

Review Article

A Review on Development and Validation of RP-HPLC Method to Detect Impurity Profiling of Methylthioninium Chloride in Pharmaceutical Dosage Form

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Impurity is defined as any substance coexisting with the original drug, such as starting material or intermediates or that is formed, due to any side reactions. According to the International Conference on Harmonization of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) guideline on impurities in new drug substances, an impurity is defined as 'any component of the new drug substance that is not the chemical entity defined as the new drug substance'. There are different methods for detecting and characterizing impurities with TLC, HPLC, and HPTLC etc. Methylthioninium chloride (INN, or methylene blue,) is an investigational drug being developed by the University of Aberdeen and TauRx Therapeutics that has been shown in early clinical trials to be an inhibitor of Tau protein aggregation. The drug is of potential interest for the treatment of patients with Alzheimer's disease. In vitro studies suggest that methylene blue might be an effective remedy for both Alzheimer's and Parkinson's disease by enhancing key mitochondrial biochemical pathways. It can disinhibit and increase complex IV, whose inhibition correlates with Alzheimer's disease.

Key Words: Alzheimer's disease, International Conference on Harmonization (ICH), Parkinson's disease, Methylthioninium chloride, Impurity.