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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0753.1-2009

**Breathing system filters for anaesthetic and respiratory use -
Part 1: Salt test method to assess filtration performance**

麻醉和呼吸用呼吸系统过滤器 第1部分：评价过滤性能的盐试验方法

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Table of Contents

- 1 Scope
- 2 Terms and definitions
- 3.1 Principle

Foreword

YY/T 0753 "anesthesia and respiratory breathing system filters," including the following sections. Evaluation of filter performance test methods for salt;.

--- Part 2. Non-filtration aspects. This section is YY/T Section 10753 of. YY/T 0753 is identical with this part of ISO 23328-1.2003 "anesthesia and respiratory breathing system filters - Part 1. Review Test methods for filtering salt price performance. " Appendix A of this section is normative annex, appendix B, Appendices C and D are informative appendices. This standard by the National Standardization Technical Committee on Narcotic breathing apparatus and (SAC/TC116) and focal points. This standard drafting units. Shandong Medical Devices Product Quality Inspection Center. The main drafters of this standard. Ping Wu, Song Jinzai, Wan Min, Zhang Bo. YY/T 0753.1-2009/ISO 23328-1.2003

YY/T 0753 This section gives a test method for evaluating breathing system filters (BSF) filtration performance. Breathing system filters for reducing inhaled or exhaled by the number of particulate matter (including microbial). In clinical use of breathing system filters exposed to various humidity levels. Since the filtration performance of breathing system filters may be affected Effect of moist air, the test will be breathing system filters exposed to moist air simulated clinical use (see Appendix A). Trials, the most penetrating particle size range (ie, 0.1 μ m ~ 0.3 μ m) sodium chloride particles on the respiratory system as a particle filter Challenge tests (see Appendix C). As we all know, microbes and may pass through the "channel" (channeling) and "bypass" (grow-through) pathway across the filter broadcast. There is no acceptable quantitative methods for these occasional shortcomings. This test method is to provide comparable, but could not confirm the clinical Correlation. Therefore, this section only provides test methods should not be drawn from the risk factor. YY/T 0753.1-2009/ISO 23328-1.2003 Anesthesia and respiratory breathing system filters Part 1. Evaluation of filter performance test methods for salt

1 Scope

YY/T 0753.1 is the method that measures what a breathing system filter actually stops. It specifies the sodium chloride aerosol test used to assess the filtration performance of filters in anaesthetic and respiratory breathing systems: a defined salt aerosol is drawn through

the filter and the penetration measured, giving a number that can be compared between products. Breathing filters are the barrier between a patient and a ventilator circuit in both directions, and their claimed efficiencies are meaningless without a common method, since penetration depends strongly on particle size and flow. Part 2 covers the connectors, resistance and dead space. For a manufacturer or an importer of breathing filters for the Chinese market, this is the method behind the filtration claim.

YY/T 0753 This section gives a short-term challenge in the air particles of sodium chloride test method to evaluate the respiratory gas for filtering Breathing system filters the filtering performance. This section applies to clinical respiratory system Breathing system filters. This section does not apply to other types of filters, such as for protection Vacuum source or gas sampling lines are used to filter compressed gas or bio-filters for protecting respiratory measurement test equipment. NOTE. respiratory filters unfiltered aspect see YY/T 0753.2.

2 Terms and definitions

The following terms and definitions apply

YY/T 0753 of this section.

2.1 Is expected to reduce the respiratory system, including means include microbial particles spread.

2.2 Sodium chloride flow breathing system filters the air flow concentration of particles. NOTE. Challenges concentration expressed in milligrams per cubic meter.

2.3 The concentration of the respiratory system filters the air discharged from the sodium chloride particles.

Note. The breakthrough concentration expressed in mg per cubic meter.

2.4 Concentration flows through the respiratory system filters particles of sodium chloride concentration percentage of challenge. 2.5 100 minus penetration value. Method 3

3.1 Principle

3.1.1 allows sodium chloride solution by atomizing the stream of air atomized spray of sodium chloride and then these particles flowing through the respiratory system filters , Thereby measuring the breathing system filters ability to remove particles. Appendix B and Appendix C gives a further explanation.

3.1.2 generated aerosol containing particles from the atomizer with electrostatic charge, along with the air stream containing aerosol particles in the ionized air flow mix Together, the number of aerosol charge be reduced, the particles are neutralized to the Boltzmann equilibrium.

3.1.3 Test selected airflow represents the typical respiratory airflow filter intended use encountered.

3.1.4 By measuring the concentration of the respiratory system through the left filter a stream of particles of sodium chloride, and the air flow into the respiratory system filters
YY/T 0753.1-2009/ ISO 23328-1.2003

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