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Identifying impurities in Active Pharmaceutical Ingredients (API).

As a pharmaceutical manufacturer, it is often difficult to keep up with current standards and best practices in today's rapidly evolving regulatory environment. By fully characterising all aspects of your products you can safeguard quality, while staying ahead of regulatory requirements.

Impurities in pharmaceuticals are the unwanted chemicals that remain with the active pharmaceutical ingredients or occur as a result of improper manufacturing. The presence of these unwanted chemicals even in trace amounts may influence the efficacy and safety of your pharmaceutical products. By using sophisticated impurity profiling technologies, you can accurately determine the identity and quantity of the impurity in the pharmaceutical compound.

What can we do for you?

At DSM Resolve, we use state-of-the-art equipment and a multidisciplinary approach to precisely identify the structure of the impurity. This approach draws upon techniques like Liquid Chromatography-Mass Spectrometry (LC-MS) and Nuclear Magnetic Resonance Spectroscopy (NMR). For very low concentrations, preparative Liquid Chromatography can be performed to gather the sufficient amount of sample material that is necessary for NMR analysis. LC-MS experiments produce a structural hypothesis of the impurity, while NMR experiments are used to determine a proof-of-structure. By using both of these techniques, we can provide you with a complete

identification of the impurity. This also better enables us to identify those entities that may be of potential concern with regards to the safety and efficacy of your pharmaceuticals.

Our advanced facilities and longstanding experience in traditional pharma, biomaterials, biomarkers and sports testing produce creative solutions for your most challenging pharmaceutical issues.



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