Guidelines for the Drafting of Product Technical Requirement for Medical Devices

The Guidelines are formulated in accordance with the *Regulations on Supervision and Administration of Medical Devices* and other relevant provisions.

I. Basic Requirements

(I) The compiling of product technical requirements for medical devices shall comply with relevant laws and regulations of the State.

(II) Product technical requirements for medical devices shall adopt standard and common terms. Where special terms are involved, specific definitions shall be provided, and such terms shall be written in "4. Terms".

(III) The number of various contents in the test methods in product technical requirements for medical devices shall correspond to the number of various contents in the performance indicators in principle.

(IV) The texts, figures, formulae, units, symbols and charts in product technical requirements for medical devices shall comply with the standardization requirements.

(V) If national standards, industry standards or the Chinese Pharmacopeia are/is cited in the contents of product technical requirements for medical devices, their validity shall be ensured, and the number and year number of the corresponding standards and version number of the Chinese Pharmacopeia shall be specified.

II. Content Requirements

The contents of product technical requirements for medical devices shall comply with the following requirements:

(I) Product name. The product name in product technical requirements shall be in Chinese, and consistent with the Chinese product name in the application for registration (filing).

(II) Product model/specification and explanation of the division description. Product model and/or specification shall be specified in product technical requirements, as well as explanation of the division.

If the same registration unit has products of multiple models and/or specifications, all differences among such models and specifications shall be specified (when necessary, appropriate illustrations may be attached for explanation).

If very large, the text for model/specification expression may be provided in the form of appendices.

(III) Performance indicators

1. Performance indicators in product technical requirements refer to functionality, safety indicators and other quality control-related indicators of finished products that can be objectively judged. Evaluation contents in product design and development (e.g., biocompatibility evaluation) are not developed in product technical requirements in principle.

2. The development of performance indicators in product technical requirements shall refer to relevant national standards/industry standards, and be combined with the design characteristics, intended purpose and quality control levels of the specific products. The performance indicators shall be no lower than the applicable mandatory standards/industry standards for the products.

3. The requirements for performance indicators in product technical requirements shall be expressly specified, and may not be provided in such forms as “see the accompanying data” and “as per the goods supply contract”.

(IV) Test methods. The development of test methods shall be accordant with the corresponding performance indicators. The adoption of widely accepted or promulgated standard test methods shall be preferably considered. The development of test methods shall ensure reproducibility and operability, and specify the method of sample preparation when necessary. Corresponding illustrations may be attached for explanation, and large texts may be provided in the form of appendices.

For in-vitro diagnosis reagent products, the methods of reference/standard and sample preparation, batch and quantity of reagents used, number of tests and computing method shall be specified in the test methods.

(V) For Class III in-vitro diagnosis reagent products, the main raw materials, production technology and requirements for semi-finished products shall be specified in the product technical requirements in the form of appendices.

(VI) Number of product technical requirements for medical devices is the corresponding registration certificate number (filing number). The number of product technical requirements to be registered (filed) may be left blank.

III. Format Requirements

The format of product technical requirements for medical devices is shown in the appendix.

Appendix: Format of Product Technical Requirements for Medical Devices

Appendix

Format of Product Technical Requirements for Medical Devices

Number of product technical requirements for medical devices (Song typeface, 12 pounds, bold):

Product Name (Song typeface18 pounds, bold)

1. Product model/specification and explanation of the division (Song typeface, 12 pounds, bold) (if applicable)

1.1 ……(Song typeface, 12 pounds)

1.1.1 ……

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2. Performance indicators (Song typeface, 12 pounds, bold)

2.1 ……(Song typeface, 12 pounds)

2.1.1 ……

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3. Test methods (Song typeface, 12 pounds, bold)

3.1 ……(Song typeface, 12 pounds)

3.1.1 ……

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4. Terms (Song typeface, 12 pounds, bold) (if applicable)

4.1 ……(Song typeface, 12 pounds)

4.2 ……

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(Paging)

Appendix A……(Song typeface, 12 pounds, bold) (if applicable)

1. ……(Song typeface, 12 pounds)

1.1 ……