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**Pharmaceutical Industrial Standard of the People's
Republic of China**

中华人民共和国医药行业标准

YY0497-2005

Sterile Insulin Syringe for Single Use

一次性使用无菌胰岛素注射器

**(ISO 8537:1991 + A1:2000, Sterile single-use syringes, with or without needle, for
insulin, NEQ)**

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Foreword

This standard non-equivalently adopts international standard ISO 8537:1991 “Sterile Single-use Syringes, with or without Needle, for Insulin” and the amendment

Technical differences between this standard and ISO 8537:1991 as well as the amendment are as follows:

——This standard increases easily oxidized substance, hemolysis, acute systemic toxicity, cytotoxicity, subcutaneous stimulation or sensitization response performance indexes, adopts the test methods in GB/T 14233. 1 — 1998 “Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use--Part 1:Chemical Analysis Methods” for chemical properties and adopts the test methods in GB/T 14233. 2—1993 “Test Methods for Infusion, Transfusion, Injection Equipment for Medical Use--Part 2: Biological Test Methods” and GB/T 16886. 1 — 2001 “Biological Evaluation of Medical Devices—Part 1: Evaluation and Test” .

——This standard increases performance indexes of plungers, which shall comply with YY/T 0243—2003 “Plunger of Sterile Syringes for Single Use” standard.

——This standard cites GB 15810—2001 “Sterile hypodermic syringes for single use” standard and specifies push-and-pull acting forces during whole process of test activities after fitting of syringe coat and plunger.

——This standard adopts GB/T 2828. 1 — 2003 “Sampling Procedures and Tables for Batch Inspection Apply to Inspection of Continuous Batches)” and GB/T 2829 — 2002 Sampling Procedures and Tables for Periodic Inspection by Attributes (Apply to Inspection of Process Stability).

Annex A, annex B, annex C and annex D to this standard are normative, while annex E, annex F, annex G and annex H are informative.

This standard is proposed by National Technical Committee on Standardization of Injectors (Needles) for Medical Purposes.

This standard is drafted by Shanghai Misawa Medical Industry Co. , Ltd.

This standard is under the jurisdiction of National Technical Committee on Standardization of Injectors (Needles) for Medical Purposes.

Drafters of this standard: Wang Hongbin, Sang Weidong, He Bin.

Sterile Insulin Syringe for Single Use

1 Scope

This International Standard specifies requirements and test methods for sterile syringes with or without needles intended for single use solely for the injection of insulin and primarily in humans. It covers syringes for use with 40 units of insulin/ml (U-40) and 100 units of insulin/ml (U-100).

Sterile syringes specified in this International Standard are intended for use soon after filling as they are not suitable for containing insulin over extended periods of time.

2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all subsequent modifications (including all corrections) or revisions made thereafter do not apply to this standard. However, the parties that reach an agreement according to this standard are encouraged to study whether the latest versions of these documents may be used. For the undated documents so quoted, the latest versions (including all modification sheets) apply to this document.

GB /T 1962. 1 -2001 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment (idt ISO 594-1:1996)

GB/T 2828-1987 Sampling procedures and tables for lot-by-lot inspection by attributes (Apply to inspection of successive lots or batches)

GB/T 2829-1987 Sampling procedures and tables for periodic inspection by attributes (Apply to inspection of stability for productive process)

GB 6682-1992 Water for laboratory use; Specifications

GB /T 14233. 1- 1998 Infusion, transfusion, injection equipment for medical use-- Part 1: Chemical analysis methods

GB /T 14233. 2- 2005 Test methods for infusion, transfusion, injection equipment for medical use-- Part 2: Biological test methods

GB 15810-2001 Sterile hypodermic syringes for single use (eqv ISO 7886-1: 1993)

GB 15811-2001 Sterile hypodermic needles for single use (eqv ISO 7864: 1993)



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