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PHARMACEUTICAL INDUSTRY STANDARD

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Medical Plasma Virus Inactivated Device

医用血浆病毒灭活箱

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Introduction

This Standard provides basic technical guidance to medical plasma virus inactivated device of different light sources, design structures and specification models.

Medical plasma virus inactivated device is a device of preparing clinically infused virus inactivated plasma for blood collection and supply institutions, and clinical medical institutions. It is used cooperatively with methylene blue virus inactivated device. Medical plasma virus inactivated device is mainly applicable to photochemical method for plasma virus inactivation technology. In other words, after adding an appropriate amount of virus inactivating agent---methylene blue to plasma and placing it in the device, plasma can receive certain amount of illumination at a certain temperature. Under the illumination, sway the plasma, so that the plasma that contains methylene blue can receive uniform and effective illumination energy, which will reach the effect of virus inactivation. Medical plasma virus inactivated device is an exclusive supporting device that guarantees safe, effective and reliable plasma virus inactivation through the photochemical method.

Medical plasma virus inactivated device provides appropriate illumination conditions to plasma virus inactivation through the photochemical method. Effective illumination conditions for virus inactivation depend on the variety of light source and the intensity of illumination that is emitted from a specific waveband, and illumination energy that plasma receives. There are two commonly seen light sources of virus inactivated device in the market: florescence and LED, and the duration of illumination also varies with the intensity of illumination. In consideration of these, this Standard specifies that illumination parameters stipulated by manufacturers shall be satisfied in tests with methods provided by the manufacturers. However, satisfying these parameters does not signify that it can reach an ideal effect of virus inactivation. Manufacturers shall take the responsibility of verifying the validity of these parameters and confirming the effect of virus inactivation in accordance with relevant national-level stipulations.

Furthermore, manufacturers of medical plasma virus inactivated device shall confirm that there is no obvious adverse influence on blood component quality and function and verify infusion safety after virus inactivation. Thus, after virus inactivation, blood component can comply with relevant national-level stipulations.

Medical Plasma Virus Inactivated Device

1 Scope

This Standard specifies the general requirements, test methods, inspection rules, marking, instruction for use and packaging of medical plasma virus inactivated device (hereinafter referred to as virus inactivated device).

This Standard is applicable to medical plasma virus inactivated device that is matched with virus inactivated device that is stipulated in YY 0765.1.

2 Normative References

The following documents are indispensable to the application of this Standard. In terms of references with a specified date, only versions with a specified date are applicable to this Standard. The latest version (including all the modifications) of references without a specified date is also applicable to this Standard.

GB 4793.1 Safety Requirements for Electrical Equipment for Measurement, Control and Laboratory Use - Part 1: General Requirements

GB/T 14710 Environmental Requirement and Test Methods for Medical Electrical Equipment

GB/T 18268.1 Electrical Equipment for Measurement, Control and Laboratory Use - EMC Requirements - Part 1: General Requirements

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 0765.1 Sets for Inactivation of Viruses in Blood and Blood Components for Single Use. Part 1: Sets for Virus Photodynamic Inactivation with Methylene Blue

3 Terms and Definitions

The following terms and definitions are applicable to this Standard.

3.1 Stable Operating State

Stable operating state means after virus inactivated device is activated, indicated temperature reaches 2 °C ~ 8 °C; illumination intensity reaches the range explicitly instructed by manufacturers.

3.2 Effective Inactivation Area

5.3 Illumination Intensity

Conduct the test in accordance with methods stipulated by manufacturers.

5.4 Smoothness and Reliability of Load Shelf

Under the maximum load, conduct visual inspection of whether the load shelf in the virus inactivated device can operate smoothly and reliably; whether the extraction is flexible; whether there are obvious sway and distortion.

5.5 Alarm Temperature

When the practical simulated temperature and illumination intensity exceed the limitation, use sound level meter to measure alarm sound level at a distance of 1 m from the front panel and 1 m from the ground.

5.6 Time Setting

Use a timer to measure the practical operating hours of virus inactivated device; calculate the deviation from the previously set time.

6 Inspection Rules

6.1 Inspection Type

Inspection of virus inactivated device shall be divided into exit-factory inspection and model inspection.

6.2 Exit-factory Inspection

Exit-factory inspection items of each virus inactivated device (including process inspection and/or ultimate inspection) shall at least include 4.2 ~ 4.9.

6.3 Model Inspection

6.3.1 Model inspection shall be conducted under any of the following circumstances:

a) When new products are put into production;

b) When there are significant changes in structure, critical components and technology;

c) When production is resumed after production suspension and rectification;

d) When there are significant differences between the result of exit-factory inspection result and the last model inspection;

e) When it is stipulated by contract or requested by management department.

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