Review

Review on Ayush Oral Disintegrating Tablets (ODT's)—A Novel Solid Oral Dosage Form for Pediatric and Geriatric Use

Shree Devi M. S. * , Ashwin Kumar K. , Sathiyarajeswaran P. , Vinayak S. , Muthukumar N. J.

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Shree Devi M. S. [1,*], Ashwin Kumar K. [1], Sathiyarajeswaran P. [2], Vinayak S. [1] and Muthukumar N. J. [3]

[1] Dept of Pharmacy, R & D, Siddha Central Research Institute (CCRS) Arumbakkam, Chennai 600106 India

[2] Siddha Regional Research Institute, Kuayavar palayam-Pudhucherry 605013 India

[3] Director General, Central Council for Research in Siddha, Ministry of Ayush, Govt. of India, Chennai 600047, India

* Correspondence: shreemd@gmail.com; Tel.: +91 94430 56180

Abstract: This review highlights the innovative development of orally disintegrating tablets (ODTs) derived from Siddha traditional herbal medicine dosage forms. It emphasizes the advancements and transformative approaches in Siddha medicine that enable its integration into modern ODT's formulations, primarily aimed at improving patient compliance. The focus is particularly on pediatric and geriatric populations, addressing the unique challenges in adapting traditional formulations into contemporary dosage forms. Additionally, the incorporation of taste-masking techniques to enhance palatability for herbal drugs and enhance the patient compliance is discussed. Key aspects of preparation techniques, evaluation parameters, and strategies for ensuring the efficacy and stability of these formulations are comprehensively reviewed. This work underscores the potential of ODTs to enhance the accessibility and therapeutic acceptability of traditional herbal medicine Siddha across diverse age groups.

Keywords: orally disintegrating tablets; traditional herbal medicine; Ayush; Siddha medicine; patient compliance; taste masking; modern dosage forms; pediatric and geriatric populations; formulation challenges

1. Introduction

The traditional Indian medicinal system represents one of the most ancient traditional medical practices, underpinned by a robust scientific framework and a substantial historical record of therapeutic efficacy and cultural relevance [1]. The Indian system of medicine encompasses six distinct, officially recognized practices known as Ayush: Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy [2].

1.1. Siddha: A Revered System of Traditional Medicine

Siddha, a traditional medical system from India, is one of the oldest healing practices, originating in South India around 5000 BC. This system has Dravidian roots and is entirely documented in the Tamil language. It has been shaped by local traditions, deeply connected to the ancient Dravidian culture. The Siddha system is regarded as a scientific manifestation of the insights of the Siddhars, who were ancient scholars. According to Siddha literature, there are eighteen Siddhars who lived during various periods in southern India, each providing unique medicinal prescriptions for different ailments, which are now accessible in printed texts and palm leaf manuscripts. As one of the earliest indigenous health practices, it is crucial to preserve the Siddha system effectively and ensure its continuity for future generations [3].Many treatments for even the most challenging diseases have been developed from traditional medicines through advancements in science, such as reverse

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pharmacology and network pharmacology.In the tribal and rural areas, Siddha healers play a major role in providing healthcare and preserving traditional medical practices [4].

The Principles of Siddha medicine are based on the Five Elements (Aimpootham) and the Three Humors (Muththaddukal). It provides safe and effective herbal and herbo-mineral treatments for a broad spectrum of common and rare diseases, along with recommendations for lifestyle modifications, including diet. Siddha medicine includes 32 types of internal and 32 external medicinal preparations.[5].A combination of two or more herbs in mixture of powder form is refered as chooranam It is prepared by grinding either single or multiple ingredients such as dried roots, rhizomes, bark, wood, flowers, resins, leaves, seeds, and fruits [6]. but some defects and issues are associated with chooranas such as inconsistent dosage and measurement issues, palatability and patient compliance, stability and susceptibility to environmental factors,Difficulty in Transportation and Storage, Risk of Spillage and Cross-Contamination,Inconvenience in Administration, Shorter Shelf Life and Quality Control Issues, Risk of Inhalation or Throat Irritation.

