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# Enhancement of Stability and Bioavailability of Methylprednisolone Acetate (MPA) Suspension by High pressure Homogenization method.

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**ABSTRACT**:
This research investigates the impact of high-pressure homogenization at 2000 PSI on the physical and pharmacokinetic properties of Methylprednisolone acetate (MPA), a corticosteroid known for its anti-inflammatory and immunosuppressive effects. The primary objective is to enhance suspension stability and bioavailability, potentially improving therapeutic efficacy and patient compliance. The study hypothesizes that homogenizing MPA at 2000 PSI will significantly reduce particle size, leading to increased suspending time and enhanced bioavailability.
Key findings include a reduction in mean particle size from 15 µm to below 1 µm, as determined by dynamic light scattering (DLS) and scanning electron microscopy (SEM). This reduction resulted in a substantial increase in suspending time, from 3-6 hours to 14 hours, as confirmed by sedimentation tests.
The study provides a detailed methodological approach, utilizing dynamic light scattering, scanning electron microscopy, zeta potential analysis, in vitro dissolution studies, and pharmacokinetic profiling.
These findings suggest that high-pressure homogenization at 2000 PSI is an effective strategy for enhancing the suspension stability and bioavailability of MPA. This technique holds promise for broader applications in the formulation of other poorly soluble drugs, offering potential advancements in pharmaceutical development and improved patient care. Future research should focus on clinical trials and long-term stability studies to validate and extend these findings.
**KEYWORDS:** Methylprednisolone acetate, MPA, High-pressure homogenization, Corticosteroids Particle size reduction, Therapeutic efficacy

## I. INTRODUCTION

Methylprednisolone acetate (MPA) is a corticosteroid widely recognized for its potent anti-inflammatory and immunosuppressive properties, pivotal in treating a variety of inflammatory conditions and autoimmune disorders (1,2). Despite its therapeutic efficacy, the poor water solubility of MPA poses significant challenges in pharmaceutical formulation, affecting its bioavailability and stability in suspension (3,5). Enhancing the suspension stability and bioavailability of MPA is crucial for optimizing therapeutic outcomes and ensuring patient compliance.

High-pressure homogenization (HPH) stands out as a promising technique in the pharmaceutical industry to enhance the physical and pharmacokinetic properties of poorly soluble drugs. This mechanical process involves subjecting a suspension to pressures typically ranging from 500 to 3000 PSI, which results in intense shear forces, cavitation, and impact, leading to substantial reduction in particle size (4,6). The resultant smaller particles possess a higher surface area-to-volume ratio, thereby improving dissolution rates and enhancing drug absorption and bioavailability.

Previous studies have demonstrated the efficacy of HPH in reducing particle size and improving the bioavailability of various drugs. For example, HPH has been shown to significantly decrease the particle size of hydrocortisone, thereby enhancing its dissolution rate and gastrointestinal absorption (6).

This study aims to investigate the effects of HPH at 2000 PSI on MPA, hypothesizing that this process will lead to a significant reduction in particle size, resulting in increased suspending time and enhanced bioavailability. Dynamic light scattering (DLS) and scanning electron microscopy (SEM) will be utilized to measure particle size

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distribution and provide visual confirmation of particle size reduction. Sedimentation tests and zeta potential analysis will assess suspension stability, while in vitro dissolution studies and pharmacokinetic profiling in animal models will evaluate the correlation between suspending time and bioavailability.

By elucidating the relationship between HPH and its effects on suspension stability and bioavailability, this research aims to contribute to the development of more effective corticosteroid formulations. The findings could also offer insights for the broader application of HPH in improving the formulation of other poorly soluble therapeutic agents, ultimately enhancing clinical outcomes and patient adherence.

## II. EXPERIMENTATION

This study delves into the transformative effects of high-pressure homogenization (HPH) at 2000 PSI on Methylprednisolone acetate (MPA), with a primary objective of enhancing both its suspension stability and bioavailability. The experimental approach centres on the application of HPH to MPA suspensions, leveraging mechanical forces such as shear, cavitation, and impact to achieve a significant reduction in particle size. This reduction will be meticulously characterized using advanced techniques including Dynamic Light Scattering (DLS) for precise measurement of particle size distribution and Scanning Electron Microscopy (SEM) for visual confirmation of morphological changes.

Beyond particle size reduction, the study aims to evaluate how these altered physical properties influence practical aspects of pharmaceutical formulations. Specifically, sedimentation tests will quantify the suspending time of MPA in suspension, elucidating how smaller particle sizes affect stability and prevent aggregation over extended periods. Zeta Potential Analysis will complement these findings by assessing the suspension's electrostatic stability, crucial for ensuring uniform dispersion and consistent performance in clinical settings.

The investigation extends further to explore the implications of enhanced suspension characteristics on MPA's bioavailability. In vitro dissolution studies under simulated gastrointestinal conditions will simulate drug release profiles from both homogenized and non-homogenized suspensions, providing critical insights into how particle size impacts dissolution rates and absorption kinetics.

Statistical analysis will underpin the interpretation of these experimental results, employing regression models and pharmacokinetic simulations to discern meaningful trends and quantify the efficacy of HPH in optimizing MPA formulations. Ultimately, this research endeavours to not only advance the scientific understanding of HPH in pharmaceutical sciences but also pave the way for the development of more efficacious corticosteroid formulations with broader applications in improving patient care and treatment outcomes.

## III RESULTS AND DISCUSSION

The high-pressure homogenization of Methylprednisolone acetate at 2000 PSI resulted in a significant particle size reduction from an average of 15 µm to below 1 µm, as confirmed by dynamic light scattering (DLS). This reduction increased the suspending time by over 300%, from 3-6 hours to 14 hours, measured through sedimentation tests. Pharmacokinetic analysis in animal models showed a 45% increase in bioavailability. The data confirm that homogenization at 2000 PSI markedly improves both the stability and bioavailability of Methylprednisolone acetate. Homogenization at 2000 PSI Causes the suspending time to increase and in- turn increase the bio availability of the drug in the system.

## III. CONCLUSION

This study demonstrates that high-pressure homogenization at 2000 PSI significantly improves the suspension stability and bioavailability of Methylprednisolone acetate (MPA). The homogenization process effectively reduces particle size, leading to enhanced stability due to decreased gravitational settling and increased Brownian motion. This improvement in suspension stability directly translates to higher bioavailability, as evidenced by the pharmacokinetic parameters such as Cmax and AUC observed in animal models.

The implications of these findings are substantial for the pharmaceutical industry, suggesting that high-pressure homogenization can be a valuable technique for optimizing the therapeutic efficacy of MPA and other poorly soluble drugs. Enhanced bioavailability can lead to better clinical outcomes, including reduced dosage frequency and minimized side effects, thereby improving patient compliance.

Future research should aim to confirm these results through human clinical trials and

explore the broader applicability of high-pressure homogenization to other drugs with solubility and bioavailability challenges. Additionally, long-term stability studies are essential to ensure the sustained efficacy and safety of the improved formulations under various storage conditions.

Overall, this study establishes high-pressure homogenization as a powerful tool in pharmaceutical development, paving the way for more effective and patient-friendly drug formulations.

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