Dissolution Techniques For Evaluation Of Novel Drug
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Acid Dissolution Method for the Analysis of Plutonium in Soil

Fast Dissolving/Disintegrating Dosage Forms (FDDFs) have been commercially available since the late 1990s. FDDFs were initially available as orodispersible tablets, and later, as orodispersible films for treating specific populations (pediatrics, geriatrics, and psychiatric patients). Granules, pellets and mini tablets are among latest additions to these dosage forms, which are still in the development pipeline. As drug delivery systems, FDDFs enable quicker onset of action, immediate drug delivery, and sometimes offer bioavailability benefits due to buccal/sublingual absorption. With time, FDDF have evolved to deliver drugs in a sustained and controlled manner. Their current market and application is increasing in demands with advances in age adapted dosage forms for different patients and changing regulatory requirements that warrant mandatory assessments of new drugs and drug products before commercial availability. This book presents detailed information about FDDFs from their inception to recent developments. Readers will learn about the technical details of various FDDF manufacturing methods, formulation aspects, evaluation and methods to conduct clinical studies. The authors also give examples of marketed fast disintegrating/dissolving drug products in US, Europe, Japan, and India. This reference is ideal for pharmacology students at all levels seeking information about this specific form of drug delivery and formulation.

The Handbook of Pharmaceutical Controlled Release Technology reviews the design, fabrication, methodology, administration, and classifications of various drug delivery systems, including matrices, and membrane controlled reservoir, bioerodible, and pendant chain systems. Contains cutting-edge research on the controlled delivery of biomolecules! Discussing the advantages and limitations of controlled release systems, the Handbook of Pharmaceutical Controlled Release Technology covers oral, transdermal, parenteral, and implantable delivery of drugs discusses modification methods to achieve desired release kinetics highlights constraints of system design for practical clinical application analyzes diffusion equations and mathematical modeling considers environmental acceptance and tissue compatibility of biopolymeric systems for biologically active agents evaluates polymers as drug delivery carriers describes peptide, protein, micro-, and nanoparticulate release systems examines the cost, comfort, disease control, side effects, and patient compliance of numerous delivery systems and devices and more!

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

Dissolution experiments were conducted on radioactive sludge from Tank 7, before transfer of the contents of Tank 7 to Tank 51, and the subsequent sludge in Tank 51 to evaluate the effectiveness of the DWPF Cold Chem Method. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a room temperature Dissolution operation. The DWPF Cold Chem Method is a...
Experiments were performed with non-radioactive sludge to determine if the room temperature HF-MN03 dissolution method used in the DWPF on the Slurry Receipt and Adjustment Tank samples will be effective on the Sludge Batch 3 feed that contains Tank 7 sludge. This dissolution method is particularly rapid and convenient and has been used in the DWPF for several years to minimize analytical turnaround times.

Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in chronological order with comprehensive design of experiments based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

