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Guidelines for treatment and reuse of fermentation-based pharmaceutical wastewater

Lignes directrices pour le traitement et la réutilisation des eaux usées pharmaceutiques issues de la fermentation

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Foreword

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This document was prepared by Technical Committee ISO/TC 282, *Water reuse*, Subcommittee SC 4, *Industrial water reuse*.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

With the development of the social economy and the improvement of people's living standards, the public's demand for drugs to improve the quality of life and prolong lifespan is continually increasing. Pharmaceutical manufacturing ranks among the top five industries in the global economy. Fermentation-based pharmaceuticals, such as analgesics, anti-inflammatory drugs, antibiotics, lipid regulators, receptor blockers and X-ray contrast agents, have been widely used in health treatment. At the same time, the impact of drug pollution and pharmaceutical wastewater discharge has become a global hot topic of concern for environmental protection. At present, traces of drugs have been detected in sewage wastewater, drinking water and rivers in many different places, including the United States, China, Australia, Europe and Africa, and research shows that one of the reasons is the discharge of pharmaceutical wastewater.

Pharmaceutical manufacturing is generally divided into two categories: biopharmaceutical production and chemical pharmaceutical production. Fermentation-based pharmaceutical production is one kind of biopharmaceutical production with a long history of development, relatively advanced technology and wide application. Fermentation-based drugs include antibiotics, vitamins, amino acids and other types of drugs. The fermentation pharmaceutical production process not only requires a stable supply of pure water, but also produces a large amount of wastewater. Studies have found that such wastewater usually contains high levels of waste solvent, refractory organic matter, residual drugs and salt. Meanwhile, for different production processes, such as bacteria screening, refining and purification, drying, packaging and other steps, the concentration of pollutants in organic wastewaters varies greatly. The chemical oxygen demand (COD_{Cr}) can reach 4 410 mg/l to 40 000 mg/l.

The rapid development of the fermentation-based pharmaceutical production industry also poses challenges to the treatment and discharge of wastewater, as well as the management of water resources. If wastewater is released into the environment without effective treatment, pharmaceutical pollutants will cause water-quality risks, thus adversely affecting the aquatic ecosystem and public health. In recent years, many countries have put forward new requirements for the reclamation treatment of industrial wastewater and introduced many laws and regulations on the reuse of the treated wastewater, requiring treated wastewater to be reused in various applications, such as in-plant production, greening and irrigation. However, there is still a lack of reasonable technical specifications for the reclamation treatment and reuse of fermentation pharmaceutical industry wastewater in terms of how to select the most suitable treatment technology for each type of wastewater and how to efficiently recycle or reuse the wastewater.

This document is intended to help solve the current technical problems regarding the treatment and reuse of fermentation-based pharmaceutical wastewater. In view of the particularity of the production processes generating fermentation-based pharmaceutical wastewater, this document puts forward the general recommendations of the process flow and technology selection for reuse of wastewater after treatment under different pollution loads. At the same time, according to the different reuse scenarios of treated wastewater, different reuse water treatment technologies are recommended to meet the reuse requirements in each scenario. This document can provide theoretical support and technical guidance for the treatment and reuse of fermentation-based pharmaceutical wastewater. At the same time, it can be conducive to promoting technology advancement, product upgrading, energy conservation and emission reduction of fermentation-based pharmaceutical enterprises. Moreover, it can promote the standardized and the high-quality development of fermentation-based pharmaceutical wastewater treatment and reuse projects, improve water efficiency and thus promote a more sustainable and high-quality development of the whole industry.

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Guidelines for treatment and reuse of fermentation-based pharmaceutical wastewater

1 Scope

This document provides technical guidance for fermentation-based pharmaceutical wastewater treatment and reclamation for different reuse purposes.

This document contains information on pollution loading, general principles and applicable wastewater treatment and reclamation treatment. In addition, example processes for wastewater treatment and reclamation are listed to support different treatment conditions and reuse purposes.

2 Normative references

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

ISO 20670:2023, *Water reuse — Vocabulary*

3 Terms, definitions and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 20670:2023 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1 Terms and definitions

3.1.1
denitrification
reduction of nitrate and nitrite to the end product nitrogen (in the form of gas) by the action of bacteria

[SOURCE: ISO 11733:2004, 3.6]

3.1.2
fermentation-based pharmaceutical wastewater
process and non-process wastewater generated in the production operations of fermentation pharmaceutical enterprises

Note 1 to entry: Process wastewater refers to the in-situ residual mother liquor and wastewater produced in the process of *fermentation-based pharmaceutical production* (3.1.3). Non-process wastewater refers to wastewater produced by cooling or cleaning equipment and from washing ground surfaces.

3.1.3
fermentation-based pharmaceutical production
process of producing antibiotics or other active pharmaceutical ingredients by fermentation and producing drugs through separation, purification, refining and other processes

Note 1 to entry: The types of drugs can be divided into antibiotics, vitamins, amino acids and other categories.

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