YY

PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

ICS 11.080.040

C 30

YY/T 0313-2014

Replacing YY/T 0313-1998

Medical polymer products - Requirement for package and information supplied by manufacturer

医用高分子产品

包装和制造商提供信息的要求

Issued on: June 17, 2014 **Implemented on: July 1, 2015**

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Foreword

This Standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces the YY/T 0313-1998 *Package, label, transport and storage for medical polymer products*. Compared with YY/T 0313-1998, the major changes in this Standard are as follows:

— MODIFY the standard name;

— MODIFY the “Scope” applicable to this Standard (SEE Chapter 1 in this edition);

— MODIFY the “Normative references” (SEE Chapter 2 in this edition);

— MODIFY partial contents of the “Terms and definitions” (SEE Sections 3.7, 3.8 and 3.17 in this edition and Sections 3.8, 3.17 and 3.18 in 1998 edition);

— RECLASSIFY the products; DELETE the “Disinfection products” and relevant contents (Sections 4.1 and 5.2 in 1998 edition);

— MODIFY the requirements for sterile package as “in line with GB/T 19633.1 and relevant standards” (SEE Section 5.2.3 in this edition and Section 5.3.3 in 1998 edition);

— Since the categories of corrugated boxes vary from three to two, due to GB 6543 updated in normative references, this Standard has also been modified accordingly (SEE Section 5.3.3 in this edition and Section 5.4.3 in 1998 edition);

— ADD the requirements for the information supplied by manufacturer (SEE Chapter 6 in this edition);

— The symbols for product package have been partially modified (SEE Section 6.3 in this edition);

— DELETE the Chapter 7 “Transport and storage” (Chapter 7 in 1998 edition);

— MODIFY the Annex A as “Guidelines for the information of medical devices required to be supplied for meeting the requirements of EU Council Directive 93/42/EEC” (SEE Annex A in this edition and Annex A in 1998 edition); and

Medical polymer products - Requirement for package and information supplied by manufacturer

1 Scope

This Standard specifies the requirement for package and information supplied by manufacturer of medical polymer products.

Note: The provisions of national regulations and product standards take precedence over this Standard.

2 Normative references

The following documents are essential to the application of this document. For dated references, only the editions with the dates indicated are applicable to this document. For undated references, only the latest editions (including all the amendments) are applicable to this document.

GB/T 3102 (all parts) *Quantities and units*

GB/T 4892 *Dimensions of rigid rectangular packages - Transport packages*

GB/T 6543 *Single and double corrugated boxes for transport packages*

GB/T 7408 *Data elements and interchange formats - Information interchange - Representation of dates and times*

GB/T 19633.1 [1] *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems*

YY/T 0466.1 *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements*

YY/T 0468 *Nomenclature - Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange*

YY/T 1119 *Terminology relating to medical polymer products*

[1] Being approved.

It refers to the legal person or natural person who is expected to accept the information supplied by the manufacturer.

4 Product classification

4.1 When designing the product package, TAKE account of the product's sanitary requirements first, then the requirements for the package combined with the product's specific circumstances and physical properties. Therefore, it is necessary to classify the products.

4.2 The products are classified as general products and non-sterile products according to the sanitary requirements.

4.3 According to the physical properties, the products are classified as:

— Class A: extrusion resistant products;

— Class B: the products whose quality will be affected after extrusion;

— Class C: the products whose quality will be severely affected after extrusion;

— Class D: the particles, liquid or ointment material or products soaked in preservative solution.

Note: The products are classified in accordance with the physical properties for easy reference in the product standards. Specific products can be determined depending on their structure, size, value and safety.

5 Package requirements

5.1 General requirements

5.1.1 The product packages shall be applicable to the storage and transport processes. Ensure that the product quality is not affected during normal storage and transport.

Note: The test methods for some transport packages are specified in GB/T 4857.

5.1.2 The primary package materials of the product shall be non-toxic to human bodies, and shall not react with the contents and thus affect the quality of the product and package, thereby ensuring the safety and effectiveness of the use of the contents.

5.1.3 The product package shall be convenient for the use of the product.

be added if necessary.

6 Requirements for the information supplied by the manufacturer

6.1 Product identification information

6.1.1 Product category

When the category of medical devices belonging to the product needs to be explained in the information supplied, priority shall be given to the denomination in YY/T 0468.

6.1.2 Product denomination

The products shall give priority to the names specified in relevant standards and the terminology specified in YY/T 1119.

6.1.3 Batch code

The product's batch code shall be composed of letters and / or figures. However, it can also be expressed in other ways, for instance, using a machine-readable code.

6.2 Product service information

6.2.1 General requirements

Any way of supplying information with the product shall take account of the prospective users, service conditions, the safety and effectiveness of the use of single device, etc.

The appropriate ways of supplying information shall be based on the risk assessment, and shall be consistent with the training, experience and degree of education of prospective users.

Note: The information supplied is required to conform to the requirements of EN 1041 in some international standards for medical devices. The guidelines for the information required to be supplied for meeting the requirements of EU Council Directive 93/42/EEC given in EN 1041 are given in Annex A. For the medical devices using these international standards, the guidelines supplied in Annex A are mandatory.

6.2.2 Special requirements

6.2.2.1 Applicability

The dates shall be expressed in the format of YYYY-MM-DD, YYYY-MM or YYYY given in GB/T 7408.