Liquid Waste Organization (LWO) identified aluminum dissolution as a method to mitigate the effect of having about 50% more solids in High Level Waste (HLW) sludge than previously planned. Previous aluminum dissolution performed in a HLW tank in 1982 was performed at approximately 85 C for 5 days, which became the baseline aluminum dissolution process. LWO initiated a project to modify a waste tank to meet these requirements. Subsequent to an alternative evaluation, LWO modified the tank to allow for aluminum dissolution on sludge destined for Sludge Batch 5, but within a limited window that would not allow time for any modifications for tank heating. A variation of the baseline process, dubbed Low Temperature Aluminum Dissolution (LTAD), was developed based on the constraint of available energy input in Tank 51 and the window of opportunity, but was not constrained to a minimum extent of dissolution. ltad was dissolved as a much amount as possible within the time available. This process was intended to operate between 55 and 70 C, but for a significantly longer time than the baseline process. LTAD proceeded in parallel with the baseline project. The preliminary evaluation at the completion of LTAD focused on the material balance and extent of the aluminum dissolved. The range of values of extent of dissolution, 56% to 64%, resulted from the variation in liquid phase sample data available at the time. Additional solid phase data is available from a sample taken after LTAD to refine this range. This report provides additional detailed evaluation of the LTAD process based on analytical and field data and includes: a summary of the process chronology; a determination of an acceptable blending strategy for the aluminum-laden supernate stored in Tank 11; an update to the determination of aluminum dissolved using more complete sample results; a determination of the effect of LTAD on uranium, plutonium, and other metals; a determination of the rate of heat loss from a quiescent tank; and an evaluation of the aluminum dissolution rate model and actual dissolution rate. LTAD was successfully completed in Tank 51 with minimal waste tank changes. The following general conclusions may be drawn about the LTAD process: (1) Dissolution at about 60 C for 46 days dissolved 64% of the aluminum from the sludge slurry. (2) The aluminum-laden leach solution decanted to Tank 11 can be blended with a wide variety of supernates without risk of precipitating the dissolved aluminum based on thermodynamic chemical equilibrium models. (3) Uranium and plutonium leached into solution without corresponding leaching of iron or manganese. (4) The concentration of the total uranium and plutonium in the leach solution was indistinguishable from other tank farm supernates, thus, the leach solutions can be managed relative to the risk of criticality like any other supernate. (5) A small amount of mercury leached into solution from the sludge causing the liquid phase concentration to increase to 6 to 10 fold, which is consistent with the 4 to 14 fold increase observed during the 1982 aluminum dissolution demonstration. (6) Chromium did not dissolve during LTAD. (7) Chloride concentration increased in the liquid phase during LTAD due to chloride contamination in the 50% sodium hydroxide solution. (8) The rate of heat loss from Tank 51 at temperatures above 45 C appeared linear and predictable at 8E+7 cal/hr. (9) The rate of heat transfer from Tank 51 did not follow a simplified bulk heat transfer model. (10) Prediction of the aluminum dissolution rate was prone to error due to a lack of active specific surface area data of sludge particles. (11) The higher than expected dissolution rate during LTAD was likely due to smaller than expected particle sizes of most of the sludge particles. While evaluating the LTAD process, the decanted salt solution from Tank 41 that was stored and sampled in Tank 49 was determined to be supersaturated relative to aluminum. Supersaturation in Tank 49 is not a risk to LTAD. However, storing and processing of this supernate carries a risk of solids precipitation, primarily in the form of gibbsite or boehmite. Blending with the supernate in Tank 11 neither increases nor decreases this risk. LTAD was initiated as an opportunity to substantially mitigate the planned increase in canister production and DWPF lifetime after the realization of more sludge solids stored in the HLW tanks. As determined from the preliminary evaluation of LTAD, the direct benefit of the decanted liquid stored in Tank 11 represents 45 canisters at 34% waste loading with potential indirect benefits for much larger reductions. Application of an aluminum dissolution process to the remaining high aluminum content sludge will potentially reduce the planned canister production by several hundred canisters at 34%-38% waste loading.

A knowledge of clay is important in many spheres of scientific endeavor, particularly in natural sciences such as geology, mineralogy and soil science, but also in more applied areas like environmental and materials science. Over the last two decades research into clay mineralogy has been strongly influenced by the development and application of a num ber of spectroscopic techniques which are now able to yield information about clay materials at a level of detail that previously would have seemed inconceivable. This information relates not only to the precise characterization of the individual clay components themselves, but also to the ways in which these components interact with a wide range of absorbate molecules. At present, however, the fruits of this research are to be found principally in a somewhat widely dispersed form in the scientific journals, and it was thus considered to be an appropriate time to bring together a compilation of these spectroscopic techniques in a way which would make them more accessible to the non-specialist. This is the primary aim of this book. The authors of the various chapters first describe the principles and instrumentation of the individual spectroscopic techniques, assuming a minimum of prior knowledge, and then go on to show how these methods have been usefully applied to clay mineralogy in its broadest context.

This book is an Up-to-date and authoritative account on physicochemical principles, pharmaceutical and biomedical applications of hydrogels. It consists of eight contributions from different authors highlighting properties and synthesis of hydrogels, their characterization by various instrumental methods of analysis, comprehensive review on stimuli-responsive hydrogels and their diverse applications, and a special section on self-healing hydrogels. Thus, this book will equip academia and industry with adequate basic and applied principles related to hydrogels.
and folding endurance of the film. The responses were analyzed using ANOVA and by the polynomial equation. All the formulations were then evaluated for disintegration time, weight variation, and drug content and dissolution studies. Stability study shows that there was no significant change in physical appearance, disintegration time, thickness, drug content and in vitro drug release of the formulation. Fast dissolving film is an innovative concept for quick release of the drug.

