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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1535-2024

Replacing YY/T 1535-2017

Medical devices for human assisted reproductive technology - Human sperm viability assay (HSVA)

人类辅助生殖技术用医疗器械 人精子存活试验

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document replaces YY/T 1535-2017 "Biological Evaluation of Human Sperm Survival Tests for Medical Devices Used in Human In Vitro Assisted Reproductive Technology" Compared with YY/T 1535-2017, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) In the "Scope", the test methods of human sperm survival test are increased to three. human sperm motility test, human sperm motility recovery test and human sperm cryopreservation and resuscitation studies (see Chapter 1);

b) The term "human sperm viability test" was changed to "human sperm motility test" and its definition was changed (see 3.1.1,.2017 Edition) 3.1.1);

c) The definition of "sperm motility" has been changed (see 3.1.2,

3.1.2 of the.2017 edition);

d) The term "sperm motility classification" was changed to "sperm movement classification" and the definition was changed (see 3.1.4,

3.1.4 of the.2017 edition);

e) Change the terms "sperm motility coefficient" and "relative sperm motility coefficient" to "sperm motility ratio" and "relative sperm motility ratio" respectively. Ratio" (see 3.1.5, 3.1.6,

3.1.5,

3.1.6 of the.2017 edition);

f) Added terms and definitions used in human sperm motility recovery test and human sperm cryopreservation test (see 3.1.7,

3.1.8 and 3.1.9);

g) Some abbreviations have been changed (see 3.2,

3.2 of the.2017 edition);

1 Scope

YY/T 1535 is the biological safety test that every consumable touching gametes in an IVF laboratory has to pass. The human sperm viability assay exposes sperm to the device or its extract and measures how many remain motile over time, and it is used because embryos and gametes are more sensitive to trace contamination than any cell line in a standard cytotoxicity test: a dish, pipette or medium that passes conventional biocompatibility can still stop an IVF cycle. The standard defines how the assay is performed and interpreted for assisted reproduction devices in China. It sits with YY/T 1989 on the determination of sugars in assisted reproduction media. For a manufacturer of IVF consumables or media seeking Chinese registration, this is the test a reviewer expects behind the safety claim.

This document describes the test methods for human sperm survival of medical devices used in human assisted reproductive technology, including human sperm motility test test, human sperm motility recovery test and human sperm cryopreservation test. The human sperm motility test is applicable to the evaluation of culture fluids and instruments that are in direct contact with sperm in medical devices used in human assisted reproductive technology. Toxicity risks that may arise from instruments/consumables. According to the situation, evaluate the possible sperm toxicity risk of culture fluids and instruments/consumables. The human sperm motility recovery test is suitable for evaluating the possible toxicity risk of sperm brake fluids and similar products. To evaluate the potential toxicity risk of sperm brake fluid or similar products and to determine the recovery of sperm vitality after direct contact with sperm brake fluid or similar products. The human sperm cryo-thawing test is suitable for evaluating the sperm toxicity and cryo-thawing injury risks that may be caused by human sperm cryopreservation products. By observing the direct contact between sperm and sperm freezing solution and the recovery of sperm vitality after freezing and thawing, it is possible to judge whether the sperm freezing solution product has Risk of toxicity and cryo-thawing injury.

2 Normative references

The contents of the following documents constitute essential clauses of this document

through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 16886.12 Biological evaluation of medical devices Part

3.1 Terms and definitions The terms and definitions defined in

YY/T 0995 and the following apply to this document.

3.1.1 After co-culturing sperm with the test product or its extract, the toxicity risk of the test product to sperm is determined by observing changes in sperm motility.

3.1.2 Sperm motility Motile sperm in semen, expressed as the percentage of motile sperm to all sperm.

3.1.3 Sperm motility assay Determination of sperm motility.

3.1.4 There are four levels of sperm motility. rapid progressive motility, slow progressive motility, non-progressive motility and inactivity.

12 Sample preparation and reference samples

YY/T 0995 Terms and definitions of medical devices for human assisted reproductive technology