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Acid Dissolution Method for the Analysis of Plutonium in Soil **Poorly Soluble Drugs** **A Simple, Low-cost Method for the Dissolution of Metal and Mineral Samples in Plastic Pressure Vessels** *Sealed-tube Dissolution Method for Determination of Nitride Nitrogen in Boron Carbide* **Pharmaceutical Dissolution Testing** **Testing of the Defense Waste Processing Facility Cold Chemical Dissolution Method in Sludge Batch 9 Qualification** An Agitator and a Gelatin Dissolution Method Using Said Agitator *Improvements to biorelevant dissolution testing: lyophilized media, buffer alternatives and miniaturized apparatus* **Development of a Dissolution Method for Analysis of a PULSYS TM "Antibiotic A" Product Containing 4 Pulses** *Dissolution, Bioavailability & Bioequivalence* In Vitro-In Vivo Correlations **Media for in Vitro Dissolution Testing of Polysaccharide Based CDDS** *Improved Selective Dissolution Method for Determining Calcite and Dolomite in Soils* *A New Consecutive Dissolution Method for the Analysis of Slag Cements* Acid Dissolution Method for the Analysis of Plutonium in Soil **Water Movement in the Bay of Fundy Cannot be Measured by Gypsum Dissolution Method** Symposium on the Mechanisms of Hydrocarbon Reactions *Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence* Dissolution Stability for Packaging Application *An in Vitro Dissolution Method for the Evaluation of an Intramammary Infusion Product* **Guideline for the Format and Content of the Human Pharmacokinetics and Bioavailability Section of an Application Development of a Solvent Dissolution Method for Elemental Analysis of Paint** Dissolution Technology PHYSICAL MODEL APPROACH TO THE MECHANISTIC INVESTIGATION OF CHOLESTEROL GALLSTONE DISSOLUTION RATES.. **BIOMIMETIC DISSOLUTION** *Fracture Dissolution of Carbonate Rock* *Investigation of Dissolution and Dispersion Behavior of Ritonavir from Amorphous Solid Dispersion* **Development and Characterization of a Novel Drug Dissolution Test Method Using a Quartz Crystal Microbalance** **Pharmaceutical Dissolution Testing** Novel Formulation Strategies with a Mechanistic Approach to Improving the Dissolution of a Poorly Water-soluble Drug Solubility enhancement of poorly water-soluble drugs by solid dispersion *Nitroglycerin Sustained Release Tablet. Formulation Design and Evaluation* Experimental Determination of the Agitation Requirements for Solids Suspension in Dissolution Systems Using a Mini Paddle Apparatus **Spray Dried Nano-crystalline Powders and In Vitro Dissolution Performance** **Hydrodynamic Effects of an Arch-shaped Fiber Optic Probe in a Dissolution Testing Apparatus 2** Predictive in Vitro Dissolution Tools **PhD thesis Dissolution and Precipitation of Dipyridamole** *A Method Validation for Dissolution of Pizotifen Maleate in Acugrain Tablet 0.5mg by Using High Performance Liquid Chromatography/UV-VIS Detector* **Sustainable Natural Fiber Composites**

This book represents the invited presentations and some of the posters presented at the conference entitled "In Vitro-In Vivo Relationship (IVIVR) Workshop" held in Sep tember, 1996. The workshop was organized by the IVIVR Cooperative Working Group which has drawn together scientists from a number of organizations and institutions, both academic and industrial. In addition to Elan Corporation, which is a drug delivery com pany specializing in the development of ER (Extended Release) dosage forms, the IVIVR Cooperative Working Group consists of collaborators from the University of Maryland at Baltimore, University College Dublin, Trinity College Dublin, and the University of Not tingham in the UK. The principal collaborators are: Dr. Jackie Butler, Elan Corporation Prof. Owen Corrigan, Trinity College Dublin Dr. lain Cumming, Elan Corporation Dr. John Devane, Elan Corporation Dr. Adrian Dunne, University College Dublin Dr. Stuart Madden, Elan Corporation Dr. Colin Melia, University of Nottingham Mr. Tom O'Hara, Elan Corporation Dr. Deborah Piscitelli, University of Maryland at Baltimore Dr. Araz Raoof, Elan Corporation Mr. Paul Stark, Elan Corporation Dr. David Young, University of Maryland at Baltimore The purpose of the workshop was to discuss new concepts and methods in the devel opment of in vitro-in vivo relationships for ER products. The original idea went back ap proximately 15 months prior to the workshop itself. For some time, the principal collaborators had been working together on various aspects of dosage form development. The gypsum dissolution method was originally introduced by freshwater ecologists for a wide variety of purposes where water movement data were required. This report describes an investigation to adapt the gypsum dissolution method for Bay of Fundy conditions, to test the assumptions necessary for the method in a unidirectional flow-through flume, and to compare the method with conventional current-meter methods in field conditions. Background on gypsum dissolution theory is followed by the techniques used to make gypsum cylinders used in the investigation. This is followed by results of flume calibration & field tests. The final section discusses the feasibility of the method for providing a general index of water movement in well-mixed water bodies like the Bay of Fundy. The book covers such diverse topics as cellulose fibers in cement paste and concrete, biodegradable materials for dental applications, coconut and pineapple fiber composites, biodegradable plastic composites, durability against fatigue and moisture, physical and mechanical characterization of fiber composites, improving the hydrophobic nature of fiber composites, and hybrid natural fiber composites. Keywords: Fiber Reinforced Composites, Biodegradable Composites, Polymethyl Methacrylate, Cellulose Fibers, Coconut Fibers, Biocomposites, Resol-Vegetable Fibers, Pineapple Natural Fiber Composite, Dental Applications, Cement Paste, Concrete, Thermoplasticity, Fatigue, Moisture, Thermal Conductivity. Dissolution in different steps of pharmaceutical drug development was considered in this work. Dissolution is used as informative tool throughout the entire development process: After identification of a possible drug candidate, intrinsic dissolution in different buffer media is tested for physicochemical characterization. In galenics dissolution is used to develop and optimize formulations by comparative release studies. During scale-up dissolution testing is used to observe influence of process or parameter changes. For regulatory affairs all of these dissolution studies are of interest and many have to be presented to the authorities. Most of the dissolution testing designs in pharmaceutical development are following pharmacopoeial monographs or general chapters and official guidelines. In addition these “official” dissolution testing setups, a progression of more innovative dissolution methods closer to physiological conditions are used. Devices simulating movement and flow of the GIT combined with media simulating the gastrointestinal fluids are often used. Disadvantages of these methods are that they are time-consuming and expensive, both of which limit throughput. The aims of this thesis were to (a) reduce time consumption regarding preparation of biorelevant dissolution, (b) increase biorelevance of the media FaSSIF and FeSSIF by substituting the non-physiological buffer systems for bicarbonate and (c) to increase throughput by miniaturization of dissolution devices. To meet the first goal a novel preparation method for the biorelevant media FaSSIF and FeSSIF was established. The conventional method uses chlorinated organic solvent, is time-consuming in preparation (approx. 