To overcome these defects some of the alternative formulation methods need to be adopted for chooranas such as tablets, capsules, oral disintegrating tablet, oral disintegrating mini tablets etc.

1.1.1. Chooranas in Siddha Medicines [7]

As per the siddha formulary of India Some of the chooranas are listed below
Amukkara chooranam
Attatic chooranam
Seendhil chooranam
Seeraga chooranam
Sivathai churnam
Sundaivatral chooranam
Inji churnam
Kalarchi chooranam
Mayiliragadhi chooranam
Nilavagai chooranam
Parangipattai chooranam
Talisadi chooranam
Thirikadugu chooranam
Triphala chooranam

1.2. Oral Disintegrating Tablet

The oral delivery of active pharmaceutical ingredients has traditionally relied on conventional dosage forms such as tablets, capsules, and liquids, primarily due to their straightforward manufacturing processes and cost-effectiveness [8].The CDER as a part of FDA has defined that the odt is a orally admisnistering solid dosage form containing medicinal substance while placed upon the tongue it must follows the two basic characteristics that is the tablet disintegrants with in 30 seconds or less and the tablet weight of 500mg or less. However, projections from the National Institute of Population and Social Security Research indicate that by 2013, individuals aged 65 and older would constitute over a quarter of Japan's population, resulting in a significant number of elderly patients encountering difficulties with medication adherence due to compromised swallowing abilities [9]. Moreover, swallowing dysfunction and dysphagia represent significant challenges for effective oral pharmacotherapy [10]. To overcome these problems, one of the emerging dosage forms is the orally disintegrating tablet (ODT), which is advantageous as it disintegrates rapidly in the oral cavity upon contact with saliva, thereby obviating the requirement for swallowing. ODTs are particularly beneficial for delivering pharmaceuticals to heterogeneous patient populations, including geriatric and pediatric groups, who frequently exhibit impaired swallowing capabilities due to various physiological and psychological factors. This demographic transition underscores the necessity for innovative dosage forms that cater to the specific needs of older adults,

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ultimately enhancing medication adherence and improving therapeutic outcomes.Comparing to the chewable tablet the oral disintegrating tablets are slightly different in which the odt doesnot need any action of chewing or drinking liquid were the disintegration was takes places in the tongue followed by drug absorption [11].

1.2.1. Objective

The objective of this study is to formulate a novel dosage form within Siddha medicine by converting traditional chooranam into an orally disintegrating tablet, aligned with the guidelines of the Indian Pharmacopoeia.

1.2.2. Ideal Properties of Oral Disintegrating Tablet

It should be easily administered without the need for water and should disintegrate or dissolve in the oral cavity within seconds [12]. It need to produce pleasant feeling in the mouth and not leave any residue in the mouth after administration [13]. It facilitates a high level of drug incorporation [14]. It Need to Improve patient adherence.

1.2.3. Merits of Oral Disintegrating Tablet

There is no risk of airway obstruction during swallowing, which ensures safeadministration and enhances patient compliance [15]. Easy to administer for patients with difficulty swallowing tablets(dysphagia), as well as for unconscious in coma , bedridden patients, pediatric, and geriatric patients [16]. Cost effective Doesnot need water to swallow,Pregastric absorption of drugs leads to enhance the bioavailability of drugs and and patient compliance. Enables convenient administration and accurate dosing compared to powder formulations. Compared to liquid dosage forms, it offers more advantages in administration and is easier to carry. Prevents from first pass metabolism [17].

2. Discussion

Traditional herbal medicinal drugs are typically available in traditional dosage forms, which may be inconvenient for geriatric and pediatric patients due to issues such as difficulty in swallowing or taste. However, converting these traditional herbal dosage forms into novel, conventional dosage forms, such as orally disintegrating tablets (ODTs), could enhance patient acceptability, particularly for pediatric populations. These novel dosage forms offer several advantages, including ease of administration, faster onset of action, and improved bioavailability. Compared to traditional dosage forms, novel formulations benefit from the higher regulatory standards set by pharmacy councils, ensuring their safety, efficacy, and quality. This shift toward more patient-friendly formulations could improve adherence to treatment, particularly in vulnerable groups, and expand the accessibility of traditional herbal medicines in modern healthcare.

