RESEARCH PAPER

Bilayer Tablet Technology in Ayush Systems: Formulation Strategies, Challenges, and Quality Evaluation of Herbal–Herbo Mineral Dosage Forms

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ABSTRACT

Ayush medicines are increasingly being modernized through the integration of advanced pharmaceutical technologies to enhance patient compliance, dosing precision, and product stability. While bilayer tablet technology has been extensively explored in allopathic systems, its application in traditional medicine remains underdeveloped. The incorporation of Herbal – Herbo mineral components into bilayer tablet systems presents unique challenges, including interfacial adhesion between layers, structural instability due to elastic recovery, and variability in phytochemical composition.

This review critically examines formulation strategies, mechanical considerations, physicochemical characterization techniques (including FTIR, DSC, XRPD, and ICP-OES), and Quality by Design (QbD) approaches relevant to the development of Herbal – Herbo mineral bilayer tablets. Particular emphasis is placed on interfacial integrity, crystallinity changes, elemental profiling, and drug release kinetics modelling.

Furthermore, the challenges and limitations associated with adapting traditional combination dosage forms into bilayer tablet systems are discussed. This review also identifies key research gaps and proposes future directions for the scientific validation and global acceptability of Ayush-based bilayer tablet formulations.

Keywords: Bilayer tablet technology, Herbal – Herbo mineral formulations, Interfacial stability, Physicochemical characterization, Quality by Design (QbD), Release kinetics modelling

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INTRODUCTION

In the modern era of medicine [1], increasing emphasis is placed on the development of scientifically validated and standardized traditional medicinal systems, particularly Ayush-based formulations. In these systems, herbal and herbo-mineral preparations are widely used in conventional dosage forms such as Chooranam, Parpam, decoctions, and compressed tablets [2]. Although these traditional dosage forms are therapeutically effective, they often face limitations related to standardization, dose uniformity, patient compliance, stability, and regulatory alignment [3].

The conversion of traditional formulations into modern pharmaceutical dosage forms can improve reproducibility, enhance global acceptability, and ensure compliance with contemporary regulatory requirements. Furthermore, the incorporation of advanced pharmaceutical technologies can significantly improve the quality, safety, and consistency of therapeutic outcomes [4].

Bilayer tablets represent an emerging and versatile drug delivery system in modern pharmaceutics. In this approach, two distinct layers are combined into a single dosage form [5], allowing for the separation of incompatible components, modulation of drug release profiles, and enhancement of therapeutic efficacy. These systems can incorporate either a single drug with different release characteristics or two different drugs to achieve a desired therapeutic effect [6].

Despite significant advancements in drug delivery technologies in modern pharmaceutical sciences [7], comparatively limited attention has been given to adapting these technologies to traditional systems of medicine. Traditional formulations exhibit inherent variability, including differences in particle size (e.g., Chooranam vs. Chendooram and Parpam), phytochemical composition, and deformation behaviour. These variations introduce several formulation challenges when integrating herbal and herbo-mineral drugs into bilayer tablet systems.

Key challenges include elastic recovery, poor flow properties, compaction difficulties associated with ultrafine particles, variability in drug content uniformity, and stability concerns [8]. Each traditional preparation possesses unique material characteristics that necessitate systematic pharmaceutical evaluation.

These challenges can be addressed through structured approaches such as pre-formulation studies, optimized formulation design, and comprehensive post-compression evaluation. Such strategies

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enable reproducible performance, improved product quality, and enhanced regulatory compliance.

While bilayer tablet systems in conventional pharmaceuticals have undergone extensive analytical and mechanical evaluation, tailored formulation strategies specifically designed for herbal and herbo-mineral matrices remain limited.

Therefore, this review aims to comprehensively examine formulation strategies, mechanical and analytical evaluation techniques, and optimization approaches for the development of pharmaceutically acceptable bilayer tablet systems. By bridging traditional herbal and herbo-mineral concepts with modern pharmaceutical principles, this work seeks to provide a structured framework for improving scientific validation and global acceptance of Ayush-based bilayer tablet formulations.

