



Handbook of Pharmaceutical Excipients: 35 years of enabling pharmaceutical formulation development

By **Bruno C Hancock**

A one stop guide to the properties for excipients, their safe use and application



Pharmaceutical Excipients

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2020 saw the publication of the ninth edition of the Handbook of Pharmaceutical Excipients, published jointly by Pharmaceutical Press and the American Pharmacists Association.

Since the appearance of the first edition in 1986, the **Handbook of Pharmaceutical Excipients** has continued to make an important contribution to the development of pharmaceutical dosage forms. It began in the 1970s as a result of the enthusiasm of a few UK and US pharmaceutical scientists who believed passionately in the need for a comprehensive English language data resource on excipients, due to considerable developments that were occurring in the fields of pharmaceuticals, pharmaceutical technology, and product development and manufacture. Earlier, scientists working for Ciba-Geigy, Hoffman-La Roche and Sandoz Ltd, based in Switzerland, had produced a typescript document in 1974, entitled *Katalog pharmazeutischer Hilfsstoffe* (catalogue of pharmaceutical excipients), which contained German-language monographs for nearly 100 excipients used by Swiss pharmaceutical companies.

With assistance and encouragement from the publishers of the *Katalog* a collaborative project between the Royal Pharmaceutical Society of Great Britain (RPSGB) and the American Pharmaceutical Association Academy of Pharmaceutical Research and Science (APhA-APRS) was set up, which became the foundation of the first edition of the **Handbook**.

Steering committees were established in the US and UK under the respective chairmanship of Zak T. Chowhan (Syntex), Jack Cooper (Ciba Geigy), and Robert F. Weir (RPSGB). The second edition was published in 1994 with Ainley Wade (RPSGB) as editor along with the installment of a professional editor, Paul Weller. Art Kibbe (APhA), who was a member of the US steering committee for the second edition, was appointed editor of the third edition.



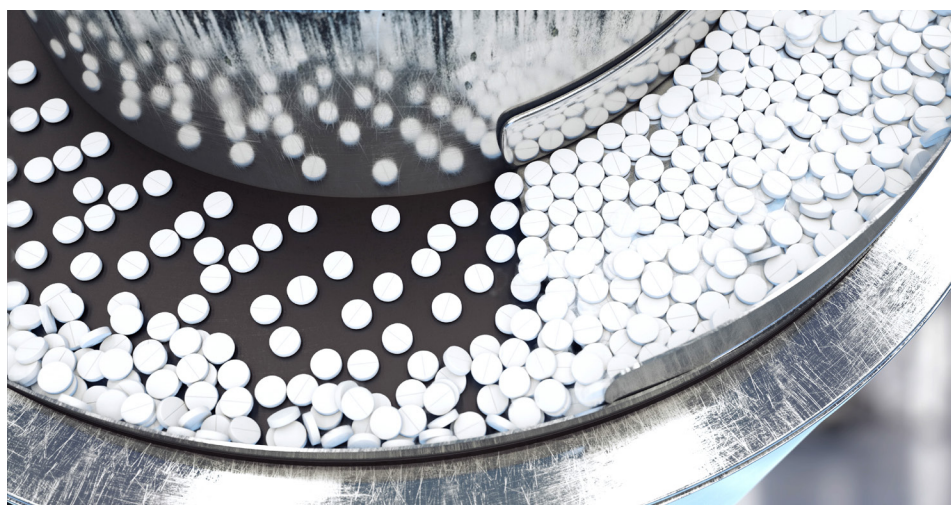
Expansion

During the 1980s and 1990s, the pharmaceutical industry grew rapidly and there were major changes in pharmaceutical development and technology. In addition, regulatory agencies were putting a much greater emphasis on understanding excipients as part of the development of new formulations. The importance of characterization of the excipients used in dosage forms was becoming an increasingly critical factor for consideration, leading to a thirst for knowledge and information in this area.

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Excipients were no longer being regarded as just inert materials - they had their own chemical and physical profiles that could affect the delivery and efficacy of the active ingredients in a formulation - and so there was a need for obtaining quality physico-chemical data relevant to their functionality, which nowadays are prevalent in many research papers. The systematic gathering of such data had not previously been undertaken and the **Handbook** provided, for the first time, the specialist information needed by pharmaceutical formulators.

As a consequence of increasing interest in the characterization of excipients, the second and third (2000) editions of the **Handbook** adapted to reflect and support the industry with an expansion of content - adding information on excipient applications, properties, safety, and regulatory status. Laboratory project committees formed for the first and third editions were tasked with generating technical data and test criteria to add standard values for physical properties, many of which are still included in the monographs today. These committees have not reformed since that time because the characteristics of the excipients can now be extracted from the published literature. And so, the current, standardized format of the **Handbook** was established during this period.



