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Optimization and appraisal of Bi-layered tablets containing divalproex sodium to augment therapeutic effectiveness

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Abstract

The current study aimed to optimize and evaluate bi-layered tablets of Divalproex Sodium designed for improved therapeutic effectiveness in the treatment of epilepsy, bipolar disorder, and migraine. The formulation combined an immediate release (IR) layer with a sustained release (SR) layer to ensure rapid onset and prolonged action. Compatibility studies confirmed no significant interaction between the drug and excipients. Evaluation of pre- and post-compression parameters including hardness, friability, drug content, and in vitro dissolution studies demonstrated desirable characteristics. The IR layer achieved 97.31% drug release within 30 minutes, while the SR layer sustained release up to 96.34% over 960 minutes. Stability studies over 56 days confirmed the physical and chemical integrity of the formulation. These findings support the feasibility of bi-layered tablets of Divalproex Sodium as an effective delivery system for managing neurological disorders.

Keywords: Divalproex Sodium; Bi-layered tablet; Epilepsy; Bipolar disorder; Sustained release; Immediate release; *In vitro* dissolution

1. Introduction

Divalproex Sodium is a widely prescribed antiepileptic and mood-stabilizing agent effective in managing epilepsy, bipolar disorder, and migraine. Conventional dosing requires multiple administrations daily, affecting patient compliance and therapeutic efficacy. Bi-layered tablets offer a solution by combining immediate and sustained drug release mechanisms within a single unit, potentially enhancing clinical outcomes and reducing side effects. The objective of this study was to formulate and evaluate bi-layered tablets of Divalproex Sodium that ensure immediate therapeutic action and maintain plasma concentration over an extended period.

2. Material and methods

Materials included Divalproex Sodium and various excipients like microcrystalline cellulose, lactose, PVP K30, etc. Preformulation studies such as melting point, solubility, and FT-IR were conducted. Formulation design used pharmacokinetic-based dosing and employed wet granulation for both IR and SR layers. Post-formulation evaluations included weight variation, hardness, friability, drug content, and *in vitro* dissolution using USP apparatus II. Stability was tested over 56 days at 40±2°C and 75±5% RH.

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3. Results

Preformulation confirmed appropriate properties and compatibility. IR layer released 97.31% of the drug within 30 minutes; SR layer released 96.34% over 960 minutes. Hardness, friability, and drug content were within acceptable ranges. Stability study confirmed formulation integrity.

4. Discussion

The developed bi-layered formulation successfully delivered Divalproex Sodium in immediate and sustained phases, improving therapeutic potential and patient compliance. Superdisintegrants enhanced rapid dissolution, while matrix polymers ensured prolonged drug release

5. Conclusion

The optimized bi-layered tablets showed promising results in drug release, physical parameters, and stability. This delivery system holds potential for enhanced treatment of neurological disorders requiring Divalproex Sodium.

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