2 hours) and needs to be done daily. The investigated method uses freeze-drying for the preparation of instant biorelevant media. The instant media only consist of bile salt and lecithin in mixed micelles. In situ preparation is done by simply adding blank buffer to the rapidly dissolving lyophilisate. Freeze-dried product gave comparable results to freshly prepared media and improved reproducibility. Comparison to commercial available instant media indicated superiority of the freeze-drying method. Next, a buffer system based on the more physiological bicarbonate buffer was investigated. A method to maintain a stable buffer system throughout the dissolution testing. The buffer therefore was created by sparging carbon dioxide into alkali saline solution to forming carbonate and bicarbonate as buffer system. At equilibrium the media was transferred to the vessels and supply of carbon dioxide continued by sparging the gas above the solution. Therewith bubble formation could be minimized, although not excluded. Only a small range of buffer strength and pH combinations was possible. The lowest pH still providing effective buffer capacity (5 mmol/l/?pH) was 5.5. Physiologically relevant buffer capacities of 10 and 30 mmol/l/?pH were tested at pH 6.5. The buffer turned out to be very sensitive against pH modifying agents by loosening its buffer capacity and strength. Standard deviations were generally higher. No superiority over conventional buffer systems like phosphate or acetate buffer regarding IVIVC was given. Therefore it is concluded that bicarbonate buffer is not a suitable medium for in vitro dissolution testing. Subsequently methods for small scale dissolution testing were established. Improvement of throughput in dissolution testing was achieved. The investigated BI miniDiss method can be used to test release profiles of small particulate formulations or intermediates. High throughput excipient screening for early formulation is possible by using the well-plate method. In the first series of tests, downscaling by factor 10 was conducted by miniaturizing and automating standard dissolution apparatus. Small vessels of 20 ml volume and paddles of about 8 mm diameter were used. Automating was done by sampling through paddle hollow shafts and online UV/VIS measurement. Since no filtration was possible due to the small sample volume, the true % dissolved was calculated using mathematical scatter correction of spectra from turbid solutions. In this way, release profiles comparable to standard dissolution testing were obtained. Cleaning and restart is accelerated and therewith throughput increased. The 10fold reduced consumption of drug formulation reduces API consumption, so that a larger variety of formulations can be prepared and tested with the same amount of API. The BI miniDiss is limited to multiparticulates like pellets, extrudates, minitablets, granules or intermediates. Downscaling of matrix or IR tablets will likely result in different results due to changed surface to volume ratio. The well-plate method offers a miniaturization of factor 100. Dissolution of multiparticulates showed significant differences compared to standard methods. However, ranking of formulations was possible in several cases. The well-plate method is not suitable for conducting comparative release profiles. However, it can be used for selection of excipients by supersaturation testing. It is an informative tool in early formulation screening helping to optimize formulation of poorly soluble compounds. As last part of the work, the BI miniDiss was used to screen various buffers to finding the best media for IVIVC, retrospectively. The BI miniDiss proved to be useful as a fast and cost and effective screening method. In summary, several improvements in dissolution for pharmaceutical development purposes have been developed regarding consumption of API, costs and efficiency. An easy and rapid preparation of biorelevant media was established making their use in pharmaceutical development and routine quality control more feasible. The miniaturized dissolution methods and the improved high-throughput fulfil demands from pharmaceutical industries to facilitate API-saving methods in development. The goal of the project is to develop and assess the feasibility and economic viability of an innovative concept that may lead to commercialization of new gas-storage capacity near major markets. The investigation involves a new approach to developing underground gas storage in carbonate rock, which is present near major markets in many areas of the United States. Because of the lack of conventional gas storage and the projected growth in demand for storage capacity, many of these areas are likely to experience shortfalls in gas deliverability. Since depleted gas reservoirs and salt formations are nearly non-existent in many areas, alternatives to conventional methods of gas storage are required. The need for improved methods of gas storage, particularly for ways to meet peak demand, is increasing. Gas-market conditions are driving the need for higher deliverability and more flexibility in injection/withdrawal cycling. In order to meet these needs, the project involves an innovative approach to developing underground storage capacity by creating caverns in carbonate rock formations by acid dissolution. The basic concept of the acid-dissolution method is to drill to depth, fracture the carbonate rock layer as needed, and then create a cavern using an aqueous acid to dissolve the carbonate rock. Assessing feasibility of the acid-dissolution method included a regional geologic investigation. Data were compiled and analyzed from carbonate formations in six states: Indiana, Ohio, Kentucky, West Virginia, Pennsylvania, and New York. To analyze the requirements for creating storage volume, the following aspects of the dissolution process were examined: weight and volume of rock to be dissolved; gas storage pressure, temperature, and volume at depth; rock solubility; and acid costs. Hydrochloric acid was determined to be the best acid to use because of low cost, high acid solubility, fast reaction rates with carbonate rock, and highly soluble products (calcium chloride) that allow for the easy removal of calcium waste from the well. Physical and chemical analysis of core samples taken from prospective geologic formations for the acid dissolution process confirmed that many of the limestone samples readily dissolved in concentrated hydrochloric acid. Further, some samples contained oily residues that may help to seal the walls of the final cavern structure. These results suggest that there exist carbonate rock formations well suited for the dissolution technology and that the presence of inert impurities had no noticeable effect on the dissolution rate for the carbonate rock. A sensitivity analysis was performed for characteristics of hydraulic fractures induced in carbonate formations to enhance the dissolution process. Multiple fracture simulations were conducted using modeling software that has a fully 3-D fracture geometry package. The simulations, which predict the distribution of fracture geometry and fracture conductivity, show that the stress difference between adjacent beds is the physical property of the formations that