

Translated English of Chinese Standard: YY/T0191-2011
www.ChineseStandard.net → Buy True-PDF → Auto-delivery.
Sales@ChineseStandard.net



PHARMACEUTICAL INDUSTRY STANDARD
OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.040.30

C 36

YY/T 0191-2011

Replacing YY/T 0191-1994

Abdominal suction tube

腹腔吸引管

Issued on: December 31, 2011

Implemented on: June 01, 2013

Issued by: State Food and Drug Administration

Table of Contents

Foreword.....	3
1 Scope.....	4
2 Normative references.....	4
3 Product classification	5
4 Requirements.....	6
5 Test methods.....	7
6 Inspection rules.....	8
7 Marking	9
8 Packaging, transportation, storage	10

Abdominal suction tube

1 Scope

This Standard specifies the product classification, requirements, test methods, inspection rules and marking, packaging, transportation, and storage of abdominal suction tubes.

This Standard applies to the abdominal suction tube (hereinafter referred to as the suction tube). The product is installed on the suction device for liquid suction during abdominal surgery.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 1220, Stainless steel bars

GB/T 1527, Drawn tube of copper and copper alloys

GB/T 2828.1, Sampling procedures for inspection by attributes - Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

GB/T 2829, Sampling procedures and tables for periodic inspection by attributes (apply to inspection of process stability)

GB/T 4423, Copper and copper alloy cold-drawn rod and bar

GB/T 6463, Metallic and other inorganic coatings - Review of methods of measurement of thickness

GB/T 10610, Geometrical product specifications (GPS) - Surface texture: Profile method - Rules and procedures for the assessment of surface texture

YY 0076-1992, Coating classifications for metal product - Technical conditions

YY/T 0149-2006, Medical instruments of stainless steel - Test methods of corrosion resistance

YY/T 0171-2008, Surgical instruments - Packaging, Marking and Instructions

3.2 Materials

The suction tube shall be made of stainless-steel material that is specified in GB/T 1220 or copper materials that are specified in GB/T 1527 and GB/T 4423.

4 Requirements

4.1 Dimensions

The outer diameter dimension D_1 of the suction tube joint shall meet the requirements of Table 1.

4.2 Patency

The suction tube shall be smooth; the water absorption shall not be less than 2 000 mL/min.

4.3 Soundness

The suction tube shall be welded firmly; the welding part shall not be loose, cracked or broken.

4.4 Compatibility

The threaded connection of the suction tube shall be well matched, and there shall be no looseness or jamming.

4.5 surface roughness

The value of the surface roughness R_a of the outer surface of the suction tube shall not be greater than 0.4 μm .

4.6 Corrosion resistance

4.6.1 The stainless-steel suction tube shall have good corrosion resistance; its surface state after the test shall not be lower than the requirements for grade b in 5.4 of YY/T 0149-2006.

4.6.2 The copper suction tube shall not have damage or corrosion marks which cannot be removed by wiping after a saturated steam test at 134 °C ~ 138 °C for 20 minutes.

4.7 Electroplating

The electroplating of the copper suction tube shall meet the requirement for D·L₃Ni7/Cr0.3 that is specified in YY 0076-1992.

4.8 Appearance

4.8.1 The inner and outer tubes of the suction tube shall be smooth and round, free of sharp edges, burrs and cracks.

4.8.2 There shall be a suction hole at the top of the outer tube; the arrangement of the surrounding suction holes shall be even and tidy, and the number shall be no less than 18.

4.8.3 There shall be no obvious blisters and accumulations at the weld of the suction tube.

5 Test methods

5.1 Dimensions

Use a general or special measuring tool to measure; the dimensions of the suction tube shall meet the requirements of 4.1.

5.2 Patency

Carry out the test under the condition of a negative pressure of $50\text{ kPa} \pm 2\text{ kPa}$, which shall meet the requirements of 4.2.

5.3 Soundness test

Fix the tube body of the suction tube; load a load of 50 N on the axial and perpendicular joints of the suction tube, respectively, for 5 s; observe the welding position, which shall meet the requirements of 4.3.

5.4 Compatibility test

Imitate the use action to manually disassemble the suction tube, which shall meet the requirements of 4.4.

5.5 Surface roughness

Use the sample piece comparison method or the profile method (GB/T 10610) for measurement, which shall meet the requirements of 4.5.

Use the profile method for measurement during arbitration.

5.6 Corrosion resistance

5.6.1 Perform the test according to the boiling water test method in YY/T 0149-2006, which shall meet the requirements of 4.6.1.

5.6.2 Use the saturated steam at a temperature of $134\text{ }^{\circ}\text{C} \sim 138\text{ }^{\circ}\text{C}$ to perform the test for 20 minutes; repeat the test 20 times (the interval is based on the

This is an excerpt of the PDF (Some pages are marked off intentionally)

Full-copy PDF can be purchased from 1 of 2 websites:

1. <https://www.ChineseStandard.us>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Select your country (currency), for example: USA (USD); Germany (Euro).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Tax invoice can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with download links).

2. <https://www.ChineseStandard.net>

- SEARCH the standard ID, such as GB 4943.1-2022.
- Add to cart. Only accept USD (other currencies - <https://www.ChineseStandard.us>).
- Full-copy of PDF (text-editable, true-PDF) can be downloaded in 9 seconds.
- Receiving emails in 9 seconds (with PDFs attached, invoice and download links).

Translated by: Field Test Asia Pte. Ltd. (Incorporated & taxed in Singapore. Tax ID: 201302277C)

About Us (Goodwill, Policies, Fair Trading...): <https://www.chinesestandard.net/AboutUs.aspx>

Contact: Wayne Zheng, Sales@ChineseStandard.net

Linkin: <https://www.linkedin.com/in/waynezhengwenrui/>

----- The End -----