The International Pharmaceutical Excipients Council

Good Distribution Practices Guide

for Pharmaceutical Excipients

Version 3
2024

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.

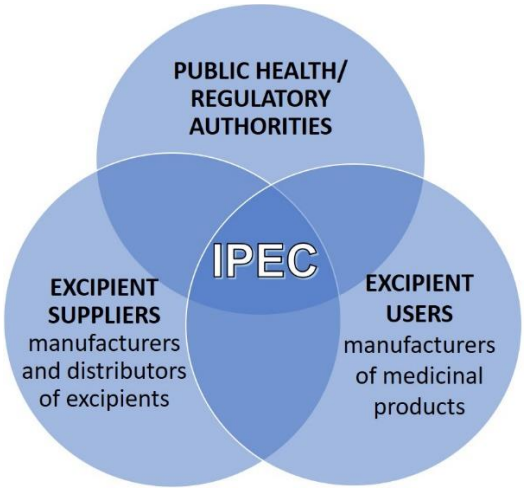
This guide was created to help companies understand current expectations on this topic and is not intended for use by third party certification bodies to conduct audits or to certify compliance with the guide.

FOREWORD

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors, and end-users. At the current writing there are regional pharmaceutical excipient industry associations located in the Americas, Europe, Japan, China, and India. IPEC's objective is to contribute to the 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 *excipient 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 laws and regulations applying to excipients will vary

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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 most current version of any applicable regulatory requirement. Versions referenced in the guide were based on versions available at the time the guide was published.

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

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

This guide has been written to provide guidance for those companies involved in the supply chain of pharmaceutical excipients. Examples based on practical experience are provided to facilitate the application of GDP. However, alternative approaches may be acceptable.

This guide provides additional explanatory notes to:

"Good Trade and Distribution Practices for Pharmaceutical Starting Materials" [1]

The explanatory notes in this guide are the views of The International Pharmaceutical Excipients Council (IPEC) Federation and not necessarily those of the WHO.

This document is a revised version of The IPEC Good Distribution Practices Guide for Pharmaceutical Excipients first published in 2006 and updated in 2017.

*NOTE: Refer to the "International Pharmaceutical Excipients Council Glossary: General Glossary of Terms and Acronyms" for definitions [2]. The first use of a term found in the glossary will be in **BOLD**.*

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Table of Contents (TOC)

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This guide was developed by representatives of the associations which constitute the IPEC Federation (IPEC). The IPEC Federation 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 its thanks to the employers of those same contributors who provided the necessary time and resources, without which this guide would not be possible.

IPEC Federation would like to acknowledge the World Health Organisation (WHO) for their extensive efforts in developing the guidelines "*Good Trade and Distribution Practices for Pharmaceutical Starting Materials*" [1] which is valued by the IPEC Federation as a significant step in the development of tools for the improvement of safety and quality of starting materials and finished pharmaceuticals.

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