



Press Release

Brussels (Belgium), 16 November 2022

The International Pharmaceutical Excipients Council Federation, (IPEC Federation) announces the availability of the updated IPEC Stability Guide for Pharmaceutical Excipients (Version 2, 2022). The guide was originally published in 2010. This guide is widely used globally.

The primary goal of the guide is to offer best practice and guidance when establishing excipient stability programs. The guide provides excipient manufacturers with strategies for assessing an overall approach to stability and how to set up programs to support regulatory filings, aid in maintaining the quality of the excipient, and to define and substantiate recommended storage conditions and shelf-life claims. These include re-evaluation dates, expiration dates, and use-by dates.

Following this guide provides confidence to the pharmaceutical end user that an excipient will continue to meet the excipient manufacturer's specifications or monograph requirements if the excipient is stored in an unopened container at its recommended storage condition up to the shelf-life claim.

The most significant change to the guide is the re-arrangement of information found under section 2.1, "General Guidelines" for the excipient stability program. The 2010 version had separate sections for defining and discussing specific requirements for very stable, stable and limited stable excipients, along with a section on classification. However, the revised guide defines the unique requirements for very stable, stable and limited stable excipients within the classification section and created separate sections, as shown below:

2010	2022 revision
<ul style="list-style-type: none">• Very stable (2.1.1)• Stable (2.1.2)• Limited stability (2.1.3)• Classification (2.1.4)	<ul style="list-style-type: none">• Classification (2.1.1) (including very stable, stable and limited stable)• Considerations for New or Chemically Novel Excipients (2.1.2)• Considerations for Modifications to Excipients (2.1.3)• Ongoing Stability Studies (2.1.4)• Documentation (2.1.5)

Throughout the guide efforts were made to harmonize terminology, add clarification, reorganize information and remove redundancies. Although limited changes were made to the structure and

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content for sections 2.2 through 2.4, separate sections were created for out of specification results (2.3.8) and labelling (2.5).

Finally, the guide was converted to an IPEC Federation guide and the reference section was updated 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](#) and national/regional members' websites. Thereafter, the guide will be made available to the general public.

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