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A REVIEW FOR FORMULATION AND EVALUATION OF DIFFERENT PHARMACEUTICAL DOSAGE FORM USING CALORIMETRY

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1. INTRODUCTION

Calorimetry plays a key role in understanding the heat transfer during chemical and physical processes. This scientific technique measures energy changes, which are vital in various fields of research. The principles governing calorimetry rely on fundamental thermodynamic concepts. By examining this field, one can appreciate how calorimetry contributes to advancements in academia and industry alike.[1]

An in-depth exploration of calorimetry enhances knowledge, highlighting its practical applications and recent developments. Understanding these aspects can lead to improved methodologies and innovative use in different scientific areas.

Methodology Experimental Design

The design of calorimetric experiments is critical to obtaining reliable and meaningful data. Typically, experimental setups are defined by:

- **Calibration**: Ensuring that calorimeters are accurately calibrated improves data reliability.
- **Control Variables**: Identifying and controlling external conditions minimizes variability in heat measurements.

Data Collection Techniques

Effective data collection techniques are essential in calorimetry. Some documented approaches include:

- **Real-time monitoring**: Continuous measurements facilitate the tracking of heat flow during experiments.
- **Data logging**: Utilizing software for data management enhances analysis accuracy, providing clearer insights into experimental results.

Understanding these methodologies allows for better application of calorimetric principles in diverse research settings. The implications of such knowledge extend beyond academic pursuits, impacting real-world applications in energy systems, pharmaceuticals, and nanotechnology.[2]

Foreword to Calorimetry

Calorimetry plays a vital role in many scientific and industrial fields, proving essential for understanding heat transfer during physical and chemical processes. This introduction will explore the significance of calorimetry, emphasizing its contributions to both theoretical research and practical applications. The ability to accurately measure heat allows researchers to comprehensively analyze energy changes, making this technique foundational in disciplines such as chemistry, biology, and material science.

Definition and Importance

Calorimetry is defined as the science of measuring the amount of heat involved in chemical reactions or physical changes, along with heat capacity. It is important for several reasons:

- **Energy Transfer Understanding**: Calorimetry helps identify how energy moves within systems, which is crucial for studies in thermodynamics.
- **Thermodynamic Properties**: By measuring heat changes, scientists can derive key properties such as enthalpy and specific heat, effectively linking calorimetry to thermodynamic laws.
- **Practical Applications**: In industries, calorimetry evaluates fuel efficiency, assesses food quality, and even checks material heat stability, making it

indispensable not only in research but also in manufacturing.

Overall, calorimetry connects theoretical principles with practical needs, bridging gaps that unveil deeper insights into material behavior and reaction energetics.[3]

Historical Milestones

Calorimetry's development is marked by several key milestones that chart its evolution:

1. **Early Discoveries**: The concept began in the 18th century, with scientists like Joseph Black researching heat capacities and latent heat concepts.
2. **Calorimeter Invention**: In the latter half of the 18th century, scientists created the first calorimeters, allowing systematic experiments to measure heat transfer.
3. **First Law of Thermodynamics**: The formulation of this law in the 19th century provided a theoretical base for calorimetric studies.
4. **Technological Advancements**: With the 20th century, advancements in technology led to precise instruments, such as bomb calorimeters, enhancing the scope of calorimetry.

The historical trajectory of calorimetry demonstrates how this field has adapted and evolved, continually finding relevance in an ever-expanding array of scientific inquiries.

"Calorimetry is not merely about measuring heat; it is about unlocking the secrets of energy transformation in nature."[4]

Fundamental Principles of Thermodynamics

Understanding the fundamental principles of thermodynamics is essential for comprehending calorimetry. These principles form the backbone of how heat transfer is quantified and analyzed during various processes. The First and Second Laws of Thermodynamics elucidate the conservation of energy and the directionality of energy flow. This knowledge enhances our ability to accurately measure heat changes in physical and chemical reactions, allowing researchers to gain insights into reaction mechanisms and energy efficiencies.[5]

First Law of Thermodynamics

The First Law of Thermodynamics states that energy cannot be created or destroyed; it can only change forms. In calorimetry, this translates to the principle of energy conservation where the total energy of an isolated system remains constant. When heat is absorbed or released, it is crucial to recognize that this energy transfer must be accounted for in the measurements. For instance, if a chemical reaction takes place in a calorimeter, the heat released during the reaction appears as a change in temperature within the system. Thus, the First Law serves as the foundation for quantifying heat transfer.[6]