has the greatest influence on fracture characteristics by restricting vertical growth. The results indicate that by modifying the fracturing fluid, proppant type, or pumping rate, a fracture can be created with characteristics within a predictable range, which contributes to predicting the geometry of storage caverns created by acid dissolution of carbonate formations. A series of three-dimensional simulations of cavern formation were used to investigate three different configurations of the acid-dissolution process: (a) injection into an open borehole with production from that same borehole and no fracture; (b) injection into an open borehole with production from that same borehole, with an open fracture; and (c) injection into an open borehole connected by a fracture to an adjacent borehole from which the fluids are produced. The two-well configuration maximizes the overall mass transfer from the rock to the fluid, but it results in a complex cavern shape. Numerical simulations were performed to evaluate the ability of storage caverns produced by the acid-dissolution method to store natural gas. In addition, analyses were conducted to evaluate cavern stability during gas injection and withdrawal from storage caverns created in carbonate formations by the acid-dissolution method. The stability analyses were conducted using FLAC2D, a commercially available geotechnical analysis and design software. The analyses indicate that a tall cylindrical cavern with a domed roof and floor will be stable under the expected range of in situ and operational conditions. This result suggests that it should be feasible to avoid mechanical instabilities that could potentially diminish the effectiveness of the storage facility. The feasibility of using pressure transients measured at the ground surface was investigated as a means to evaluate (Abstract truncated). The intrinsic cohesive nature of micronized poorly water-soluble drug particles often promotes the formation of drug agglomerates with reduced surface areas for dissolution. The objective of this thesis was to investigate novel and innovative formulation strategies to improve the de-agglomeration behaviour and in vitro dissolution rate of a micronized model poorly water-soluble drug, indomethacin. In the first approach, various micronized poorly water-soluble excipients (including aluminium hydroxide, barium sulphate, calcium phosphate and calcium sulphate) were incorporated into lactose-based indomethacin interactive mixtures. In the second approach, the indomethacin powders were mechanically dry coated (by mechanofusion) with force control agents (such as magnesium and sodium stearate). Mathematical modelling approaches were explored using multi-exponential and mechanism-based models in order to gain an insight into the de-agglomeration and dissolution mechanisms.Dissolution of the various mixtures and coated powders of indomethacin was conducted with an automated dissolution apparatus (Erweka DT6, Germany) using the USP paddle method in buffered media at pH 5.0 under sink conditions. Dissolution data were modelled with multi-exponential equations via the standard-two-stage (STS) estimation method and mechanism-based models were developed by population estimation methods in S-ADAPT. Particle size distributions of the raw materials, interactive mixtures and coated powders were measured by laser diffraction using the Mastersizer S (Malvern Instruments Ltd., UK). The dispersion of indomethacin mixtures was measured by laser diffraction in dissolution media under non-sink conditions. The addition of cohesive aluminium hydroxide and calcium phosphate (10% each) to binary lactose-based interactive mixtures of 10% indomethacin was found to counter-intuitively and significantly increase the dissolution rate of indomethacin. The improvements in dissolution for these ternary mixtures were unrelated to pH effects but associated with the ability of the poorly water-soluble excipients to facilitate the de-agglomeration of indomethacin agglomerates. Multi-exponential modelling revealed increases in the estimated initial concentration (Cd) and dissolution rate constant (kd) of dispersed indomethacin particles upon addition of the cohesive additives to the binary mixtures. Dissolution of indomethacin was found to increase as a function of the concentration of aluminium hydroxide (5-20%) added to the binary mixtures. Where three particle size fractions of aluminium hydroxide (with significantly different D90 sizes) were used, increasing the proportion of larger particles of the aluminium hydroxide increased the dissolution rate of indomethacin. Modelling revealed increases in the kd for the ternary 5-20% aluminium hydroxide mixtures compared with the binary mixture, indicating larger exposed surface areas of dispersed indomethacin particles to the dissolution medium; Cd increased with both the concentration and particle size of the added aluminium hydroxide to the mixtures. Monitoring the extent of particle dispersion over time in dissolution media under non-sink conditions demonstrated an increasing trend in dispersion during the first 12 minutes for the ternary mixtures containing 5-15% aluminium hydroxide; however, no change in the degree of dispersion was observed for the mixture incorporating micronized aluminium hydroxide particles. The underlying mechanisms of dissolution were elucidated and quantified by development of a mechanism-based compartmental model. A series of 5 transit compartments included into the model successfully described the slow initial dissolution rate of the indomethacin mixtures. More importantly, this indicated that agglomerates had inter-converted to dispersed particles; the mean dissolution time of the dispersed particles decreased with the addition of aluminium hydroxide to the binary mixtures. For the ternary mixtures incorporating at least 10% aluminium hydroxide, the faster dissolution was attributed to lower mean de-agglomeration times and reduced initial concentrations of agglomerates compared with the binary mixture. This supported the hypothesized phenomenon of the role of aluminium hydroxide in enhancing the de-agglomeration of cohesive indomethacin powders. Dry coating micronized powders of indomethacin with magnesium stearate (0.25, 1, 5%) and sodium stearate (5%) by mechanofusion resulted in significantly reduced intrinsic cohesion. Initial increases in the dissolution of indomethacin were found to be dependent on the concentration of magnesium stearate that was mechanofused onto the drug powders; X-ray photoelectron spectroscopy analysis confirmed a thicker surface coating was achieved with increasing concentrations of the hydrophobic material. The dissolution enhancing effect of the indomethacin powders mechanofused with 5% sodium stearate was attributed to its surfactant properties that increased the dispersion of indomethacin agglomerates. Initial drug release (during the first 10 minutes of the dissolution study) from the coated powders was able to be described by a matrix-diffusion system in accordance with the Higuchi model. Application of these novel and innovative formulation strategies which demonstrated enhanced dissolution of indomethacin would greatly benefit in the development of poorly water-soluble drug formulations with potentially improved oral bioavailability. Master's Thesis from the year 2010 in the subject Medicine - Pharmacology, grade: -, Universtiy of Dhaka (M. Pharm, in Pharmaceutical Technology), language: