

# **Data Sheet**

Version: v1 Revision date: 06/05/2024

#### 1. Identification

Product name Manufacturing Site WFI Quality Water Boecillo; Valladolid Spain

#### 2. Description

Water for Inyection (WFI) Quality Water, Animal-derived component-free, meets the most stringent USP and/or EP compendial grade specifications. Manufactured in an ISO 13485:2016 and GMP-certified facility, located in Boecillo, Valladolid (Spain), following GMP compliant procedures to ensure the highest quality standards. It provides you the confidence to achieve exceptional results, with unparalleled purity and reliability with a secure supply chain.

3. Size, SKU and Packaging			
Cat. No.	E0335	E0361	E0371
Size	1 L	20 L	200L
Packaging	PET Bottle	Single-use container	Single-use container with Plastic Drum

### 4. Storage & Stability specifications

- Shipment at Ambient Temperature.
- Storage: Room Temperature (15 30 °C).
- **Shelf life:** 24 months from data of manufacturing, based on our Accelerated Stability Testing Program, with both Normal and Accelerated Stability Testing Programs ongoing.

### 5. Applications

For Research Use Only or Further Manufacturing. Not for diagnostic use or direct use in humans or animals.

## 6. Quality

WFI Quality Water is manufactured in an **ISO 13485:2016 and GMP-certified facility**, located in Boecillo, Valladolid (Spain), following GMP compliant procedures to ensure the highest quality standards. Our process include:

- Batch-to-batch consistency.
- Facilities audited regularly Quality audits.
- Lot specific CoAs and QA review previously to release a product.
- Material traceability, documented procedures and documented employee training.
- Equipment maintenance and monitoring records.

Canvax GMP Buffers are manufactured and tested in accordance with **Ph. Eur. 5.2.12** for "Raw materials of biological origin for the production of cell-based and gene therapy medicinal products" and **USP <1043>** on ancillary materials.

**Disclaimer:** It is the end user's responsibility to ensure that the final product meets the requirements of the application for which it is to be used.

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