Second Law of Thermodynamics

The Second Law of Thermodynamics introduces the concept of entropy, emphasizing that energy transformations increase disorder in a system. This principle is particularly relevant in calorimetry as it helps elucidate why some processes are spontaneous while others are not. Specifically, when analyzing a calorimetric experiment, one must consider how the absorbed or released heat contributes to the overall change in entropy. Understanding these relationships allows scientists to predict the feasibility and efficiency of chemical reactions, guiding the design and optimization of experiments.[7]

Types of Calorimeters

The study of calorimetry hinges significantly on the proper selection of calorimeters. Different types offer distinct advantages suitable for various experimental needs. Understanding these types helps researchers choose the right tool for their specific measurements. This is pivotal because the results obtained can vary considerably based on the calorimeter used. The following sections will expand on four notable types of calorimeters: differential scanning calorimetry, bomb calorimetry, isothermal microcalorimetry, and titration calorimetry. Each serves unique purposes and is beneficial in specific contexts.[8]

Differential Scanning Calorimetry

Differential scanning calorimetry (DSC) is a prevalent method in thermal analysis. It measures how much energy is required to increase the temperature of a sample compared to a reference under controlled conditions. This technique offers precise measurement of heat flows associated with phase transitions, such as melting or crystallization. Benefits of DSC:

- High sensitivity to thermal transitions.
- Ability to gather data on specific heat capacities.
- Insights into material stability and degradation.

DSC is widely used in both materials science and pharmaceuticals. It assists in formulation development, ensuring products have desirable thermal properties.[9]

Bomb Calorimetry

Bomb calorimetry is designed to measure the heat of combustion of substances. This technique uses a strong, sealed vessel, known as a bomb, for burning a sample in pure oxygen. The heat released is absorbed by a surrounding water jacket, allowing for accurate measurements.

Considerations for Bomb Calorimetry

- Useful for determining calorific values of fuels and food.
- Requires careful calibration and maintenance of equipment.
- The high pressures involved necessitate strict safety considerations.

The data gathered through bomb calorimetry is critical for assessing energy content, helping industries in fuels, food, and biological research.[10]

Isothermal Microcalorimetry

Isothermal microcalorimetry focuses on measuring minute heat changes in processes occurring at constant temperature. It is especially useful for studying biochemical reactions and processes that require high sensitivity. The equipment can detect very small amounts of heat, even at the micro or nanomolar scale.

Key Uses of Isothermal Microcalorimetry

- Studies of enzyme kinetics
- Monitoring of binding interactions
- Drug solubility and stability assessments

This technique's sensitivity makes it indispensable in research areas where low concentrations of substances are involved, furthering understanding in biology and chemistry.[11]

Titration Calorimetry

Titration calorimetry combines titration and calorimetry to measure heat changes during a chemical reaction. As the reactants are added, the heat change is continuously monitored, providing real-time thermodynamic data.

Advantages of Titration Calorimetry

- Insight into enthalpy changes of reactions
- Able to study complex multi-step reactions
- Can identify reaction stoichiometry

It bridges the gap between calorimetry and solution chemistry, giving valuable information in chemical research and industrial applications.

"The selection of the correct calorimeter can significantly influence the quality and accuracy of experimental results."

Understanding the types of calorimeters is essential. Each technique has its strengths and limitations. Researchers must consider these factors to make informed choices that will benefit their specific studies.[12]

Calorimetric Techniques in Practice

Understanding calorimetric techniques is crucial for anyone engaged in research that entails the measurement of heat transfer. These techniques provide the foundational methods through which scientists can elucidate thermodynamic behavior and energy changes occurring during chemical reactions or physical processes. The precision and accuracy of calorimetric techniques greatly influence the reliability of results in experimental setups. This section aims to present key aspects surrounding sample preparation, calibration methods, and data analysis procedures.

