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Pharma

Streamlining productivity and reducing costs: Opella's transition to Vanquish Flex UHPLC

Opella.

Keywords
(U)HPLC, (Ultra)high-performance liquid chromatography, method development, method transfer, method modernization, solvent waste reduction, cost savings

Introduction

Opella Healthcare, headquartered in Neuilly-sur-Seine, France, benefits from its long-standing pharmaceutical heritage and specializes in the development, manufacturing, and commercialization of consumer health products. With operations spanning multiple countries and a strong legacy of scientific excellence inherited from Sanofi, Opella Healthcare is committed to delivering high-quality, accessible healthcare solutions.

As a continuation of the partnership initiated with Sanofi in 2021 to upgrade their liquid chromatography (LC) instruments with Thermo Fisher Scientific technology, this collaboration now extends to Opella. The partnership helped Opella boost productivity and reduce costs, while providing Thermo Fisher Scientific with valuable insights into how their instruments perform in both research and quality control labs.

The Ocoyoacac site in Mexico is focused on consumer healthcare products, manufacturing over-the-counter syrups and multivitamin supplements. As previously executed at an Opella site in France,[1] Opella's Ocoyoacac site replaced outdated high-performance liquid chromatography (HPLC) systems with Thermo Scientific™ Vanquish™ Flex Ultra-High-Performance Liquid Chromatography (UHPLC) Systems to enhance lab efficiency. With these new systems, several important analytical methods have been modernized, complying with regulatory recommendations for updating equipment and improving method management.

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The International Council for Harmonisation (ICH) Q14 guidance,[2] adopted in November 2023, advises on the continuous improvement of analytical procedures through equipment upgrades and new technologies to boost specificity, precision, and accuracy.

Updates to the United States Pharmacopeia (USP) Chapter <621>[3] allow flexibility in modernizing liquid chromatographic methods. These changes let users adjust column dimensions, flow rates, and other parameters for isocratic and now gradient methods without the need for re-validation.

Instrument and method modernization

The Ocoyoacac site produces 45 batches of a specific syrup per year, each requiring liquid chromatography testing for assay, impurity, and preservative analysis. Originally, the API and related substances assay method and the preservative method were developed separately and submitted to the authorities as two independent analytical methods (Figures 1A and 1B). This resulted in a significant amount of analysis time, sample preparation, and data processing.

The site operates their HPLC systems under Waters™ Empower™ CDS software, which was a consideration during the feasibility stage of the partnership. The Thermo Fisher team provided assurances that the implementation of Vanquish systems into an Empower network would be smooth and straightforward. This proved to be the case, ensuring that existing workflows were not disrupted. This seamless integration allowed users to continue processing data in the same manner as before, maintaining consistency and reliability in their analytical processes.

Vanquish Flex UHPLC systems were chosen for their ability to perform both HPLC and UHPLC methods, providing the site flexibility in the methods that they could run on the systems. This enabled legacy HPLC methods to be readily modernized to take advantage of modern column technologies and handle the higher backpressure generated by these methods.

The goal was to reduce overall analysis time and the number of instruments used. To achieve this, the legacy methods have been combined into a single UHPLC method. Figures 1A, 1B, and 1C compare the chromatograms from the previous legacy methods to the modernized combined one. The use of the Vanquish Flex UHPLC system resulted in a significant reduction in the total run time from two hours and twenty minutes to twenty-four minutes, which means a savings of one hour and fifty-six minutes and thus shortens the analytical run time by approximately 80% (Table 1).

