YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0981-2016

Single-use rinse syringes for facial features

一次性使用五官冲洗器

Issued on: March 23, 2016 **Implemented on: January 1, 2017**

Issued by: National Medical Products Administration

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1 Scope

YY/T 0981 is the product standard for the single-use irrigation syringe used on the eye, ear, nose and mouth. It is a low-cost, high-volume device whose requirements are nonetheless specific: the tip has to deliver a controlled stream without traumatising delicate tissue, the barrel and plunger have to move smoothly enough for one-handed use, and the whole assembly has to be sterile and free of particulates, since it is used on mucous membranes and on the eye. The standard sets those requirements together with the packaging and labelling, and the corresponding test methods. For a manufacturer or an importer of ophthalmic and ENT irrigation devices for the Chinese market, this is the governing product standard.

This standard specifies the terms and definitions, structure and marking, materials, requirements, test methods, packaging, marking and storage for single use of facial features rinse syringes (hereinafter referred to as syringe). This standard is applicable to the syringes used in clinical facial features department.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 1962.1 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1. General requirement

GB/T 1962.2 Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 2. Lock fittings

GB/T 6682 Water for analytical laboratory use - Specification and test methods

GB/T 14233.1-2008 Test methods for infusion, transfusion, injection equipment for medical use - Part 1. Chemical analysis methods

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use - Part 2. Biological test methods

GB 15810 Sterile hypodermic syringes for single use

GB 15811-2016 Sterile hypodermic needles for single use

GB/T 16886.1 Biological evaluation of medical devices. Part 16. Toxicokinetic study design for degradation products and leachables

GB 18279.1 Sterilization of health care products. Ethylene oxide - Part 1. Requirements for development, validation and routine control of a sterilization process

GB 18279.2 Sterilization of health care products - Part 2. Guidance on the application of GB 18279.1

GB 18280.1 Sterilization of health care products. Radiation - Part 1. Requirements for development, validation and routine control of a sterilization process for m

GB/T 18457 Stainless steel needle tubing for the manufacture of medical devices

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

3 Terms and definitions

The following terms and definitions apply to this standard.

3.1 Nominal capacity The capacity of the injector indicated by the manufacturer.

Note. the injector structure is shown in figure 1.

3.2 Graduated capacity When the piston fiducial line moves in axial direction one or several given calibration intervals, the volume of water of temperature 20°C±5°C discharged from the injector.

3.3 Total graduated capacity The injector capacity between the zero-scale line and the furthest scale line.

3.4 Maximum usable capacity The connection between the needle seat and the needle shall be firm. Tension test shall be performed according to GB 15811-2016, the two parts shall not be loosened or separated.

6.1.2.8 Protective sheathing The needle seat and the sheathing shall be well matched. The sheathing shall not fall off naturally. The separation force of the two shall not be greater than 15N.

6.1.2.9 Smoothness The rinsing needle shall be unimpeded. The stylet specified in GB 15811-2016 can freely pass through, or, with water pressure of no more than 100 KPa, the flow shall not be less than 80% of the flow of the needle of the same external diameter and length and the minimum inner diameter specified in GB/T 18457 under the same condition.
6.2. Chemical requirements

6.2.1 Extractable metal content In comparison of the leaching solution of the syringe and the same batch of blank control solution, the total content of heavy shall be <=5 μg/mL.

6.2.2 pH value The difference of pH value of the leaching solution of the syringe and the same batch of blank control solution shall be no more than.

6.2.3 Readily oxidizable substance In comparison of the leaching solution of the syringe and the same batch of blank control solution, the difference of consumption of 0.002mol/L potassium manganate solution shall be <=

0.5 mL.

6.2.4 Ethylene oxide residue The residual amount of ethylene oxide shall be <=10 μg/g.

6.3 Biological requirements

6.3.1 Bio-compatibility Conduct biological evaluation of the syringe in accordance with GB/T 16886.1. The evaluation result shall be no biological hazard.

6.3.2 Sterility

i) Warning to check the integrity of each package before use.

9.2 Medium packaging The medium packaging shall include the following markings.

a) Description of the contents, including nominal capacity and quantity;

b) The word "aseptic" or equivalent symbol;

c) The word "single use" or equivalent symbol;

d) Production date and/ or batch number;

e) Name and address of the manufacturer or supplier;

f) Year of invalidation;

g) The specification of the attached rinsing needle shall be indicated.

9.3 Large packaging The large packaging shall include the following markings.

a) Description of the contents, including nominal capacity and quantity;

b) The word "aseptic" or equivalent symbol;

c) The word "single use" or equivalent symbol;

d) date and / or lot number of production;