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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0286.3-2017

Special infusion sets - Part 3: Light-resistant infusion sets for single use

专用输液器 第3部分：一次性使用避光输时器

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Foreword

All content of this Part is mandatory. YY 0286 "Special infusion sets" consists of 6 parts. - Part 1. Infusion sets with precision filters for single use; - Part 2. Fluid lines for use with pressure infusion equipment and accessories for single use; - Part 3. Light-resistant infusion sets for single use; - Part 4. Single-use infusion equipment for use with pressure infusion apparatus; - Part 5. Bottle-type and bag-type infusion sets for single use; - Part 6. Flow rate-setting and adjustable infusion sets for single use. This Part is Part 3 of YY 0286. This Part was drafted in accordance with the rules given in GB/T 1.1-2009. This Part was formulated based on GB 18458.3-2005 "Special infusion sets - Part 3 . Light-resistant infusion sets for single use". Compared with GB 18458.3- 2005, in addition to editorial modifications, the main technical changes are as follows: - modified the introduction; - deleted the marking requirements; - added 65% ethanol (CH3CH2O) aqueous solution and 50% polyethylene glycol 400 aqueous solution in extraction solution in Annex C. Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights. This Part shall be under the jurisdiction of National Technical Committee on Medical Infusion Apparatus of Standardization Administration of China (SAC/TC 106). The drafting organizations of this Part. Shandong Medical Device Quality Inspection Center, Wuhan Zhixun Chuangyuan Technology Development Co., Ltd., Shandong Xinhua Ande Medical Products Co., Ltd., Jiangxi Hongda Medical Instrument Co., Ltd., Tianjin Hana Medical Materials Co., Ltd., Beijing

With the continuous development of infusion technology and the increasing clinical

requirements, some infusion sets that can adapt to specific clinical requirements have been produced one after another. Since the development of the product is endless, it is not possible to include all the special requirements of the infusion set in a standard. Therefore, each part of YY 0286 regulates these specialized infusion sets only for one clinical special requirement. Some specialized infusion sets may belong to a variety of special infusion sets, and the applicable parts of YY 0286 shall be executed at the same time. Some drugs in the clinic need to be transfused in dark conditions, such as sodium nitroprusside, nitroglycerin, and vitamin B2. Common infusion sets that comply with GB 8368 cannot meet this infusion requirement. Therefore, it is necessary to use the light-proof infusion device specified in this Part of YY 0826. All components of light-resistant infusion sets that are in connection with the liquid are required to have light resistance. This Part only specifies the light resistance performance for the drip bucket and the pipe. Since other components are limited by their dimensions, they are not subject to light resistance requirements and are controlled by the manufacturer. It is the responsibility of the device manufacturer to protect light-resistant infusion sets from stabilizing during shelf life without discoloration. Standard Annex B and Annex C give methods for decolorization evaluation of light-resistant infusion sets. The four alternative solvents given in Annex C are more suitable for device manufacturer to perform decolorization test. The device packaging shall identify the drugs that are known to be incompatible. The current methods to realize light resistance of infusion sets include. - monolayer structure made from light-resistant pellets; - composite structure made of light- resistant layer and non-light- resistant layer; - partial shielding of the use of shading devices (such as light-resistant hood on drop bucket); - combination the above methods. For light-resistant infusion sets equipped with a shading device, the light-resistant test of this Standard does not apply to shielded parts. For the infusion sets made of a combination of a light-resistant layer and a non- light- resistant layer, the influence of the thickness of each layer, the total wall Special infusion sets - Part 3. Light-resistant infusion sets for single use

1 Scope

YY 0286.3 is Part 3 of the Chinese special infusion set series, covering the single-use light-resistant set. A number of widely used drugs degrade under ambient light during infusion, among them several vitamins, chemotherapeutic agents and nitroprusside, and a light-resistant set is the practical answer: the tubing and chamber are pigmented or sleeved so that the drug reaching the patient is the dose that was prescribed. The requirement that distinguishes it from a standard set is therefore the light transmission of the fluid path, on top of all the ordinary infusion set requirements. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of light-protected infusion sets, this is the governing standard.

This Part of YY 0286 specifies the single use of fluid material added with light- resistant agent, requirements for gravity infusion type infusion set, hereinafter referred to as "the

light-resistant infusion sets". This Part also provides guidelines for the performance of materials used in light- resistant infusion sets and their quality specifications.

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 601-2002, Chemical Reagent - Preparations of Standard Volumetric Solutions

GB 8368, Infusion sets for single use - Gravity feed

3 General requirements

The requirements specified in GB 8368 apply to this document.

4 Materials

Materials for production of light-resistant infusion sets and their components shall meet the requirements of Clause 5. The components of the light-resistant infusion sets that are in connection with liquid medicine shall also meet the requirements specified in Clauses 6 and 7.

Annex C

(normative) Discoloration chemical test method - visual colorimetry C.1 General Discoloration chemical test method - visual colorimetry selects 4 different solutions for 2h cycle test. C.2 Solution preparation C.2.1 c[HCL]=

0.1 mol/L hydrochloric acid solution. prepare 1000 mL according to the provisions of

4.2 in GB 601-2002; C.2.2 c[NaOH]=

0.1 mol/L sodium hydroxide solution. weigh