



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Acupuncture needles
(English Translation)**

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1 Scope

This standard specifies the product classification, technical requirements, test methods, inspection rules and marking, packaging, transport and storage requirements of acupuncture needles.

This standard applies to unsterilized acupuncture needles and disposable acupuncture needles for acupuncture therapy (hereinafter referred to as sterile acupuncture needles).

2 Normative references

GB 191 Packaging - Pictorial marking for handling of goods

GB/T 2828 Sampling procedures and tables for lot-by-lot inspection by attributes (Apply to inspection of successive lots or batches)

GB/T 4240 Stainless steel wires

GB/T 4342 Metallic materials - Vickers microhardness test

GB/T 4506 Method for the test of sharpness and strength of needles tips

3 Product categories

3.1

The acupuncture needles are divided into two types. sterile acupuncture needles (disposable sterile acupuncture needles) and unsterilized acupuncture needles (acupuncture needles).

3.2

The handle type of acupuncture needle is divided into flat-handle needle, ring-handle needle, flower-handle needle.

3.3

The sterile acupuncture needle is divided into two types. with needle- inserting tube, without needle-inserting tube.

3.4

The specifications of the acupuncture needle are expressed by the diameter of the needle x the length of the needle.

3.5

The type of acupuncture needle is as shown in the Figure below. The basic size shall meet the requirements of Table 1.

the provisions of clause 4.4.

5.4.2 Sharpness test of needle's tip

It is performed according to the requirements of GB/T 4506. It shall comply with the provisions of clause 4.5.

5.4.3 Toughness test of needle's body

Wind the needle's body in a tight spiral around the mandrel having a diameter of 3 times the diameter of the needle's body along the spiral direction. If the length of the needle's body is 13 mm, wind the needle for two circles; for the needle's body of other lengths, wind it for five circles. The results shall comply with the provisions of clause 4.6.

5.4.4 Test of the connection firmness between the needle's body and the

needle's handle

First measure the length of the needle's body, then fix the needle's body in the clamp. On the end face of the needle's handle, use the force as specified in clause 4.8 to perform shockless pulling test along the axial direction of the needle's body, then measure the length of the needle's body. The results shall meet the requirements of clause 4.8.

5.4.5 Test of needle handle's burr

Use hands to touch the handle of the acupuncture needle, it shall not have the sense of burrs.

5.4.6 Test of corrosion resistance of needle's body

Remove the oil from the needle's body. Immerse it in 10% citric acid solution for 5 h at room temperature. Take it out. Place it in steaming water to boil it for

30 min. Cool it at room temperature for 48 h. Then remove it and let it evaporate naturally in the air; or use hot air to dry it. Visually observe the surface of the needle's body. It shall be free from rusting.

5.4.7 Sterility test

From each batch of sterile products, randomly take 40 samples. Randomly divide them into two groups, each group contains 20 samples. Perform parallel test.

The sterility test shall be carried out in accordance with the sterility test method in the Appendix of the 1990 version of the Pharmacopoeia of the People's

Republic of China. The results shall comply with the provisions of clause 4.14.

c. Type, specifications.

7.3 Acupuncture needles of the same specification shall be packed in a medium-sized carton. The inspection certificate shall be placed in the carton.

The carton shall have the following markings.

- a. Manufacturer's name and trademark;
- b. Product name;
- c. Type, specification, quantity;
- d. This standard number.

7.3.1 The medium-sized packaging box for the sterile acupuncture needles

shall also have the following markings.

- a. It is prohibited to use if the small package is damaged;
- b. Date of sterilization;
- c. Effective period of sterilization.

7.3.2 The inspection certificate shall have the following markings.

- a. Manufacturer's name;
- b. Inspector's code;
- c. Date of inspection.

7.3.3 There shall be a seal on the box, there shall be a packer's code on the seal.

7.4 Acupuncture needles of the same specifications are packed into large-sized corrugated boxes.

7.4.1 The carton shall have the following markings.

- a. Manufacturer's name and address;
- b. Product name;
- c. Model, specification, quantity;
- d. Date of manufacture and exit-factory batch number;
- e. Gross weight;
- f. Volume (length x width x height);
- g. This standard number;
- h. Words or signs such as "Handle with care", "Avoid heat", which shall comply with the provisions of GB 191.

The words or signs on the carton shall be guaranteed not to be obscured after long-time.

7.4.2 The large-sized packing carton for sterile acupuncture needles shall also has the following markings.

- a. Date of sterilization (instead of date of manufacture);
- b. Method of sterilization;
- c. Effective period of sterilization.

7.4.3 The carton shall be affixed with a seal, on which there shall be the packer's code.

7.5 Packaging quantity and the packaging with special needs are as specified in the order contract.

7.6 Transport requirements are as specified in the order contract.

7.7 Acupuncture needles shall be stored in a corrosive-gas-free, well-ventilated, clean room with a relative humidity of not more than 80%.

8 Others

8.1

After the packaging, the acupuncture needles shall be rust-free within two years from the date of exit-factory, subject to the provisions of storage.