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Design, Formulation and Development of Triple-Combination Bilayer Antiretroviral Tablets

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Abstract: ***Human Immunodeficiency Virus (HIV) remains a major global health challenge, requiring lifelong antiretroviral therapy (ART) for effective disease management. Triple-drug regimens are the standard of care; however, long-term treatment may reduce patient adherence because of pill burden and drug incompatibility. Bilayer tablet technology provides an effective fixed-dose combination approach by separating incompatible drugs while enabling immediate and sustained drug release within a single dosage form. This review highlights the design, formulation strategies, evaluation methods, current developments, challenges, and future prospects of triple-combination bilayer antiretroviral tablets. The technology offers significant potential to improve treatment adherence, therapeutic efficacy, and patient convenience in HIV management.***

Keywords: Human Immunodeficiency Virus (HIV), Antiretroviral Therapy (ART), Bilayer Tablet, Fixed-Dose Combination (FDC), Controlled Drug Release, Quality by Design (QbD)

I. INTRODUCTION

Human Immunodeficiency Virus (HIV) is a chronic viral infection that primarily targets $CD4^+$ T lymphocytes, resulting in progressive weakening of the immune system and, if untreated, progression to Acquired Immunodeficiency Syndrome (AIDS). Combination antiretroviral therapy (ART), particularly triple-drug regimens, has significantly improved patient survival by suppressing viral replication and restoring immune function.

Despite its effectiveness, lifelong ART is often associated with pill burden, complex dosing schedules, and reduced patient adherence. Fixed-dose combination (FDC) formulations, particularly bilayer tablets, provide an effective strategy to overcome these limitations. Bilayer tablet technology is an advanced oral drug delivery system that enables the incorporation of multiple active pharmaceutical ingredients with distinct release characteristics into a single dosage form while minimizing drug–drug incompatibility. By providing both immediate and controlled drug release, this formulation strategy enhances product stability, simplifies treatment, promotes patient adherence, and supports improved therapeutic outcomes. Consequently, triple-combination bilayer antiretroviral tablets represent a promising approach for effective long-term management of HIV infection.

II. CURRENT DEVELOPMENTS

The successful development of triple-combination bilayer antiretroviral tablets requires careful selection of active pharmaceutical ingredients (APIs) based on their physicochemical compatibility, stability, dosage requirements, and pharmacokinetic characteristics. Comprehensive preformulation studies are performed to evaluate drug–excipient compatibility and optimize formulation performance. Common analytical techniques include Fourier Transform Infrared Spectroscopy (FTIR), Differential Scanning Calorimetry (DSC), X-ray Diffraction (XRD), and micromeritic characterization of powder blends.Bilayer tablets are commonly manufactured using direct compression or granulation techniques, depending on the properties of the formulation. The finished tablets are evaluated for critical quality attributes such as hardness, friability, weight variation, thickness, drug content uniformity, in vitro dissolution, layer adhesion strength, and stability. Stability studies are generally conducted in accordance with the International Council for Harmonisation (ICH) guidelines to ensure product quality, safety, and efficacy throughout its shelf life.

III. CHALLENGES AND FUTURE PERSPECTIVES

Despite the advantages of bilayer tablet technology, several formulation and manufacturing challenges remain. Common issues include insufficient interlayer adhesion, incompatibility between active ingredients, variability in drug-release profiles, and difficulties associated with large-scale manufacturing. Future research is expected to focus on the application of Quality by Design (QbD) principles, the use of advanced polymeric materials, nanotechnology-based drug delivery systems, and personalized dosage forms. These innovations may improve formulation robustness, manufacturing efficiency, and therapeutic outcomes in HIV treatment.

IV. CONCLUSION

Triple-combination bilayer antiretroviral tablets offer an innovative and effective pharmaceutical approach for HIV management by integrating multiple drugs into a single dosage form. This technology has the potential to reduce pill burden, improve patient adherence, enhance treatment convenience, and optimize long-term therapeutic outcomes. Continued advancements in formulation strategies and manufacturing technologies are expected to further strengthen the clinical utility of bilayer tablet systems in antiretroviral therapy.