English, comment: Subrata Bhadra, Lecturer, Department of Pharmaceutical Technology, University of Dhaka, successfully completed his M. Pharm. in Pharmaceutical Technology from the same institute and conducted his thesis under the supervision of Professor Dr. Abu Shara Shamsur Rouf, a renowned scientist and also the co-author of this book. Author research interests lie primarily in the area of design and fabrication of sustained release solid dosage form, and development and validation of analytical methods., abstract: The aim of the present studies was to develop and characterize 2.6 mg sustained release matrix tablets of Nitroglycerin. Tablets were prepared by direct compression method. Methocel K15M CR and Methocel K100LV CR polymers were used as rate retarding agents in nine formulations (F-1 to F-9). The granules were evaluated for angle of repose, loose bulk density, tapped bulk density, Carr's index, Hausner ratio, moisture content, total porosity and assay. The tablets were subjected to diameter, thickness, assay, uniformity of content, assay after 1Month at 40 C+75%RH, hardness, friability, and in vitro dissolution studies. The granules showed satisfactory flow properties, compressibility, and drug content. All the tablet formulations showed acceptable pharmacotechnical properties and complied with pharmacopoeial specifications for tested parameters. The in vitro dissolution study was carried out for 8 hour using USP-2009 Apparatus-I (Rotating

basket method) in distilled water as the dissolution medium. The release mechanisms were explored and explained by Zero order, First order, Higuchi, Korsmeyer-Peppas and Hixson-Crowell equations. Nine formulations were prepared by using three variable ratio of two polymers; Methocel K15M CR (25%, 20% and 15%) and Methocel K100LV CR (15%, 10% and 5%) where all th Introduction, Historical Highlights, and the Need for Dissolution Testing Theories of Dissolution Dissolution Testing Devices Automation in Dissolution Testing, by William A. Hanson and Albertha M. Paul Factors That Influence Dissolution Testing Interpretation of Dissolution Rate Data Techniques and of In Vivo Dissolution, by Umesh V. Banakar, Chetan D. Lathia, and John H. Wood Dissolution of Dosage Forms Dissolution of Modified-Release Dosage Forms Dissolution and Bioavailability Dissolution Testing and the Assessment of Bioavailability/Bioequivalence, by Santosh J. Vetticaden Dissolution Rediscovered, by John H. Wood Appendix: USP/NF Dissolution Test. Till date, pursuit for cost effective and animal sparing colon specific bio-relevant dissolution media has been a foremost challenge facing pharmaceutical scientists over many decades.It is problematic to mimic the dynamic and ecologically diverse features of the colon in dissolution vessel.With the knowledge of enormous colonic microflora, the predominant species Bacteroides, Bifidobacterium, Eubacterium, Streptococcus and Lactobacillus species were cultured in 12% w/v skimmed milk powder and 5%w/v grade "A" honey. Probiotic culture was added to the dissolution media in order to test the drug release of polysaccharide based formulations. USP dissolution apparatus I/II with gradient pH dissolution method were used to evaluate the drug release from formulations meant for colonic drug delivery. Drug release from 5-fluorouracil granules and metronidazole tablets were assed under gastric, small intestine conditions and also within a simulated colonic environment involving existing rat caecal, human fecal media and compared with novel probiotic media. The present method can be successfully applied for the drug release testing of any oral formulations meant for colonic delivery. Dissolution has emerged as a key method during development of medicines and for quality control of marketed products. At the early stage of development, dissolution guides the selection of toxicology and first test in man formulations. At later stages of development, dissolution tests are performed to compare prototype formulations, the robustness of the manufacturing process, to indicate stability and to assure safe release and reproductibility of the products to the market. However despite they wide use in pharmaceutical development, several challenges still exist. In particular, there is a lack of thorough identification and understanding of the critical quality attributes that control dissolution of Active Pharmaceutical Ingredient and Drug Product. Dissolution exhibits clearly a higher predictability if it can be extrapolated directly to in vivo behavior. Thepresent work focuses on the optimization of the existing and alternative dissolution techniques to lay a foundation for Quality by Design (QbD) principles, In Vitro/In Vivo Correlation (IVIVC) and In Vitro/In Vivo Relationship (IVIVR). The dissolution applied on API and on differente formulations types (Immediate release and extended release form) during the different development phases as well as for generic has been explored. Simple and cost effective dissolution methods were shown to be potential surrogate for in vivo performance and serve as well for strong quality control method. The future perspectives and central role of dissolution testing are presented and discussed. 1. Evolution of dissolution testing 5; 2. Theory of dissolution 11; 3. Theoretical concepts for the release of a drug from dosage forms 37; 4. Effect of the physicochemical properties of the drug on dissolution rate 53; 5. Factors affecting the rate of dissolution of solid dosage forms 73; 6. Effects of storage and packaging on the dissolution of drug formulations 107; 7. Factors relating to the dissolution apparatus 115; 8. Effect of the test parameters on dissolution rate 145; 9. Dissolution of suspensions 173; 10. Dissolution of topical dosage forms (creams, gels, and ointments) 189; 11. Dissolutions of suppositories 205; 12. Dissolution characteristics of controlled-release systems 215; 13. Methods for enhancement of the drug-dissolution characteristics 265; 14. Developing a new dissolution method 285; 15. Bioavailability, definitions and historical perspective 297; 17. In vitro modeling for drug absorption 315; 18. Pharmacokinetic considerations in bioavailability studies 335; 19. Bioavailability and variations in drug blood levels 367; 20. Bioavailability and the biologic response 385; 21. Measurements of bioavailability 399; 22. General issues to be considered in conducting bioavailability studies 415; 23. Bioavailability of controlled-release dosage forms 425; 24. In vivo release and bioavailability of topical preparations 437; 25. Methods for enhancement of bioavailability 455; 26. Bioequivalence: general definitions 477; 27. Bioequivalence: case histories 481; 28. Correlation of in vitro rate of dissolution with in vivo bioavailability 491; 29. Determination of bioequivalence and its regulatory aspects 517; 30. The official bioequivalence protocols and therapeutic equivalence 533. Summary Solid dispersions are a promising approach for controlled release drug delivery systems as both the bioavailability enhancement of poorly water-soluble drugs as well as the sustained release of water-soluble drugs are possible to optimize their in vivo performance. Different methods for the manufacture of solid dispersion systems have been introduced in literature. In the present work, two methods are compared: hot-melt extrusion and ultrasound-assisted compaction technique. Various carrier systems and drugs with different physicochemical