The International Pharmaceutical Excipients Council

Excipient Stability Guide

For Pharmaceutical Excipients

Version 2
2022

This document represents voluntary guidance for the excipient industry and the contents should not be interpreted as regulatory requirements. Alternatives to the approaches in this guide may be used to achieve an equivalent level of assurance for excipient quality.

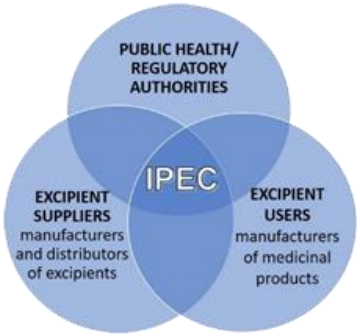
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and users. At the time of writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to international excipient standards development and harmonization, provide information useful for new excipient development and introduction, and offer best practice and guidance concerning excipient development.

IPEC has three major stakeholder groups:

1. Excipient manufacturers and distributors, defined as suppliers in this document,
2. Medicinal (drug) product manufacturers, defined as users in this document, and
3. Public health and regulatory authorities.



This guide is intended to be voluntary, to indicate best practice, and to be globally applicable. However, it should be recognized that the rules and regulations applying to excipients will vary from region to region and country to country. In addition, the rules and regulations are continually evolving. It is the responsibility of the reader to review the latest version of the applicable regulatory guidance; however, the version referenced in the guide will be based on the version available at the time the guide was published.

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In this guide, pharmaceutical excipient(s) will be referred as excipient(s). This guide may be applied to veterinary medicines, as appropriate with reference to specific veterinary guidance and regulations.

Throughout the guide, justification implies that a decision is made based on a scientific, quality and/or regulatory considerations.

This guide offers best practice and guidance in the establishment of an excipient stability program. The excipient supplier may be a manufacturer or a distributor (or both). The guide highlights the factors to consider when planning and executing a scientific study that will determine the stability of an excipient.

*Note: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms [1]" for definitions. The first use of a term found in the glossary will be in **BOLD**.*

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This guide was developed by representatives from International Pharmaceutical Excipients Council (IPEC) member companies. IPEC is an industry association whose members consist of excipient manufacturers, distributors, and users.

IPEC greatly appreciates the many hours devoted by the core team of individuals and other contributors listed below, to make this guide available to IPEC members and the broader excipient community. Equally, IPEC extends thanks to the employers of those same contributors who provide the necessary time and resources, without which, this guide would not be possible.

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