RATIONALE FOR HERBAL–HERBO-MINERAL BILAYER TABLET DEVELOPMENT

In traditional AYUSH systems of medicine, particularly in Siddha practice, certain dosage forms are frequently administered in combination, such as chooranam with chendooram or parpam, to enhance therapeutic efficacy, absorption, and bioavailability. These combinations are based on traditional principles of synergistic interaction, wherein mineral components are believed to enhance the pharmacodynamic activity, potency, or absorption of herbal drugs.

However, this conventional mode of co-administration presents several practical challenges, including issues related to dose accuracy, patient compliance, frequent dosing, and inconvenience in handling multiple dosage forms. Such limitations may negatively impact patient adherence, especially among elderly individuals and those with chronic conditions[9].

Bilayer tablet technology offers a promising and systematic approach to address these challenges by integrating herbal and herbo-mineral components into a single, organized dosage form comprising two distinct layers. In this system, one layer may contain the herbal component, while the other incorporates the herbo-mineral formulation. This design preserves the individual characteristics of each component while enabling controlled or simultaneous drug release, depending on therapeutic requirements.

The bilayer approach enhances dose precision, reduces dosing frequency, and improves patient compliance without compromising the traditional principle of combined administration. Additionally, it provides flexibility in modulating release profiles, including immediate, sustained, or controlled release, based on modern pharmaceutical design strategies[10].

Importantly, for Ayush-based formulations, bilayer systems can be specifically designed to achieve simultaneous disintegration and release of both layers, thereby maintaining the classical concept of synergistic action while incorporating modern dosage form advantages.

Therefore, the development of herbal–herbo-mineral bilayer tablets represent a rational and innovative strategy to modernize traditional formulations, improve patient convenience, and ensure better therapeutic outcomes, while preserving the fundamental principles of traditional medicine.

VARIOUS CHALLENGES IN THE DEVELOPMENT OF BILAYER TABLETS INCORPORATING HERBAL AND HERBO-MINERAL DRUGS

1. MATERIAL-RELATED CHALLENGES

The inherent complexity of herbal and herbo-mineral drugs presents significant challenges in bilayer tablet development when compared to synthetic drug systems. Herbal materials contain a diverse range of phytoconstituents with varying physicochemical properties, and their composition may fluctuate due to environmental, seasonal, and geographical factors. These variations can significantly influence critical parameters such as bulk density, compressibility, flow properties, and moisture content, ultimately affecting tablet integrity and performance [11].

Moisture sensitivity is another critical concern. Many herbal materials are hygroscopic and prone to degradation under humid conditions, which may promote microbial growth and compromise mechanical strength and long-term stability [46].

Unlike synthetic drugs, where well-defined active pharmaceutical ingredients are present, herbal formulations often exhibit therapeutic effects through synergistic interactions among multiple constituents. This complexity makes it difficult to identify and control critical quality attributes (CQAs), thereby complicating the implementation of Quality by Design (QbD) approaches [12].

Herbo-mineral components introduce additional challenges due to their ultrafine particle size and distinct physicochemical behaviour. These materials often exhibit poor flow properties and are prone to segregation during die filling [43]. Furthermore, the presence of metallic ions may interact with excipients or influence stability, although this area remains insufficiently explored [37].

2. PROCESS- AND MECHANICAL-RELATED CHALLENGES

Bilayer tablet compression is inherently more complex than monolayer tablet manufacturing and is associated with a higher risk of defects such as delamination, layer separation, capping, and lamination. These defects may occur immediately after compression or during storage and are primarily attributed to differences in elastic recovery, insufficient interfacial bonding, and mismatched mechanical properties between layers [13].

In herbal–herbo-mineral systems, the two layers often exhibit different deformation behaviours. Herbal materials typically undergo plastic deformation, whereas mineral components tend to exhibit brittle fracture. This mismatch can lead to stress concentration at the interface, increasing the likelihood of interfacial cracking and layer separation during decompression [14].

