Agilent Case Study:

A Conversation with Dr. A. Siva Lakshmi Devi of Laurus Labs

Trace-Level Quantification of Mutagenic Nitrosamine Impurities

Dr. A. Siva Lakshmi Devi is the Assistant Vice President and Head of AD-Generics at Laurus Labs of Hyderabad, India. A pharmaceuticals industry professional for nearly 20 years, she has expertise in solid-state and impurity characterization, encompassing advanced analytical techniques such as LC/MS/MS, GC/MS/MS, NMR, and XRD.

Dr. Devi has been using an Agilent 6470 LC/TQ in her lab for more than 18 months to perform trace-level quantification of potential genotoxic impurities in APIs and formulation products, which are analyzed to ensure the quality and safety of pharmaceuticals. She recently spoke with Agilent about her experiences using the 6470 LC/TQ.

Dr. A. Siva Lakshmi Devi

Assistant Vice President and Head of AD-Generics
Laurus Labs, Hyderabad, India

Agilent: **Describe some of the analytical challenges faced by the pharma industry today, and what your lab has done to address these challenges.**

Dr. Devi: With increasing regulatory requirements, and to help ensure safe products, today's analytical labs have to deliver highly sensitive and reproducible results. Our major focus is to support quantitative LC/MS/MS method development for the analysis of N-nitrosamine impurities in various APIs and formulations at very low levels. To achieve this, I wanted to have a triple quadrupole mass spectrometer in our laboratory, which I felt was the instrument that best matched our analytical requirements.

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Agilent: How have the Agilent team and the 6470 LC/TQ helped you achieve your goals?

Dr. Devi: We approached the Agilent team to discuss instrumentation options and how the latest technological advantages of their triple quadrupole mass spectrometers addressed our needs. Agilent has developed quantitative workflows that enable highly sensitive quantification of N-nitrosamine in various challenging APIs and formulation products using their 6470 LC/TQ, which can deliver detection limits even lower than those specified by the regulatory requirements. We made the decision to purchase an Agilent 6470 LC/TQ, and the Agilent team supported us with successful installation of the instrument and in-depth familiarization with the software and hardware features – all the necessary handholding we needed to become familiar with the instrument and get up to speed with our analysis.

Agilent: Has the 6470 LC/TQ met your expectations?

Dr. Devi: I am happy with Agilent 6470 LC/TQ – the lowest LOD and LOQ levels are easily achievable, as baseline noise is minimal and stable.

In addition to sensitivity, it's important to have an instrument that is stable and requires minimal maintenance during daily operations, so that the downtime can be reduced. The 6470 in our lab has been running for more than a year and half, and we have successfully developed and transferred highly sensitive LC/MS/MS methods for N-nitrosamine and other genotoxic impurities. The solution includes a client-server based data management platform (OpenLab ECM) that provides technical controls to securely acquire, process, report, and store data in accordance with the data integrity and compliance guidelines of US FDA 21 CFR Part 11.

In addition, I am happy with the on-time application and service support provided by Agilent. They have always been there to help us to meet our project timelines.

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Dr. A. Siva Lakshmi Devi

Figure 1. Agilent 6470B triple quadrupole LC/MS.

See how an Agilent LC/MS/MS system can help further your drug discovery and development success.

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