# The Determination of Multiple Ndsri's in Ranolazine API

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## Abstract:

Nowadays, it is exceedingly challenging to identify impurities associated to nitroso drug substances since both impurities and APIs, with the exception of the nitro group, have essentially identical structures. Authorities (USP, EDQM, PMDA, WHO, etc.) rigorously enforce the destiny and control strategy for the development of NDSRIs in their respective active pharmaceutical ingredients in accordance with latest regulatory updates on NDSRIs. It is quite challenging to create a product-specific approach for determining nitroso drug substance-related impurities because of the structural similarities between these nitroso amine impurities. Because NDSRIs are carcinogenic and mutagenic, regulatory guidelines are constantly changing their specifications. The technique development tactics and validation of Multiple nitroso drug substance related impurities in Ranolazine Active pharmaceutical ingredient sulfate and N-nitroso silodosin are described in this work.

## Keywords:

N-nitrosamine, mutagenic impurities, nitrosamine drug substance related impurities (NDSRIs), N-Nitroso Piperazine.