AQUABILITI™
IMPACTING LIVES

Real Time Stability Study of Bulk Filled Water – Customer Notice

Aquabiliti is in the process of conducting a real time Stability Study on the Bulk Filled Water to establish documented evidence of the packaged products' shelf life.

The real time Stability testing, conducted under validation YRK-QA-VAL-0120, Stability Study – Bulk Filled Water, is comprised of storing the Bulk Filled Product at ambient conditions over the shelf life of the product. Testing was conducted at Time-Zero and will be evaluated every three (3) months for the first year, every six (6) months for the second year and annually for each year after to confirm that the manufactured product remains stable under the specified storage conditions. The water will undergo Sterility Testing per USP <71>, Endotoxin Testing per USP <85>, Total Organic Carbon (TOC) Testing per USP <643>, Conductivity Testing per USP <645>, and Particulate Testing utilizing Method 1 per USP <788> at each of the sample intervals. Aquabiliti's Bulk Filled Water has achieved acceptable test results for Time Zero, three (3) months, six (6) months, nine (9) months, (12) months, eighteen (18) months and twenty-four (24) month time intervals.

All tests were conducted according to the prescribed, relevant, corresponding United States Pharmacopeia (USP) method. The test results confirm and display that the water (after 24-month real time storage) meets (or exceeds) the USP specifications for Water for Injection, USP Sterile Grade.

As evidenced by the Lot correspondent COA the Sterile Water was produced using Current Good Manufacturing Practices and evaluated with approved Aquabiliti specifications and procedures. Aquabiliti's Bulk Filled Water has a 24-month Shelf-Life Stability Claim on its packaged sterile water:

See the following attachments supporting the above claim:

YRK-QA-VAL-0120	Stability Study – Bulk Filled Water
USP <71>	Sterility Tests
USP <85>	Bacterial Endotoxins Test
USP <643>	Total Organic Carbon
USP <645>	Water Conductivity
USP <788>	Particulate Matter in Injections

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