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Book reviews

Aqueous Polymeric Coatings For Pharmaceutical Dosage Forms, 2nd Edition (Drugs and the Pharmaceutical Sciences (Series/79)
J.W. McGinity (Editor), Marcel Dekker, New York; 1997, $185.00. ISBN 0-8247-9773-6

The problems associated with the organic solvent-based film coating and the advantages of the aqueous-based polymeric systems have resulted in the first edition of this book in 1989. During the last years a lot of new products using aqueous-based coatings were formulated and numerous reformulations have taken place to replace organic-based film coatings. Thus, additional experiences were gained. Furthermore, new aqueous dispersions have been developed recently or are increasingly in use now, such as new polymers for enteric coatings, biodegradable polymers, silicone dispersions and cellulose esters. The characterization of film properties has also been expanded in the last years, especially in the field of stress-strain testing. Therefore, it was the right time to launch a second edition.

All nine chapters of the first edition have been revised, more or less enlarged and the references therein expanded. There are seven new chapters in the book. R. Bodmeier et al., wrote an excellent overview on the drug release from pellets coated with Aquacoat®, discussing also the flocculation in the dispersion, the curing process in respect to release stability and the mechanical properties of EC-films. In the subchapter 'Plasticizer' the need of enough time for the uptake of the plasticizer by the polymer particles is stressed. Perhaps, this rather general phenomenon could be better presented in a separate chapter together with time-dependent MFT-values. The pH-dependence of the release from ethylcellulosecoated pellets is discussed in the subchapter 'Surfactants' because the 'wetting hypothesis' is preferred to the 'swelling hypothesis'. M.E. Aulton et al., describe the physical properties of HPMC solutions in respect to film coating. The subchapters 'Thermal gelation' and 'Batch variations' and the discussion of the influence of the solution viscosity on the resulting film properties seem to be especially interesting. A new detailed chapter deals with cellulosic polymers for enteric coatings (S.H.W. Wu et al.). Special emphasis is given to physicochemical properties and film permeabilities. .R.C. Rowe discusses the reasons for defects in aqueous film coated tablets and develops an expert system to omit them. S.E. Frisbee et al. describe the use of biodegradable polymers (mostly polylactic acid) and L.C. Li the application of silicone elastomer as polymeric coating dispersions. The seventh new chapter, written by P.B. O'Donnell and J.W. McGinity, treats the mechanical properties of films from aqueous polymeric dispersions. The most important parameters are tensile strength or puncture strength (at break), work of failure, the respective elongation and the elastic modulus. They are all influenced by the addition of plasticizers and its permanence, moisture content and film preparation.

A lot of information is presented in this book, highly valuable for the pharmaceutical scientist involved in this area. Also most of the enteric coatings are now treated in the second edition. Special problems like the curing of coated products and its influence on release stability are repeatedly discussed. The index comprises about 650 entries, thus the user will find most of the items he is looking for. However, in some cases like MFT or release stability, the index is not very helpful. Some problems have still to be resolved finally, e.g. the importance of the osmotic pressure for the release rate of the coated products and the theoretical basis of its release stability. On the other hand, this could be the impulse for a third edition, together with more updated literature in the various chapters, the latest references are from 1995 at best. To be up-to-date nowadays, the second edition should replace the first edition in the book shelves as soon as possible.

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Pharmaceutical Powder Compaction Technology (Drugs and The Pharmaceutical Sciences Series/7 1)
Christer Nyström, Göran Alderborn (Editors), 624 pp.; $185. ISBN 0-8247-9376-5

A comprehensive textbook on this subject has been waited for by many pharmacists in research, teaching,

development and production for a long time. However, this is not a 'textbook' in its usual sense. The editors have encouraged 17 experts in particular fields to contribute, and have arranged their chapters in a logical order. Therefore, the reader will have to expect some heterogeneity and individualism.

'Interparticulate Attraction Mechanisms' by C. Fuhrer highlights the most important types of attraction forces. The chapter benefits from his broad experience in the field of physics, especially crystallography, particles and dose-forming processes.

