The Hidden Chemistry of Drug Development: the job of the R&D Scientist in the Understanding of Process Impurities

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The life of an Active Pharmaceutical Ingredient begins long before the production of the first industrial batches: the early stages of a project, long before the plant stage, play a crucial role in the success of an API production. Many factors need to be taken into account and carefully planned for, including intellectual property strategies, synthetic approaches[1], impurity management, process development and more.

Understanding impurity identity and formation is often a key factor in the designing of a process: in order to make correct decisions regarding impurity management in synthesis and stability studies, reliable and correct information is crucial. Investigations into the formation, identification, analysis and independent synthesis of impurities can change be complex and challenging, requiring the expertise and support of the R&D team. Both synthetic and analytical know-how play important roles in this kind of study.

A particularly interesting case of impurity investigation and understanding was the study of the impurity portfolio[2] of Carglumic Acid[3,4]. During this work, isolation, characterization, and Analytical Standard generation of both process and stability impurities were performed (Figure 1). The investigation led to unexpected and scientifically interesting results.

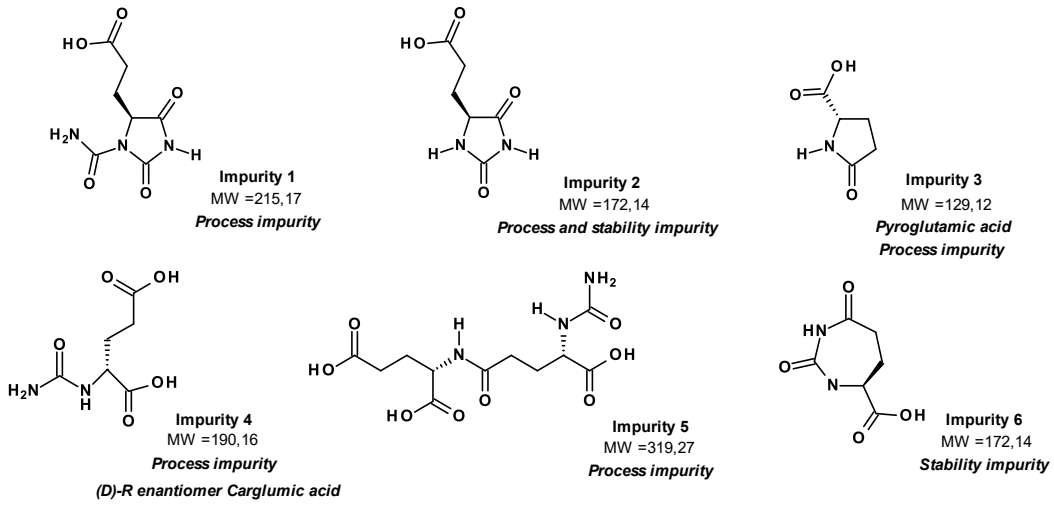

Figure 1

References:

[1] CN patent appl. CN 101168518A filed on 13.11.2007.
[2] B. Akduman, B. Arabaci, ACS Omega 2024, 9, 40346 – 40357.
[3] L. Caldovic, H. Morizono, Molecular genetics and metabolism 2010, 100, S13 – S19.
[4] A. Burlina, F. Menni, Eur Rev Med Pharmacol Sci 2022, 26 (14), 5136 – 5143.