SAMPLE PREPARATION

Sample preparation is a vital step in calorimetric analysis. The way a sample is handled can profoundly affect the measurement outcome. Key considerations include:

- **Purity of Samples**: Impurities in a sample can lead to erroneous heat measurements, affecting the conclusions drawn from the data. Therefore, using high-purity materials is imperative.
- **Size and Homogeneity**: Inconsistencies in sample size or composition can distort calorimetry results. Ensuring that samples are uniformly prepared aids in achieving reproducible measurements.
- **Phase Considerations**: Knowing the physical state of the sample (solid, liquid, gas) is essential. Each phase may require specific conditions and setups for accurate calorimetric measurements.

Proper sample preparation enhances the effectiveness of calorimetric studies and lays a robust foundation for subsequent analysis.[13]

Calibration Methods

Calibration is a crucial step that ensures the accuracy of calorimeter readings. Without proper calibration, results may lead to misinterpretations. There are several effective calibration methods:

1. **Standard Substances**: Using substances with known heat capacities allows researchers to verify the calorimeter's performance. Common standards include water and sodium chloride.
2. **Temperature Calibration**: Regular checks of temperature sensors within the calorimeter help ensure that they provide accurate readings across the required temperature range.
3. **Reference Calibration**: Involves comparing measurements from the calorimeter with those from a trusted reference method. This cross-verification can enhance confidence in the calorimetric data obtained.

Carefully conducted calibration procedures are essential for producing reliable thermodynamic data, which is instrumental for further applications.[14]

Data Analysis Procedures

Data analysis in calorimetry encompasses the interpretation of heat transfer data, often requiring specific techniques:

- **Heat Flow Measurement**: Understanding how heat flows into or out of a system is fundamental. This data needs to be meticulously processed to account for any thermal losses.
- **Software Utilization**: Many modern calorimetric experiments utilize software that can assist in real-time data collection and analysis. Tools like ThermoCalc or CALPHAD can significantly speed up the analysis process and provide clearer insights.
- **Statistical Analysis**: Applying statistical techniques to evaluate the repeatability and reliability of the

measurements also plays a role. This can include error analysis and regression methods to establish correlations between different reaction parameters.

Data analysis procedures are as critical as the experimental setups because they determine the conclusions that can be drawn from calorimetric experiments.

In summary, calorimetric techniques in practice involve meticulous attention to the details of sample preparations, careful calibration methods, and comprehensive data analysis procedures. Each element interconnects to ensure that findings from calorimetric studies are robust, precise, and applicable in various scientific fields.[15]

Applications of Calorimetry

The applications of calorimetry are vast and embody its significance in various scientific domains. This section highlights how calorimetry underpins numerous processes in chemistry, biology, and material science, providing critical insights that shape research and development. Understanding these practical applications brings to light the benefits and considerations that come with employing calorimetric techniques.

Chemical Reaction Analysis

Calorimetry plays a pivotal role in analyzing chemical reactions. It allows scientists to quantify the heat released or absorbed during reactions, which is essential for understanding reaction dynamics. Techniques such as bomb calorimetry are frequently used for combustion reactions, providing data that are vital for evaluating energy content in fuels.

Key factors include

- Accurate measurement of enthalpy changes.
- Understanding thermodynamic stability of reactants and products.
- Supporting reaction mechanism studies.

Such insights are instrumental when designing new chemical processes or improving existing ones. The ability to measure reaction heat provides foundational data that enhance knowledge in various fields, including pharmaceuticals and materials synthesis.

Biological Research

In the realm of biological research, calorimetry offers a unique window into metabolic processes. Measuring heat changes can help elucidate enzyme activity, cellular respiration, and even drug interactions within biological systems. Isothermal titration calorimetry, for instance, is widely used to study biomolecular interactions, allowing for the assessment of binding affinities and thermodynamics of complexation.

Important aspects include

- Investigation of enzyme kinetics and substrate interactions.
- Assessment of metabolic rates in different organisms.
- Insights into thermodynamic properties of biological molecules.

Such applications contribute to advancing our understanding of fundamental biological processes and can have profound implications in drug development and disease treatment strategies.[16]

Material Science Applications

Calorimetry is invaluable in material science as well, where it aids in characterizing materials and understanding phase transitions. Differential scanning calorimetry enables the examination of thermal properties of polymers, metals, and ceramics, helping identify melting points, glass transitions, and thermal stability.

Considerations in this field include

- Evaluation of thermal properties and stability.
- Analysis of phase transitions during material processing.
- Understanding crystallization pathways in synthetic materials.

