



Press Release

Brussels (Belgium), 31 March 2026

IPEC Federation announces the availability of the updated IPEC Stability Guide for Pharmaceutical Excipients (Version 3, 2026). The guide was originally published in 2010.

The guide provides excipient manufacturers with best practices and frameworks for establishing robust excipient stability programmes. It provides a structured approach to stability assessment, supporting regulatory submissions, ensuring ongoing compliance with quality requirements, and substantiating recommended storage conditions and shelf-life claims (including re-evaluation dates, expiration dates, and use-by dates).

Following this guide gives pharmaceutical end users confidence that an excipient will continue to meet manufacturer specifications or monograph requirements when stored in an unopened container under recommended conditions throughout its shelf life.

Key enhancements in this version include:

- Three risk-based stability study designs: use of historical data in lieu of formal studies, warehouse studies, and formal stability studies.
- Expanded best practice guidance covering bracketing/matrixing for compound families, stability considerations for different types of excipients (e.g. novel, CoPE) and classic excipients when used in non-traditional dosage forms (e.g. vaccines and biologicals); bulk storage, accelerated and ongoing stability, transportation studies, expiration/retest periods, and specifications for tested attributes. In addition, throughout the guide efforts were made to harmonize terminology, add clarification, reorganize information and remove redundancies.
- Differentiation between excipient and API requirements, where applicable.

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

For further information contact the IPEC Federation Secretariat at:

+32 2 213 74 40 / info@ipec-federation.org

The International Pharmaceutical Excipients Council – Federation (IPEC Federation) asbl

Rue Marie de Bourgogne 52 - 1000, Brussels, Belgium

W: ipec-federation.org T: +32 2 213 74 40 E: info@ipec-federation.org

VAT: BE 08239313 61 - IBAN: BE73 3630 6812 5160 - RPM Brussels Capital Region