properties are applied to investigate the feasibility of the technologies for pharmaceutical formulation. The formulations are compared to the corresponding untreated physical blends of the components regarding their solid state structure and dissolution behavior to assess the effect of the manufacturing technique. Ultrasound-assisted compaction technique improves the initial dissolution rate of fenofibrate, a poorly water-soluble model drug. The crystalline API is partially converted into its amorphous state. As equivalent results can be achieved if the polymers are added directly to the dissolution medium, the dissolution enhancement is attributed to an improved wettability of the drug. A statistical design of experiments is employed to investigate the effect of the process parameters on the results. Difficulties are encountered in the determination of process parameters which result in an optimal outcome. The process is very sensitive to the smallest changes of settings, for example of the position of the sonotrode. Additionally, the delivery of ultrasound energy is inhomogeneous. There is no or only insufficient user control of these parameters available. Furthermore, the duration of ultrasound energy delivery which is identified as a crucial parameter cannot be set by the user. The variable factors ultrasound energy, pressure of the lower piston and pressure of the upper piston affect the defined responses in the opposite direction. Hence, there are no settings which result in a satisfactory outcome. A strong influence of the material characteristics on the process is observed leading to a batch to batch variability. Due to an insufficient reproducibility of results, the application of the technology cannot be recommended in its current state in the pharmaceutical formulation development and/or production. Improvements in homogeneity of energy delivery, process monitoring, user control and amount of leakage are mandatory for an acceptable performance and a future application in the pharmaceutical sector. The polymers COP, HPMC and PVCL-PVAc-PEG are well suitable as carriers for hot-melt extruded formulations of fenofibrate. All three extrudates are amorphous one-phase systems with the drug molecularly dispersed in the polymer. The enhancement of the initial dissolution rate and the maximum concentration level achieved are dependent on the applied carrier system. Supersaturation levels of up to 12.1 times are reached which are not stable due to recrystallization processes. The application of blends of polymers as carriers reduces the decrease rate after cmax. Because of water absorption and polymer relaxation, the overall dissolution performance decreases with increasing storage times which can be avoided through an optimization of the packaging. If oxeglitazar is used as API, the initial dissolution rate of the extrudates is below that of the untreated drug, with the exception of the ternary blend of COP, HPMC and oxeglitazar which shows a substance-specific super-additive effect. In contrast to the other extrudates, the formulation of PVCL-PVAc-PEG and oxeglitazar does not form a molecularly dispersed solid solution of the drug in the carrier. Instead, an amorphous two-phase system is present. No changes are observed after storage, presumably due to higher glass transition temperatures of the hot-melt extruded systems which are considerably above those of the corresponding fenofibrate extrudates. With felodipine as API, the dissolution profile is enhanced with COP as single carrier. If HPMC or PVCL-PVAc-PEG is used as single or additional polymeric carriers, the dissolution is equivalent (HPMC) or lower (PVCL-PVAc-PEG) than that of the pure drug although molecularly disperse systems are present in all cases. Out of the two investigated methods only hot-melt extrusion is a suitable technology to manufacture solid dispersions with an improved dissolution behavior. The dissolution profile of the extrudates can be influenced by adding polymers with differing physicochemical characteristics. Predictions on the dissolution behavior of the extrudates with polymeric blends as carriers can be made if there is knowledge on the dissolution profiles of the corresponding single polymeric extrudates. Due to substance-specific effects, the results are not transferable from drug to drug. Even so, the data are promising as the release behavior of the manufactured extrudates can be easily modified and readily adapted to one's needs. Further research will have to be conducted to verify the concept and the relevance of the results in vivo. Zusammenfassung Feste Dispersionen sind ein vielversprechender Ansatz zur Herstellung von Drug Delivery-Systemen mit kontrollierter Wirkstofffreisetzung, da sie sowohl die Bioverfügbarkeit schlecht wasserlöslicher Arzneistoffe verbessern als auch die Freisetzung gut wasserlöslicher Arzneistoffe verzögern können und so deren in vivo Verhalten optimieren. Verschiedene Herstellungsmethoden wurden in der Literatur vorgestellt. In der vorliegenden Arbeit werden zwei Technologien miteinander verglichen: Schmelzextrusion und Ultraschall gestützte Verpressung (USAC). Verschiedene Trägersysteme und Arzneistoffe mit unterschiedlichen physikochemischen Eigenschaften werden untersucht, um die Einsatzmöglichkeit im pharmazeutischen Bereich zu überprüfen. Die Struktur der hergestellten Systeme und deren Freisetzungsverhalten werden mit den physikalischen Mischungen der Komponenten verglichen, um den Einfluss der Formulierung zu bestimmen. Durch USAC wird die initiale Freisetzungsrate von Fenofibrat, einem schlecht wasserlöslichen Modellarzneistoff, verbessert. Eine teilweise Umwandlung vom kristallinen in den amorphen Zustand tritt auf. Vergleichbare Ergebnisse werden bei einer Polymerzugabe zum Freisetzungsmedium erreicht; daher wird davon ausgegangen, dass vor allem eine verbesserte Benetzbarkeit des Arzneistoffs eine Rolle spielt. Mittels statistischer Versuchsplanung wird der Einfluss der verschiedenen Prozessparameter untersucht. Die Einstellung der Prozessparameter, um ein optimales Ergebnis zu erhalten, gestaltet sich schwierig. Der Prozess reagiert auf kleinste Veränderungen, zum Beispiel der Position der Sonotrode, überaus sensitiv. Außerdem wird die Ultraschallenergie nicht homogen übertragen. Die Kontrolle dieser Parameter durch den Anwender ist nicht oder nur unzureichend möglich. Ebenso kann die Dauer der Ultraschallapplizierung, die essentiell für den Prozess ist, nicht eingestellt werden. Die Prozessparameter Ultraschallenergie, Unterstempeldruck und Sonotrodendruck beeinflussen die Zielgrößen in entgegengesetzter Richtung. Daher gibt es keine Einstellung, die für alle Zielgrößen optimale Ergebnisse liefert. Zusätzlich ist der Prozess stark abhängig von den Eigenschaften des verwendeten Materials: Die Verwendung unterschiedlicher Polymerchargen macht eine Anpassung der Prozessparameter notwendig, um vergleichbare Ergebnisse zu erhalten. Eine ausreichende Reproduzierbarkeit der Ergebnisse für einen Einsatz dieser Technologie in Formulierungsentwicklung oder Produktion ist nicht gegeben. Eine homogene Ultraschallenergiezufuhr sowie Verbesserungen der Prozessüberwachung, der Benutzerkontrolle und eine Verminderung der austretenden Materialmenge sind für eine akzeptable Leistung und eine zukünftige Anwendung im pharmazeutischen Bereich zwingend erforderlich. Die Polymere COP, HPMC, PVCL-PVAc-PEG sind für eine Freisetzungsverbesserung von Fenofibrat mittels Schmelzextrusion