Through these applications, calorimetry not only supports the development of new materials but also ensures quality control in manufacturing processes.

"Calorimetry is not just about measuring heat; it is about understanding the very nature of interactions within materials and biological systems."

In summary, the applications of calorimetry extend far beyond conventional heat measurement. They are central to chemical reaction analysis, biological research, and material science, demonstrating the broad relevance of calorimetric techniques in contemporary scientific inquiry and industrial practices.[17]

Recent Advances in Calorimetric Techniques

Recent advances in calorimetric techniques represent a vital progression in the field of thermodynamics and materials science. These developments have broadened the horizons of calorimetry, providing deeper insights into heat transfer and properties of materials. The innovations not only enhance measurement precision but also expand the scope of experiments that can be conducted. Researchers and industries alike benefit from these advancements as they open new avenues for exploration and application.

Key elements of these advancements include

- **Improved Sensitivity**: Modern calorimeters can now detect even minute changes in heat, which is crucial for studies in nanotechnology and materials science.
- **Real-Time Monitoring**: Innovations allow for the real-time analysis of heat flow, enabling researchers to observe processes as they happen. This capability

is particularly beneficial in environments where reaction conditions can change swiftly.

- **Miniaturization**: Smaller devices can now deliver accurate measurements without requiring large sample amounts, making calorimetry more accessible and environmentally friendly.
- **Integration with Other Techniques**: New calorimetric methods can be combined with analytical techniques to provide a more comprehensive understanding of reactions and materials.

These enhancements highlight the importance of calorimetry in contemporary scientific research. They mark a significant leap forward, enhancing both the academic and industrial relevance of calorimetry.

Nanocalorimetry Innovations

Nanocalorimetry is a rapidly emerging field that focuses on measuring heat changes at nanoscale levels. This innovation allows scientists to study materials' thermal properties with unprecedented precision. With the ability to measure heat at such small scales, researchers can investigate phenomena that were previously inaccessible.

The benefits of nanocalorimetry include

1. **Enhanced Resolution**: This technique offers better resolution in measuring heat flow, crucial for investigating new materials such as nanostructures.
2. **Material Behavior**: Nanocalorimetry can elucidate thermal behavior in materials under varied conditions, enabling applications in fields like medicine and electronics.
3. **Innovative Applications**: Allowing detailed studies of phase transitions and chemical reactions at a nanoscopic level fosters advancements in drug delivery systems and energy storage solutions.

The progress in nanocalorimetry emphasizes how the study of heat transfer can lead to innovative material designs and new technological applications.

The integration of calorimetry with spectroscopy marks a remarkable advancement in analytical techniques. This synergy enhances data collection, allowing for a more nuanced examination of thermal events alongside molecular and structural interactions. Spectroscopic methods provide information about electronic, molecular, and crystal structures that complement calorimetric data.

Key considerations for this integration include

- **Comprehensive Data**: This combination gives researchers both thermal and structural data, providing a fuller picture of material behavior during reactions or phase changes.
- **Interconnected Analysis**: The simultaneous analysis through calorimetry and spectroscopy enables scientists to draw connections between energy changes and molecular dynamics in real time.
- **Versatility**: This method applies to various fields such as pharmaceuticals, polymers, and nanotechnology, where understanding the interplay between structure and heat is crucial.

The integration opens new doors for research and application, allowing for more detailed and informative studies that are essential for progress in material science and related disciplines.

"The advances in calorimetry combined with other analytical techniques enhance overall understanding, paving the way for groundbreaking developments in science and engineering."

Challenges and Limitations in Calorimetry

Calorimetry is a powerful technique used to measure heat changes in various processes. However, it is not without challenges. Understanding these issues is essential for effective application and accurate results. The two primary challenges discussed here are sensitivity issues and calibration complexity. Each of these elements plays a significant role in the reliability of calorimetric data. Recognizing and addressing these limitations help researchers improve their experimental designs and results.

