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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1550.3-2024

Guidance on the study of compatibility of infusion equipment and pharmaceutical products - Part 3: Leachable study - Unknown substances

一次性使用输液器具与药物相容性研究指南 第3部分：可沥滤物研究 未知物

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document is Part 3 of YY/T 1550 "Guidelines for Compatibility Studies of Disposable Infusion Sets and Drugs". The following parts have been published.

1.Drug adsorption studies;

2.Leachables Study Known Substances;

3.Leachable study unknowns. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Infusion Equipment (SAC/TC106). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Suzhou Baxter Medical Supplies Co., Ltd., Shandong Zhongbao KON MEDICAL APPLIANCES LIMITED. The main drafters of this document are. Zhang Min, Luo Hongyu, Shen Yong, Liu Hongying, Lü Shasha, Liu Min, Chen Fang, and Liu Lili.

Chemical characterization of medical devices generally includes determining the composition of the product (such as product structure, ingredients, physical and chemical properties, etc.), extraction research, Extractable study, leachable study, etc. Leachable study is an important part of chemical characterization of medical devices. Leachables refer

to substances released by medical devices or materials during clinical use, generally including Residual agents, process residues, degradation products, monomers and additives in materials (including stabilizers, antioxidants, plasticizers, colorants, etc.) According to the different research systems of leachables, they can be divided into known leachables (target leachables) identified based on relevant information and leachables identified based on Unknown leachable studies can be performed to identify potential known leachables and can also be used to support biological evaluations. The need for conducting research on unknown leachable substances should be comprehensively assessed for the risks of clinical use of infusion sets. The general requirement to conduct unknown leachables studies when conducting compatibility studies between liquid devices and drugs does not mean that conducting unknown leachables studies is necessary. Need process. The study of unknown leachables generally needs to consider organic and inorganic substances, among which organic substances are qualitatively divided into three categories according to their volatility. volatile Volatile organic compounds (VOCs), semi-volatile organic compounds (SVOCs) and non-volatile organic compounds (NVOCs). Although a variety of techniques can be used to detect organic leachables, the analytical techniques used to screen for the three types of organic leachables mentioned above are different. Analysis of unknown leachables The method is different from the known substance research. The selected unknown substance analysis system should refer to GB/T 16886.18-2022 for appropriate methodology. verify. YY/T 1550 "Guidelines for Compatibility Studies between Disposable Infusion Sets and Drugs" is planned to consist of three parts.

1.Drug adsorption study. The purpose is to establish the drug adsorption under simulated clinical infusion conditions or clinical infusion conditions, single use Research methods for drug adsorption during contact between infusion devices and drugs.

2.Leachable substances. The purpose is to establish the conditions under which a single infusion of a liquid can be prepared. Study method for the known substances in leachable materials during the contact between infusion sets and drugs.

3.Leachable unknowns. The purpose is to establish the unknowns of a single infusion under simulated clinical infusion conditions or under clinical infusion conditions. A study method for unknown substances in leachable materials during the contact between infusion sets and drugs. Study on the compatibility of disposable infusion equipment with drugs Guidelines Part

1 Scope

YY/T 1550.3 addresses the hardest part of an extractables and leachables study: the peaks nobody can name. It is Part 3 of the Chinese guidance series on the compatibility between single-use infusion equipment and the drugs passing through it, and it covers the study of unknown leachable substances, the compounds that migrate out of the plastic into the drug

solution and appear in the chromatogram without matching any reference. The framework has to say when an unknown must be identified, when it can be handled by a threshold, and what evidence supports either choice. For a manufacturer of infusion sets or a pharmaceutical company qualifying a delivery device for the Chinese market, this is the reference the leachables assessment is built on.

This document describes the process of single-use infusion sets in contact with drugs under simulated clinical infusion conditions or clinical infusion conditions. Methods for the investigation of unknowns in leachables. This document applies to specific infusion sets that require studies of unknown leachables and, when necessary, alternative solvents or proposed solutions for the drug that have been demonstrated. For drugs to be infused, unknown leachable substances should be studied. Other infusion devices can be used for reference if evaluation is required.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 threshold below which the analyst need not characterize, analyze, or characterize extractables or leachables for potential toxicological evaluation. Quantification or reporting. [Source: GB/T 16886.18-2022, 3.2]

3.2 A method designed to detect, identify, and semi-quantitatively estimate all relevant analytes present in test samples at concentrations above established reporting thresholds (e.g., AETs). method. [Source: GB/T 16886.18-2022, 3.4]

3.3 Qualitative identification Assign molecular structures and chemical names to organic compounds, and assign constituent elements or, as appropriate, molecular structures and their chemical names to inorganic compounds. Chemical name of the process. [Source: GB/T 16886.18-2022, 3.19]

3.4 Quantification The process of determining the concentration of an analyte in a sample. [Source: GB/T 16886.18-2022, 3.30]

3.5 Semi-quantitative analysis The concentration of the analyte is provided by using the response of one or more surrogate substances and the analyte and surrogate phases are specifically stated. Methods for analyzing responses.