

# **PHARMACEUTICAL EXCIPIENTS**

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To Annie and Fred



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## FOREWORD

This small volume is written from a European's (my!) perspective of the need for information on what excipients (by which I mean ingredients in a pharmaceutical product other than the active ingredient) are used in the European Union. It was prepared after I found that it was difficult to identify in one place information on what excipients are used in what dosage forms.

You may be thinking “Why would you want to know in the first place?”

The answer is that this information can be useful when a pharmaceutical manufacturer is considering the development of a new product. It may be that during the development process it is identified that in order to meet desirable product characteristic goals it is necessary to consider the use of a new excipient.

The use of a new excipient (or even finding a new use for an existing one) requires additional data to support the proposed use – relevant European Union documents suggest that the data requirements for a novel excipient might be similar to those for a new drug substance. There can be some reduction in – or even elimination of – the data requirements when it can be shown that the excipient is already in use (hopefully by the same route of administration) in other pharmaceuticals or in foodstuffs or cosmetics.

Why is it not easy to find this information?

There is no single publicly-available source of details on the formulation of authorised pharmaceutical products in the European Union that lists the excipients that have been used in them. There is a data base available by subscription from the Medicines and Healthcare products Regulatory Agency in the United Kingdom but this requires a sizable initial and annual subscription fee, and in any case is not particularly effective in determining what products contain which excipients and in any case is limited to products approved in the UK. There is also a database available at the Swedish Medical Products Agency, but this is also limited to products approved in Sweden. There is no database of the ingredients approved in products that have gone through the Centralised Procedure. And most of the published information sources

(including Martindale, Vidal etc) do not have up to date information that can be searched easily for information on excipients.

This situation differs considerably from that applying in the United States where the Food and Drug Administration has for a considerable period published information on 'inactive ingredients' included in approved products. Recently this has been made available in the form of an electronic file that can be used to generate a spreadsheet. Compared to an earlier iteration of this information source, the number of products that include a particular excipient has now been omitted. This has required recourse to an earlier (1996) listing that did include such information in some of the Tables in the present volume.

This volume is an attempt to start finding available information and placing it in a public forum. If this is thought to be useful and even helpful it would be possible to prepare updated editions on a fairly regular basis. Feedback from readers would be appreciated.

The format of the book is largely tabular. The availability of an electronic version of the tables should hopefully allow simple searches to be undertaken. One of the problems with this is that many excipients are known by different terms in different places. An attempt has been made to include as many alternative names as the author is aware of. This will, of course, be incomplete. Comments from readers on necessary corrections and additions would be welcomed.

Brian Matthews

Croydon

February 2005

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## BIOGRAPHY

Brian Matthews graduated with Honours (Batchelor of Pharmacy) from the University of London and gained a Doctor of Philosophy from the same University. He is a Fellow of the Royal Pharmaceutical Society of Great Britain and of The Organisation for Professionals in Regulatory Affairs.

Brian worked with the British Pharmacopoeia Commission secretariat and with the Medicines Control Agency and its predecessors in the United Kingdom (now the Medicines and Healthcare product Regulatory Agency) before joining Alcon Laboratories. He is currently Senior Director, EC Registration and is based in Hemel Hempstead, UK.

Brian is a member of the Parenteral Drug Association and the Drug Information Association as well as the Royal Institution of Great Britain. He is currently the Secretary of the Eye-Care Industries European Economic Interest Grouping (a trade association for manufacturers involved in the development of ophthalmic medicines).

In addition to his interests in the pharmaceutical sector, Brian is also active in a number of fields in the medical device sector and serves on a number of British, European and International Standards committees, including chairing groups working on standards for sourcing of animal materials for use in medical devices and for aseptic processing as applied to liquid medical devices. He also serves on British Pharmacopoeia committees dealing with pharmaceutical issues and excipients.

Brian is a member of the editorial board for the Regulatory Affairs Journal (Pharma) and the Regulatory Affairs Journal (Devices) as well as the European Journal of Parenteral and Pharmaceutical Sciences. He is a former member of the editorial board of Drug Development and Industrial Pharmacy.

Brian has published a number of papers on regulatory aspects of pharmaceuticals and medical devices. He has been a contributing editor to *Pharmaceutical Product Licensing: Requirements for Europe and International Pharmaceutical Products Registration: Aspects of Quality, Safety and Efficacy*. In addition, he has also contributed chapters to *Modern Pharmaceutics* and to *Drug Stability (Principles and Practices)*.