Loratadine is a non sedative anti-histaminic drug. Its major use is in control of congestion, sneezing, runny nose and itching that a patient suffers with an allergic attack or an infection. It has poor solubility in water. Therefore, the solubility and drug release were enhanced using the solid dispersion technique and fast dissolving tablet were formulated. Solid dispersion prepared using Poloxamer 407, PEG 6000 and urea. The solid dispersion were evaluated for saturation solubility, drug content and in vitro dissolution study and it was characterized using FT-IR, X-RD, SEM and DSC study. The fast dissolving tablets of loratadine was formulated using crospovidone and crosscarmellose sodium by direct compression method. The tablets were evaluated for thickness, hardness, weight variation, friability, disintegration time and % in vitro drug release. A 2³ factorial design was used to study the effect of Loratadine: Poloxamer 407 and crospovidone on disintegration time and % in vitro drug release. The responses were analyzed using ANOVA. The obtained model was validated & optimized formulation was prepared as suggested by the software.

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 2500 references allow practising scientists to fully understand the role of dissolution tests 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 edited 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 formulation and drug development and dissolution; 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 biophysically 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; A guide to 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.

Guides readers on the proper use of in vitro drug release methodologies in order to evaluate the performance of special dosage forms. In the last decade, the application of drug release testing has widened to a variety of novel/special dosage forms. In order to predict the in vivo behavior of such dosage forms, the design and development of the in vitro test methods need to take into account various aspects, including the dosage form design and the conditions at the site of application and the site of drug release. This unique book is the first to cover the field of in vitro release testing of special dosage forms in one volume. Featuring contributions from an international team of experts, it presents the state of the art of the use of in vitro drug release methodologies for assessing special dosage forms' performances and describes the different techniques required for each one. In Vitro Drug Release Testing of Special Dosage Forms covers the in vitro release testing of lipid based oral formulations; chewable oral drug products; injectables; drug eluting stents; inhalation products; transdermal formulations; topical formulations; vaginal and rectal delivery systems and ophthalmics. The book concludes with a look at regulatory aspects. Covers both oral and non-oral dosage forms. Describes current regulatory conditions for in vitro drug release testing. Features contributions from well respected global experts in dissolution testing. In Vitro Drug Release Testing of Special Dosage Forms will find a place on the bookshelves of anyone working with special dosage forms, dissolution testing, drug formulation and delivery, pharmacovigilance, and regulatory affairs.

The first edition of Inductively Coupled Plasma Spectrometry anidits Applications was written as a handbook for users who wanted abetter understanding of the theory augmented by a practical insight how best to approach a range of applications, and to provide useful starting point for users trying an approach or technique newto them. These objectives have been retained in the second edition but a slight shift in emphasis gives the volume an overall perspective that is more forward looking. Structured into 11 chapters, the current edition is a thorough revision of the previous book, covering the principles of inductively-coupled plasmas, instrumentation, methodology and applications with environmental analysis, earth science, food science and clinical medicine. Each chapter, written by internationally recognized leaders in their specific subject areas, provides enough detail to be useful to both the new and experienced users. Full account is taken of recent developments, such as high resolution instruments, novel detection systems and electrosparytechniques. Written for all analytical scientists but particularly those involved in atomic spectroscopy and in environmental, geochemical, clinical or food analysis, this timely and informative book will be an essential reference in their use of inductively coupled plasmas to achieve their own scientific goals.

A practical guide to Quality by Design for pharmaceutical product development. Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development; Puts the focus on the industrial aspects of the new QbD approach; Includes several illustrative examples of applications of QbD in practice; Offers advanced specialist topics that can be systematically applied to industry; Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

There are unique challenges in the formulation, manufacture, analytical chemistry, and regulatory requirements of low-dose drugs. This book provides an overview of this specialized field and combines formulation, analytical, and regulatory aspects of low-dose development into a single reference book. It describes analytical methodologies like dissolution testing, solid state NMR, Raman microscopy, and LC-
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MS and presents manufacturing techniques such as granulation, compaction, and compression. Complete with case studies and a discussion of regulatory requirements, this is a core reference for pharmaceutical scientists, regulators, and graduate students.


