المنظمة العربية للتنمية الصناعية والتعدين

مركز المواصفات والمقاييس

مشروع مواصفة قياسية عربية

القطن الطبي الماص – المتطلبات

إعداد: الهيئة العامة للغذاء والدواء" المملكة العربية السعودية

هذه الوثيقة مشروع لمواصفة قياسية عربية تم عرضها على القاعدة التفاعلية لإبداء الرأي والملاحظات عليها، لذلك فإنها عرضة للتغيير والتبديل ولا يجوز الاعتماد عليها كمواصفة قياسية عربية موحدة إلا بعد اعتمادها من قبل اللجنة الاستشارية العليا للتقييس والمجلس التنفيذي للمنظمة العربية للتنمية الصناعية والتعدين

الهيئة العامة للغذاء والدواء

Saudi Food and Drug Authority

SFDA.MD 7002/2023

The Saudi Standard

Absorbent medical cotton wool – Requirements

11.120.20

القطن الطبي الماص – المتطلبات

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19/01/2023

مواصفة سعودية

تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمستلزمات الطبية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمستلزمات الطبية سواء كانت مستوردة أو مصنعة محلياً، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل فريق العمل رقم (SFDA/MDS/TC 45) "فريق عمل مواصفات المنتجات النسيجية الطبية" بإعداد المواصفة السعودية رقم (SFDA.MD 7002/2023) "القطن الطبي الماص– المتطلبات"، وقد تم إعداد المشروع بعد استعراض المواصفات ذات الصلة. وقد تم إقرار اعتماد المواصفة بقرار معالي الرئيس التنفيذي للهيئة بتاريخ (١٤٤٤/٠٦/٢٦).

Foreword

The Saudi Food & Drug Authority is an independent organization mainly responsible for regulating imported/locally produced food, drug and medical devices, which includes, inter alia, setting their standards. After reviewing a whole set of relevant standards, the SFDA Medical Devices Sector, as part of the TOR of Technical team NO. (SFDA/MDS/TC 45), has developed Standard No (SFDA.MD 7002/2023). The standard was approved by SFDA CEO decision dated (26/06/1444).

Absorbent medical cotton wool – Requirements

1 Scope

This standard specifies the requirements for absorbent medical cotton wool packed in the form of rolls, balls or pads.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

SFDA.MD 7003/2022, *Absorbent medical cotton wool – Test methods*
ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*
ISO 11737-1, *Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products*
ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply:

3.1 absorbent medical cotton wool
product made from cotton and mainly used in the medical setting for the purpose of absorbing body fluids and wiping the intact skin with liquid antiseptic solution applied

4 Requirements

4.1 Composition
Absorbent medical cotton wool shall be composed of new good quality cotton fibers. The fibers shall be white, clean, purified, well carded and well bleached.

4.2 Cotton rolls
Cotton rolls shall be interleaved with clean parchment paper and shall show appreciable resistance when pulled.

4.3 Fiber length
The average fiber length shall be not less than 10 mm.

4.4 Freedom from impurities
Absorbent medical cotton wool shall be free from other fibers, threads, neps, rends, seeds or other impurities.

4.5 Freedom from harmful substances
The finished absorbent medical cotton wool shall not contain substances harmful to human body.

4.6 Water soluble substances

The water-soluble extract shall not exceed 0.5% by mass of the absorbent medical cotton wool and shall be neither acidic nor alkaline in nature.

4.7 Ether soluble substances

The ether-soluble extract shall not exceed 0.5% by mass of the absorbent medical cotton wool.

4.8 Ash content

The ash content of absorbent medical cotton wool shall not exceed 0.4% by mass.

4.9 Color of extract

The resulting color of extract when tested for coloring matter shall be a very pale yellow without bluish or greenish tinge.

4.10 Surface active substances

The aqueous extract of the absorbent medical cotton wool shall be free from surface-active substances.

4.11 Fluorescent spots

When tested for fluorescence, a 5 g absorbent medical cotton wool in the form of 5 mm thick layer shall show not more than a single fluorescent spot under UV light wavelength of 365 nm.

4.12 Sinking time

The sinking time of the absorbent medical cotton wool shall not exceed 10 sec.

4.13 Water holding capacity

The water holding capacity of the absorbent medical cotton wool shall not be less than 23 grams per gram.

4.14 Sterilization

The sterilization of sterile absorbent medical cotton wool shall be in accordance with ISO 11135.

4.15 Microbial contamination (bioburden)

The microbial contamination of non-sterile absorbent medical cotton wool shall be tested in accordance with ISO 11737-1.

4.16 Loss on drying

The percentage loss in absorbent medical cotton wool mass on drying at 105ºC shall not be more than 8%.

4.17 Corrected mass

The corrected mass of pure absorbent medical cotton wool shall be in accordance with 7.5.

5 Sampling

5.1 Division of consignment

The consignment of absorbent medical cotton wool shall be divided into lots of packages (cartons or boxes) of which each lot shall contain the same type of the form of the absorbent cotton wool and of the same production batch.

5.2 Sample size

Certain number of samples shall be withdrawn from each lot of packages (cartons or boxes) in accordance with ISO 2859-1:2003. Each sample consists of a number of absorbent medical cotton wool packets.

6 Test methods

The sample for laboratory testing shall be tested in accordance with SFDA.MD 7003/2022.

7 Packing

7.1 Materials

The finished absorbent medical cotton wool shall be packed in a packet made of plastic, cellophane or clean unused paper or other packing material.

7.2 Protection from foreign matter

The packet shall be firmly closed to protect the absorbent medical cotton wool from foreign matter.

7.3 Reclosing

The packet shall permit reclosing to protect the remaining cotton in case of partial usage.

7.4 Secondary packaging

The packets shall be packed in cartons or boxes.

7.5 Corrected-to-labeled-mass ratio

The corrected mass of pure absorbent medical cotton wool in the packets compared to the labeled mass on the packet shall be in accordance with table 1.

Table 1 Corrected-to-labeled-mass ratio

Labeled Mass (g)	Corrected Mass (g)
Less than 25	90% of the labeled mass
25	23
50	47
100	96
250	245
500	492
1000	990
2000	1985
More than 2000	99.25% of the labeled mass

8 Labeling

Each packet shall be legibly and clearly marked in Arabic or English. For the home-use absorbent medical cotton wool, the labeling shall be in both Arabic and English.

8.1 Primary package

The primary package (packet) shall be marked with the following information:

a) the name and/or trade mark of the manufacturer;
b) the statement “Absorbent Medical Cotton Wool”;
c) the corrected mass of pure absorbent medical cotton wool;
d) country of origin;
e) date of production/batch No; and
f) expiry date.

8.2 Secondary package

The secondary package (carton or box) shall be marked information stated in 8.1 in addition to the following:

a) number of packets in the carton or the box; and
b) instructions for storage.

Bibliography

[1] SASO-179, *Absorbent medical cotton wool*