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Traditional Chinese medicine — General requirements for industrial manufacturing process of red ginseng (Panax ginseng C.A. Meyer)

Médecine traditionnelle chinoise — Exigences générales pour le procédé de fabrication industrielle du ginseng rouge (Panax ginseng C.A. Meyer)



ISO 19610:2017(E)



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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).

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For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 249, *Traditional Chinese medicine*.

Traditional Chinese medicine — General requirements for industrial manufacturing process of red ginseng (*Panax ginseng* C.A. Meyer)

1 Scope

This document specifies the general requirements for the industrial manufacturing process of red ginseng from *Panax ginseng* C.A. Meyer which is the only species from which red ginseng is processed[6-11]. It is intended that manufacturers perform the appropriate washing, steaming, drying and packaging processes to assure the quality of red ginseng products for consumers.

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 14159, Safety of machinery — Hygiene requirements for the design of machinery

WHO Guidelines for drinking-water quality, fourth edition

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 http://www.iso.org/obp
- IEC Electropedia: available at http://www.electropedia.org/

3.1

fresh ginseng

ginseng root harvested from the field, before being washed

3.2

washed ginseng

raw ginseng root washed with drinking water to remove any foreign matter and which is then used as the starting material for manufacturing red ginseng

3.3

steamed ginseng

ginseng produced through a process of steaming the washed ginseng to gelatinize the starch content

3.4

red ginseng

ginseng root from *Panax ginseng C.A.* Meyer, treated with steam and then dried and packaged as whole or cut roots

3.5

cultivated years

number of years of cultivation after budding seeds

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3.6

foreign matter

soil, dust, dirt, insects and other contaminants

3.7

expiration date

date until which the manufacturer guarantees the quality and safety of red ginseng product under defined conditions

3.8

red ginseng product

red ginseng that is packaged in appropriate packaging material

place of cultivation

place at which ginseng was cultivated

3.10

lot number

number assigned by the manufacturer to a group of uniform products for tracing the product history

General

4.1 Starting material

Starting material for manufacturing red ginseng is fresh ginseng which has been cultivated for four to six years.

4.1.1 **Pesticides**

Levels of pesticides residue for fresh ginseng are specified in accordance with domestic and/or international regulations.

Heavy metals 4.1.2

Levels of heavy metals for fresh ginseng are specified in accordance with domestic and/or international regulations.

For information on levels of heavy metals, see ISO 18664:2015, Table A. NOTE

4.2 Factory environment

Working environment shall be designed to reduce the potential for contamination during the processing of red ginseng.

4.3 Machines

4.3.1 General

Equipment and utensils which come in direct contact with the fresh ginseng shall be of appropriate design and construction to ensure the quality of the red ginseng.

4.3.2 **Washing machine**

4.3.2.1 General

Washing machine shall completely remove foreign matter from the fresh ginseng.

4.3.2.2 Function of washing machine

For the mass washing of fresh ginseng, a washing machine that has the following functions is required:

- a) it shall be able to spray water at a sufficient pressure to remove foreign matter but that does not cause damage to the fresh ginseng;
- b) the washing machine spray function shall be designed to wash every surface of the fresh ginseng;
- c) it shall be designed in accordance with ISO 14159.

4.3.3 Steaming machine

4.3.3.1 General

Steaming machine shall generate saturated steam and maintain the required temperature for the duration of the processing.

4.3.3.2 Function of steaming machine

For the mass steaming of washed ginseng, a steaming machine with the following functions is required:

- a) the temperature of the machine shall be controlled;
- b) it shall be designed to distribute the steam evenly on the washed ginseng;
- c) it shall be designed in accordance with ISO 14159;
- d) the internal structure shall be designed to be adequately cleaned and properly maintained.

4.3.4 Drying machine

4.3.4.1 General

Drying machine shall be designed to maintain the proper temperature and humidity.

4.3.4.2 Function of drying machine

For large-scale drying of steamed ginseng, the drying machine requires the following functions:

- a) the temperature and humidity inside the dryer shall be well controlled;
- b) it shall be designed to deliver a uniform flow of dry air to the steamed ginseng;
- c) it shall be designed in accordance with ISO 14159;
- d) the internal structure shall be designed to be adequately cleaned and properly maintained.

4.3.5 Packaging machine

4.3.5.1 General

Packaging machine shall be designed for red ginseng to be packaged appropriately.

4.3.5.2 Function of packaging machine

Packaging machine shall be designed in accordance with ISO 14159.