3. Materials and Methods

3.1. Preparation of Chooranam

Preparation of chooranam is followed by the traditional Indian siddha medicine formulary methods. The chooranam were prepared in the laboratory using the listed authenticated raw drugs [7]. The listed drugs are dried at certain temperatures and powdered separately further the powder is sieved through a fine mesh then the required quantities are weighed and mixed uniformly. Furthermore in the preparation of tablets the chooranam are described as API

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3.1.2. Salient Features of Herbal APIs (Chooranam) and Excipients [18]

Chooranam are prepared from single or multiple number of herbal plants by various traditional methods used as APIs for the preparation of herbal ODT tablets. Suitable excipients need to be selected which are biocompatible and don't affect the systematic effects and tablet properties considerable such as solubility, particle size, hygroscopicity, compressibility, can change the features of ODT. For the preparation of ODTs there are several criteria needs to be followed by the drug such as the drug should be ionised dispersed and penetrated into the mucosa without leaving any residue on the oral cavity with pleasant and palatable to enhance the patient acceptability furthermore, for frequent use the active ingredient weight should be less than 50mg low production cost environmentally resistance conventional procedures for packing which is elegant appealing to patients. In the formulation of odt excipients plays a crucial rate by fulfilling the requirements, such as taste masking, water solubility, enhanced dispersibility. As per IP regulation the excipients should be used and within the ranges excipients needed for ODT preparations are listed in the Table 1.

Table 1. list of excipients and its characteristics.

Excipients	**Function**	**Example**
Super disintegrant	It produces rapid disintegration anddissolution rate. In the presence of other ingredients like water soluble excipiets and effervescent agents furtherenhances the disintegration process.	Microcrystalline cellulose Crospovidone, sodium starch gpycolate, carboxyl methyl cellulose, pregelatinated starch [19].
Binder	Maintains the integrity strength of tablet until administration	PVP, Hydroxy propyl methyl cellulos, poly vinyl alcohol
Filler	Increases bulkiness of tablet	Sugar and sugar based derivatives (Maltos, mannitol, lactilol, xylitol)
Surface active agents	Enhances solubilization and reduces interfacial tension of ODT.	Starch hydrolysate, sodium doecylsulfate, sodium lauryl sulphate [20].
Lubricants	Reduces the friction between the punchesand enhances bulkiness of the tablet	Magnesium stearate, zinc state, Poly ethyleneglycol, magnesium lauryl sulphate [21].
Sweetner	Masking the unpleasant taste the tabletsbacts as taste masker	Sucralose, aspartame, sodiumsaccharine
Flavors	Enhances the patient compliance and acceptability	Peppermint, clove oil, anise oil, citrus oils, fruit essences [19].

3.2. Preparation Methods of ODTs

Various conventional methods have been developed for the preparation of ODTs such as direct compression, lyophilization, spray drying, sublimation, cotton candy process, mass extrusion, phase transition process, melt granulation, molding [22]. These methods are summarised below.

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3.2.1. Direct Compression

It's the simplest and cost effective method using conventional equipments and excipients to manufacture oral disintegrating tablets. In this method addition of disintegrants at optimum levels in the tablets. It enhances the disintegration and dissolution rate but it results in lower hardness compared to conventional tablets. To overcome these problems different granulation methods are used to enhance the product characteristics.

3.2.1.1. Key Aspects

It is similar to conventional tablets but with higher percentage of disintegrants, to enhance the disintegration process in the tablets, easiest and cost effective method.

3.2.2. Freeze Drying [23]

It is also called lyophilization. In this method the drugs are dispersed/dissolved in a carrier of aqueous solution. Then the mixture is filled by pouring into the wells of perforated blister packs. The trays with blister packs are then passed through liquid nitrogen freezing tunnel for freezing. Then the frozen liquids blisters are refrigerated to continue the freeze drying finally the the blisters are packed

3.2.2.1. Key Aspects

The end product is highly porous low disintegration time rapid absorption and increased bioavailability. But this method has a major drawback such as high production costs and a time-consuming process and conventional packing are not suitable for this products.

