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OF THE PEOPLE'S REPUBLIC OF CHINA

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Series vacuum freezing dryer for pharmaceuticals

药用真空冷冻干燥机

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Series vacuum freezing dryer for pharmaceuticals

1 Scope

This Standard specifies the classification and marks, requirements, test methods, inspection rules, marks, user instructions, packaging, transport and storage of series vacuum freezing dryer for pharmaceuticals.

This Standard is applicable to series vacuum freezing dryer for pharmaceuticals (hereinafter referred to as the freezing dryer).

2 Normative references

The following referenced documents are indispensable for the application 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.

GB 150-1998, *Steel pressure vessels*

GB 151-1999, *Tubular heat exchangers*

GB/T 191, *Packaging and shipping icon logo*

GB 5226.1-2008, *Electrical Safety of Machinery - Electrical Equipment of Machines - Part 1: General Requirements*

GB/T 9969, *General Principles for Preparation of Instructions for Use of Industrial Products*

GB/T 10111, *Generation of random numbers and procedures applied to sampling inspection for product quality*

GB/T 13306, *Plates*

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

GB/T 16769, *Metal-cutting machine tools - Measurement method of sound pressure level*

YY/T 0216-1995, *Editorial nominating method for the model designation of pharmaceutical machinery*

not be less than 5°C.

4.3.9 The drying oven and the steam trap shall be installed with illuminated mirror with safety voltage.

4.3.10 The automatic tamping operation shall be stable, no crawling phenomenon is allowed, and the pressing force can be adjusted.

4.3.11 The vacuum control system of the freezing dryer shall be equipped with a sterile filter and be able to perform integrity testing.

4.3.12 The user operation permission setting of the freezing dryer control system shall not be less than three levels.

4.3.13 The process parameters of the freezing dryer control system shall be able to set, control, display and record. The operation state shall be displayed.

4.3.14 The drying oven door of the steam sterilizing freezing dryer shall have safety interlocking device. When the temperature in the oven is less than 40°C and the pressure is equal to atmospheric pressure, the oven door can be opened.

4.3.15 The freezing dryer shall be able to perform cleaning in place of the inner surface of the drying oven and shelves on each floor.

4.3.16 The freezing dryer shall be able to perform sterilization in place of the inner surface of the drying oven and shelves on each floor, which is certified as sterile.

4.3.17 When the freezing dryer is in operation, its noise value shall not exceed 78dB(A) of sound pressure level.

4.3.18 The absolute pressure of the drying oven and steam condenser after 45min vacuuming shall be no more than 2.7Pa.

4.3.19 The vacuum leak rate of the freezing dryer and steam condenser shall not be greater than 0.025 Pa·m³/s.

4.3.20 The capture capacity of the steam trap is not less than 10 kg/m² per 24h at an absolute pressure of 2.7Pa.

4.4 Electrical safety performance

4.4.1 The continuity of the protection and connection circuit of the electrical system shall comply with the provisions of 8.2.3 of GB 5226.1-2008.

4.4.2 The insulation resistance of the electrical system shall comply with the provisions of 18.3 of GB 5226.1-2008.

the liquid nitrogen freezing dryer. Check whether the control system has the status of each component, and whether the control data is displayed or recorded.

5.3.14 Safety interlock test.

- a) When the temperature in the drying oven is greater than 40°C, the drying oven door lock mechanism cannot be opened.
- b) When the pressure in the drying oven is greater than atmospheric pressure, the drying oven door lock mechanism is opened.

5.3.15 In-place cleaning test.

Spray 3% concentration of riboflavin solution on the wall of the drying oven and the shelf surface. Wait for 30 minutes to start cleaning in place. After the cleaning, the hand-held violet light with a radiation wavelength of 320 nm to 400 nm and an irradiance of 1000 μm or more and W/cm^2 shall be used, and the dark spot is observed at a distance of 38 cm from the surface to be measured. Check the dry box wall and shelf surface.

5.3.16 In-place sterilization test.

After cleaning the drying oven, the biological indicator made from the spores of the thermophilic spores is placed on the shelf in the drying oven. When the cold spot temperature rises to 121°C and the pressure reaches 0.11MPa, the biological indicator shall be taken out after 30min of incubation and placed directly at 56°C~60°C for 24h~48h. After removing, determine the sterilization effect according to the color reaction. The sterilization shall be qualified after it is cultured, removed and remains purple. The sterilization shall be unqualified if it turns yellow.

5.3.17 Noise test.

In the normal operation of the freezing dryer with a sound level meter according to GB/T 16769 test method to test the noise of the freezing dryer.

5.3.18 Absolute pressure test of freezing dryer.

Dry the drying oven, steam condenser and vacuum pump under dry conditions of the drying oven and steam condenser. After starting the vacuum pump to vacuum the drying oven and vapor condenser for 45min, check the vacuum degree.

5.3.19 Vacuum leakage rate test of freezing dryer.

When the pressure in the drying oven and steam condenser reaches 5Pa, close the vacuum pump of the isolation valve and keep the pressure for 30min, record

7 Marks, user instructions, packaging, transport and storage

7.1 Marks

7.1.1 Each freezing dryer shall fix the product label in a conspicuous position. The size and requirements of the label shall comply with the provisions of GB/T 13306.

7.1.2 The freezing dryer label shall contain the following information:

- a) product name and model number;
- b) product main parameters;
- c) product number and manufacturing date;
- d) name of manufacturer, trademark;
- e) product standard number.

7.1.3 The packing box storage and transport marks shall meet the requirements of GB/T 191. Outside the packing box, there shall be the following information:

- a) product name and model number;
- b) shipping date;
- c) names of sender and receiver;
- d) name of the sending and receiving stations;
- e) gross weight, overall dimensions;
- f) packaging, storage, and transport graphic marks.

7.2 User instructions

The user instructions of the freezing dryer shall meet the requirements of GB/T 9969.

7.3 Packaging

7.3.1 The packaging of the freezing dryer shall meet the requirements of GB/T 13384.

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