5 Industrial manufacturing process of red ginseng

5.1 General

As fresh ginseng has high water content, it is subject to degradation by enzymes and spoilage by microbial contamination, making the product easily damaged as the storage period increases.

However, the stability increases as fresh ginseng is processed to red ginseng (see Figure 1).

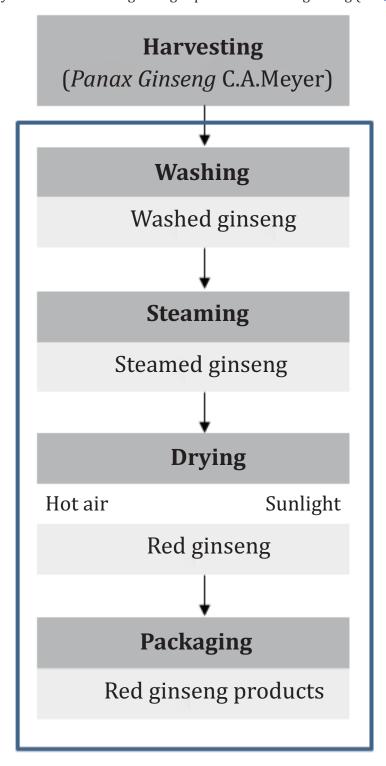


Figure 1 — Industrial manufacturing process of red ginseng

After the fresh ginseng is harvested, the washing and steaming processes are performed consecutively, followed by drying with sunlight or hot air dryer until the appropriate moisture content is met for the improved storage characteristics.

5.2 Washing

5.2.1 General

Harvested fresh ginseng shall be washed hygienically to completely remove soil and other foreign matter.

5.2.2 Quality of water

Quality of water for washing fresh ginseng shall meet the requirements of the WHO Guideline for Drinking Water Quality.

5.2.3 Washing procedure

Appropriate measures for washing shall be implemented for removing soil and debris completely from fresh ginseng. A washing procedure for fresh ginseng is recommended as below:

- a) wash the fresh ginseng with a tumbler or low damageable conveyor type washer through a high pressure water spray to remove the foreign matter such as soils;
- b) rewash if the washed ginseng is not completely washed by visual check;
- c) any method that can remove the foreign matter successfully will be appropriate.

5.3 Steaming

5.3.1 General

Process of steaming is an important stage in determining the quality of red ginseng. Fresh ginseng contains about 30 % starch which is gelatinized with heat treatment. The steaming process shall provide enough heat for a sufficient period of time to gelatinize the starch.

NOTE Ginseng starch crystallization is gradually lost at between 65 °C and 70 °C and changes to a gel formation. The gelatinization starts at 61 °C and is completely done at 88 °C. However, this result came from using the purified starches, so a higher temperature is required for enough gelatinization from ginseng steaming[5][13].

5.3.2 Classification for steaming

5.3.2.1 **General**

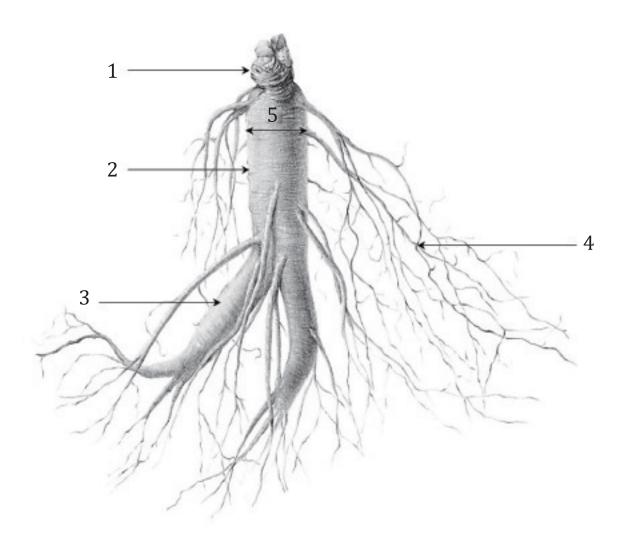
It is necessary that different steaming conditions are utilized depending on the root thickness in order to maintain the quality of red ginseng.

5.3.2.2 Size classification

Basis of classification by size as below:

- size classification is determined by measuring the diameter of the tap root;
- the representative diameter of the tap root is measured at the thickest part of washed ginseng (Figure 2);
- washed ginseng is divided into three groups; large, medium, small (see <u>Table 1</u>).

NOTE Washed ginseng can be divided further into subgroups, if necessary.



