

Book reviews

Handbook of Pharmaceutical Controlled Release Technology

Donald L. Wise (Editor) Marcel Dekker, New York; 2000, 904 pages, US\$ 225; ISBN 0-8247-0369-3

This new handbook mainly focuses oral and dermal technologies for controlled drug delivery with some parenteral aspects. Some chapters are of review type character whereas many others are extended research articles summarizing the authors research in a specific field. In the first part, different polymers used in drug delivery carriers are described starting with tablets prepared from cellulose ethers or polyvinylalcohol and gels prepared from acrylate and methacrylate polymers. Very much driven by N. Peppas and previous co-workers the focus is on swelling and diffusional release including mathematical models. Furthermore, complexing polymers and smart self-regulating or pulsatile systems are discussed. The second part on mechanism-based classification of controlled release devices again focuses on the work of the group from Purdue University using hydrogels for swelling controlled release for oral application and bioadhesive approaches. The part is closely related to part one and there is some redundancy. The interesting section on osmotic implantable delivery systems sticks out. Part III switches back and forth between micro- and nanoparticulate release systems for parenteral application. There are some weaknesses in the quality of the graphs as well as the scientific content. Numerous references for microencapsulation technologies, microencapsulated drugs and microsphere preparation by solvent evaporation are given but you miss the controlled release aspect. Surprisingly, the only release profiles from microparticles are given in the nice chapter on stability of drug microencapsulated in PLGA systems. Finally at the beginning of Part IV you find the long overdue 'Overview of controlled release systems'. But after this promising start the book continues with basic information on sustained release tablet formulation. Five chapters cover transdermal delivery with three of them about electro- and ultrasound supported transport and one on neural networks for optimization of transdermal delivery. I was dreadfully missing information on commercially successful TTS systems. Part V on peptide and protein release systems with two general chapters on stability and one on biodegradable hydrogels loaded with growth factors and a very thin description on IL-2 formulated with PLGA again leaves too many subjects untouched. Part VI presents an omnium-gath-

erum of applications by the group of Donald Wise himself spiked with a more interesting chapter on osmotic drug delivery from asymmetric membrane film-coated dosage forms and concluded by a very short and general pharmacoeconomic evaluation of controlled release dosage forms. The editor anticipates the book to be a most useful guide for industrial and academic research directors and program managers but in this case I would expect more information on commercial approaches and alternatives. As a scientist you would like to obtain high quality reviews from a handbook on pharmaceutical controlled release and you will be a little bit disappointed.

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Good Manufacturing Practices for Pharmaceuticals

Sidney H. Willing (Editor), 5th ed., Marcel Dekker, New York-Basel; 2001-02-07

This is the 5th edition of the well known book which has now been revised and extended. It is entirely aimed at the requirements of the FDA and as such reflects the US policy towards domestic and foreign producers of drugs. For this reason the knowledge of the contents is a must for all those who have to submit to US-inspections in Europe. The subtitle 'A Plan for Total Quality Control from Manufacturer to Consumer' already shows the claim made by the book, and it is self evident that only the American philosophy is the right one.

This work begins with a presentation of the status of the US Regulations on current good manufacturing practices (CGMP) followed by special sections on: finished pharmaceuticals, organization and personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packing and labelling controls, holding and distribution, laboratory controls, records and reports, returned and salvaged drug products, repacking and relabelling, bulk pharmaceutical chemicals, recalls and VGMPs, controlled

substances safeguards, the inspection procedure for compliance in the US, FDA pre-approval inspections, other approaches to quality, import and export of pharmaceuticals, and enhancement of global product distribution. The lengthy appendix covers the following five chapters: Food and drug modernization act, components/repackages, hearing procedures when FDA proposes the imposition of civil money penalties, changes currently considered 'important', USP24-NF19 information.

After going through 732 pages of regulatory matters and explanations which regulate everything with documentation

carried to perfection one can question the aims of this book. The drug no longer appears to be the most important thing in the production process, but the documentation. In future everything is to be monitored from the solvent of the first synthesis step of a drug to perhaps the excretion of a metabolite.

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