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Traditional Chinese medicine — Detection of irradiated natural products by photostimulated luminescence

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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

Ionizing radiation (gamma ray, X-ray or beam) is used extensively for the sterilization of medical devices and for a variety of other materials and products. However, irradiation of traditional natural products for sanitation purposes is not permitted by the regulations of most countries. It is necessary to set up a method to identify whether a product has been subjected to irradiation, because overexposure to irradiation can have negative effects on product quality. Irradiation detection methods will help to reduce international trade friction, assist governments in strengthening irradiation supervision and help enterprises to choose non-irradiated raw materials.

Currently, several independent methods are used to identify irradiated foodstuffs. Some of them can be used to identify irradiated natural products. After studying natural products and improving detection rules, photostimulated luminescence (PSL) has become one of the most suitable methods of detection. It is not only a screening method but also a confirmation method with application of F-factor. It can be used widely because of its simplicity and low cost.

Traditional Chinese medicine — Detection of irradiated natural products by photostimulated luminescence

1 Scope

This document specifies a method using photostimulated luminescence (PSL) to detect the radiation status of natural products. It can be used to identify whether raw and traditionally processed Chinese medicinal materials and solid forms of manufactured product made from these materials have been irradiated by ionizing radiation (gamma, X-ray or beam). It is not applicable for use in testing liquid dosage forms or partially solid extracted dosage forms that do not contain directly crushed medicinal materials.

2 Normative reference

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 terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
photostimulated luminescence
PSL
radiation-specific phenomenon resulting from energy stored by trapped charge carriers

Note 1 to entry: Release of this stored energy by optical stimulation can result in a detectable luminescence signal.

[SOURCE: EN 13751:2009, 2.1]

3.2
PSL intensity
amount of light detected during photostimulation, in photon count rate

[SOURCE: EN 13751:2009, 2.2]

3.3
screening PSL
PSL intensity (3.2) recorded from the sample as received or following preparation

[SOURCE: EN 13751:2009, 2.3]

3.4
calibrated PSL
PSL intensity (3.2) recorded from the test sample following irradiation to a known dose, after initial PSL measurement

[SOURCE: EN 13751:2009, 2.4]

3.5
F-factor
ratio of *calibrated PSL* (3.4) to *screening PSL* (3.3)

4 Principle

Most natural products that are either cultivated or wild contain silicate minerals, calcite or hydroxyapatite. When exposed to ionizing radiation, these materials store energy in charge carriers trapped in structural, interstitial or impurity sites. Trapped high-energy electrons can be released by stimulation with light, leaving electron holes in the crystal lattice. The energy thus released is detected as luminescence.

5 Apparatus

5.1 PSL system, consisting of pulsed stimulation sources (infrared ray), photon counting system, detector, sample chamber and computer for controlling unit.

5.2 Disposable 5-cm Petri dishes, with covers.

5.3 Radiation source, delivering ^{60}Co-rays or X-rays used at a fixed radiation dose of 1 kGy before measurement of calibrated PSL. Alternative sources can be used if they are satisfactory.

5.4 Negative/positive reference, non-irradiated and irradiated (above 1 kGy) paprika powders or other suitable references used for instrumental calibration.

6 Procedure

6.1 General

Avoid light exposure and cross-contamination when dispensing and handling samples.

Medicinal materials and manufactured product follow the same procedure.

6.2 Sampling technique

6.2.1 General operation

Grind the material into fine powder and mix well. Weigh about 2 g sample, dispense it into the Petri dish to cover the base in a thin layer and put the lid on to keep out dust before the measurement. Three replicate test samples can be prepared in parallel.

As for samples which are difficult to grind into fine powder, such as the big candied pills, grind into small particles as much as possible and mix well.

6.2.2 Sample quantity

For general samples, 2 g is appropriate. For high-density samples, the quantity of samples should be appropriately increased. For light and loose samples, the quantity of samples should be reduced. The sampling quantity requires the bottom of the Petri dishes to be covered completely.

6.3 Instrumental calibration

6.3.1 Instrumental parameter

The acquisition frequency is 1 time/s, and acquisition duration is 60 s.

6.3.2 Dark count

Photon count rate detected in the empty sample chamber with absence of stimulation shall be less than 50.

6.3.3 Empty chamber test

PSL intensity count of the empty Petri dish shall be less than 700. This step shall be repeated periodically, for example every 10 samples or upon the positive samples.

6.3.4 Negative reference count

Weigh 2 g non-irradiated reference of paprika powder and dispense into the Petri dish to cover the base in a thin layer. The count value shall be less than 700.

6.3.5 Positive reference count

Weigh 2 g irradiated reference of paprika powder and dispense into the Petri dish to cover the base in a thin layer. The count value shall be more than 5 000.

6.4 Detection of the sample

6.4.1 Screening PSL

Detect three replicate test samples and record their respective PSL values. If the results of the three replicate test samples are all below 700, calibrated PSL does not need to be conducted.

NOTE 700 is an empirical value, which is equivalent to the background level referring to the use of 5-cm Petri dishes.

6.4.2 Calibrated PSL

After the screening PSL detection, cover the lid of the dish to avoid loss or contamination, irradiate the samples in the ^{60}Co or X-ray at 1 kGy dose, then determine their respective PSL values. During handling, care should be taken not to shake the sample.

6.4.3 F-factor calculating

Calculate the ratio of calibrated PSL value to the corresponding screening PSL value to get the F-factor, then calculate the average value.

6.5 Result evaluation

Use the criterion in Table 1 to judge whether the sample is irradiated or not. If the F-factor in one or two test samples is less than 10, while the rest are more than 10, then three more test samples shall be prepared and analysed to exclude false-positive results. The result shall be determined by the average value of F-factor in these six samples.