Key

- 1 rhizome
- 2 tap root
- 3 lateral root
- 4 fibrous root
- 5 representative diameter of the tap root

Figure 2 — Tap root and diameter for measuring part of ginseng

5.3.3 Steaming condition

The classification of the starting material by size allows for selection of the appropriate steaming condition (see Table 1) depending on the size of each ginseng tap root.

Tap water shall be used for steaming.

Table 1 — Example for steaming conditions for washed ginseng

| Size of washed ginseng | Tap root diameter | Condition for steaming |
|------------------------|-------------------|---|
| Large | ≥35 mm | Time duration at least 100 min between 95 °C and 100 °C |
| Medium | 25 mm ~ 35 mm | Time duration at least 90 min between 95 °C and 100 °C |
| Small | ≤25 mm | Time duration at least 80 min between 95 °C and 100 °C |

The starch of washed ginseng should be sufficiently gelatinized by steaming with proper temperature and time.

5.4 Drying

5.4.1 General

The steamed ginseng can be either dried by sunlight or hot air drying can be applied. In traditional processing, the drying method for red ginseng does not differ from that of other medicinal herbs in that it is usually dried by sunlight. However, drying by using machines has become a common method as a part of industrialization and this method is recommended in terms of hygienic control of contamination from microorganisms, foreign matter, etc.

5.4.2 Drying guidelines

The steamed ginseng may be dried by hot air or by sun drying method, and the final water content should be maintained lower than 15,5 %.

5.4.3 Hot air drying

Use of drying conditions on steamed ginseng adopted in domestic and/or international regulations is recommended.

5.4.4 Sun drying

Drying of the steamed ginseng is done under sunlight until the final water content is under 15.5 %.

The sun drying facility shall be maintained hygienically.

The sun drying facility is recommended to be designed as follows:

- a) the drying facility should be a separate space constructed of transparent materials such as plastic, glass, vinyl, etc.;
- b) it shall be protected from insects, pollution and other contaminants;
- c) the drying facility shall be well ventilated so that the moisture can evaporate quickly.

Since the water content of steamed ginseng is high as much as $65\% \sim 85\%$, an additional step to lower the water content to an appropriate level may be carried out prior to the sun drying.

6 Packaging and labelling

6.1 General

For red ginseng which has a water content under 15,5 % after being dried. Vacuum packaging is one example to keep the product safe for a long term (other packaging methods to keep the quality may be applied). The packaged product must have clear and accurate information about the product on the label.

6.2 Packaging

Packaging methods may vary depending on the expiration date and product forms, however, following conditions should be covered:

- containers for filling should be clean before filling;
- packaging materials should be able to protect the contents from moisture absorption or any impacts during the distribution and storage of the product;
- packaging materials should not cause a decline in the product quality;
- unit package should be sealed so that the product cannot be opened and repackaged randomly.

Vacuum packaging could be a good example for a long term quality.

6.3 Labelling

6.3.1 General

Labelling shall be in accordance with the labelling regulation of each country in which the red ginseng is distributed.

Recommended labelling information on the outer package:

- a) product name;
- b) net weight;
- c) cultivated years;
- d) place of cultivation;
- e) lot number;
- f) product country of origin;
- g) manufacturer;
- h) manufacturer address;
- i) manufacturing date;
- j) expiration date.

Table 2 — Example of red ginseng product label

| | Information | Example |
|----|---------------------------|--|
| a) | Product name | KGC Red Ginseng – CHEONG KWAN JANG |
| b) | Net weight | 600g |
| c) | Cultivated years | 6 Years |
| d) | Place of cultivation | Republic of Korea |
| e) | Lot number | 150323-57 (as product ID) |
| f) | Product country of origin | Republic of Korea |
| g) | Manufacturer | Korea Ginseng Corporation(KGC) |
| h) | Manufacturer address | Nae-Ri, Gyuam-Myun, Buyeo-Gun, Chungchungnam-Do, Republic of Korea |
| i) | Manufacturing date | 2000.00.00 |
| j) | Expiration date | 2000.00.00 |

Printed and embossed information on packaging and labelling should be legible and resistant to fading or erasing.

6.3.2 Expiration date

Expiration date if required by domestic and/or international regulation is determined by the manufacturer depending on the storage, packaging materials and condition.

Indicators for determination of the expiration date could be active constituents (e.g. ginsenoside), moisture content, micro-organism (e.g. aerobic plate count, coliforms, etc.) and physical, or organoleptic properties.

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