3.2.3. Molding [24]

In this method the tablets are produced by molding under low pressure compared to the conventional tablets compression pressure by using water soluble comtents with hydro alcoholic solvents.

3.2.3.1. Key Aspects

Less compact and more porous enhancing rapid disintegration and dissolution.

3.2.4. Sublimation

Inert solid material that volatilize rapidly like urea, camphor, ammonium carbonate were added to the other tablet contents and compressed directly due to endothermic reaction. the inert solid materials are volatilized this process is sublimation due to this porous structure generated on the compressed tablets [18,25].

3.2.4.1. Key Aspects

Rapid disintegration/ dissolution due to porous in nature heat-sensitive drugs are not suitable due to harmful residual adjuvants

3.2.5. Spray Drying

In this method the liquid mixture of drug and excipients are sprayed into the hot chamber which creates porous structure then the resulting microparticles are combined with mannitol and kneaded with distilled water and dried at 60oC for 2 hours after drying the resulted granules are sieved mixed with the additional excipients are compressed into tablets [26].

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3.2.5.1. Key Aspects

This method are suitable for inhalation and oral formulation, rapid disintegration and dissolution but high in production cost.

3.2.6. Cotton Candy Process

A specialised spinning device is used to produce crystalline flosses the flosses were formed by flash melting and spinning saccharides or polysaccharides such as polymaltodextrin at high temperatures180-266^{o}C [19],[27].

The resulting flosses of matrix is milled and mixed with api and additional excipients further compressed into oral disintegrating tablets.

3.2.6.1. Key Aspects

Mainly implemented for taste masking, rapid disintegration, accumulation of large quantity of drugs. But thermoliable drugs are not suitable.

3.2.7. Mass Extrusion

In this process water soluble solvents such as polyethylene glycol, ethanol or methanol are used to soften the drug mixture which is than extruded through a syringe or sieve mesh after extrusion the volatile solvents are removed by evaporation [28]. As a result a solidified string shaped gel is obtained and which is than crushed and added to additional excipients converted into ODT by compaction methods.

3.2.7.1. Key Aspects

In this method the drug taste is masked, and makes the drug more porous to enhance the disintegration.

3.3. Quality Control Test

3.3.1. For Herbal Drug

As per PLIM & IP regulation the Quality control parameters for herbal drugs is studied.

3.3.1.1. Authentication Study [29]

Various methods are often used for authentication, identification, and discrimination purposes. These methods involve single approaches such as molecular-based techniques, chemical fingerprinting, and morphological and anatomical analysis. Overall, each of these methods has a different approach to the authentication of herbal-related products, and the choice depends on the specific needs.

3.3.1.2. HPTLC

High-performance thin-layer chromatography (HPTLC) was conducted on 20×10 cm silica gel 60 F254 plates, using a mobile phase composed of ethyl acetate, methanol, formic acid, and water in a ratio of [20:2.5:0.5:2 (v/v)]. Standard solutions of Quercetin, Rutin, Luteolin, and Vitexin (each at a concentration of 1 mg/mL, with 5.0 µL of each) were applied to the plates in 10 mm bands. The application of the samples was carried out using an automated band applicator with a 100 µL syringe. The settings used for application were as follows: band length of 10 mm, application rate of 10 sec/µL, a distance of 4 mm between bands, 1.5 cm from the plate edge, and 2 cm from the bottom of the plate. For band quantification, densitometric scanning was performed using specific scanning software. The scan was carried out in absorption/reflection mode with a slit size of 5 × 0.1 mm, a scanning speed

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of 20 mm/s, and a monochromator bandwidth of 20 nm.[30]. The system was optimized for wavelengths of 254 nm, 366 nm, and within the visible range.

3.3.2. For Formulated ODTs

Quality control parameters for ODTs is slightly different from conventional tablets such as wetting time, absorption ratio, moisture uptake, taste evaluation and invivo disintegration time are used for ODT they are classified into following two types [18].