Compression force is a critical parameter in bilayer tablet development. Excessive pre-compression of the first layer may result in over-compaction, reducing interfacial bonding with the second layer. Conversely, insufficient compression can lead to weak tablets with poor hardness and increased friability. Therefore, optimization of pre-compression force, dwell time, and punch velocity is essential to achieve adequate interlayer adhesion without compromising structural integrity [15].

Lubricant concentration also plays a significant role. The excessive use of hydrophobic lubricants, such as magnesium stearate, may reduce interfacial bonding by forming a coating on particle surfaces, thereby decreasing tablet tensile strength [16,17]. Careful optimization of lubricant concentration is therefore necessary to maintain adequate interparticle bonding.

Layer weight ratio is another important factor affecting bilayer tablet integrity. An imbalance in layer weight—particularly when the herbal layer is significantly bulkier than the herbo-mineral layer—can lead to disparities in density and particle size distribution. This may result in poor die filling, weight variation, and compromised interfacial bonding [18]. The ultrafine nature of herbo-mineral components further complicates flowability and uniform layer formation. These challenges can be mitigated through appropriate excipient selection and optimization of process parameters such as layer thickness and compression force [19].

3. AYUSH-SPECIFIC CONCEPTUAL AND REGULATORY CHALLENGES

In addition to material and mechanical constraints, the integration of AYUSH-based formulations into bilayer tablet systems presents conceptual and regulatory challenges. Traditionally, combinations such as Chooranam and Chendooram are co-administered to achieve synergistic therapeutic effects. However, in bilayer tablet systems, differential release profiles may alter the classical concept of synchronized drug action [20].

To address this concern, bilayer tablets intended for Ayush applications should be specifically designed to achieve simultaneous disintegration and release of both layers, thereby preserving the traditional principle of synergistic administration without altering pharmacodynamic behaviour.

Another important challenge is related to dose individualization. In traditional systems, drug dosage is often tailored based on disease condition and patient-specific factors. The use of fixed-dose bilayer tablets may limit such flexibility and potentially deviate from personalized therapeutic approaches. However, this limitation can be addressed by designing formulations within acceptable classical dosage ranges and incorporating adaptable dosing strategies.

Furthermore, regulatory standardization of herbal and herbo-mineral formulations remains complex due to variability in raw materials, lack of well-defined markers, and limited global harmonization guidelines [12]. These challenges necessitate the development of robust scientific validation frameworks to ensure quality, safety, and efficacy while maintaining the integrity of traditional medicinal principles.

FORMULATION AND PROCESS DESIGN CONSIDERATIONS IN HERBAL–HERBO-MINERAL BILAYER TABLETS

The successful development of herbal–herbo-mineral bilayer tablets require a systematic approach that integrates both material properties and process parameters. As discussed previously, challenges such as variability in physicochemical characteristics, interfacial adhesion, and compressibility behaviour must be addressed through careful formulation design and process optimization. Rather than modifying a single parameter, a multivariate approach involving excipient selection, granulation technique, and compression conditions is essential to achieve a stable and reproducible bilayer tablet system [12].

SELECTION OF EXCIPIENTS AND THEIR IMPACT

Excipients play a critical role in determining the mechanical strength, compatibility, and release behaviour of bilayer tablets. In herbal–herbo-mineral systems, excipient selection becomes more complex due to differences in particle size, density, morphology, and moisture sensitivity between the two layers.

Binders are essential for providing interparticle cohesion and mechanical strength; however, excessive binder concentration may increase tablet hardness and delay disintegration. Similarly, disintegrants must be optimized to ensure efficient tablet breakup and simultaneous drug release from both layers [28].

Diluents contribute to bulk formation and improve flow properties, particularly in herbo-mineral components where ultrafine particles may lead to poor flow and segregation. The use of suitable diluents can help achieve uniform die filling and consistent compression behaviour.