'The Importance of Intennolecular Bonding Forces and the Concept of Bonding Surface Area' by C. Nyström and P.-G. Karehill divides factors for tablet strength into the dominating bonding mechanism and the surface area over which these bonds are active, and particle shape, surface texture, and size. Mostly only the latter have been studied so far. Advantages of fragmenting materials are outlined, provided the elastic component is limited.

'Porosity-Pressure Functions' are carefully reviewed by P. Paronen and J. Ilka. Using the Heckel function as an example, emphasis is put on the problems of statistical evaluation of mathematical transformation of normally- distributed data, ignored in many contributions. 'Most often the Heckel equation is strictly speaking invalid on most stages of compaction of pharmaceutical powders'. 'Force-Displacement and Network Measurements in Compression Studies' by G. Ragnarsson reviews proper calibration procedures, then quantitative analysis of force/displacement curves and the derivation of parameters. Effects of interparticulate friction and the important, but still problematic assessment of an energy balance during compaction are discussed. 'Viscoelastic Models' by F. Muller delineates the theoretical background of visco-elasticity during tabletting as a basis for understanding force-relaxation phenomena and creep characteristics. The classical Maxwell- and Voigt-Kelvin models and generalized ones are developed, paving the way to understand the construction of rather impressive constitutive equations. Consequences due to interactions of viscous and elastic features in the models, when the speed of deformation is altered, are demonstrated. Explicit solutions for linear creep compliance, and ways to estimate parameters from dynamic compaction experiments are outlined. Fritz Muller admits, consolingly, "All theses relations show on the one hand the possibilities to obtain information and on the other hand the difficulties to apply the theory to the process of powder compaction", a point illustrated in detail in the concluding remarks concerning practical applications.

'Application of Percolation Theory and Fractal Geometry to Tablet Compaction' by H. Leuenberger, R. Leu, and J.-D. Bonny, projects the course of formation of a tablet into these concepts, then the properties of the product 'tablet', leading to critical relative densities, which indicate changes in the internal structure of the material being densified.

Combining Leuenberger's and Heckel's equation seems fascinating, yet might need caution in light of chapter 3 in this very same book.

'Mechanical Strength' by P.N. Davies and J.M. Newton shortly discusses direct tensile testing and flexural tests, in more detail the diametral compression test, with emphasis on effects of loading conditions and rates. Considering anisotropy in real pharmaceutical specimens is recommended, since theory in general is based on isotropic ones. The total process of loading and the answer of the specimen should be regarded, instead of settling on a mere maximum value causing the 'crush'. 'Tablet Surface Area' by N.A. Armstrong takes up concepts already addressed in chapter 2. The evidence derived from only gas adsorption, gas permeametry, and porosimetry, respectively, is reviewed, then the high value of studies using different experimental methods is exemplified. 'Rationale for and the Measuring of Tableting Indices' by E.N. Hiestand shows the broad experience of the author. Remarks concern measurements of fracture strength, effects of flaws and inhomogeneity, and of visco-elasticity and strain rate. Strain rate is important in measuring tensile strength by compression tests. The latter is stated not to be a sufficient indicator of the tableting properties unless divided by the impact hardness. Advantages of experimental procedures to determine the Brittle Fracture Index are illustrated. A thoughtful consideration of 'Needed precision' closes the discussion.

'Particle Dimension' by G. Alderborn reviews relevant literature in detail. The physical properties of the compact are evaluated by those of the interparticulate pore system and by the properties of the particles constituting the compact. The particle size of a powder being compacted is first discussed by comparison to comminution, then with regard to its effects on tablet strength. 'Mechanical Properties' by R.C. Rowe and R.J. Roberts promises, at least in more general parts, similar information as the previous chapter 'Mechanical Strength'. Its value, then, is more in the practical information, e.g. allowing to compare results on Young's moduli obtained for zero porosity by testing flexure compaction, and indentation, the latter both for crystals and for compacts. The data are critically discussed in comparison. Procedures to determine the Critical Stress Intensity factor are discussed. The pragmatic synopsis of several parameters may provide a basis for predicting the consolidation mechanisms of powdered material.

