Evaluation of a New HPLC, a New Tandem MS and a New Data Processing Software for General Clinical Use

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Introduction

There is an increasing interest in using LC-MS/MS in clinical laboratories because even small deviations from the protocols, can lead to a smaller amount of samples, and measure several analytes in a single run.

Starting from the 1950's, breath samples had been analyzed by MS, followed by body fluids and other samples belonging to the clinical laboratory. Various ionization mass spectrometric techniques have been developed for the detection, analysis and measurement of target compounds. In addition, the development of tandem mass spectrometers has provided a wide variety of technologies for analyzing samples. The use of tandem mass spectrometry for analyzing samples supports the capability of the technology to detect and identify a wide range of compounds, including parent compounds and metabolites. Various innovative mass spectrometry technologies have been developed for the detection and analysis of target compounds in small volumes of body fluids, the development of tandem mass spectrometers has provided a wide variety of technologies for analyzing samples and the pharmaceutical industry uses mass spectrometry to analyze new drug candidates.

In this study, we evaluated three Class I medical devices to address these challenges: Prelude MD HPLC, Endura MD MS (Thermo Finnigan LLC, a part of Thermo Fisher Scientific), and Prelude MS Software (Thermo Scientific). The study was conducted to determine the performance of these devices in terms of reliability, precision, and robustness.

Overview

Performance: This study evaluated a medium-size channel HPLC, a new tandem MS and a data processing software for general clinical use, focusing on the areas of stability, reliability and automation.

Material and Methods: The study was conducted at a clinical laboratory using a medium-size channel HPLC, a new tandem MS and a data processing software for general clinical use. The HPLC was equipped with a stainless steel column and a double-pulsed valve. The tandem MS was equipped with a heated electrospray ionization (HESI) probe or a positive ionization (APCI) probe in a polarity switching mode using the following conditions:

- Mass Spectrometer: Thermo Scientific™ Endura MD™ mass spectrometer
- Data Analysis: Thermo Scientific™ Accucore™ aQ column (50x2.1mm, 1.8micron)

The data processing software includes three levels of user permissions for technicians, allowing for secure and efficient data management.

Conclusions

The analytical performance of Prelude MD HPLC and Endura MD MS was demonstrated in this study. Stability, sensitivity, and linearity were excellent for the 20 analytes analyzed. The data processing software provides a user-friendly interface and supports secure data management.

Results

The study demonstrated the performance of these three devices in terms of reliability, precision, and robustness. The data analysis was performed using the Thermo Scientific™ Endura MD™ mass spectrometer and the data processing software.

| Table 1. Concentrations of Stability Study | Table 4. HPLC Parameters for Robustness Study | Table 2. Tandem MS Parameters | Table 3. Stability of Mass Ion Ratios | Table 5. Tandem MS Parameters for Robustness Study | Table 6. HPLC Parameters for Robustness Study | Table 7. Stability of Mass Ion Ratios | Table 8. Stability of Mass Ion Ratios

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