The International Pharmaceutical Excipients Council

& The Pharmaceutical Quality Group

The Joint Good Manufacturing Practices Guide

For Pharmaceutical Excipients

Version 5
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.

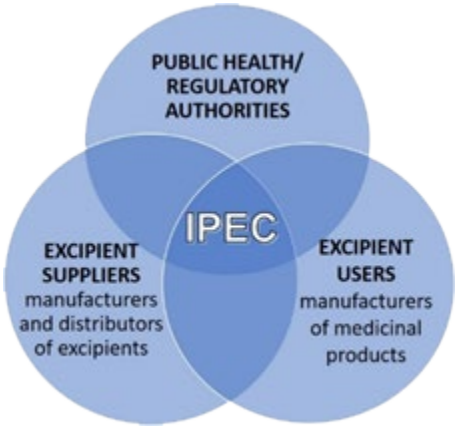
FOREWORD

IPEC

The International Pharmaceutical Excipients Council (IPEC) is an international industry association formed by excipient manufacturers, distributors and 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 manufacture.

IPEC has three major stakeholder groups:

1. excipient manufacturers and distributors, defined as suppliers in IPEC documents,
2. pharmaceutical manufacturers, defined as users in this document, and
3. public health and regulatory authorities.



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PQG

The PQG was formed in 1977 to promote development of a consistent approach to pharmaceutical quality and good manufacturing practice. The group has since expanded, and in 1990 the PQG published three codes of practice to cover pharmaceutical raw materials, printed and contact packaging materials. In 1995 the codes were revised and were integrated with ISO 9002:1994. The code for raw materials was revised and reissued as PS 9100:2002 Pharmaceutical excipients, an application standard and GMP guide for pharmaceutical excipients.

For further information, visit www.pqg.org.

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.

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.

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ACKNOWLEDGEMENTS

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

IPEC and PQG greatly appreciate 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 and PQG extend their 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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