



BSI Standards Publication

Guidelines for treatment and reuse of fermentation-based pharmaceutical wastewater

National foreword

This British Standard is the UK implementation of ISO 12370:2025.

The UK participation in its preparation was entrusted to Technical Committee B/505/50, Water reuse.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2025
Published by BSI Standards Limited 2025

ISBN 978 0 539 21237 2

ICS 13.030.20; 13.030.50

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 January 2025.

Amendments/corrigenda issued since publication

Date	Text affected
------	---------------



**International
Standard**

ISO 12370

**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*

**First edition
2025-01**

Reference number
ISO 12370:2025(en)

Full document details: BS ISO 12370:2025

© ISO 2025  **Documents**
Document Sharing Hub



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms, definitions and abbreviated terms	1
3.1 Terms and definitions	1
3.2 Abbreviated terms	2
4 Pollution loading	2
4.1 Classification of wastewater	2
4.2 Wastewater volume	3
4.3 Quality of produced wastewater	4
5 General principles	4
6 Wastewater treatment processes	5
6.1 Pretreatment process	5
6.2 Biological treatment process	6
6.2.1 General	6
6.2.2 Hydrolysis acidification reactor	6
6.2.3 UASB reactor	7
6.2.4 Activated sludge process	7
6.2.5 IFAS process	7
7 Reclamation treatment processes	8
7.1 General	8
7.2 Denitrification	8
7.3 Activated carbon adsorption	8
7.4 Coagulation precipitation	8
7.5 Membrane separation	9
7.6 High-efficiency sedimentation tank	9
7.7 Ion exchange	9
7.8 MBR	10
7.9 Fenton oxidation	10
7.10 Ozone catalytic oxidation	10
7.11 Ultraviolet disinfection	10
8 Example processes for wastewater treatment and reclamation	10
Annex A (informative) Pharmaceutical wastewater quality	11
Annex B (informative) Influent quality for membrane separation	13
Annex C (informative) Examples of treatment and reclamation processes for fermentation-based pharmaceutical wastewater	14
Bibliography	17

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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.

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.

