Information

Fighting tuberculosis: EUROAPI's rifampicin API meets new requirements for nitrosamine impurity standards

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EUROAPI announces that its rifampicin API meets the new requirements for nitrosamine impurity standards. Rifampicin is one of the most commonly used antibiotics to treat tuberculosis and is on the World Health Organization's (WHO) list of essential medicines. The Group has implemented a new manufacturing process at its Brindisi site (Italy) to provide its customers with a premium quality rifampicin API with low levels of nitrosamines to meet the requirement of key health authorities.

Thanks to a good understanding of the root cause of nitrosamines and a thorough review of all the steps in the process, EUROAPI's improved industrial operations allow for a higher quality product, as evidenced by the results of nitrosamine levels obtained at laboratory and industrial scale. Overall, the new process, that is under industrial Process Performance Qualification, allows for a 10-fold reduction factor in nitrosamine impurities. The packaging step has also been modified to avoid any increase in nitrosamines during the storage.

"Identifying the root cause for nitrosamine impurities in anti-infective molecules has been a challenge over the last years. Thanks to the hard work of our R&D and industrial teams, we have been able to monitor and control all the parameters and can now provide our customers with a high-quality API that meets the new regulatory standards," said Thierry Durand, Chief Research & Development Officer of EUROAPI. *"WHO figures show that tuberculosis is the second leading infectious killer after COVID-19 and we are proud to contribute to better management of this major public health burden."*

Tuberculosis is an infectious disease caused by a type of mycobacteria. It most commonly affects the lungs and is found in all countries and age groups. According to the WHO, a total of 1.6 million people died from tuberculosis in 2021 and an estimated 10.6 million people fell ill with tuberculosis worldwide. Ending the tuberculosis epidemic by 2030 is among the health targets of the United Nations Sustainable Development Goals.

The European Medicines Agency (EMA) has assessed the risk of the formation or presence of nitrosamines during the manufacture of human medicines and has issued guidelines to avoid the presence of nitrosamine impurities. Nitrosamines are chemical compounds classified as probable human carcinogens based on animal studies. The EMA considers that there is a very low risk that nitrosamine impurities at the levels found in medicines could cause cancer in humans, and the risk to patients from not taking their rifampicin medicines far outweighs any potential risk from the nitrosamine compound, yet permanently supporting manufacturers to reduce the content to a safer limit for patient.