Case Study

Reliable Analytical Method Development and Validation

The Challenge A medium-size pharmaceutical company approached Patheon to develop and validate a method for quantification of several potential genotoxic impurities (GTIs) in their drug substance. The customer's procedure, which included a derivatization step prior to analysis, suffered from variable recovery.

The Solution After reviewing the technical information and chemical structures, Patheon recommended a direct method based on LC/MS. A triple quadrupole LC/MS/MS procedure based on multiple reaction monitoring of parent/fragment ion pairs offered the high speed and sensitivity required for this method.

The Outcome Patheon's method was successfully validated over a range of 1 to 21 ng/mL for six potential GTIs with good linearity ($r \geq 0.99$) and recovery (94 to 112%).

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