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BSI Standards Publication

Membrane-based generation of water for injection (WFI)

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National foreword

This British Standard is the UK implementation of ISO 22519:2023. It supersedes BS ISO 22519:2019, which is withdrawn.

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.

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2023-04-04

Membrane-based generation of water for injection (WFI)

*Production d'eau pour préparations injectables (EPPI) utilisant
des membranes*



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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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*.

This second edition cancels and replaces the first edition (ISO 22519:2019), which has been technically revised.

The main changes are as follows:

- title changed;
- PW systems removed from the Scope;
- document structure revised.

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

The water quality specifications for water for injection (WFI) are given in national and International Standards and are well defined and understood.

The WFI generation systems potentially have to be able to cope with fluctuating feed water quality and be in accordance with the company policy and current good manufacturing practice (cGMP).

Properly engineered, constructed, operated and maintained membrane-based generation systems can have comparable reliability in meeting WFI quality specifications with low operational costs in comparison with thermal-based WFI generation. At the time of publication, all major pharmacopoeia allow non-distillation-based WFI generation, with the exception of the Chinese Pharmacopoeia. The Chinese Pharmacopoeia has initiated revisions to related standards.

This document has been developed to address the lack of an International Standard concerning membrane-based WFI generation.

The aim of this document is to:

- set out clear principles needed for reliable membrane-based generation of WFI;
- improve membrane-based generation of WFI process systems and methods;
- combine relevant standards, guidelines and global expert knowledge into one International Standard;
- consider in-system microbiological aspects of WFI generation;
- standardize expectations for membrane-based WFI generation.

This document provides a global benchmark that can be used by industries that use the WFI generation system.

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Membrane-based generation of water for injection (WFI)

1 Scope

This document provides a benchmark for evaluation of the design, operation and performance of water for injection (WFI) generation systems based on membranes.

This document is applicable to the design of new systems.

This document covers the following topics:

- principles of membrane-based WFI generation systems;
- process design, construction, operation and maintenance of membrane-based WFI generation systems;
- controlling membrane-based WFI generation system parameters.

This document does not cover the following topics:

- validation;
- distillation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 20670, *Water reuse — Vocabulary*

3 Terms, definitions and abbreviated terms

For the purposes of this document, the terms and definitions given in ISO 20670 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

pretreatment

equipment and process stages up to and including the first-pass reverse osmosis (RO) pump or other membrane-based primary bioburden reduction step

3.1.2

generation system

equipment and process stages after (downstream) reverse osmosis (RO) stage 1 pump