

## Data Sheet



### QT WFI QUALITY WATER

QT WFI Quality Water is produced in an ISO 9001, ISO 13485 certified and FDA registered facility using potable water which is subjected to extensive purification with 2 reverse osmosis passes and final filtration of 0.1µm. This process provides WFI Quality water meeting the United States Pharmacopeia (USP) specifications for Water for Injection (WFI). QT WFI Quality water is additionally filtered at 0.22 micron during filling then double-bagged in an ISO 7 classified environment, and terminally sterilized by gamma irradiation to a 10<sup>-6</sup> Sterility Assurance Level (SAL).

QT WFI Quality Water comes with a lot specific Certificate of Analysis (COA) and/or a Certificate of Irradiation (COI) making it convenient for facilities to obtain WFI-quality water, without the hassle of validation and costly maintenance of a WFI system.

#### Features

- Produced in ISO 9001, ISO 13485 certified and FDA registered facility
- Meets USP specifications for WFI
- Low endotoxin levels
- Lot specific COA and/or COS for each shipment

#### Applications

- QT WFI Quality water is intended for use as a diluent for disinfectants, sanitizers or cleaners which are applied on hard non-porous surfaces in cleanrooms or other critical environments such as floors, walls, counters, tools, carts and other equipment.
- QT WFI Quality water can also be used for rinsing of hard non-porous surfaces.



#### QT Water for Injection Specifications

Colour	Colourless liquid
Clarity	Clear
Odour	Odourless
pH	4.0 – 7.5
Total Organic Carbon (APHA 5310B)	≤ 500 µg/L
Microbial limit test/Heterotrophic Plate Count (APHA 9215D 2005)	≤ 10 CFU/100ml
Conductivity	≤ 1.3 µS/cm
Bacteria Endotoxin (LAL Kit by Cape Cod)	< 0.25 EU/ml
Sterility test (USP 71) (only for sterile products)	No growth detected

#### PRECAUTIONARY STATEMENT

**Not to be used for Parenteral Administration. Not for use in sterile irrigation, injection, infusion, or as a potable product. QT WFI Quality Water is intended for manufacturing and general laboratory use only.**

Part No.	Description	Quantity	Dimension	Weight	HS Code
QT9620-169	Sterile WFI, 5L	4 X 5L /case	410mm (L) x 260mm (W) x 300mm (H)	20.26 kg	30049099
QT9620-10L	Sterile WFI, 10L	1 X 10L /case	220mm (L) x 260mm (W) x 320mm (H)	10.80kg	30049099

#### PMA QuantumTec Life Science Solutions

- No.11, Lintang Beringin 3, Diamond Valley, 11900 Penang, Malaysia. • Tel: 604-626 5518
- Website: [www.quantumtec.com.my](http://www.quantumtec.com.my) • Email: [pmasales@pma-asia.com](mailto:pmasales@pma-asia.com)