Lubricants are necessary to reduce die wall friction during compression; however, excessive use—especially of hydrophobic lubricants such as magnesium stearate—can adversely affect interfacial bonding and reduce tablet tensile strength. Therefore, careful optimization of lubricant concentration is required to maintain both manufacturability and tablet integrity [16,29].

GRANULATION METHODS SUITABLE FOR HERBAL–HERBO-MINERAL BILAYER TABLETS

Granulation plays a crucial role in improving powder flow, compressibility, and interfacial adhesion in bilayer tablet formulations. Due to the heterogeneous nature of herbal and herbo-mineral materials, the choice of granulation technique must be tailored to individual material characteristics such as hygroscopicity, particle size distribution, and thermal sensitivity [22].

WET GRANULATION

Wet granulation is particularly suitable for herbal drug layers, which often exhibit poor flow properties due to their fibrous nature. The formation of granules using appropriate binders enhances flowability and compressibility, thereby improving tablet integrity. However, care must be taken to control drying temperature to prevent degradation or loss of heat-sensitive phytoconstituents [23,24].

DRY GRANULATION

Dry granulation or roller compaction is preferred for herbo-mineral components that are sensitive to moisture and possess ultrafine particle size. This method improves particle size uniformity and flow properties without exposing the material to solvents. However, excessive compaction pressure may reduce porosity and adversely affect drug release characteristics [25,26].

DIRECT COMPRESSION

In cases where both herbal and herbo-mineral powders exhibit acceptable flow and compressibility properties, direct compression can be employed. This method simplifies the manufacturing process by eliminating granulation steps and is advantageous when compatibility between components and excipients has been thoroughly evaluated [27].

COMPRESSION PROCESS AND BILAYER TABLET FORMATION

The compression process is a critical determinant of bilayer tablet integrity, strength, and drug release behaviour. Bilayer tablet manufacturing typically involves a two-step compression process, where the first layer undergoes pre-compression followed by the addition and compression of the second layer.

Adequate pre-compression of the first layer is essential to establish interfacial bonding; insufficient pre-compression may weaken the interface, whereas excessive pre-compression may reduce mechanical interlocking between layers [21]. Final compression force must also be optimized, as over-compression can delay disintegration and drug release, while under-compression may lead to poor mechanical strength and increased risk of delamination [15].

Differences in elastic recovery and deformation behaviour between herbal and herbo-mineral layers can generate residual stress at the interface, increasing the likelihood of layer separation. Therefore, optimization of compression parameters—including compression force, dwell time, and punch velocity—is essential to ensure structural stability and consistent performance of bilayer tablets.

TYPES OF BILAYER TABLET PRESS

Bilayer tablets are manufactured using either single-sided or double-sided tablet presses, each with distinct operational characteristics.

In single-sided presses, both layers are sequentially filled into the same die cavity and compressed. This method is associated with challenges such as layer mixing, weight variation, and reduced interfacial control [31].

In contrast, double-sided tablet presses employ separate filling stations and allow independent pre-compression of each layer prior to final compression. This approach provides better control over layer weight, improves interfacial adhesion, and enhances overall tablet integrity. Double-sided presses are therefore preferred for herbal–herbo-mineral systems, where differences in density and compressibility between layers are significant [30,32].

ANALYTICAL TECHNIQUES FOR CHARACTERIZATION OF HERBAL–HERBO-MINERAL BILAYER TABLETS

The development of herbal–herbo-mineral bilayer tablets require comprehensive physicochemical and analytical characterization to ensure compatibility, stability, and quality of the formulation. Due to the complex nature of herbal and mineral components, a

combination of analytical techniques is essential to evaluate chemical composition, structural properties, and potential interactions between components.

PHYTOCHEMICAL CHARACTERIZATION

Phytochemical evaluation is a fundamental step in the development of herbal-based formulations, as herbal drugs contain a wide range of secondary metabolites such as alkaloids, glycosides, flavonoids, tannins, and saponins. These constituents may influence physicochemical properties and interact with excipients during formulation.