geeignet. Es liegen einphasige, molekulardisperse feste Lösungen vor. Abhängig von der Trägersubstanz wird die initiale Freisetzungsrate unterschiedlich stark erhöht, ebenso die maximale Konzentration des Arzneistoffes in Lösung. Eine bis zu 12.1-fache Übersättigung wird erreicht, die aufgrund von Rekristallisationsprozessen nicht stabil ist. Der Einsatz von polymeren Mischungen reduziert die Geschwindigkeit des Konzentrationsabfalls. Die Absorption von Wasser und Relaxationseffekte vermindern die Freisetzungserhöhung mit zunehmender Lagerdauer; dieser Entwicklung kann durch eine Optimierung des Packmittels entgegengewirkt werden. Wird der ebenfalls schwer wasserlösliche Arzneistoff Oxeglitazar verwendet, so ist die initiale Freisetzungsrate der Extrudate der des reinen Arzneistoffs unterlegen, mit Ausnahme der ternären Mischung von COP, HPMC und Oxeglitazar, die einen substanzspezifischen überadditiven Effekt aufweist. PVCL-PVAc-PEG-Oxeglitazar-Extrudate bilden im Gegensatz zu den übrigen Formulierungen keine molekulardisperse feste Lösung, sondern ein amorphes Zwei-Phasen-System. Eine Veränderung während der Lagerzeit wird nicht beobachtet, vermutlich aufgrund der höheren Glasübergangstemperaturen dieser Systeme. Lediglich das Freisetzungsprofil von COP-Felodipin-Extrudaten ist verbessert. Gegenüber dem reinen Arzneistoff ist die Freisetzung der übrigen Extrudate vergleichbar (HPMC) oder verringert (PVCL-PVAc-PEG), obwohl auch hier molekulardisperse Systeme vorliegen. Von den beiden untersuchten Technologien ist lediglich die Schmelzextrusion geeignet, um feste Dispersionen mit einem verbesserten Freisetzungsverhalten herzustellen. Das Freisetzungsprofil der Extrudate kann durch den Zusatz von Polymeren mit unterschiedlichen Eigenschaften optimiert und vorhergesagt werden, wenn das Freisetzungsprofil der Einzelpolymer-Extrudate bekannt ist. Die Ergebnisse sind aufgrund von substanzspezifischen Effekten nicht von Arzneistoff auf Arzneistoff übertragbar. Nichtsdestotrotz sind die Erkenntnisse dieser Arbeit vielversprechend, da gezeigt wird, dass das Freisetzungsprofil der Extrudate leicht beeinflusst und an spezifische Anforderungen angepasst werden kann. Weitere Untersuchungen sind notwendig, um das Konzept und die Relevanz der Ergebnisse in vivo zu überprüfen. The pharmaceutical industry is at a critical juncture. With little remnants of the "Golden Age of the Pharmaceuticals" and applied pressure from large companies experiencing a dissipation of proprietary compounds, trends indicate a transition from a decade of stagnant productivity to one in which high throughput screening technologies and computational chemistry have diversified the discovery of new chemical entities (NCE). Despite these advances, drug discovery has been challenged by chemical entities that present delivery limitations due to the properties of their molecular structure. A recent evaluation of development pipelines indicated that approximately 70% of drug candidates exhibit poor aqueous solubility; thereby, resulting in erratic dissolution and insufficient bioavailability. Due to intrinsic physical properties, these compounds are known by the biopharmaceutics classification system (BCS) as class II compounds and are amendable to solubility and bioavailability enhancement platforms. Approaches such as pH adjustment, micronization, nanosuspensions, co-solvent solubilization, cyclodextrin inclusion complexation, salt formation, emulsified drug formulations and amorphous solid dispersions (ASD) are commonly utilized to maximize bioavailability and enrich in vivo absorption by prolonging exposure to high concentrations of dissolved drug in the gastrointestinal tract (GIT). Single-phase amorphous systems, such as solid dispersions, have been the focal point of the aforementioned practices as a result of their ability to promote a state of drug supersaturation over an extended duration of time. Within the structure of this dissertation, the application of concentration enhancing polymers for bioavailability enhancement of low solubility compounds was evaluated using solvent and fusion-based solid dispersion technologies. Exploiting a variety of analytical methodologies and tools, formulations produced by spray drying and hot melt extrusion (HME) techniques were investigated for sufficient dissolution enhancement. Studies revealed the selected formulation approaches provided a viable platform for manufacturing solid dispersions by illustrating systems that offered rapid and prolonged periods of supersaturation. While of the applications of single-phase amorphous solid dispersions are continuously expanding, their dissolution behavior is not as well understood. The overarching objective of dissolution testing during formulation development is to achieve biological relevance and predict in vivo performance. Proper in vitro dissolution testing can convey the influence of key in vivo performance parameters and be implemented for assessment and comparison of ASD formulations. Studies suggest that existing research fails to accurately address the intricacies associated with the supersaturated state. Upon solvation and during transit in the GIT, several high-energy drug-containing species are present in addition to free drug. Although these species are not absorbed in vivo, they play a pivotal role in generating and maintaining the supersaturation of a drug substance and function to replenish the supply of free drug as it permeates across the gastrointestinal membrane. Established dissolution apparatuses and methodologies in the United States Pharmacopeia (USP) focus on evaluation of total dissolved drug and may not be physiologically relevant for determining the amount of drug absorbed in vivo. Within the framework of this dissertation, a dissolution methodology was designed to reflect the physiochemical, physiological and hydrodynamic conditions that transpire throughout dissolution and absorption of an ASD during transit in the GIT. The apparatus and model present the ability to understand the kinetics and mechanisms of dissolution, supersaturation and nucleation. To support this hypothesis, analytical methods including high pressure liquid chromatography (HPLC) with ultraviolet (UV) detection were developed and fully validated. In parallel, a novel plasma membrane treatment was established to fabricate biomimetic membranes that possessed a hydrophilic and hydrophobic surface. The treated membranes are comprised of applied surface chemistries that emulate the unstirred aqueous layer created by microvilli protruding from the intestinal epithelial membrane as well as lipophilic constituents corresponding to the epithelial lipid membrane. Calculated in vitro similarity (f2) and difference (f1) factors support the hypotheses that plasma treated microporous polymer membranes exhibit biorelevant properties and demonstrate adequate biorelevance for in vitro dissolution studies. The described dissolution methodology has been applied as a tool for selection of candidates to move forward to pharmacokinetic studies. In a culminating study, in vitro - in vivo correlations (IVIVC) were performed employing the universal membrane-permeation non-sink dissolution method for formulations of Carbamazepine. To demonstrate the utility of the methodology, multiple level C correlations were established. The membrane-permeation model enables quantitative assessment of drug dissolution and absorption and offers a means to predict the relative in vivo performance