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New White Paper Alert : Analytical solutions to detect Sartan impurities

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Need for robust and highly sensitive analytical solutions to detect Sartan impurities

Determine genotoxic nitrosamines in ARB class of drugs with gas chromatography and mass spectrometry techniques

Angiotensin-receptor blockers (ARBs) or sartans are among the most widely used medicines for hypertension and heart failure. After nitrosamine impurities were discovered in valsartan by the US FDA & EMA, the industry saw several costly global recalls by various global regulatory authorities. The US FDA and EMA have recommended that manufacturers of ARBs (sartans) review their manufacturing processes so that they do not produce nitrosamine impurities and after a transition period with very strict limits on the levels of these impurities, their generic sartans should contain no quantifiable levels of these impurities. The Thermo Scientific™ TSQ™ 9000 triple quadrupole GC-MS/MS system can detect trace levels of these genotoxic impurities in complex drug matrices while meeting all the sensitivity and repeatability requirements of current regulations and exceeding the requirements of the much stricter control limits expected in the near future.

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