VELTEK ASSOCIATES, INC.

TECHNICAL DATA FILES

VAI® WFI Quality Water

USP Grade Bulk Water for Injection

Product Description

VAI manufactures a USP grade bulk Water for Injection (WFI) that is processed to comply with the standards required by the pharmaceutical, biotechnology, medical device, and healthcare industries. **VAI® WFI Quality Water** is an innovative solution for GMP facilities that demand the use of a sterile WFI quality water in their daily operations but do not have it readily available on site. **VAI WFI Quality Water** is ready-to-use and can be used throughout any facility for chemical formulation, disinfectant dilution, cleaning, rinsing, and lubrication. Lubrication of moving parts, process lines, and conveyors is essential for continuous and effortless manufacturing. **VAI's WFI Quality Water** is produced from a 6 effect distilled water system that is validated, routinely monitored, and passes all USP monograph requirements for "Water for Injection".

VAI WFI Quality Water is filled in ISO 5 (Grade A/B, former Class 100), filtered at 0.2 microns, and subsequently terminally sterilized to 10^{-6} sterility assurance level. Each lot of **VAI WFI Quality Water** is sterility tested according to current USP Compendium, is tested for endotoxins, is completely traceable, and has been completely validated for sterility and shelf life. **VAI WFI Quality Water** is delivered each time with a lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation.

VAI WFI Quality Water is available sterile in multiple container sizes including an 11 oz aerosol, a 16 oz trigger spray, a 1 gallon, a 2 gallon, and a 200 liter drum. The 11 oz aerosol spray can precipitates in a broad spray/mist without aspiration of the room's air during use. Non-aspiration ensures that the master reservoir of **VAI WFI Quality Water** remains sterile from the first drop to the last drop. Included with each aerosol can of **VAI WFI Quality** is a nozzle extensions that allow operators to use in hard to reach places or on intricate mechanical parts. Each sterile container of **VAI WFI Quality Water** is individually double bagged and packaged in two liner bags using the ABCD Cleanroom Introduction System®.

***VAI WFI Quality Water** is not for human or animal injection, diagnostic, or therapeutic use.*

Quality and Manufacturing

- Filled in an ISO 5 (Grade A/B, Former Class 100)
- Filtered at 0.2 microns
- Components are air washed with 0.2 micron filtered air before assembly
- Gamma irradiated at 10^{-6} SAL
- Lot sterility tested according to current USP compendium
- Lot tested for endotoxins
- Completely traceable from start to finish
- Completely validated for sterility and shelf life
- Produced from a validated 6 effect distilled water system
- Passes all USP monograph requires for "Water for Injection"

VAI WFI Quality Water – USP Grade Bulk Water for Injection	
Certificate of Analysis	**Specifications**
Conductivity:	</= 5uS/cm
TOC:	<8.0 mg/L
LAL Result:	<0.25 EU/ml
Appearance:	Clear Liquid
Ammonia:	</= 0.2 ppm
Residue on Evaporation:	Max 0.001%
pH:	5.0 – 7.0
Calcium:	No Turbidity
Nitrates:	<0.2 ppm
Expiration Period:	2 years

Features and Benefits

- Each sterile container is double bagged packaged in easy tear bags
- Quadruple bagged in the ABCD Cleanroom Introduction System®
- Individually labeled with lot number and expiration
- Delivered with lot specific Certificate of Analysis, Certificate of Sterility, and Certificate of Irradiation
- Available in sterile in multiple container sizes
- Ready-to-use
- Available in 11 oz aerosol that will not aspirate the room's air
- 11 oz aerosol delivered with one unattached nozzle extension for use in hard to reach areas or when lubricating intricate machinery and equipment parts
- For use on a multitude of surfaces
- Lubricates for continuous and effortless manufacturing
- Meets the needs for USP grade WFI when required in cleanroom operations
- Ideal for operations that do not have USP grade WFI readily available

VAI-WFI-SP-11Z with Nozzle Extension

Uses

- Cleanroom operations that do not have USP grade WFI readily available
- Chemical formulation and disinfectant dilution
- Lubricating
- Rinsing and cleaning
- Use limitations: not for human or animal injection, diagnostic, or therapeutic use

ABCD Cleanroom Introduction System®

The ABCD Cleanroom Introduction System is a packaging system that allows operators/users to take the package through each level of classified areas by simply removing one bag at a time. Each bag acts as barrier protecting the finished product from becoming a carrier of viable and non-viable contamination. This prevents the need to decontaminate each outer bag prior to entering a cleaner area. In this packaging system, sterilized groups of containers are contained in two outer bags and after each are removed individual containers are each additionally contained in two easy tear bags.

