tube formed of united petals, often separating at the mouth into a flared shape

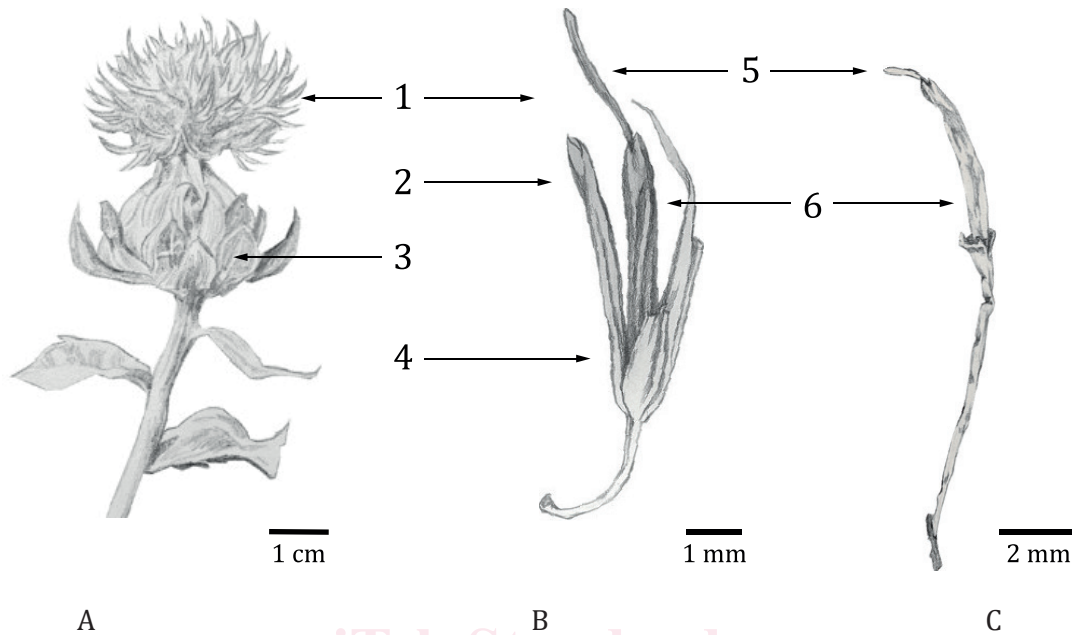
3.3

tubular corolla

regular and gamopetalous corolla with the petals fused to form a tube

4 Descriptions

Carthamus tinctorius flower is the dried tubulose flower of *Carthamus tinctorius* Linné (Compositae). The flower is collected in summer when it turns from yellow to red, then dried in a shaded area or under the sun, as shown in [Figure 1](#).



Key

- A plant with capitulum
- B single tubulose flower
- C stigma and stamen
- 1 tubulose flower
- 2 lobe
- 3 phyllary
- 4 tubular corolla
- 5 stigma
- 6 stamens

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Figure 1 — Structure of *Carthamus tinctorius* flower

5 Quality and safety requirements and recommendations

5.1 General characteristics

The following requirements shall be met before sampling:

- a) *Carthamus tinctorius* flower shall be clean and free from foreign matter including additional pigments;
- b) the presence of living insects, mouldy flower and external contaminants which are visible to the naked eye shall not be permitted.

5.2 Morphological features

- a) The tubulose flower without the ovary is 1 cm to 2 cm in length.
- b) The tubular corolla is orange-red to red, slender, long, and 5-lobed at the apex.

- c) The lobe is in the shape of a narrow cord, 5 mm to 8 mm in length.
- d) There are 5 stamens and yellowish white anthers are fused into a tube.
- e) The stigma is long cylindrical and slightly branches at the apex.
- f) The texture is soft.
- g) The odour is slightly fragrant; and the taste is slightly bitter.

5.3 Thin-layer chromatography feature

The identification of *Carthamus tinctorius* flower by a thin-layer chromatography shall present spots or bands with the same colour and position corresponding to those of the standard solution.

5.4 Moisture

The mass fraction of moisture should be determined and should not be more than 13,0 %.

5.5 Total ash

The mass fraction of total ash should not be more than 18,0 %.

5.6 Acid-insoluble ash

The mass fraction of acid-insoluble ash should be determined and should not be more than 5,0 %.

5.7 Absorbance

The absorbance of red pigment at 518 nm should be determined and should not be less than 0,20.

5.8 Water-soluble extract

The mass fraction of water-soluble extract should be determined and should not be less than 30,0 %.

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5.9 Marker compound(s)

The mass fraction(s) of marker compound(s), such as flavonoids like hydroxysafflor yellow A or kaempferol, should be determined.

5.10 Heavy metals

The mass fractions of heavy metals such as arsenic, mercury, lead and cadmium should be determined.

5.11 Pesticide residues

The mass fractions of pesticide residues should be determined.

5.12 Sulfur dioxide

The mass fraction of sulfur dioxide should be determined.

5.13 Aflatoxins

The mass fraction of aflatoxins should be determined.

6 Sampling

Sampling of *Carthamus tinctorius* flower shall be carried out in accordance with the method specified in ISO 23723.

7 Test methods

7.1 Macroscopic identification

Samples of not less than 200 g are taken from each batch randomly and observed with the naked eye, smelled and tasted.

7.2 Thin-layer chromatography identification

See [Annex A](#) for additional information.

7.3 Determination of moisture

The test method specified in ISO 23723 shall apply.

7.4 Determination of total ash

The test method specified in ISO 23723 shall apply.

7.5 Determination of acid-insoluble ash

The test method specified in ISO 23723 shall apply.

7.6 Determination of absorbance of red pigment

See [Annex B](#) for additional information.

7.7 Determination of water-soluble extract

The test method specified in ISO 23723 shall apply.

7.8 Determination of marker compound(s)

See [Annex C](#) and [Annex D](#) for additional information on determination of the mass fractions of hydroxysafflor yellow A and kaempferol.

7.9 Determination of heavy metals

The test method specified in ISO 18664 shall apply.

7.10 Determination of pesticide residues

The test methods specified in ISO 22258 shall apply.

7.11 Determination of sulfur dioxide content

The test method specified in ISO 22590 shall apply.

7.12 Determination of aflatoxins

The test method specified in ISO 22283 shall apply.