Sensitivity Issues

Sensitivity refers to the ability of a calorimeter to detect small changes in heat. For many experiments, precise measurement of heat changes is crucial. However, various factors can affect sensitivity:

- **Instrumental Limitations**: Different calorimeters have different sensitivity levels. For instance, differential scanning calorimeters often have better sensitivity compared to traditional ones. Yet, all instruments suffer from limits based on design and operational conditions.
- **Environmental Interference**: Variations in temperature, humidity, or even vibrations can impact measurement sensitivity. These external factors often lead to noise in the data, obscuring the true heat flow.
- **Sample Size**: The amount of sample used in a calorimetric experiment can affect measurements. Smaller samples may lead to more significant fluctuations in heat measurement. This trade-off is critical for obtaining reliable data.

"The sensitivity of calorimetric measurements directly influences the accuracy of thermodynamic data, making it a crucial aspect to consider in experimental setups."

To overcome these sensitivity challenges, researchers must carefully select the appropriate calorimeter. Additional strategies include controlling the experimental environment and using larger sample sizes when feasible. All these efforts aim to enhance the precision of calorimetric measurements.

Calibration Complexity

Calibration is vital for ensuring that calorimetric results are accurate and reliable. However, the calibration process can be complex. Considerations that contribute to this complexity include:

- **Standard Reference Materials**: Using incorrect or poorly characterized standards can lead to inaccuracies. Researchers must ensure the materials used for calibration have well-defined thermodynamic properties.
- **Methodological Variations**: Different calorimetric techniques may require different calibration procedures. For example, bomb calorimeters necessitate a distinct calibration method compared to isothermal microcalorimetry. Understanding the specific requirements for each type is critical.
- **User Expertise**: The operator's understanding of the calibration process contributes significantly to the outcome. A lack of experience can lead to misinterpretation of data or incorrect adjustments.

The impact of calibration complexity is profound. If not addressed correctly, it can introduce significant errors in experimental data, leading to flawed conclusions. Therefore, a meticulous approach to training and protocol development is essential.[18]

1. FORMULATION AND EVALUATION OF DIFFERENT PHARMACEUTICAL DOSAGE FORMS USING CALORIMETRY

FORMULATION AND EVALUATION OF TABLET USING CALORIMETRY

Differential scanning calorimetry (DSC) and thermogravimetry (TG) were used in order to evaluate the thermal stability of an enalapril maleate formulation packaged in two types of packaging, polyvinyl chloride/aluminum blister and aluminum strip. Enalapril and the excipients employed in the formulation were also evaluated by TG and DSC. Tablets were analyzed before and after storage in an acclimatized room at 40°C and relative humidity of 75 % for 90 days. The DSC and TG results were compared with the results of dosage of enalapril and related compounds obtained by high-performance liquid chromatography. These results indicate an occurrence of chemical interaction between enalapril maleate and the excipients during its storage. After storage, it was observed that the enalapril content reduced and the predominant degradation product was diketopiperazine for both types of packaging. The predominance of diketopiperazine could be related to the absence of sodium bicarbonate in the tablets, alkalinizing agent employed in the thermal stabilization of the drug.[19]

FORMULATION AND EVALUATION OF CAPSULE USING CALORIMETRY

Meloxicam is a non-steroidal anti-inflammatory drug with highly variable bioavailability due to its poor aqueous solubility and dissolution. This work aimed to improve meloxicam bioavailability by formulating it in oro dispersible capsules containing a soluble complex of the drug with beta-cyclodextrin. Complexes were prepared by different methods and characterized by differential scanning calorimetry. Orodispersible capsule shells were prepared from conventional hard gelatin capsule shells by freeze-drying and evaluated by image analysis microscopy and moisture content estimation. Formulae containing the freeze-dried complex and different fillers were prepared and characterized for their flowability, moisture content and moisture absorption behavior. The orodispersible capsules were evaluated in-vitro and in-vivo in comparison with meloxicam commercial tablets (Mobic TM). Inclusion complexes between meloxicam and beta-cyclodextrin were formed and the dissolution efficiency was greatly enhanced by the freeze-dried product. The formulations containing mannitol or anhydrous lactose as fillers were superior and disintegrated within 23 s. The dissolution efficiency after 60 min exceeded 98% for the orodispersible capsules while its value was only 79% for Mobic TM. In comparison with Mobic TM, the tested orodispersible capsules showed a 1.7-fold increase in the average Cmax, a 0.5-fold decrease in the average tmax and a 1.4-fold increase in the average AUC0-4 of meloxicam. Orodispersible capsules containing meloxicam/beta-cyclodextrin freeze-dried complex markedly improve meloxicam bioavailability.[20]