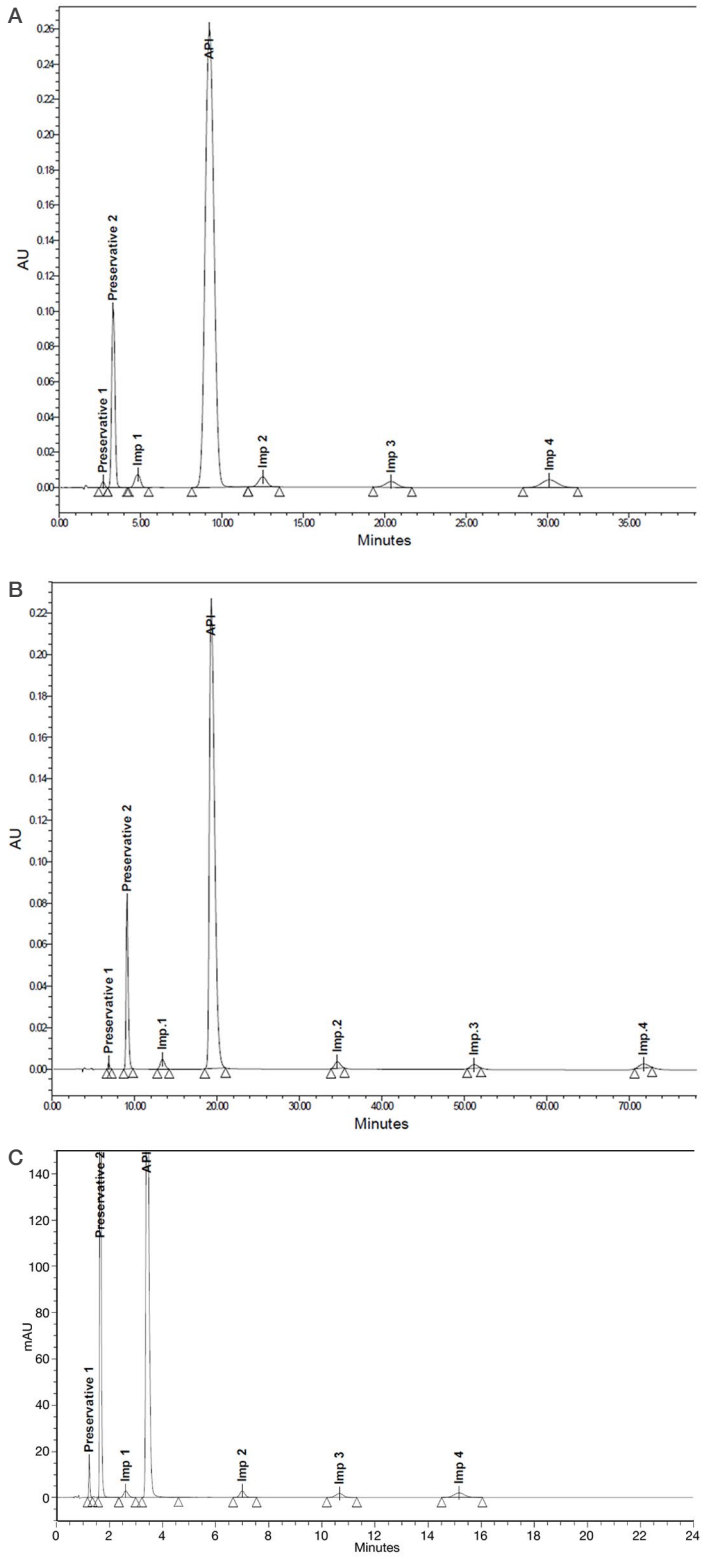

Figure 1. (A) Assay and impurities – Chromatogram before method modernization; (B) Preservatives – Chromatogram before method modernization; (C) Combined assay/impurity/preservatives after method modernization on the Vanquish Flex UHPLC system.

The transition from the previous double sample and solvent preparations to a single preparation by switching to Vanquish Flex UHPLC instruments significantly increased Opella's productivity and drastically reduced costs.

Table 1. Legacy method versus Vanquish Flex UHPLC method run time.

Legacy method run time (min)		Vanquish Flex UHPLC method run time (min)
Assay and impurity	Preservatives	Assay and impurity and preservatives
40	100	24

Figure 2 demonstrates the productivity gain of the modernized Vanquish Flex UHPLC method compared to the legacy method when running a comparative study of four lots of syrup.

