



Press Release

Brussels (Belgium), 5 February 2024

The International Pharmaceutical Excipients Council Federation, (**IPEC Federation**) announces the availability of the updated IPEC Technically Unavoidable Particle Profile (TUPP) Guide for Pharmaceutical Excipients (Version 2, 2024). The guide was originally published in 2014 as a joint IPEC-Americas-IPEC Europe guide, and then published as an IPEC Federation Guide in 2015. This guide is widely used globally.

The purpose of this guide is to provide understanding between excipient manufacturers and excipient users on the types of normal, inherent, visibly different and technically unavoidable particles. This guide describes the expectations regarding the exchange of information comprising an investigation and leading to the proper disposition of affected excipient.

The concepts presented in this guide should be considered as part of a risk evaluation for use of excipients in drug products. This guide is not meant to deal with foreign contamination or adulteration.

The content in the 2024 revision, as well as better aligned with IPEC's general guideline policies and format requirements, provides clarifications on requirements and responsibilities of suppliers and users.

Throughout the guide, efforts were made to remove redundancies and to update references to include more current regulations and guides/guidelines.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](https://www.ipecfederation.org) and national/regional members' websites. Thereafter, the guide will be made available to the general public.

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