FORMULATION AND EVALUATION OF POWDER USING CALORIMETRY

Yellow smoke powders are produced by mixing an oxidant (potassium chlorate), a fuel (lactose), and a dye (auramine). Mixtures also contain high-energy material, nitrocellulose, and occasionally include stabilizers, such as sodium bicarbonate, magnesium carbonate and grease. These formulations can become unstable leading to self-ignition. In order to investigate the reason for that, thermogravimetric analysis (TG) and differential scanning calorimetry of the raw materials and mixtures, under different conditions and various mixing processes in air, were carried out. It has been found that that some conditions, such as the ambient temperature used to dry the powder, the high relative humidity and the granulation process and particle size, do not provoke the powder self-ignition. Yellow smoke powders three-phased decomposition initiates around 202 °C and leaves about 40 % of mass residue. Thermal analysis reveals that auramine reacts with potassium chloride in the mixture. Oxidation lactose and auramine occurs at 190 and 208°C, respectively. The exposure to strong acids leads to a strong reaction that, in some cases, reaches the powder ignition.[21]

FORMULATION AND EVALUATION OF LOZENGES USING CALORIMETRY

Curcuminoid are the natural bioactive polyphenolic compounds with diverse biological activities such as antiinflammatory, antibacterial, antiviral, anticancer, antioxidant, neuroprotective, hepatoprotective, throat infection, and wound healing activities. However the clinical use of curcumin has been limited due to its poor aqueous solubility and limited gastrointestinal absorption. Hard boiled lozenges (HBL) are attractive dosage form with better therapeutic potential and presentation. The present study focuses on development and characterization of curcumin based hard boiled lozenges from sugar and isomalt. The lozenegs were than evaluated for quality parameters such as hardness, friability, dissolving time and dissolution studies. Characterization of lozenges was done by advanced techniques such as Differential Scanning Calorimetry (DSC), The stability of curcumin in the lozenges formulation was confirmed using HPTLC, LC-MS analysis and in vitro biological activity such as antimicrobial (E.coli and S.aureus) antioxidant activity (DPPH) and anti-inflammatory activity (COX-1 and COX-2). The XRD, FT-IR and DSC results indicates partial transformation of curcumin into its amorphous form in the HBL formulation. HPTLC and LC-MS analysis indicates the curcumin is stable during hot-melt-molding (HMM) process without any substantial interaction between curcumin and the lozenges matrix. The in vitro bioactivity study showed that formulation does not affect the in vitro antimicrobial, anti-inflammatory and DPPH activity in the final products. Overall, the interesting finding of this study suggested that curcumin lozenegs can provide attractive and alternative platform to develop new formulation for existing phytochemicals and other active pharmaceutical ingredients.[22]

FORMULATION AND EVALUATION OF INJECTION USING CALORIMETRY

In the calorimeters used for the determination of thermodynamical properties of liquid environments, the mixture takes place when injecting liquid in the mixture zone, this injection incorporates an additional calorific power that is a function of the volumetric heat capacity of the injected liquid and the injection flow. In this article, it is rewritten Tian's equation including this additional power to relate correctly the experimental output to the mixture enthalpy. It is applied Tian's equation, once it has been corrected, to two types of calorimeters: flow-microcalorimeters and isothermal titration calorimeters. In this second case, it has been taken into account the classical operating mode (titration) and the continuous liquid injection mode. Tian's equation, completed with all the energetic terms additional to the mixture process, is of great interest for the scientific and academic community because it allows to explain, in a simple and effective way, the operation of these instruments.[23]

FORMULATION AND EVALUATION OF SUSPENSION USING CALORIMETRY

The purpose of this research was to mask the intensely bitter taste of primaquine phosphate (PRM) and to formulate suspension powder (cachets) of the taste masked drug. Taste masking was done using beta-cyclodextrin. To characterize and formulate taste masked cachets of PRM, the 1:25 M physical mixture was selected based on bitterness score. Phase solubility studies, differential scanning calorimetry (DSC), were performed to identify the physicochemical interaction between drug and carrier, hence its effect on dissolution. Cachets were evaluated for angle of repose, sedimentation characterization and pH. *In vitro* drug release studies for physical mixture and kneaded system were performed at pH, 1.2 and 6.8. Bitterness score was evaluated using gustatory sensation test. Phase solubility studies showed weak interaction between PRM and CD. The FTIR, DSC and XRPD studies indicated inclusion complexation in physical mixture and kneaded system. In addition, kneaded system and physical mixture exhibited better drug release at pH 1.2 and negligible effect at pH 6.8. Cachets prepared using physical mixture, (DS24), showed complete bitter taste masking and easy redispersibility. Taste evaluation of cachets in human volunteers rated tasteless with a score of 0 to DS24 and 3 to DS25. Thus, results conclusively demonstrated successful taste masking and formulation of cachets with taste masked drug.[24]

