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International Journal of Pharmaceutics 124 (1995) 145

international journal of pharmaceutics

Book Review

Achieving Sterility in Medical and Pharmaceutical Products
Nigel A. Halls, Glaxo Manufacturing Services,
Marcel Dekker Inc., New York/Basel/Hong Kong, 1994.
ISBN: 0-8247-9014-6.
Price $110; 281 pages.

In pharmaceutical terms, sterility is often defined as the total absence of viable organisms. Achieving sterility is an important aspect of quality assurance which requires both a fundamental knowledge of the procedures involved and technical expertise. Monographs in Pharmacopoeias worldwide classify those products for which sterility is a prerequiste and, indeed, the tragic consequences of the medical use of such contaminated products have been highlighted over many years. Therefore, knowledge of sterility and sterility testing and sterilisation procedures is essential for those industries who manufacture such products.

This text describes the major methods by which sterility may be achieved and therefore is aimed at practitioners who wish to enhance their knowledge of the fundamentals of sterilisation and the associated techniques, at interested personnel who are involved in sterilisation technology but who do not have a strong academic background in the area, and also at recent graduates who have recently moved into, or are wishing to move into the sterile products manufacturing industries.

The need for sterility is described in the first chapter and is reinforced by the use of powerful examples of the consequences of non-sterility The second chapter outlines the concepts of sterility and sterility assurance, including descriptions of the mathematical descriptions of the sterilisation process. The following six chapters describe the fundamental and applied aspects of the principle sterilisation methods, namely, gamma radiation, saturated steam, dry heat sterilisation and depyrogenation, ethylene oxide, filtration and aseptic manufacture. The concluding final chapters illustrate the factors involved in the maintenance of sterility (and how this can be evaluated) and parametric release and other regulatory issues. One area of sterilisation which is not covered in this text is the chemosterilisation of pharmaceutical equipment. However, as the emphasis of the text is on sterilisation of products as part of or at the end of a manufacturing process, description of chemosterilisation is not warrented.

In my opinion the text has been well written and conveys sufficient information concerning the sterilisation processes to both the uninitiated in the field and also to the sterilisation specialist who would endeavour to increase his or her experience in other sterilisation procedures. The author of the text has ensured that both the practical and theoretical aspects of sterilisation and sterilisation processes have been successfully described in such a manner so as not to compromise one area at the expense of the other. I would wholeheartedly recommend this text to those in the pharmaceutical or allied industries who are currently involved in, or wish to become involved in the sterilisation of medical and pharmaceutical products.

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