

JIS

JAPANESE INDUSTRIAL STANDARD

**Plastic Vials for
Frozen Storage and Ultra
Low-Temperature Preservation**

JIS K 3603—1990

Translated and Published

by

Japanese Standards Association

In the event of any doubt arising,
the original Standard in Japanese is to be final authority.



JAPANESE INDUSTRIAL STANDARD

J I S

Plastic Vials for Frozen Storage and Ultra
Low-Temperature Preservation

K 3603-1990

1. Scope

This Japanese Industrial Standards specifies plastic⁽¹⁾ vials used for frozen storage and ultra low-temperature preservation of -80°C or under of cells without varying the character thereof (hereafter referred to as "vials") in fields relevant to biotechnology.

Note (1) The plastic herein means polyethylene, polypropylene, etc.

Remark: The units and numerical values given in { } in this Standard are based on the traditional units and are appended for informative reference.

2. Definitions

To the main terms used in this Standard the definitions in JIS K 0114, JIS K 0211, and JIS K 3600 apply, and to other terms following definitions apply:

- (1) sterilization To sterilize or deplete a microbe.
- (2) radiation sterilization Sterilization which is performed by irradiation of γ -ray or the like from a radiation source containing radioactive isotopes.
- (3) ethylene oxide sterilization Sterilization which is performed by a gas containing ethylene oxide.
- (4) electron ray sterilization Sterilization which is performed by irradiation of electron rays.

3. Classification

Vials shall be classified into sterilization products and non-sterilization products. The sterilization products shall be classified into three classes according to the sterilization.

Applicable Standards:

JIS K 0114-General Rules for Analytical Method in Gas Chromatography
JIS K 0211-Technical Terms for Analytical Chemistry (General Part)
JIS K 0512-Hydrogen
JIS K 1107-High Purity Nitrogen
JIS K 3600-Technical Terms for Biotechnology
JIS K 8101-Ethanol (99.5) [Ethyl Alcohol (99.5)]
JIS Z 9031-Random Sampling Methods

(1) Sterilization Products

- (a) A sterilization product by radiation sterilization.
- (b) A sterilization product by ethylene oxide sterilization.
- (c) A sterilization product by electron ray sterilization.

(2) Non-sterilization Product

4. Quality

The character of vials shall be as follows.

- (1) Appearance Vials shall be uniform in the distribution of wall thickness and free from flaws, cracks, etc.
- (2) Low Temperature Resistance When subjected to the test of 6.2, vials shall be free from abnormalities.
- (3) Asepsis When subjected to the test of 6.3, sterilization products shall be aseptic.
- (4) Residual Ethylene Oxide When vials are subjected to the test of 6.4, the value of residual ethylene oxide shall be as agreed upon between the parties concerned with delivery.
- (5) Radiation Resistance Products exposed by radiation such as γ -ray or the like shall show no remarkable change on standing in quality.
- (6) Sealing Performance Vials shall be good in sealing performance.

5. Construction and Dimensions

5.1 Construction Vials shall be so constructed as to be stoppered, cylindrical or ampulla and shall be capable of being sealed by melting.

Remarks 1. Vials with "collar" may be also used. An example of the vial with "collar" is shown in Fig. 1.

Fig. 1. An Example of Vial with "Collar"

