



| CUSTOMER

Valisure, LLC, headquartered in New Haven, Connecticut, has built its reputation as an online pharmacy that independently evaluates the chemical composition of medications before they reach consumers. Their stringent testing standards have led them to reject over 10% of on-market medication batches they have evaluated.

| CHALLENGE

To meet their metals testing requirement, Valisure's laboratory needs sample prep solutions that enable them to quickly dispense rigorously-tested and verified medications to their customers.

| SOLUTION

Milestone's ultraWAVE has allowed Valisure to prepare multiple types of samples simultaneously for analysis on the Agilent 7800 ICP-MS system, which is critical to meeting their pharmacy's 24-hour testing turnaround requirement.

| BACKGROUND

Founded in 2015, Valisure is the first and only pharmacy to independently batch-test the medications they receive to confirm the drugs are suitable for their customers before they dispense them. With an estimated 80 percent of ingredients in U.S. medications now being manufactured overseas and approximately four drug recalls in the U.S. every day, medication quality is constantly called into question. Seeing the need to "chemically validate" the drugs that it receives prior to dispensing them, Valisure tests for correct dosage, major inactive ingredients, proper dissolution, and the presence of carcinogens and/or trace metals. Currently, Valisure estimates that it rejects over 10% of on-market medication batches based on these testing standards.

Valisure does not manufacture any medications. They purchase their medications from the same American distributors used by other pharmacies. What makes them unique is that unlike other pharmacies, Valisure performs rigorous independent testing on its medications prior to dispensing them to consumers. In early 2019, Valisure's corporate team made the decision to add USP <232>/<233> testing to its lengthy list of testing standards, which makes it

LAB PROFILE SAMPLE PREP | PHARMACEUTICALS



"I don't have experience with other microwave digestion solutions, which speaks volumes to how easy the ultraWAVE is to operate. The system is easy to use and very fast. It was more or less plug-and-play after 2 days of training from Milestone. And when I had questions, Milestone provided excellent support." - Jake Chiles, Research Associate

necessary for them to run trace metals testing on a broad range of medications. The vast differences in reactivity of the samples they needed to prepare made it apparent that they would face a sample bottleneck if they employed a rotor-based microwave digestion solution for their testing, since these systems typically prepare only one type of sample per run. The corporate team also wanted a solution that would be quick to adopt, so they could start testing medications as soon as possible.

| ultraWAVE: SRC MICROWAVE TECHNOLOGY

After evaluating rotor-based digestion systems, the Valisure team turned their attention to the ultraWAVE and its unique Single Reaction Chamber technology. Unlike rotor-based systems, Milestone's ultraWAVE allows mixed sample types to be digested in the same run, while ensuring all samples reach the same high temperature and pressure required for complete digestion. This capability dramatically speeds up processing and eliminates under-digested samples. In addition, the ultraWAVE's unique design prevents venting, which provides reliable recoveries for volatile elements such as mercury and sulfur. If they were to employ a rotor-based system, Valisure quickly realized that this would result in an unacceptable bottleneck in their process due to the wide range of medications



Research Associate, Jake Chiles of Valisure

they dispense. The ability to process mixed-batch samples in the same run is one of the primary reasons behind Valisure's decision to purchase an ultraWAVE, as explained by Kaury Kucera, PhD, Valisure's Chief Scientific Officer.

"The ultraWAVE has been amazing and has allowed us to keep up with our business demands. Without the ultraWAVE's ability to run mix-batch samples, we likely would have been forced to choose between testing only pharmaceutical or supplement samples. Instead, today we're able to run everything, from patches to creams to topicals to tablets, everything we need in just a few runs per day." - Kaury Kucera, PhD, Chief Scientific Officer

| FUTURE PLANS

Valisure's use of the ultraWAVE has enabled them to broadly test the wide range of medications that they receive for trace metals. The system has also provided the Valisure team with the ability to scale testing for additional medications, as their pharmacy continues to grow and acquire new customers.

| ABOUT MILESTONE

With over 50 patents and more than 25,000 instruments installed in laboratories around the world, Milestone has been widely recognized as the global leader in metals prep technology. For more than 30 years, Milestone has pioneered innovative solutions that help atomic spectroscopists deal with challenging samples, meet their trace metals detection limit and accuracy objectives, and improve overall lab throughput.



MILESTONE
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