



# Press Release

Brussels (Belgium), 19 May 2026

IPEC Federation announces the availability of the updated IPEC Composition Guide for Pharmaceutical Excipients (Version 3, 2026). The guide was originally published in 2009.

This guide provides an approach for excipient manufacturers to establish excipient composition profiles. Composition profiles may be used for regulatory purposes, assessing quality consistency, manufacturing process monitoring and change control, establishing product specifications, or evaluating excipient safety by excipient suppliers and/or users.

Key enhancements in this version include:

- Inclusion for biotech and fermentation-derived excipients;
- Updates and reorganization of content for Section 4.1 Types of components and physico-chemical characterization of excipients;
- Addition of glossary terms and definitions for types of excipient components;
- Example of a composition profile template (Annex).

In addition, throughout the guide efforts were made to harmonise terminology, clarification, and remove redundancies.

The guide will be available, initially exclusively to IPEC members for a three-month period, on the [IPEC Federation](#) and national/regional members' websites.

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