

Evaluation of the risk of nitrosamine impurities

“During the summer 2018, authorities become aware of the presence of some nitrosamines in API – (Valsartan – presence of N- nitrosodimethylamine (NDMA) – other sartans – presence of N-nitrosodiethylamine NDEA). These nitrosamines were already known as probable carcinogenic compounds but their presence in the sartans was not then identified.”

To read the whole document, please download the white paper.