Preliminary qualitative screening using standard chemical tests, such as Mayer's and Dangendroffs tests for alkaloids and the Salkowski reaction for phytosterols, helps identify major classes of phytoconstituents [33]. Such studies are essential for understanding drug–excipient compatibility and for selecting suitable excipients that minimize incompatibility risks.

HIGH-PERFORMANCE THIN LAYER CHROMATOGRAPHY (HPTLC)

High-performance thin layer chromatography (HPTLC) is a widely used analytical technique for the qualitative and quantitative evaluation of herbal drugs. It serves as an important tool for fingerprinting and quality control of complex herbal mixtures.

HPTLC analysis is typically performed using silica gel plates as the stationary phase and an optimized mobile phase based on the polarity and solubility of the phytoconstituents [34,35]. The developed chromatograms are visualized under ultraviolet light at wavelengths such as 254 nm and 366 nm, enabling identification of characteristic compounds based on their retention factor (Rf) values [36]. This technique is particularly useful for ensuring batch-to-batch consistency and detecting adulteration in herbal formulations.

ELEMENTAL ANALYSIS OF HERBO-MINERAL COMPONENTS (ICP-OES)

Inductively coupled plasma optical emission spectroscopy (ICP-OES) is a reliable analytical technique used for the quantitative determination of elemental composition in herbo-mineral formulations. In bilayer tablet systems containing mineral components such as Parpam and Chendooram, elemental profiling is essential to ensure that both therapeutic elements and potential toxic metals—including lead (Pb), arsenic (As), cadmium (Cd), and mercury (Hg)—remain within permissible limits [37].

The integration of herbal and mineral layers may alter elemental distribution or introduce contamination during processing, which can be effectively detected using ICP-OES. This technique enhances the scientific validation, safety assessment, and global acceptability of AYUSH formulations. However, distinguishing between therapeutically processed mineral forms and toxic elemental impurities remains a challenge [38].

FOURIER TRANSFORM INFRARED SPECTROSCOPY (FTIR)

Fourier transform infrared spectroscopy (FTIR) is widely used to evaluate potential interactions between herbal constituents, herbo-mineral components, and excipients. Changes such as shifts in characteristic peaks, disappearance of functional group signals, or the appearance of new peaks may indicate chemical interactions, complex formation, or incompatibility within the formulation [39].

In bilayer tablet systems, where two distinct layers are in close contact, FTIR plays a crucial role in assessing interfacial compatibility and chemical stability. However, interpretation of FTIR spectra in herbal–herbo-mineral systems can be challenging due to overlapping peaks arising from complex phytochemical compositions [40].

DIFFERENTIAL SCANNING CALORIMETRY (DSC)

Differential scanning calorimetry (DSC) is used to evaluate thermal behaviour, drug–excipient compatibility, and the stability of herbal–herbo-mineral systems. Thermal analysis can reveal changes in melting point, crystallinity, and degradation patterns, which may occur due to interactions between components during formulation or compression [41].

Such thermal transitions can significantly influence mechanical properties, structural integrity, and drug release characteristics of bilayer tablets. Therefore, DSC serves as a critical tool in ensuring formulation stability and compatibility.

X-RAY POWDER DIFFRACTION (XRPD)

X-ray powder diffraction (XRPD) is employed to assess the crystalline and amorphous nature of formulation components. Herbo-mineral ingredients typically exhibit distinct crystalline diffraction patterns, whereas herbal materials often display partially amorphous characteristics [41].

During tablet compression, high compression forces and interfacial interactions may induce changes in crystallinity, potentially affecting drug release behaviour and mechanical strength. XRPD analysis is therefore essential for confirming phase stability, detecting structural modifications, and ensuring the physicochemical integrity of both individual layers and the final bilayer tablet.

However, interpretation of XRPD data in complex polyherbal systems may be challenging due to overlapping diffraction peaks and heterogeneous composition.