Master’s Thesis from the year 2010 in the subject Medicine - Pharmacology, University of Dhaka (M. Pharm, in Pharmaceutical Technology, language: English, 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 matrix 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, 3Month, 6Month, 12Month, 18Month, 24Month, hardness, friability, and in vitro dissolution studies. The granules showed satisfactory flow properties, compressibility, and drug content. All the tablet formulations showed acceptable pharmaceutical characteristics and complied with pharmacopeial specifications for tested parameters. The in vitro dissolution study was carried out for 8 hour using USP-2009 Apparatus-(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 varying the variable ratio of (20% and 15%) and (25% and 5%) and all the formulations (F-1 to F-9) contained 0.5% colloidal silicon dioxide and 1% magnesium stearate. Among these nine formulations, six formulations; F-2 (Methocel K15M CR: Methocel K100LV CR = 25% : 10%), F-3 (Methocel K15M CR : Methocel K100LV CR = 25% : 5%), F-4 (Methocel K15M CR : Methocel K100LV CR = 20% : 15%) F-5 (Methocel K15M CR: Methocel K100LV CR = 20% : 10%), F-6 (Methocel K15M CR : Methocel K100LV CR = 20% : 5%) and F-7 (Methocel K15M CR : Methocel K100LV CR = 15% : 15%) met the official specification of release profile. It was also found that the type and the amount of polymers significantly affect the time required for 50% (T50% or MD50) of drug release, release rate constant and diffusion exponent. Higher the MD50 value indicates a higher drug retaining capacity of the polymers and vice-versa. Kinetic modeling of in vitro dissolution profiles revealed the drug release mechanism of all proposed formulations followed anomalous type or non-Fickian transport (n=0.43 and n

Pharmaceutical Preformulation and Formulation: A Practical Guide from Candidate Drug Selection to Commercial Dosage Form reflects the mounting pressure on pharmaceutical companies to accelerate the new drug development and launch process, as well as the shift from developing small molecules to the growth of biopharmaceuticals. The book meets the need for advanced information for drug preformulation and formulation and addresses the current trends in the continually evolving pharmaceutical industry. Topics include: Candidate drug selection Drug Discovery and development Preformulation predictions and drug selections Product design to commercial dosage form Biopharmaceutical support in formulation Development The book is ideal for practitioners working in the pharmaceutical arena—including R&D scientists, technicians, and managers—as well as for undergraduate and postgraduate courses in industrial pharmacy and pharmaceutical technology.

Evaluation of Defense Waste Processing Facility (DWPf) Chemical Process Cell (CPC) cycle time identified several opportunities to improve the CPC processing time. The Mechanical Systems & Custom Equipment Development (MS & CED) Section of the Savannah River National Laboratory (SRNL) recently completed the evaluation of one of these opportunities - the possibility of using an Isolok sampling valve as an alternative to the Hydrgard valve for taking DWPf process samples at the Slurry Mix evaporator (SME). The use of an Isolok for SME sampling has the potential to improve operability, reduce maintenance time, and decrease CPC cycle time. The SME acceptability testing for the Isolok was requested in Task Technical Request (TTR) HLW-DWPf TTR-2010-0036 and was conducted as outlined in Task Technical and Quality Assurance Plan (TTQAP) SRNLRP-2011-0045. RW-033P QA requirements applied to the task, and the results from the investigation were documented in SRNL-STI-2011-00693. Measurement of the chemical composition of study samples was a critical component of the SME acceptability testing of the Isolok. A sampling and analytical plan supported the investigation with the analytical plan directing that the study samples be prepared by a cesium carbonate (Cs2CO3) fusion dissolution method and analyzed by Inductively Coupled Plasma - Optical Emission Spectroscopy (ICP-OES). The use of the cesium carbonate preparation method for the Isolok testing provided an opportunity for an additional assessment of this dissolution method, which is being investigated as a potential replacement for the two methods (i.e., sodium peroxide fusion and mixed acid dissolution) that have been used at the DWPf for the analysis of SME samples. Earlier testing of the Cs2CO3 method yielded promising results which led to a TTR from Savannah River Remediation, LLC (SRR) to SRNL for additional support and an associated TTQAP to direct the SRNL efforts. A technical report resulting from this work was issued that recommended that the mixed acid method be replaced by the Cs2CO3 method for the measurement of magnesium (Mg), sodium (Na), and zirconium (Zr) with additional testing of the method by DWPf Laboratory being needed before further implementation of the Cs2CO3 method at that laboratory. While the SME acceptability testing of the Isolok does not address any of the open issues remaining after the publication of the recommendation for the replacement of the mixed acid method by the Cs2CO3 method (since those issues are to be addressed by the laboratories responsible for the DWPf Laboratory), the Cs2CO3 testing associated with the Isolok testing does provide additional insight into the performance of the method as conducted by SRNL. The performance is to be investigated by looking to the composition measurement data generated by the samples of a standard glass, the Analytical Reference Glass - 1 (ARG-1), that were prepared by the Cs2CO3 method and included in the SME acceptability testing of the Isolok. The measurements of these samples were presented as part of the study results, but no statistical analysis of the measurements was conducted as part of those results. It is the purpose of this report to provide that analysis, which was supported using JMP Version 7.0.2.