'Granule Properties' by G. Alderborn and M. Wikberg considers the result of the volume reduction of porous granules to be 'a large aggregate of small, strongly cohered granules', a graphical representation

of which decorates the cover of the book. Following the pore structure with increasing densification is sensitive, but mostly only the volume is followed with increasing applied pressure and described by aid of the Heckel function. The granule porosity and strength, besides secondary factors, mainly affect compactability. 'Modeling the Compression Behavior of Particle Assemblies from the Mechanical Properties of Individual Particles' by W.C. Duncan-Hewitt is a delightful chapter for anyone with a sense for masterly use of language and didactic refinement. It encourages the reader to proceed in looking for meaningful experiments within our real world of many-factor problems. Materials characterization applicates fundamental assumptions of the rate theory of plastic deformation, including the concept of mechanical activation-so intensively propagated by the late Reinhard Huttenrauch, which should be seen in some opposition to the visco-elastic analysis, so comprehensively outlined by F. Muller in chapter 5. Stepwise procedures for predicting compaction behaviour are developed in principle, their power and restrictions demonstrated with examples. A critical evaluation of the state of predicatability arrived at gives hope, since the compaction behaviour so some materials could be predicted from mechanical properties of single crystals.

'Materials for Direct Compaction' by G.K. Bolhuis and Z.T. Chowhan is a plea for direct compression. 'Filler-binders' and important excipients, e.g. celluloses, starches, inorganic slats, polyols, lactoses, other sugars, and *c*-processed products are discussed and compared, along with some d.c. forms of active substances, very valuable for the practitioner. 'Compaction Properties of Binary Mixtures' by J.T. Fell demonstrates the still limited research in this field until 1991 and, that compaction properties of binary mixtures are clearly not yet predictable: 'The complexity of the system and the large influence of experimental variables means that simple theoretical approaches are likely to be grossly misleading'. 'Lubricant Sensitivity' is reviewed by G.K. Bolhuis and A.W. Holzer. The authors very carefully review the particular studies and results, since many studies consider only one or a few factors, which lead to results contradictory to others. They concluded, that 'the susceptibility of a material to lubricants like magnesium stearate is a complex function of a number of factors including surface area, surface texture, flowability, mixing properties, and consolidation behaviour'. Finally, rules are derived to limit the sensitivity of tabletting materials to the still most commonly used lubricant: magnesium stearate. 'The Development and Optimization of Tablet Formulations Using Mathematical Methods' by F. Podczeck outlines how the various possible interactions among the many constituents during tabletting and within the finished product may be taken into account. Many valuable interrogation and question marks, respectively, are given for practical application of statistical design and evaluation. The power of the principal component analysis and of cluster analysis to isolate the most important variables as uncorrelated pricipal components, and of the cluster analysis in grouping a set of objects into classes of similar objects, and canonical analysis are demonstrated, using experimental data as examples. Sections on 'mathematical optimization' and on 'experts systems' finish this part. In 'expert systems' very valuable remarks are given to prevent the novice from expecting too much in relation to his ability to put meaningful facts into the system.

A roughly 15-page index finishes the book, allowing numerous connections between the various contributions. Apparently it has been the purpose of the editors not to press the articles into a common form and style. Even cross-references are given not very frequently. Consequently, some redundant information, as well as some contradictions in attitude result. The literature published in the German language seems widely ignored. Quite a number of typing errors and some deficiencies in the language should be polished in a second edition. The book has great value for scientists as well as industrial pharmacists. It contains very valuable review, discussion, guidelines, and even data which cannot be found elsewhere.

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Good Manufacturing Practices For Pharmaceuticals: A Plan for Total Quality Control, 4th edition.
S.H. Willig, J.R. Stoker (Editors), Marcel Dekker, New York; 1997. 520 pp.; $99.75; ISBN 0-8247-9770-1

This book is a comprehensive and practical reference text that describes in adequate detail some of the most recent FDA guides and guidelines pertaining to current good manufacturing practice (CGMP). The book is logically subdivided into 22 chapters that discuss the CGMP regulations contained in Title 21 of the Code of Federal Regulations, inspection procedures for compliance in the United States, enforcement alternatives in the United States available to the FDA, controlled substances, FDA requirements for bulk pharmaceutical chemicals, FDA pre-approval inspections and investigations, CGMP principles and guidelines for other countries, alternative quality programs such as the Malcolm Baldrige National Quality Award and ISO 9000 series, the import and export of pharmaceuticals and other