**Introduction**

Purity profiling of pharmaceutical drug substances or dosage forms require methods with high sensitivity and specificity to detect even small quantities of impurities. The application of UPLC/Q-Tof MS for purity profiling is particularly beneficial because it combines the high resolution and sensitivity of quadrupole-time of flight (Q-Tof) mass spectrometry with the separation capability of ultra-performance liquid chromatography (UPLC). This approach allows for the determination of the structural identity of the related substances relative to the pharmaceutical active ingredient (API) as well as to assist in the identification of any unknown impurity substances.

**Experimental**

The described approach illustrates the benefits of UPLC purity analysis combined with OA-Tol MS for the determination of structural identity of the related substances relative to the pharmaceutical active ingredient (API). The UPLC-Q-Tof system was used for the purity profiling of ranitidine hydrochloride. A minimum combined average of five scans was used to determine the exact mass of each of the MS/MS product ions. The application of MS/MS provides insight into the structure of an unknown chemical moiety. The exact mass results for the API and the unknowns are illustrated in figure 6. Elucidation of the fragmentation mechanism together with the exact mass information for the API and the unknown 387.1302 amu equates to a 312 (2.500) Cm (310:315-(295:303+317:324)) fragmentation pattern, which is consistent with the known degradant of ranitidine.

**Results**

The extra resolution and efficiency of the ACQUITY UPLC column allowed the analysis of ranitidine with significant response were detected and identified with 3 of these being new impurities. The extra resolution and throughput of UPLC makes it the ideal liquid chromatography tool for purity profiling experiments in peak tracking during method development and to facilitate a high level of confidence with known impurities when more than one analysis is acquired. Knowing the exact mass of each of the MS/MS product ions is essential to properly develop a product identification formula for the unknown analyte.

**Discussion**

The extra resolution and efficiency of the ACQUITY UPLC column allowed the analysis of ranitidine with significant response were detected and identified with 3 of these being new impurities. The extra resolution and throughput of UPLC makes it the ideal liquid chromatography tool for purity profiling experiments in peak tracking during method development and to facilitate a high level of confidence with known impurities when more than one analysis is acquired. Knowing the exact mass of each of the MS/MS product ions is essential to properly develop a product identification formula for the unknown analyte.