Industrial residues are obtained from all treatments of raw materials in industry during the process of mining, raw materials treatment and final usage. During these processes of enrichment, optimization and utilization of raw materials only part of the original material can be used for the dedicated application and some left-over parts remain. This contribution focuses on the development of new materials for the utilization of the left-over parts, especially from the mining industry, where the residues are characterized by a large variety of compositions, and their chemical, physical and mineralogical properties can be identified. Also different characterization methods for analysing the potential for pozzolanes, due to their potential of CO2-reduction, are also included. Based on this knowledge secondary reusable materials due to their evaluation of Defense Waste Processing Facility (DWPf) Chemical Process Cell (CPC) cycle time identified several opportunities to improve the CPC processing time. The Mechanical Systems & Custom Equipment Development (MS & CED) Section of the Savannah River National Laboratory (SRNL) recently completed the evaluation of one of these opportunities - the possibility of using an Isolok sampling valve as an alternative to the Hydrgard valve for taking DWPf process samples at the Slurry Mix evaporator (SME). The use of an Isolok for SME sampling has the potential to improve operability, reduce maintenance time, and decrease CPC cycle time. The SME acceptability testing for the Isolok was requested in Task Technical Request (TTR) HLW-DWPf TTR-2010-0036 and was conducted as outlined in Task Technical and Quality Assurance Plan (TTQAP) SRNLRP-2011-0045. RW-033P QA requirements applied to the task, and the results from the investigation were documented in SRNL-STI-2011-00693. Measurement of the chemical composition of study samples was a critical component of the SME acceptability testing of the Isolok. A sampling and analytical plan supported the investigation with the analytical plan directing that the study samples be prepared by a cesium carbonate (Cs2CO3) fusion dissolution method and analyzed by Inductively Coupled Plasma - Optical Emission Spectroscopy (ICP-OES). The use of the cesium carbonate preparation method for the Isolok testing provided an opportunity for an additional assessment of this dissolution method, which is being investigated as a potential replacement for the two methods (i.e., sodium peroxide fusion and mixed acid dissolution) that have been used at the DWPf for the analysis of SME samples. Earlier testing of the Cs2CO3 method yielded promising results which led to a TTR from Savannah River Remediation, LLC (SRR) to SRNL for additional support and an associated TTQAP to direct the SRNL efforts. A technical report resulting from this work was issued that recommended that the mixed acid method be replaced by the Cs2CO3 method for the measurement of magnesium (Mg), sodium (Na), and zirconium (Zr) with additional testing of the method by DWPf Laboratory being needed before further implementation of the Cs2CO3 method at that laboratory. While the SME acceptability testing of the Isolok does not address any of the open issues remaining after the publication of the recommendation for the replacement of the mixed acid method by the Cs2CO3 method (since those issues are to be addressed by the laboratories responsible for the DWPf Laboratory), the Cs2CO3 testing associated with the Isolok testing does provide additional insight into the performance of the method as conducted by SRNL. The performance is to be investigated by looking to the composition measurement data generated by the samples of a standard glass, the Analytical Reference Glass - 1 (ARG-1), that were prepared by the Cs2CO3 method and included in the SME acceptability testing of the Isolok. The measurements of these samples were presented as part of the study results, but no statistical analysis of the measurements was conducted as part of those results. It is the purpose of this report to provide that analysis, which was supported using JMP Version 7.0.2.

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The ultimate goal of drug product development is to design a system that maximizes the therapeutic potential of the drug substance and facilitates its access to patients. Pharmaceutical Dosage Forms: Tablets, Third Edition is a comprehensive resource of the design, formulation, manufacture, and evaluation of the tablet dosage form, an

Enzymes have interesting applications in our biological system and act as valuable biocatalysts. Their various functions allow enzymes to
develop new drugs, detoxifications, and pharmaceutical chemistry. Research Advancements in Pharmaceutical, Nutritional, and Industrial Enzymology provides emerging research on biosynthesis, enzymatic treatments, and bioengineering of medicinal waste. While highlighting issues such as structural implications for drug development and food applications, this publication explores information on various applications of enzymes in pharmaceutical, nutritional, and industrial aspects. This book is a valuable resource for medical professionals, pharmacists, pharmaceutical companies, researchers, academics, and upper-level students seeking current information on developing scientific ideas for new drugs and other enzymatic advancements.