



Press Release

Brussels (Belgium), 21 February 2023

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the “**Questionnaire for Excipient Nitrosamines Risk Evaluation**” (version 1, 2023).

This document is equivalent to the form developed and previously published by IPEC Europe, of which the latest version was made available in January 2023 (version 4.3).

Its aim is to assist excipient manufacturers collect data in a standardised format that drug product manufacturers need to perform their nitrosamine risk assessments.

This rebranding was deemed appropriate as the IPEC Europe Questionnaire has been adopted and used globally and a decision was taken to make the same format available through all IPEC associations. We recommend the IPEC Federation Questionnaire should be used for new evaluations only as the content of the form remains largely unchanged.

Clarifications were made in both IPEC Federation and Europe documents on question 4, process water quality.

The Questionnaire is available for download immediately via the website www.ipec-federation.org and the websites of regional IPEC (IPEC-Americas, IPEC China, IPEC Europe, IPEC Japan and IPEC India).

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