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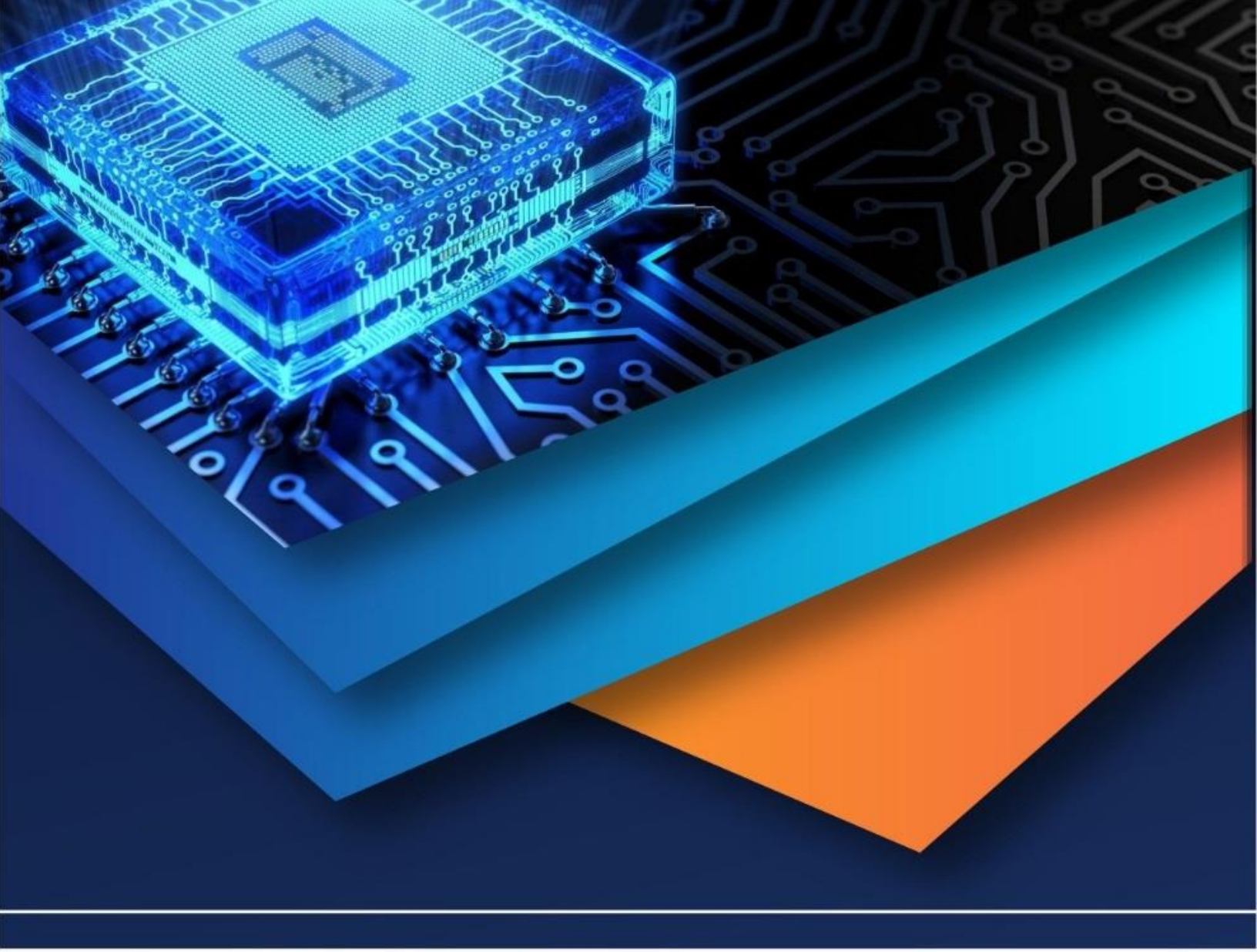

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