of amorphous solid dispersions for BCS class II drug substances. The best means of selective dissolution of ordinary portland cement (OPC) from ground granulated blast-furnace slag (BFS) cements has been, until now, a sodium-based alkaline aqueous solution of ethylenediamine-tetraacetate with chelating properties supplemented by the presence of 6% triethanolamine (TEA). Explore the cutting-edge of dissolution testing in an authoritative, one-stop resource In Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence: Science, Applications, and Beyond, distinguished pharmaceutical advisor and consultant Dr. Umesh Banakar delivers a comprehensive and up-to-date reference covering the established and emerging roles of dissolution testing in pharmaceutical drug development. After discussing the fundamentals of the subject, the included resources go on to explore common testing practices and methods, along with their associated challenges and issues, in the drug development life cycle. Over 19 chapters and 1100 references allow practicing scientists to fully understand the role of dissolution, apart from mere quality control. Readers will discover a wide range of topics, including automation, generic and biosimilar drug development, patents, and clinical safety. This volume offers a one-stop resource for information otherwise scattered amongst several different regulatory regimes. It also includes: A thorough introduction to the fundamentals and essential applications of pharmaceutical dissolution testing Comprehensive explorations of the foundations and drug development applications of bioavailability and bioequivalence Practical discussions about solubility, dissolution, permeability, and classification systems in drug development In-depth examinations of the mechanics of dissolution, including mathematical models and simulations An elaborate assessment of biophysiologically relevant dissolution testing and IVIVCs, and their unique applications A complete understanding of the methods, requirements, and global regulatory expectations pertaining to dissolution testing of generic drug products Ideal for drug product development and formulation scientists, quality control and assurance professionals, and regulators, Pharmaceutical Dissolution Testing, Bioavailability, and Bioequivalence is also the perfect resource for intellectual property assessors. Dissolution testing is widely used in the pharmaceutical industry to evaluate newly developed drug formulations and as a quality control method to insure that solid dosage forms have consistent dissolution property. Typically, samples are manually drawn from the dissolution vessel prior to analysis. An approach to overcome the limitations of manual sampling consists in the use of sampling probes, such as fiber optic probes, permanently inserted in the dissolution medium and continually sampling the drug concentration in it as the solid dosage form dissolves. Despite their advantages, permanently inserted fiber optic probes can alter the normal fluid flow within the vessel and produce different dissolution testing results. In this study, the hydrodynamic effects introduced by an arch-shaped fiber optic probe in a USP Dissolution Testing Apparatus 2 are studied by: (1) conducting dissolution tests, with and without the probe, using Prednisone tablets fixed at nine different locations at the bottom of the vessel and comparing the dissolution profiles obtained using statistical tools; and (2) experimentally determining the velocity profiles in the vessel, with and without the probe, using Particle Image Velocimetry (PIV) and quantifying changes in the flow velocities on selected horizontal iso-surfaces. The results show that the arch shaped fiber optic probe does have a baffling effect on the hydrodynamics in the dissolution vessel. This effect results in changes in the velocities in the fluid flow, and therefore in changes in the dissolution rate of the tablets undergoing testing. The baffle effect is observed mainly in the region where the probe is inserted. However, this perturbation is also found to reach the region below the impeller and to change the velocity profile there, resulting in differences in dissolution profiles when the tablets are fixed at positions that are downstream of the probe and within the low velocity region below the impeller. On the other hand, the hydrodynamic effect generated by the probe does not appear to be particularly strong. In most dissolution testing runs, the changes in dissolution profile are not large enough to fail the tests, according to the FDA criteria (f1 and f2 values). The PIV

measurements additionally show that the baffle effect is not strong enough to break the overall flow pattern, or to affect the region around the impeller, which is dominated by the main flow generated by the impeller. It can be concluded that the hydrodynamic effects generated by the arch-shaped fiber optic probe are real and observable, resulting in slightly modification of the fluid flow in the dissolution vessel and therefore in detectable differences in the dissolution profiles. However, these effects are limited and do not typically lead to dissolution testing failures. For each sludge batch that is processed in the Defense Waste Processing Facility (DWPF), the Savannah River National Laboratory (SRNL) tests the applicability of the digestion methods used by the DWPF Laboratory for elemental analysis of Sludge Receipt and Adjustment Tank (SRAT) Receipt samples and SRAT Product process control samples. DWPF SRAT samples are typically dissolved using a method referred to as the DWPF Cold Chemical or Cold Chem Method (CC), (see DWPF Procedure SW4- 15.201). Testing indicates that the CC method produced mixed results. The CC method did not result in complete dissolution of either the SRAT Receipt or SRAT Product with some fine, dark solids remaining. However, elemental analyses did not reveal extreme biases for the major elements in the sludge when compared with analyses obtained following dissolution by hot aqua regia (AR) or sodium peroxide fusion (PF) methods. The CC elemental analyses agreed with the AR and PF methods well enough that it should be adequate for routine process control analyses in the DWPF after much more extensive side-by-side tests of the CC method and the PF method are performed on the first 10 SRAT cycles of the Sludge Batch 9 (SB9) campaign. The DWPF Laboratory should continue with their plans for further tests of the CC method during these 10 SRAT cycles. The aim of this study was to develop ritonavir amorphous solid dispersion (ASD) formulation, investigate its aqueous dissolution and dispersion behavior, and predict potential pharmacokinetic parameters by in-silico modeling. The binary/ternary ASDs of ritonavir with PVPVA or HPMCAS-MG in the absence or presence of surfactants were prepared by using the hot-melt extrusion method. The amount of ritonavir was fixed at 20 %w/w, while amount of polymer and surfactant in the formulation was varied. The film-casting technique was used to confirm the miscibility of drug and polymer in the absence and presence of surfactant in different formulations. PXRD and DSC analyze were carried out to determine solid state properties of the neat ritonavir and solid dispersion formulations prior to conducting dissolution and dispersion testing. All in-vitro dissolution and dispersion studies were performed under non-sink condition at pH 2 (0.01N HCl), pH 4.5 (acetate buffer), and