## **Innovative Impurity Isolation and Identification Techniques at BOC Sciences to Address Pharmaceutical Impurity Issues**

BOC Sciences announced impurity isolation and identification services using traditional and innovative impurity techniques.

New York City, New York Jun 30, 2022 (Issuewire.com) - BOC Sciences announced impurity isolation and identification services using traditional and innovative impurity techniques. "We're happy to have achieved consensus with global pharmaceuticals to deal with the NDMA risk and other impurity concerns. We will continue to provide full support taking advantage of our rich experience and expertise," stated the marketing director at BOC Sciences. Active Pharmaceutical Ingredient (API) and novel drug development must proceed with impurity control to minimize product side effects. However, impurity reports in recent years about NDMA within successful drugs on the market, including Valsartan, Losartan, Irbesartan, Ranitidine, and Metformin, have raised FDA's attention and public worries as NDMA is highly hepatotoxic, and excess NDMA in drugs can pose great danger to patients. Therefore, global pharmaceuticals have posed restrictions to control the amount of NDMA impurity within a safe limit.

BOC Sciences, together with its professional separation and purification team, is capable of providing efficient impurity isolation and identification services with flexible strategies to help pharmaceutical clients develop safer drugs, including but not limited to isolating and identifying impurity with both conventional and innovative methods. To achieve the quantitative analysis, their researchers precisely separate impurities thus obtaining highly purified single components. They additionally conduct residual solvent (GC) and water content (Karl Fischer) impurity tests. Nevertheless, they use techniques such as HPLC, LC-MS, IR, UV-VIS, 1HNMR, 13CNMR, and other qualitative analyses of impurities for identification. In addition to the conventional techniques mentioned above, BOC Sciences provides an alternative method to remove small molecular impurities below six angstroms and with a throughput 100 times higher. This technology is developed based on patented materials (the self-assembled, highly symmetrical, ultrasmall inorganic cages directed by surfactant micelles, invented by a research team at Cornell University) with well-defined six-angstrom porosity that allows products to be identified from impurities. Moreover, the chromatography column is further designed to achieve 100 times higher throughput.

A senior scientist at BOC Sciences revealed, "the new technology can be used to remove precursor or small molecular impurities under 6 angstroms, such as carcinogens and degradation products. Our initial proof-of-concept experiment has successfully demonstrated the technology's feasibility for the separation of small molecular impurities that have recently led to recalls due to the unacceptable level of NDMA contaminations in the high-blood-pressure drug, *Irbesartan*."BOC Sciences can offer the isolation and identification of more than 10,000 impurities, such as azides, hydrazines, benzene sulfonates, p-benzene sulfonates, methylbiphenyls, valeryl chloride, *etc.* 

## **About BOC Sciences**

BOC Sciences is an innovative organization that continuously assesses, adapts, and accelerates the overall strategy and offers industrial solutions to the most pressing drug development issues. With a variety of analytical equipment and customer-recognized experts, BOC Sciences can develop suitable methods for drug impurities of different chemical properties, including NDMA, to achieve breakthroughs in detection limits for analytical methodology.

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Source: BOC Sciences

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