

Medical Device Product Technical Requirements No: : XTFDA 20150010

Medical cotton ball

1. Product model / specification and its division description

1.1 According to the classification of raw materials, It is divided into: cotton ball raw materials for: skim cotton

1.2 Product model/ packaging specification

Product model: 0.2g/grain-3g/grain (Special specifications are customized according to customer requirements)

Packing specification: 500g/bag、400g/bag、300g/bag、250g/bag、200g/bag、100g/bag、50g/bag、20g/bag、10g/bag (Special specifications shall be executed according to the order contract requirements)

1.3 It belongs to the medical health materials according to the medical device management classification.

1.4 It is non-sterile according to supply status and valid for three years.

2. Performance standard

2.1 Product model requirements

It shall meet the requirements of Table 1

Table 1

Model(g)	Weight(g)	Weight allowance ±(g)	Model(g)	Weight(g)	Weight allowance ±(g)
0.2g	0.2	±0.02	1.7	1.7	±0.17g
0.3g	0.3	±0.03	1.8	1.8	±0.18g
0.4g	0.4	±0.04	1.9	1.9	±0.19g
0.5g	0.5	±0.05	2.0	2.0	±0.2
0.6g	0.6	±0.06	2.1	2.1	±0.21
0.7g	0.7	±0.07	2.2	2.2	±0.22
0.8g	0.8	±0.08	2.3	2.3	±0.23

0.9g	0.9	±0.09	2.4	2.4	±0.24
1g	1	±0.1	2.5	2.5	±0.25
1.1	1.1	±0.11	2.6	2.6	±0.26
1.2	1.2	±0.12	2.7	2.7	±0.27
1.3	1.3	±0.13	2.8	2.8	±0.28
1.4	1.4	±0.14	2.9	2.9	±0.29
1.5	1.5	±0.15	3.0	3.0	±0.3
1.6	1.6	±0.16			
Special specifications are customized according to customer requirements					

Table 2

Model (g/grain)	Specification (g/bag)	Deviation
0.2g/grain-3g/grain	500	±50
	400	±40
	300	±30
	250	±25
	200	±20
	100	±10
	50	±5
	20	±2
	10	±1
Special specifications shall be executed according to the order contract requirements		

2.2 appearance requirements

The cotton fiber of the cotton ball should be soft, white, odorless, and free from yellow spots, stains, and foreign objects.

3 Test method

3.1 gram weight requirement

Test method: Measure with general measuring tools or special measuring tools, and it shall meet the requirements in Table 1 and Table 2.

3.2.2 Water absorption time: The cotton ball should absorb water and sink below the liquid surface within 10 seconds.

3.2.3 Water absorption: the water absorption per gram of cotton ball should not be less than 23g.

3.2.4 Packaging: The packaging is complete and undamaged. The label on the outer packaging should be filled out clearly and neatly, and the content should include: manufacturer name, product name, production batch number, etc.

3.3. Inspection method

3.3.1 Appearance: visual inspection

3.3.2 Water absorption time test: Take 5g samples from three different positions of the same batch of products, respectively put the samples loosely into a place with a height of 8.0cm, a diameter of 5.0cm, a direct copper wire of 0.4mm, and a basket mesh size in the 1.5cm-2.0cm and accurately weighed cylindrical copper wire test basket, immerse the basket from a horizontal height of 10cm into a beaker with a diameter of 11cm-12cm that has been filled with 20 degrees of water, and record that the basket sinks into the water. Calculate the average value of the three measurement results.

3.3.3 Water absorption test: After the water absorption time test, take the basket out of the water, hang it for 30 seconds, then transfer it to an accurately weighed clean beaker, weigh it accurately with a balance with a sensitivity of 0.1g, and calculate it three times. The average of the measurement results.

3.3.4 Packaging: visual inspection

3.4 Sampling inspection requirements

When the batch size is less than 500 pieces, random inspection shall be carried out at a rate of 5%, not less than 5 pieces; when the batch size is less than 1,500 pieces, random inspection shall be carried out at a ratio of 2-3%, not less than 10 pieces; when the batch size is more than 1,500 pieces 1-2% of the samples will be randomly inspected, not less than 15 pieces.

Judgment rules

There shall be no more than 2 unqualified products in one inspection, and if there are 2 unqualified products, double re-inspection shall be performed, and no more than 1 product shall be unqualified in the re-inspection, otherwise the batch shall be judged as unqualified.

4. The term

4.1 Scope

This standard specifies the classification, requirements, test methods, inspection rules, marks,

labels, packaging, transportation and storage of medical cotton balls.

4.2 Normative references

The clauses in the following documents become the clauses of this standard through the reference of this standard. For dated references, all subsequent amendments (excluding errata content) or revisions do not apply to this standard. However, parties to agreements based on this standard are encouraged to research whether to use the latest versions of these documents. For reference documents without date, the latest version shall be used in this standard.

GB/T 191-2008 Packaging, storage and transportation icon marks

YY0330-2002 Medical absorbent cotton

Appendix A

1 Logo, label

1.1 Packaging marks and labels

The small package of the product should have the following obvious signs:

- a) Product name, production batch number (determined by the release date of raw materials), expiration date;
- b) Indicate "The product is for one-time use", "Please destroy it after use", "Packaging leaks, and the product is prohibited to use after expiration"
- c) The record number of the medical device manufacturer, the record number of the medical device product, and the product technical requirement number;
- d) Production unit, address, zip code and telephone number;

1.2 Packaging, storage and transportation marks, labels

The signs of packaging, storage and transportation shall conform to the signs of "upward", "afraid of rain" and "afraid of wetness" in GB/T 191-2008 packaging, storage and transportation icon signs, and the following signs shall also be displayed on the packaging box:

- a) Product name, specification, quantity, production batch number;
- b) Outline dimensions of the box, shipping box number and part number;
- c) The license number of the medical device manufacturer, the registration number of the medical device product, and the standard number of the registered product;
- d) Shipping unit, address, zip code and telephone number.

The words and signs on the outer packaging should be guaranteed not to be blurred due to time.

2 Packaging, transportation and storage

2.1 Packaging

2.1.1 The products are sealed and packaged with plastic film according to the variety and specification, and then put into a 5-layer corrugated box for transportation and storage, and sealed with plastic paper.

2.1.2 Packaging requirements should comply with the packaging regulations in Articles 5.2 and 5.3 of YY/T 0313-1998.

2.1.3 There should be a "Product Instruction Manual" on the sealed packaging bag or inside the packaging box, and the main content of the instructions should include the main performance, scope of use, and precautions of the product.

2.1.4 There should be "product qualification certificate" in the sealed packaging bag. The product specification, quantity and inspector code should be indicated on the product certificate.

2.2 Transportation and storage

2.2.1 The product, including the package, should be able to be transported by ordinary means of transport

2.2.2 Product packaging should be kept clean and pollution-free during transportation and storage, and rain and snow are strictly prohibited.

2.2.3 Product packages should be stored in a room with a relative humidity of $\leq 80\%$, no corrosive gases and good ventilation.