



# Press Release

Brussels (Belgium), 03 November 2022

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the updated IPEC Certificate of Analysis Guide for Pharmaceutical Excipients (Version 2, 2022). The guide was originally published in 2013. This guide is widely used globally.

The primary goal of the guide is meant to provide best practices for the preparation and appropriate use of a Certificate of Analysis (COA) for pharmaceutical excipients (excipients). The goal is to standardize the content and suggest a format for COAs for excipients, and to clearly define the roles and responsibilities for the excipient manufacturer and distributor.

In addition to minor editorial changes, other changes include:

- Clarification of key points (e.g., retest date, identification testing, compendial compliance)
- Updating from an IPEC-Americas/IPEC Europe to an IPEC Federation guide, including more global verbiage and references (e.g., pharmacopoeial, skip lot testing)
- Removal for acceptability of company codes in lieu of identity and address of original manufacturing site.
- Addition of a section for COA verification by medicinal product manufacturers.
- Updated COA model (Annex 1)

The guide will be available for download immediately via these websites: [www.ipec-federation.org](http://www.ipec-federation.org), [www.ipec-europe.org](http://www.ipec-europe.org), [www.ipecamericas.org](http://www.ipecamericas.org), [http://www.ipec.gr.jp/index\\_en/](http://www.ipec.gr.jp/index_en/) and <http://www.ipec-china.org/>.

Members of IPEC India can obtain copies via the IPEC India Secretariat [admin@ipecindia.org](mailto:admin@ipecindia.org).

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