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Book reviews

Freeze-drying/Lyophilization of Pharmaceutical and Biological products

L. Rey and J. May (Eds), Marcel Dekker, Inc., New York, ISBN 0-8247-1983-2

Nowadays, in the pharmaceutical field, there is a great number of substances which need to be stored in a dry state due to their instability in the presence of water, for example, the antibiotics, vaccines, peptides and proteins. The aim of this book is to give a large spectrum of information on freeze-drying, with the understanding that researchers now have, 100 years after the discovery of this procedure. The book is organized on a contributed chapter basis. The contributors range from theoreticians to experts with considerable practical experience.

The first chapter brings the basics of freeze-drying to the reader. The next two chapters are essentially dedicated to a better understanding of the leading role of water in this process. Chapter four gives precise and practical information on the procedures and equipment used for freezedrying. The following two chapters raise questions concerning protein structure protection and stabilization during lyophilization. Chapter seven concerns the residual moisture, in particular with respect to the levels required to maintain viability, immunological potency, or integrity of biological products. The next chapter presents the strategies required to preserve microorganisms during the freezing and drying steps. Here, emphasis is given to the different additives that can be added to the preparations. Chapter nine presents the chemical engineering and thermodynamic aspects of freeze-drying in the pharmaceutical industry. Several aspects are presented and among them, the equipment specifications required. Chapter ten is devoted to freeze-drying of vaccines. Chapter twelve raises the problems of process validation. This chapter is very informative and a survey of all critical process parameters is presented. The last chapters are dedicated to specific aspects such as elastomeric closures, cleaning-in-place and sterilization-in-place processes. Finally, Louis Rey presents some possible future applications such as semi-continuous and continuous processes, which are already used in the food industry, but which require some improvements if the standards of sterility are to be achieved.

As mentioned by the editors, this book will be useful for potential users of freeze-drying in the pharmaceutical industry. It is however, also very useful for academic researchers who want to have a better understanding of a very important process for all pharmaceutical and biological products that need to be stored in a dry state.

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Frontiers in Biomedical Polymer Applications (Vols. I and II)

Raphael M. Ottenbrite (Ed.), American Technical Publishers Ltd., England, UK. Vol. I: 1998, 317 pages, £131, ISBN: 1-56676-577-3; Vol. II: 1999, 238 pages, £115, ISBN: 1-56676-714-8

Biomedical polymers are used for a tremendous number of different applications. These applications reach from their use as raw materials for prostheses to experimental applications that emerged during the last couple of years such as tissue engineering. It is more than obvious that there are numerous points of view that one might take when having a look at the multitude of biomedical polymers that can be used for this myriad of applications. There are, for example, the aspects of surface properties of materials that are decisive for applications such as drug targeting, issues of biocompatibility a property that we require in general for biomaterials and even efficient ways of synthesis that will provide us with new polymers.

What does 'Frontiers in Biomedical Polymer Applications' focus on? The focus is on none of these fields and all of them at the same time. The book is an excellent snapshot of a scientific field that is currently changing very rapidly. Forty one groups present results from their research on biomedical polymers. The contributions cover a number of up to date scientific issues. Among them are: materials for drug delivery, biodegradable polymers, polyelectrolytes, materials surface aspects, non-viral gene therapy and many more.

Prospective readers who may profit from the books are to some extent scientists who are not yet working in the field. 'Frontiers in Biomedical Polymer Applications' gives them an impression of potential applications for biomedical materials and of the science and problems that are still ahead of us in this field. The books can be of interest to all those who are not familiar with biomaterials but who are working with

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materials that have the potential to serve as biomaterials. They can obtain a number of good hints what the needs and the potential applications for new materials are. To those who are more familiar with biological systems and medical problems, the book can give some guidance regarding the current availability of materials or the possibilities we have to develop new materials for medical and biomedical applications. For the expert finally it is a summary of the recent developments and concomitantly here and there a source of inspiration.

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Homöopathisches Arzneibuch 2000 (HAB 2000)

Amtliche Ausgabe 2000, Fortsetzungswerk 1552 Seiten. Loseblattausgabe. 2 Ringordner. Grundwerk DM209.50. ISBN 3-7692-2253-9

Since August 1, 2000 the new Homeopathic Pharmacopoeia (Homöopathisches Arzneibuch 2000) is valid in Germany and replaces the first Homeopathic Pharmacopoeia (1. Homöopathisches Arzneibuch der Bundesrepublik Deutschland) published in 1978. All homeopathic medicaments registered in the Federal Republic of Germany have to be produced according to the new Homeopathic Pharmacopoeia. The German law of medicaments states that the Homeopathic Pharmacopoeia has the same legal status as the European and the German Pharmacopoeia. The newest

regulations of the European Community regarding homeopathic medicaments are considered.

The structure of HAB 2000 is as follows: general tests and methods, reagents, techniques for the production of homeopathic medicaments and monographs. Part 1 (general tests and methods) describes only those methods which are not included into the European or German Pharmacopoeia. The techniques for the preparation of homeopathic medicaments were completely revised. In principle there are still 50 different descriptions for the production of homeopathic medicaments. The first 17 of them are directly based on Hahnemann's 'Organon' which was first published in 1796. The other methods are descriptions for anthroposophic medicaments, methods of spagyrik and organ preparations. The single monographs of the Homeopathic Pharmacopoeia 2000 describe the plant itself, the dosage forms and the prescription for their preparation, the properties, identity and purity as well as the storage conditions. They are adequate compared to monographs of the European Pharmacopoeia. Compared to the first Homeopathic Pharmacopoeia from 1978, 22 new monographs were included in the 2000 edition. Therefore, the Homeopathic Pharmacopoeia 2000 of the Federal Republic of Germany should be worldwide the most complete collection of homeopathic prescriptions and monographs. It is the basis for all people working with homeophatic medicaments in industry, hospital and retail pharmacy. From the reviewers point of view the Homeopathic Pharmacopoeia 2000 of the Federal Republic of Germany is the leading pharmacopoeia in the field of homeopathy worldwide. This explains the high level of interest from foreign countries to this book.

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