by Nick Armstrong

A High-Purity Water System for Pharmaceuticals Testing

When **Velesco Pharmaceutical Services** needed high-purity water for research laboratories at its new facility in Plymouth, MI, it chose a water treatment system that would provide affordable HPLC-grade water for analyzing pharmaceutical samples. Laboratory personnel had been using bottled HPLC-grade water, which was more expensive and not as convenient as having a purification system on site.

The system selected—the LaboStar™ TWF (tap water feed) system (**Siemens Water Technologies**, Warrendale, PA)—purifies water from a tap feed source. It includes a pretreatment module that produces reverse osmosis (RO)-quality water, and a storage tank that stores the water until it is needed. When purified water is required, the RO-quality water is sent from the storage tank to an enhanced organic-removal deionization (DI) "polishing" cartridge for further purification when Type I water is required. When the system is not in use, it circulates the water through the optional ultraviolet (UV) sterilizer and DI cartridge to maintain high-quality water. The system includes a positively charged 0.2-µm sterile filter, installed at the dispense point, which allows the system to produce water with endotoxin levels of less than 0.001 EU/mL. The system is microprocessor-controlled and includes a menu and display for checking the water conductivity or resistivity at multiple points in the system, including after the final DI cartridge.

The benefit of having a point-of-use water purification system is a continuous supply of ultrapure water on demand when it is needed. Bottled water purity can be compromised each time the bottle is opened, absorbing contaminants from the atmosphere. Also, the container can leach materials into the water. These contaminants can interfere with the analyses. Another benefit of a point-of-use system is that a single water system can be used for multiple applications in the laboratory, whereas bottled water typically is purified for a specific application.

Velesco Pharmaceutical Services is a contract research organization for the pharmaceutical industry, providing analytical method development, drug formulation, stability testing, and consulting services to biotechnology and pharmaceutical companies. It recently opened a cGMP manufacturing facility and office in Kalamazoo, MI, and has moved its Ann Arbor, MI, laboratories to the Michigan Life Science and Innovation Center (MLSIC) in Plymouth, MI.

Using HPLC and UHPLC (ultrahigh-performance liquid chromatography) instruments to analyze product samples, **Velesco** takes purified water from the LaboStar system to prepare research pharmaceutical formulations and to prepare mobile phases and sample diluents, which are run on HPLC instruments with UV and refractive index detection. For a recent project, the laboratory used high-purity water for gradient HPLC using the following specific method:

- Mobile phase A (96:4:0.1 water:tetrahydrofuran: trifluoroacetic acid)
- Mobile phase B (96:4:0.1 acetonitrile: tetrahydrofuran:trifluoroacetic acid)

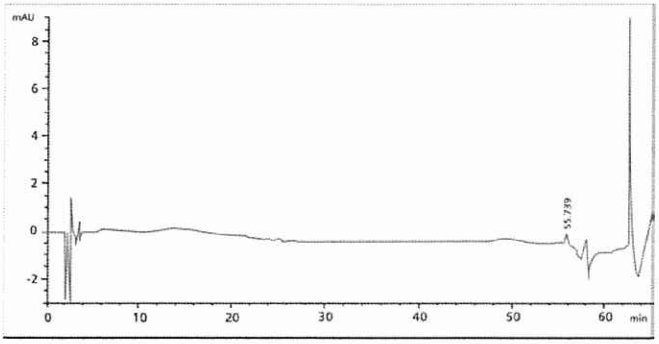

Figure 1 Water injection—LaboStar 18.2 megohm water, 75 µL onto a C18 column at 267 nm; gradient elution.

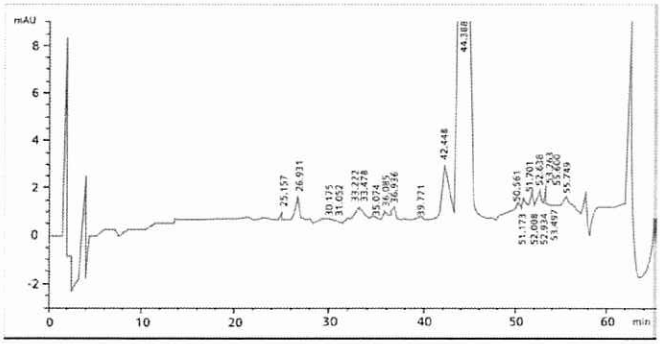

Figure 2 Active pharmaceutical ingredient—75 µL onto a C18 column at 267 nm; gradient elution.

- Gradient elution, detected at 267 nm
- Diluent 80:20:0.2 ethanol:water: trifluoroacetic acid.

The chromatogram in *Figure 1* illustrates a pure LaboStar system water blank; *Figure 2* displays an active product.

Velesco is also using the LaboStar system product water for disintegration testing, and will use it for dissolution testing in the future. A small amount of the water is utilized in the facility's drug formulation work. Installed in early 2010, the water treatment system is running well and producing the quality of water required, which is 18.2 megohm-cm.

According to Lisa Crandall, Senior Analytical Scientist at **Velesco**, "The LaboStar system is solving the problem of an affordable source of high-purity water. The biggest benefit is convenience. While the cost is slightly lower, the convenience of having on-demand purified water is fantastic. It saves me time ordering bottles of water and going to get them from our stockroom."

Crandall also feels that the system is a greener option. "Water is one of the heaviest liquids that we use. Shipping large quantities of it across the country really doesn't make environmental sense if I can just filter the tap water here on demand."

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