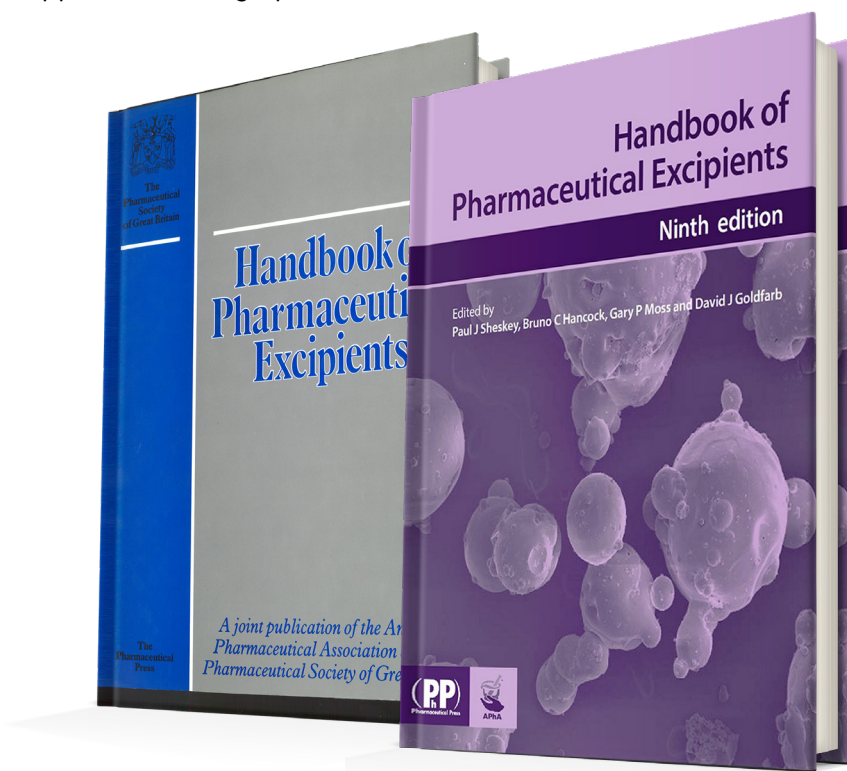
Globalization and harmonization

Increasing globalization of the pharmaceutical industry was reflected in the third edition of the **Handbook** by the addition of scientists from Japan and Hong Kong to the US steering committee. This was accompanied by a Japanese edition of the **Handbook** published by Yakuji Nippo Ltd.

Further evidence of the globalization of the industry was shown by the merging of the Steering Committees into one, collective, International Steering Committee (ISC) for the fourth edition (2003), presided over by three editors: Raymond Rowe, representing the pharmaceutical industry; Paul Sheskey, representing the excipient suppliers; and Paul Weller representing the publishers. Steering committee members were also recruited from diverse backgrounds across formulation, supply, and academia. The suppliers' database similarly evolved to become an international directory of manufacturers.

As the **Handbook** continued to reach a wider user-base for those interested in formulations in the pharmaceutical, cosmetic, and food industries, increasing general awareness in drug or health product ingredient lists meant that it has also gradually become a resource for toxicologists, lawyers, and patent attorneys. The fourth and fifth (2006) editions continued expanding on content with more monographs and manufacturer data added, and the sixth edition topped 340 monographs.