PRE-FORMULATION CONSIDERATIONS IN HERBAL–HERBO-MINERAL BILAYER TABLETS

Pre-formulation studies play a critical role in the development of herbal–herbo-mineral bilayer tablet systems, as they provide essential information on the physicochemical and mechanical properties of the formulation components. Compared to synthetic drugs, herbal and herbo-mineral materials exhibit significant variability in particle size, surface area, moisture content, and phytochemical composition, which may vary between batches [42].

Such variability can significantly influence powder flow behaviour, packing characteristics, and compressibility, ultimately affecting tablet uniformity and performance. Therefore, the evaluation of micromeritic properties—including bulk density, tapped density, Hausner's ratio, and compressibility index—is essential to assess flowability and packing behaviour [43,44]. These parameters directly impact die filling, layer uniformity, and interfacial bonding in bilayer tablets.

Herbo-mineral components, such as Parpam and Chendooram, typically possess ultrafine particle size and unique deformation characteristics. These materials may undergo plastic deformation or brittle fracture during compression, influencing compaction behaviour and mechanical strength [45]. In bilayer systems, differences in deformation behaviour between herbal and herbo-mineral layers can result in uneven stress distribution at the interface, increasing the risk of delamination.

Variations in powder density and particle size distribution may further affect layer thickness, interfacial adhesion, and weight uniformity. Additionally, moisture-sensitive herbal components may alter cohesiveness and elastic recovery, leading to instability under high humidity conditions [46].

Therefore, a systematic evaluation of powder properties—including flow characteristics, deformation behaviour, moisture content, and packing properties—is essential to ensure reproducible manufacturing, uniform layer formation, and overall tablet stability [47].

OPTIMIZATION OF HERBAL–HERBO-MINERAL BILAYER TABLETS THROUGH A QUALITY BY DESIGN (QBD) APPROACH

The development of herbal–herbo-mineral bilayer tablets require a structured and risk-based optimization strategy due to the

inherent variability and complexity of the components. The Quality by Design (QbD) approach provides a systematic framework for ensuring consistent product quality by identifying and controlling critical formulation and process variables [12].

The Quality Target Product Profile (QTPP) is defined at the initial stage of development and outlines the desired quality characteristics of the final product, including mechanical strength, interfacial integrity, stability, and drug release behaviour. These attributes collectively determine the safety, efficacy, and performance of the dosage form.

Critical Quality Attributes (CQAs) are the key physical, chemical, or biological properties that must be maintained within specified limits to ensure product quality [49]. In bilayer tablets, CQAs include hardness, friability, layer adhesion, drug content uniformity, and release profile. These attributes are directly influenced by both material properties and process conditions [50].

Critical Material Attributes (CMAs), such as particle size distribution, moisture content, and deformation behaviour of herbal and herbo-mineral components, significantly affect powder flow, compressibility, and interfacial bonding. Similarly, Critical Process Parameters (CPPs)—including compression force, dwell time, and layer sequence—play a crucial role in determining tablet integrity and performance.

To optimize these variables, experimental design approaches such as Response Surface Methodology (RSM) can be employed to systematically evaluate the relationship between independent variables (CMAs and CPPs) and dependent responses (CQAs) [51,52]. Such statistical tools are particularly valuable in bilayer tablet development, where improper optimization may lead to defects such as delamination, poor hardness, or inconsistent drug release.

The implementation of a QbD approach enhances formulation robustness, ensures reproducibility, minimizes development risks, and improves regulatory acceptability. This is especially important for AYUSH-based formulations, where variability in raw materials necessitates a scientifically controlled and well-documented development strategy.

POST-COMPRESSION EVALUATION OF HERBAL–HERBO-MINERAL BILAYER TABLETS

Post-compression evaluation is essential to ensure the quality, mechanical integrity, and performance of bilayer tablets. In herbal–herbo-mineral systems, these evaluations are particularly important due to variability in material properties and the presence of two distinct layers.

PHYSICAL APPEARANCE AND STRUCTURAL INTEGRITY

Visual inspection is performed to identify defects such as capping, lamination, or layer separation. The absence of such defects indicates adequate interfacial bonding and structural stability of the bilayer tablet [53].

