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**Pharmaceutical Machinery Industry Standard
of the People's Republic of China**

JB/T 20104-2007

Hardness tester

片剂硬度仪

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Foreword

This Standard is formulated according to "Good manufacture practice of drugs", and standardization working directive requirements of GB/T 1.1-2000 and GB/T 1.2-2002.

This Standard is formulated according to the relevant specifications of GB 5226.1-2002 "Safety of machinery - Electrical equipment of machines - Part 1: General requirements" and GB/T 14710 "The environmental requirements and test methods for medical electrical equipment", so as to ensure the performance quality and safety of products.

This Standard was proposed by China Pharmaceutical Equipment Industry Association.

This Standard shall be administrated by Pharmaceutical Equipment Industry Standardization Technical Committee.

Main drafting organization of this Standard: Tianjin Tianda Tianfa Technology Co., Ltd..

Main drafters of this Standard: Gao Yucheng, Su Lin, Wang Zhaowu, Luo Shijin, and Ye Hongyu.

Hardness tester

1 Scope

This Standard specifies the terms and definitions, marks, requirements, test methods, inspection rules and signs, packaging, transportation and storage of hardness tester.

This Standard applies to the motor-driven digital display instruments used to measure the hardness of pharmaceutical tablets (hereinafter referred to as hardness tester).

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrections) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB/T 191 Packaging - Pictorial marking for handling of goods

GB 5226.1-2002 Safety of machinery - Electrical equipment of machines - Part 1: General requirements

GB/T 6388 Transport package shipping mark

GB/T 13306 Plates

GB/T 13384 General specifications for packing of mechanical and electrical product

GB/T 14710 The environmental requirements and test methods for medical electrical equipment

YY/T 0216 Editorial nominating method for the model designation of pharmaceutical machinery

8 Signs, packaging, transportation and storage

8.1 Signs

8.1.1 The plates shall comply with the specifications of GB/T 13306. The contents of plates are as follows:

- a) Name of manufacturer;
- b) Product name and model;
- c) Trademark;
- d) Production serial number and date;
- e) Power supply voltage and maximum power;
- f) Implemented standard ID.

8.1.2 Pictorial signs of packaging, storage and transportation shall comply with the specifications of GB/T 191. There shall be signs such as "Fragile", "Keep-up", "Keep dry", "No rolling".

8.1.3 Signs of transportation and shipping shall comply with the specifications of GB/T 6388.

8.2 Packaging

8.2.1 The packaging of products shall comply with the specifications of GB/T 13384.

8.2.2 The following documents shall be within the package of tester:

- a) Product certificate;
- b) Product instructions;
- c) Packing list;
- d) Other documents (such as supporting documents to the instrument).

8.3 Transportation

Transportation is according to the specifications of order contract. The hardness testers shall be firmly fixed on the transport means during transportation. Tumbling is forbidden.

8.4 Storage

After packaged, hardness tester shall be stored in dry, ventilated, no-corrosive-gas indoor place.

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