



Press Release

Brussels (Belgium), 27 February 2024

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of its revised position paper, “**The Role of Excipients in Determining N-Nitrosamine Risks for Drug Products**”. This paper describes IPEC Federation’s position on the role of excipients when conducting N-nitrosamine (nitrosamine) risk assessments for drug products.

The presence of N-nitrosamines in drug products continues to be a global concern. Excipients are considered as a potential risk factor during the drug product risk assessment. The focus of this position paper is to expand on the potential contribution excipients may or may not have on the formation of nitrosamines in final drug products. The presence of nitrites and vulnerable amines in excipients are also considered. This revision highlights the key messages associated with excipients and how they feature in the ongoing debates on the nitrosamines topic and has been updated to reflect current perspectives.

The position paper is available for download immediately via the website www.ipec-federation.org

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