THICKNESS AND WEIGHT VARIATION

Thickness and weight variation are critical parameters that reflect uniform die filling and consistent layer distribution. In bilayer tablets, improper layer weight ratio may lead to variability in drug release and therapeutic performance [54].

HARDNESS AND MECHANICAL STRENGTH

Tablet hardness indicates the mechanical strength required to withstand handling, packaging, and transportation. Adequate hardness ensures structural integrity, while excessive hardness may delay disintegration and drug release [55].

FRIABILITY

Friability testing evaluates the ability of tablets to resist abrasion and mechanical stress. Low friability values indicate good mechanical resistance and suitability for commercial handling [57].

DISINTEGRATION TEST

Disintegration testing assesses the ability of the tablet to break down into smaller particles under physiological conditions. For bilayer tablets intended for simultaneous release, both layers should disintegrate in a coordinated manner to maintain therapeutic effectiveness [59].

IN VITRO DISSOLUTION STUDY

Dissolution studies are conducted to evaluate the rate and extent of drug release from the bilayer tablet. These studies are typically performed under standardized conditions to simulate gastrointestinal environments and ensure consistent release behaviour [60].

RELEASE KINETICS MODELLING

Drug release data are analysed using mathematical models such as zero-order, first-order, Higuchi, Korsmeyer–Peppas, and Hixson–Crowell equations to understand the release mechanism and kinetics [61].

STABILITY STUDIES

Stability studies are performed according to ICH and WHO guidelines to evaluate the effect of environmental conditions such as temperature and humidity on tablet properties. These studies ensure that the formulation maintains its physical integrity, drug content, and release profile over time [62].

DISCUSSION

The increasing global interest in Ayush systems, particularly following the COVID-19 pandemic, has highlighted the need for modernization of traditional dosage forms to meet contemporary healthcare expectations. While traditional formulations such as Chooranam remain therapeutically effective, patient preference has shifted toward more convenient and standardized dosage forms such as tablets and capsules.

The incorporation of bilayer tablet technology into herbal–herbo-mineral formulations provide a promising strategy to bridge traditional knowledge with modern pharmaceutical advancements. This approach enables improved dose precision, enhanced patient compliance, and the possibility of controlled or synchronized drug release.

However, the development of such systems requires careful consideration of traditional principles, particularly the concept of synergistic drug action and individualized therapy. The challenge lies in achieving a balance between pharmaceutical standardization and preservation of traditional therapeutic concepts.

Advancements in analytical techniques, formulation strategies, and Quality by Design (QbD) approaches offer significant opportunities to overcome these challenges. By integrating these modern scientific tools, it is possible to enhance the quality, safety, and global acceptability of Ayush-based formulations.

Thus, bilayer tablet technology represents not only a formulation advancement but also a strategic pathway for the scientific validation and global integration of traditional medicinal systems.

CONCLUSION

The development of bilayer tablets for herbal–herbo-mineral formulations represent a significant advancement in the modernization of Ayush medicinal systems. This approach enables the integration of traditional therapeutic concepts with contemporary pharmaceutical technologies, resulting in improved dose accuracy, enhanced patient compliance, and better control over drug release profiles.

Despite these advantages, several challenges remain, including variability in raw materials, interfacial instability, and the need for robust standardization strategies. Addressing these challenges requires a systematic approach involving pre-formulation studies, optimized formulation design, advanced analytical characterization, and Quality by Design (QbD) principles.

With continued research and scientific validation, bilayer tablet systems have the potential to enhance the global acceptance and clinical relevance of AYUSH-based formulations. This strategy provides a promising platform for delivering safe, effective, and standardized traditional medicines in a modern healthcare framework.

DECLARATIONS

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

Not applicable. The study did not involve humans or animals.

CONSENT FOR PUBLICATION

Not applicable.

AVAILABILITY OF DATA AND MATERIAL

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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