Ordering Information

VAI WFI Quality Water – USP Grade Bulk Water for Injection		
Part Number	**Description**	**Qty/cs.**
VAI-WFI-SP-11Z	VAI WFI Quality Water, 11 oz Aerosol Spray/Mist, Unattached Nozzle Extension, Sterile	24
VAI-WFI-16Z	VAI WFI Quality Water, 16 oz, Attached Trigger, Sterile	12
VAI-WFI-1G	VAI WFI Quality Water, 1 Gallon, Sterile	4
VAI-WFI-2G	VAI WFI Quality Water, 2 Gallons, Sterile	2
VAI-WFI-200L	VAI WFI Quality Water, 200L Drum, Single Bagged, Sterile	1
VAI-WFI-200L-2B	VAI WFI Quality Water, 200L Drum, Double Bagged, Sterile	1

VAI-WFI-1G

VAI-WFI-16Z

VAI-WFI-2G

VAI Product Label Colors

Product Name	Bottle/Can Color	Label Background Color	Bar & User Info Color	Text Color
DECON-AHOL WFI FORMULA 70% AEROSOL	COOL GREY	PRINTED CAN COOL GREY		
DECON-AHOL WFI FORMULA 70% TRIGGER SPRAY, 1 & 5 GALLON	WHITE	COOL GREY		
DECON-AHOL WFI FORMULA 70% SQUEEZE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 70% ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	COOL GREY		
DECON-AHOL WFI FORMULA 60%	WHITE	WHITE		
DECON-AHOL WFI FORMULA 91%	WHITE	WHITE		
DECON-AHOL FORMULA 99%	WHITE	WHITE		
STER-AHOL WFI AEROSOL	WHITE	PRINTED CAN WHITE		
STER-AHOL WFI TRIGGER SPRAY, 1 & 5 GALLON	WHITE	WHITE		
DECON-HAND STERILE	WHITE SEMI-TRANSPARENT	PRINTED BOTTLE		
DECON-HAND NON-STERILE	CLEAR	PRINTED BOTTLE		
DECON-HAND ASEPTI-CLEANSE BOTTLE	WHITE SEMI-TRANSPARENT	WHITE		
STERI-OIL	WHITE	WHITE		
STERI-BUFFER	CLEAR	WHITE		
DECON-PHENE	WHITE	WHITE		
DECON-CYCLE	WHITE	WHITE		
DECON-CLEAN	WHITE	WHITE		
DECON-QUAT 100	WHITE	WHITE		
DECON-QUAT 200C	WHITE	WHITE		
DECON-QUAT 200V	WHITE	WHITE		
HYPO-CHLOR 0.25%	WHITE	WHITE		
HYPO-CHLOR 0.52%	WHITE	WHITE		
HYPO-CHLOR 5.25%	WHITE	WHITE		
STERI-PEROX 3%	WHITE	WHITE		
STERI-PEROX 6%	WHITE	WHITE		
DECON-SPORE 200 PLUS (SPORICIDE)	WHITE SEMI-TRANSPARENT	WHITE		
DECON-SPORE 200 PLUS (DISINFECTANT)	WHITE SEMI-TRANSPARENT	WHITE		
STEEL-BRIGHT	WHITE	WHITE		
STERI-SILICON	WHITE	BLACK		
DECON-GLASS	WHITE	WHITE		
VAI WFI QUALITY WATER	WHITE	WHITE		
STERI-WATER	WHITE	WHITE		

PRODUCT LABELING

VAI® WFI Quality Water
USP Grade Bulk Water for Injection

(Any specific product label is available upon request.)

VAI WFI Quality Water Family of Products

Bottle Labeling

VAI® WFI Quality Water

Filtered at 0.2 microns, sterilized via gamma irradiation and lot tested for sterility and endotoxins

Ingredients:
WFI Quality Water …… 100%

SDS Number: VEL-028

Container and Product Sterilized and Distributed by:

Veltek Associates, Inc.
15 Lee Blvd.
Malvern, PA 19355-1234 USA
Tel: 1-610-644-8335
Fax: 1-610-644-8336
www.sterile.com

Veltek Associates, Inc.
Postbus 1062
8200 BB Lelystad, Nederland
Tel: +800-00888700
Fax: 1-610-644-8336
www.sterile.com

Made in USA

USE LIMITATIONS

Not for human or animal injection, diagnostic, or therapeutic use.

Additional Aerosol Can Labeling

Net Contents: 11 oz (325 mL)
SDS Number: VEL-028-A
Reorder Number: VAI-WFI-SP-11Z

PRECAUTIONARY STATEMENTS

The contents of this can are under pressure. Keep away from flame or intense heat. Do not puncture or burn empty can. Do not store in direct sunlight or temperature above 120°F (49°C). Avoid freezing.

Spill/Exposure Emergency Response Service call CARECHEM24: 866-928-0789 (USA and Canada), Arabic call +44-1235-239-671, Chinese call +86-10-5100-3039.

Additional Documentation

Upon request, the following additional documentation is available:

- Specific Product Testing Reports
- Product Validation
- Safety Data Sheet
    - **VAI WFI Quality Water** Aerosol – SDS # VEL-028-A
    - **VAI WFI Quality Water** – SDS # VEL-028
- Sample lot specific documentation packages including Certificates of Sterility, Certificate of Irradiation, and Certificate of Analysis

VAI's Sterile Chemical Manufacturing Division - SCMD manufactures a complete range of cleaning agents and disinfectants that are used daily in cleanroom operations. Overall, VAI's capabilities for manufacturing products include the ability to fill aerosol, bulk, and unitdose packages in ISO 5 (Grade A/B). Our aseptic filling operations are coupled with the validated and proven ability to irradiate a final product. Assurances are taken in every aspect of SCMD concerning sterility and particulate removal. VAI's operations mirror current GMP's and enforces the adherence to USP specifications. VAI is an EPA and FDA registered facility. To learn more about our division capabilities please visit www.sterile.com.

Patents: www.sterile.com/patents