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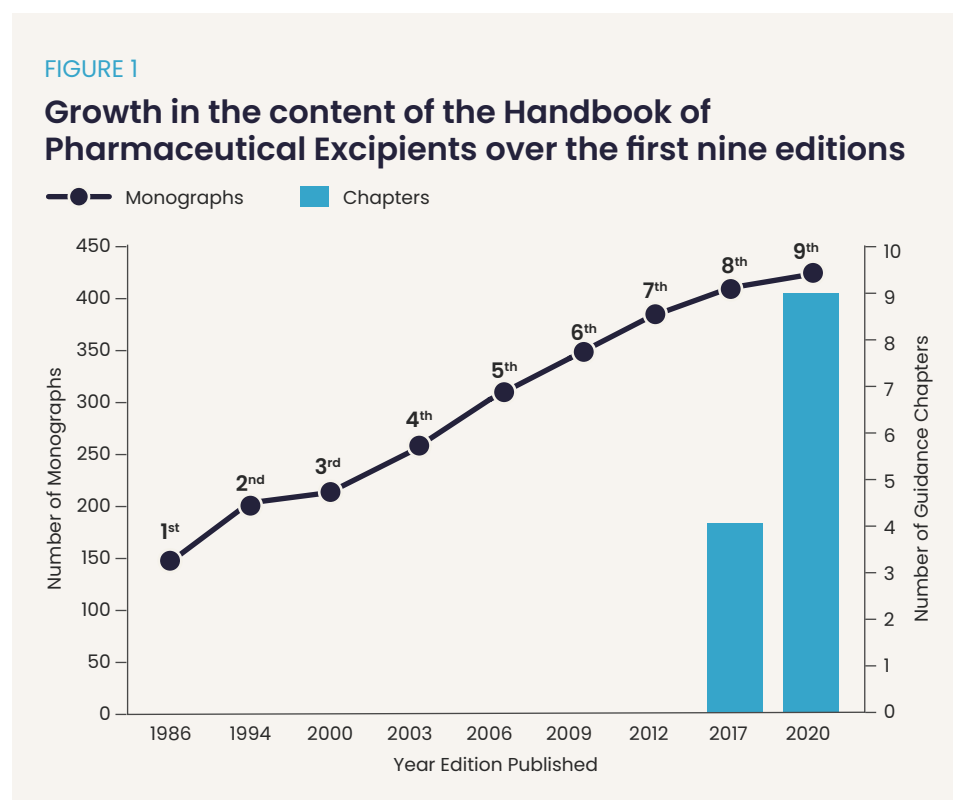
First (left) and Ninth editions of **Handbook of Pharmaceutical Excipients**



Due to the ongoing globalization of the pharmaceutical industry and a greater use of regulatory data, the harmonization of pharmacopeial specification data in the United States Pharmacopeia and National Formulary (USP-NF), the European Pharmacopeia (PhEur), and the Japanese Pharmacopeia (JP) was introduced for the sixth edition (2009). While there are no pharmacopeial data, specifications from the Japanese Pharmaceutical Excipients (JPE) and the Food Chemicals Codex (FCC) were included, if available, to provide more information. New property data for near-infrared spectra were also introduced for the sixth edition.

Continued development

The **Handbook** continued to grow with the publication of the seventh edition (2012) and the addition of several new sections to address the evolving needs of the formulation community. For instance, new coprocessed excipients were added to the **Handbook**. These are combinations of two or more excipients that have synergistic action, producing an overall effect that cannot be achieved using a physical mixture of the same combination of excipients. As an example, coprocessed mannitol with sorbitol has high compactibility and is used as a direct compression excipient. It can also be used in tableting moisture-sensitive APIs due to the lower hygroscopicity than standard sorbitol.



Starting in the eighth edition (2017), several guidance chapters on special topics written by experts in the field were included in the **Handbook**. The intention was to provide additional, complementary information about uses of excipients and to focus on topics that could not be easily addressed within the individual monographs. The first chapters included guidance on topics such as the use of excipients in pediatric dosage forms and the common functional categories of pharmaceutical excipients.

The ninth edition of the **Handbook** was published in October 2020 and the publication continues to evolve to ensure that it maintains its relevancy. Additions for the ninth edition include 13 new monographs (see Figure 1), a further five new guidance chapters, an improved supplier directory with web-page hyperlinks, and an infographic that describes the historical timeline of pharmaceutical excipients, from their first recorded mention in an Egyptian papyrus to the current day.





Summary

With over 170 international expert contributors assisting in updating each edition of the **Handbook of Pharmaceutical Excipients**, the result is a comprehensive reference work created for users by users, and one that is indispensable for those involved in drug formulation. Technological advances in publishing have led to the **Handbook** becoming electronic via CD-ROM initially, and then in 2004 in an online format via MedicinesComplete. In 2018, this online platform was redesigned, creating a modern interface where the **Handbook** content could be more easily navigated and searched. Currently, digital content is updated twice a year in May and November.

Since the publication of the first edition, the **Handbook** has adapted to developments in the pharmaceutical industry and the changing needs of its users. Our goal for the future is to continue to develop the **Handbook** so it maintains its status as the most definitive, comprehensive, up-to-date, international excipient resource for those involved in developing new medicines.

About the author

Bruno C Hancock (PhD), a US-based editor from the pharmaceutical industry. Bruno's career in formulation development has included working on spray dried dispersions, powder technology, and product design, including computational drug product design. Along with editing the **Handbook of Pharmaceutical Excipients**, he has co-authored several chapters for the ninth edition. This includes a short-form resource on the use of counterions, and a colourful overview of the history of excipients.



Pharmaceutical Excipients

Featuring practical chapters on excipient considerations for different dosage forms, and uniform excipient records detailing functional categories and property data, Pharmaceutical Excipients is essential for those involved in the development, production, control, or regulation of pharmaceutical preparations.

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