pH 6.8 (phosphate buffer), as well as in a biorelevant medium (FeSSIF-V2). Particle size analysis of the dispersed phase after dispersion of the extrudates in aqueous media was carried out in-line using a particle size analyzer. Raman spectroscopy coupling with chemometrics method was used to identify the polymorphic form of the precipitates from the extrudates after exposing to dissolution medium. The software simulation was then carried out to predict the oral absorption based on in-vitro studies. Stability studies of the ASDs were carried out at 25°C/60%RH for 1 year and 40°C/75%RH for 1 month. Ritonavir, 20%w/w, was found to be miscible with various ratios of polymers and surfactants used. Supersaturated solutions were formed and the supersaturation was maintained throughout 2 h of dissolution testing. However, above certain concentration in dissolution media, ritonavir phase separated and formed milky dispersions. Particle size analysis of the dispersed phase revealed that nano/micro particles were generated by all ASD formulations. The biorelevant media provided much higher drug dissolution as compared to that in standard phosphate buffer medium. The slurries from the extrudates containing ritonavir:PVPVA:sorbitan monolaurate at 20:70:10 % w/w revealed that mixtures of amorphous and crystalline of ritonavir were present. The predicted fraction absorbed ranged from 65 to 90%. In the solid state, all ASDs did not show any ritonavir crystallization under both the stability testing conditions. In the present study, various factors influencing formulations, physical stability and drug release of ASDs of ritonavir were studied. It was observed that there was a good correlation between in-vitro dissolution, in-line particle size monitoring and in-silico modeling which can served as a predictive tool in pharmaceutical development of the ASD for ritonavir as well as other poorly water-soluble drugs. The dissolution and dispersion testing using biorelevant media provided more accurate results on the behavior of the drug formulation than only the result from dissolution testing in standard buffers. An expertly written source on the devices, systems, and technologies used in the dissolution testing of oral pharmaceutical dosage forms, this reference provides reader-friendly chapters on currently utilized equipment, equipment qualification, consideration of the gastrointestinal physiology in test design, the analysis and interpretation of data and procedure automation -laying the foundation for the creation of appropriate and useful dissolution tests according to the anticipated location and duration of drug release from the dosage form within the gastrointestinal tract. Dissolution testing is a critical step in quality control of manufactured final products in the pharmaceutical industry. The United State Pharmacopeia (USP) Dissolution Testing Apparatus 2 (paddle) is the most widely used dissolution test devices in the pharmaceutical industry to formulate solid drug dosage forms and to develop quality control specifications for its manufacturing process. Mini vessels and mini paddle dissolution testing systems are smaller versions of the USP 2 Apparatus. The concept of the mini paddle apparatus is similar to that of the USP 2 setup but it is scaled down about to 1/5 of the volume and 40% with respect to vessel and impeller sizes. Mini vessel systems, requiring a small volume (200 mL) and a mini paddle impeller, are becoming increasing common in the pharmaceutical industry to overcome the limitations associated with the USP 2 dissolution testing method, especially for dissolution testing involving very small tablets. Mini apparatuses can be useful tools in characterizing drug release profiles since smaller sample sizes and smaller volumes of media are needed, thus offering several advantages in terms of substance, analytical, and material cost savings when evaluating release properties of drug candidates.Despite their increasing importance in dissolution testing, little information is currently available on mini vessels, and especially on the agitation speed needed to prevent "coning" effects. Typically during dissolution testing, a disintegrating tablet becomes rapidly fragmented, and the resulting solid particles may or may not become suspended depending on the agitation speed of the paddle and other geometric and operating parameters "Coning" (the accumulation of particle fragments from a disintegrating tablet) often appears in dissolution testing but can be eliminated by increasing the agitation speed N. Therefore, it is important to be able to predict the minimum rotation speed at which coning phenomena disappears in a dissolution testing system and especially in mini vessels systems.The focus of this work was the determination of the minimum agitation speed, Njs, at which the just suspended state by dispersed particles is achieved in a mini paddle system (thus removing "coning" effects). In the past, Njs, has been experimentally obtained in mixing systems by determining the agitation speed at which no particles are visually observed to be at rest on the vessel bottom for more than one to two seconds. Therefore, the first objective of this work was to develop an observer-independent method to measure experimentally Njs. This was achieved by extending to mini vessel a method that was recently developed in our laboratory and that is based on the determination of the fraction of unsuspended solids in the vessel at different agitation speed (Njs-Ds method). The results of this method agree well the visually observable values of Njs(Njs-visual).Once new method was validated in mini vessels, Njs was experimentally measured using well characterized solid particles under a number of operating conditions, such as liquid level-to-vessel diameter ratio (H/T), particle size (dp), and paddle clearance-to-vessel diameter ratio Cb/T). The results could be interpreted using the Zwietering Equation originally developed for solids suspension in baffled stirred tanks. The Zwietering "S" parameter was obtained for the mini vessel system thus enabling the use of this equation to predict when "coning" effects can be eliminated in mini vessel systems during tablet dissolution testing. This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations. Such drug products are, vis-à-vis their physical and chemical properties, inherently incompatible with aqueous dissolution. However, dissolution methods are required for product development and selection, as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding. The percentage of poorly soluble drugs, defined in classes 2 and 4 of the Biopharmaceutics Classification System (BCS), has significantly increased in the modern pharmaceutical development pipeline. This book provides a thorough exposition of general method development strategies for such drugs, including instrumentation and media selection, the use of compendial and non-compendial techniques in product development, and phase-appropriate approaches to dissolution development. Emerging topics in the field of dissolution are also discussed, including biorelevant and biphasic dissolution, the use on enzymes in dissolution testing, dissolution of suspensions, and drug release of non-oral products. Of particular interest to the industrial pharmaceutical professional, a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies, including nanosuspensions, lipid-based formulations, and stabilized amorphous drug formulations.