

Method Validation in Pharmaceutical Analysis

A Guide to Best Practice

Edited by

Joachim Ermer, John H. McB. Miller



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Preface

A number of articles and guidelines already exist dealing with the validation of analytical methods. However, the editors consider that none of the texts completely covers all aspects pertinent to analytical validation for, in particular, methods in pharmaceutical analysis. The editors have attempted, with the authors of the relevant chapters, to bring all these elements together in one book that will be useful to both analysts in the pharmaceutical industry (and beyond) as well as to assessors at the registration authorities for medicines.

Methods used in pharmaceutical analysis must be sufficiently accurate, specific, sensitive and precise to conform to the regulatory requirements as set out in the relevant guidelines of "The International Conference of Technical Requirements for the Registration of Pharmaceutical for Human Use " (ICH), which are applied by the licensing authorities and by some pharmacopoeias. The chapters in Part I deal specifically with the fundamentals of the different validation parameters, giving special emphasis to practical examples and recommendations. It is not intended to replace statistical textbooks but the editors have attempted to provide sufficient background information, illustrated by practical examples to aid the reader in understanding and choosing the relevant parameters and acceptance criteria to be considered for the application of any one analytical procedure to a particular purpose.

Contributions to Part II of this book deal with the life-cycle approach to validation starting with the qualification of equipment employed, the adaptation of ICH guidelines to the early stages of drug development, the relation between analytical variability and specification acceptance criteria, the continual assessment of the performance of the methods when in regular use, the transfer of analytical procedures, and out-of-specification results. There are also chapters dealing with the validation of pharmacopoeial methods and future perspectives for validation.

December 2004

John H. McB. Miller
Joachim Ermer

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