FORMULATION AND EVALUATION OF EMULSION USING CALORIMETRY

The stabilization of oil in water nano-emulsions by means of a polymer coating is extremely important; it prolongs the shelf life of the product and makes it suitable for a variety of applications ranging from nutraceutics to cosmetics and pharmaceutics. To date, an effective methodology to assess the best formulations in terms of thermodynamic stability has yet to be designed. Here, we perform a complete physicochemical characterization based on isothermal titration calorimetry (ITC) compared to conventional dynamic light scattering (DLS) to identify polymer concentration domains that are thermodynamically stable and to define the degree of stability through thermodynamic functions depending upon any relevant parameter affecting the stability itself, such as type of polymer coating, droplet distance, etc. For instance, the method was proven by measuring the energetics in the case of two different biopolymers, chitosan and poly-l-lysine, and for different concentrations of the emulsion coated with poly-l-lysine.[25]

FORMULATION AND EVALUATION OF SUPPOSITORY USING CALORIMETRY

Clarithromycin (CLR), a broad-spectrum antibiotic, is widely used to treat genitourinary infections caused by Gram positive bacteria via conventional drug delivery approaches, such as tablets. However, bitter taste, nausea and first pass hepatic effects hamper its usage. Moreover, CLR exhibits poor flow property making it difficult to formulate into tablet dosage form. The current study aimed to formulate CLR suppositories to address limitations associated with its oral administration. CLR suppositories were prepared using a molding method and characterized by different analytical techniques to assess the bioavailability of the drug using *in vitro* and *in vivo* models. Fourier Transform Infrared analysis indicated no significant chemical interaction between CLR and the suppository base. X-ray diffraction results showed a transformation from crystalline to amorphous form with effective drug loading. Differential scanning calorimetry analysis confirmed the thermal stability of CLR in suppository dosage form. *In vitro* drug release profile showed that drug release was sustained for 3 hrs. *In vivo* studies demonstrated significantly greater inhibition of bacterial growth after administration of suppositories (50 ± 5 mm) as compared to oral tablets (20 ± 3 mm). *In vivo* evaluation was also performed to investigate the antimicrobial efficacy against genitourinary bacterial infections.

These findings highlight the potential of CLR suppositories to improve stability and bioavailability compared to oral tablets. However, further clinical studies are needed to confirm its clinical efficacy and safety in humans.[26]

2. CONCLUSION

Calorimetry plays an important role in the formulation and evaluation of pharmaceutical dosage forms because it helps to study the thermal properties and stability of drug substances and excipients. Techniques such as Differential Scanning Calorimetry (DSC) and Isothermal Calorimetry are widely used in pharmaceutical research to understand the physical and chemical behavior of drugs during formulation.

Through calorimetric analysis, researchers can determine melting point, glass transition temperature, crystallization behavior, polymorphic transitions, and compatibility between drug and excipients. This information is very useful during the development of dosage forms such as tablets, capsules, suspensions, and creams, because it helps in selecting suitable excipients and optimizing formulation conditions.

Calorimetry also assists in detecting drug–excipient interactions, which may affect the stability, efficacy, and shelf life of pharmaceutical products. By identifying these interactions early in formulation development, scientists can modify the composition or processing methods to improve product quality.

In addition, calorimetric techniques help evaluate thermal stability, degradation kinetics, and moisture effects on dosage forms. These studies are essential for ensuring that the drug product remains safe, effective, and stable throughout its storage period**.** Overall, calorimetry is a valuable analytical tool in pharmaceutics that supports formulation design, compatibility studies, quality control, and stability assessment. Its application helps in developing stable, effective, and high-quality pharmaceutical dosage forms, ultimately improving drug performance and patient safety.

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