The units of measurement shall use the units of international system of measurement or other legal units of measurement specified in GB/T 3102.

The symbols and the safety-related identification colors shall conform to the requirements of YY/T 0466.1 and relevant standards. If they are not derived from relevant standards, an indication shall be given in the information supplied.

6.2.2.7 Changes in information supplied

For any changes in the information that has been supplied for the user, PASS on the changes clearly to the user if it is important for patient safety.

6.3 Symbols on the product packages

6.3.1 Unit package or primary package

The following symbols shall be generally marked on the unit packages or primary packages:

a) product name, model or specifications;
b) manufacturer's name, address and trademark;
c) manufacturing date, in case of no information on the service life;
d) batch code; and
e) where appropriate, the word "NON-STERILE" [2].

The following symbols shall also be marked on the unit packages or primary packages for non-sterile products:

a) the word "STERILE";
b) the words "do not use the damaged package";
c) the words "for single use"; and
d) service life.

Note: The symbols specified in YY/T 0466.1 may be used to conform to the requirements above.

6.3.2 Symbols on the shelf packages

The following symbols shall be generally marked on the shelf packages:

a) product name, model or specifications;
b) manufacturer's name, address and trademark;
c) manufacturing date, in case of no information on the service life;

[2] The name of the symbol "NON-STERILE" is "NOT STERILIZED" in YY/T 0466.1.

Annex A

(Informative)

Guidelines for the information of medical devices required to be supplied for meeting the requirements of EU Council Directive 93/42/EEC

The guidelines for the information of medical devices required to be supplied for meeting the requirements of EU Council Directive 93/42/EEC are given in Table A.1.

Table A.1 -- Guidelines for the Information of Medical Devices Required to be Supplied for Meeting the Requirements of EU Council Directive 93/42/EEC

Requirements for the information supplied of medical devices	Guidelines
General	
8.7 The packaging and / or label of the device must distinguish between identical and similar products sold in both sterile and non-sterile conditions.	According to this Standard, sterile devices are preferably the symbol given in YY/T 0466.1 or the character mark describing this state. Sterile devices shall be marked with the symbol given in YY/T 0466.1. “STERILE” is defined in YY/T 0615.1 and YY/T 0615.2. The identical devices produced by the same manufacturer will be supplied in both sterile and non-sterile conditions, with similar packages. In this case, non-sterile devices may be considered as sterile devices by mistake. Therefore, a non-sterile description shall be given prominently to ensure the safety of patients. The similarity stated herein may indicate similar devices or similar packages.
10.3 The measurements made by devices with a measuring system must be expressed in legal units.	SEE the requirements of Section 6.2.2.6.
11.4.1 The operating instructions for devices emitting radiation must give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.	Radiation is not limited to ionizing radiation. There are also other radiations, such as thermal radiation and laser radiation.
13 Information supplied by the manufacturer	

	YY/T 0466.1 may be used.
13.4 If the intended purpose of the device is not obvious to the user, the manufacturer must clearly state it on the label and in the instructions for use.	Many devices are well known to prospective users. Unpacked devices, or devices supplied with the containers for transport and storage alone may not require further identification. It is allowed to reduce the requirements for detailed description of transparent packages.
13.5 Wherever reasonable and practicable, the devices and detachable components must be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	This identification facilitates the recall of the device. Any detachable components shall be identified via their batch codes or in other appropriate ways.
13.6 Where appropriate, the instructions for use must contain the following particulars:	The information described in Sections 13.3 to 13.6 needs to be described in the language of the host country. The use of the symbols in current standards will avoid the translation of certain information.
(a) the details referred to in Section 13.3, with the exception of (d) and (e);	“with the exception of (d) (batch code) and (e) (service life)” does not exclude only these two items. A clear indication is given in Section 13.6 that the information referred to in Section 13.3 is only applicable to the items marked with “where appropriate”. For instance, in the event that the manufacturing date has been marked on the label, it will be inappropriate and impracticable to list the manufacturing date in the instructions for use. SEE the guidelines for the above-mentioned Section 13.3 (a), (b), (c), (f), (g), (h), (i), (j), (k) and (m) given in this Annex.
(b) the expected characteristics and any undesirable side-effects of the device;	The formats of the published standards citing these characteristics in relevant provisions may be used.
(c) if the device must be installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe combination;	If not within the common sense of prospective users, or not obvious, it is necessary to provide the connection method or type of the equipment applicable to this device. The descriptions in the published standards conforming to these characteristics in relevant provisions may be used to fully provide the characteristics (such as connection).
(d) all the information needed to verify whether the device is properly installed and can operate	This requirement only indicates that the installation is verified by the user, plus the details of the nature

References

[1] GB/T 191 *Packaging - Pictorial marking for handling of goods*

[2] GB/T 4857 (all parts) *Packaging - Transport packages*

[3] GB/T 16273.1 *Graphical symbols for use on equipment*

[4] YY/T 0316 *Medical devices - Application of risk management to medical devices*

[5] YY/T 0615.1 *Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices*

[6] YY/T 0615.2 *Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices*

[7] YY/T 0681 (all parts) *Test methods for sterile medical device package*

[8] YY/T 0698 (all parts) *Packaging materials for terminal sterilized medical devices*

[9] YY/T 0802 *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*

[10] EN 1041 *Information supplied by the manufacturer of medical devices*

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