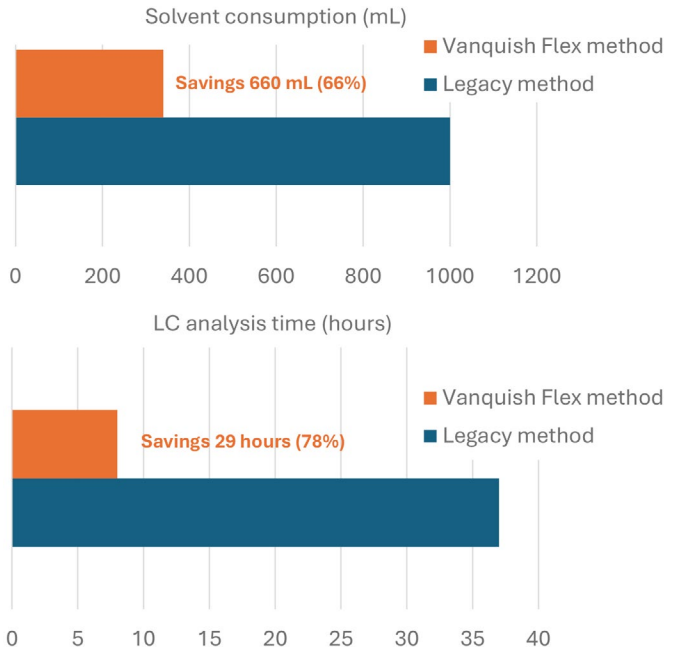

Figure 2. Summary of efficacy gain in analysis time and solvent consumption for the modernized Vanquish Flex UHPLC method. Values are calculated based on four lots of syrup.

In addition to this impressive instrument runtime savings, the laboratory labor time is also directly impacted by this modernized method. During the development phase, the sample preparation was simplified, reducing both the worktime and solvent consumption. Using only one instrument instead of two reduced the sample and mobile phase preparation time by 50%. The data processing time was also reduced by 50%, representing another savings of 3.5 days of labor per year.

The estimated yearly savings after the transition to the Vanquish Flex UHPLC system is given in Table 2. The overall savings (including labor and solvents) is estimated to be **$2,750** per year.

Table 2. Estimated yearly savings after the transition to a Vanquish Flex UHPLC system.

	Labor time (days)		Solvent consumption (L)	
	Sample prep.	Data processing	Sample prep.	Chromatographic method
Yearly savings*	5.6	3.5	18	7.4
Total	9.1		25.4	

*Yearly savings from 45 lots of syrup

Feedback from Opella's laboratory users indicates that the Vanquish Flex UHPLC is a robust system, thanks to the use of Thermo Scientific™ Viper™ Fittings. These fittings allow for easy, quick connections without leaks, ensuring reliable performance. Additionally, the same Viper fittings can be used for both HPLC and UHPLC applications, simplifying method transfer and increasing the versatility of the instrument.

The modernized method has been easily transferred from the support lab to the QC lab, enabling savings and productivity improvements from now on. Since the transfer, only one instrument has been used to run these sequences, instead of two as before.

In addition to measurable gains, there are further benefits that support the corporate social responsibilities of both Opella and Thermo Fisher Scientific. These benefits include decreasing environmental impact and energy usage while promoting public health. By shortening method durations and utilizing energy-efficient systems, energy consumption is reduced. Cutting down on chemical use and waste disposal aids in environmental conservation. Additionally, limiting exposure to solvents improves the health and safety of analysts, lowering the risk of occupational health problems and accidents.

"The column compartment of the Vanquish Flex UHPLC system is highly flexible, accommodating columns up to 30 cm in length while providing reproducible temperature control with still air or forced air heating modes. The instrument also provides excellent injection repeatability, ensuring consistent results and therefore minimizing sample repetitions. Its intuitive design includes LED lights that clearly indicate the status of the equipment, making it user-friendly and efficient."

-Ana Laura Castillo (Chemical Analyst) and Andrés López (QC Coordinator)

Conclusion

Although upgrading HPLC instruments and methods might seem daunting at first, recent technological advancements and regulatory requirements for effective analytical procedure lifecycle management have driven companies to modernize their equipment. The collaboration between Opella and Thermo Fisher Scientific focused on replacing outdated HPLC systems with modern UHPLC systems. This partnership showcases the advantages laboratories can gain from such an upgrade. These advantages encompass improved environmental health and safety, decreased instrument usage, lower solvent consumption, reduced sample preparation time, and a smaller environmental footprint. In the end, this partnership lead to substantial cost savings and increased productivity and helped to meet regulatory standards.

Vanquish systems installed within an existing Empower CDS network have been proven to operate exceptionally well, positioning Vanquish systems as an excellent solution for instrument modernization.

Acknowledgments

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