Pre compression parameter

Post compression tablet parameter

3.3.2.1. Pre Compression Parameters [51].

Pre compression parameters are evaluated for the purpose of determining the powder characteristics for subsequent processing the evaluation studies which includes bulk density, tap density, carrs index, angle of repose and hausners ratio.

3.3.2.1.1. Bulk Density

An accurately weighed quantity of powder is introduced into a 100 mL measuring cylinder. The volume of the powder in the cylinder is measured, and the bulk density is calculated using the following formula:

Bulk density= weight of the powder /volume of the powder

3.3.2.1.2. Tapped Density

An accurately weighed quantity of powder is transferred into a 100 mL measuring cylinder. The cylinder is tapped 100 times on a hard, flat surface. The tapped volume of the powder in the cylinder is noted, and the tapped density is calculated using the formula

Tapped density = weight of the powder /tapped volume of the powder

3.3.2.1.3. Flow Rate

The flow rate of granules is determined by pouring an accurately weighed quantity of granules into a funnel with an 8 mm orifice diameter. The granules are allowed to flow freely through the orifice, and the time taken for the complete dispersion is recorded [31]. The flow rate is then calculated using the formula

Flow rate =weight of the granules / time in seconds

3.3.2.1.4. Carrs Index

Carr's index is a measure of the compressibility percentage of powder blends and can be calculated using the formula

% compressibility= Df-Do/Dfx 100

Df= Bulk density

Do= Tapped density

3.3.2.1.5. Hausners Ratio [32]

H ausners ratio is determined by the basis of bulk density and tapped density by using the following formula

Hausner ratio = Tapped density/Bulk density

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Table 2. IP limits for compressibility index,flowability and hausners ratio.

Compressibility Index	Flowability	Hausner's Ratio
5–15	Excellent	1.05–1.18
12–16	Good	1.14–1.20
18–21	Fair-passable	1.22–1.26
21–33	Poor	1.30–1.54
33–37	Very poor	1.50–1.61
>40	Very-very poor	>1.61

3.3.2.1.6. Angle of Repose [33]

The angle of repose is defined as the maximum possible angle between the horizontal plane and the surface of the pile of powder. In loose powder or granules, the frictional force can be measured by the angle of repose, which indicates the flow property of the powder.The angle of repose is determined by placing a funnel at a standard, defined height (h). The powder is allowed to flow through the funnel, forming a pile [50]. The angle of repose is calculated using the height and radius of the powder heap.

Table 3. IP Limits for angle of repose.

Angle of repose	Flowability
<25°	Excellent flow
25–30°	Good
30–40°	Satisfactory or passable
40–50°	Poor
>50°	Very poor or damp

3.3.2.1.7. FTIR Study

This study was performed to determine whether the active ingredients are compatible with the excipients. Individual excipients were also analyzed using FTIR within the range of 4000–600 cm^{-1}. After recording, changes in the vibrational or stretching bands of key functional groups in the FTIR spectrum were used to indicate drug-excipient interactions. In this method, the pellet was prepared using the potassium bromide pressed pellet technique. The developed pellets were placed in the IR chamber of the FTIR spectrophotometer, and the spectrum of functional groups was determined using the software [34].

3.3.2.2. Post Compression Tablet Parameter

3.3.2.2.1. Organoleptic Characteristics

The shape and size of uncoated tablets were examined, whether in round, oval, or caplet form, with weights ranging from 150 mg to 900 mg. The color of the tablets was assessed under both natural and artificial light. Additionally, the dimensions and gloss finish were also determined [35].

3.3.2.2.2. Weight Variation

Weight variation is determined by weighing randomly taken 20 weighs individually tablets from a batch and calculate the average weight of the tablet once the average weight is obtained the mean weight is calculated [47].

For lower limit:

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Minimum weight – Average weight/Average Weight × 100

For upper limit: Maximum weight – Average weight/Average Weight × 100

Table 4. IP limits for weight variation.

Weight average (mg)	Max SD.
Less than 85mg	10
85mg – 250mg	7.5
Greater than 250	5

3.3.2.2.3. Hardness and Thickness [36]

Hardness of the tablet is termed as force require to break the tablet, By randomly taking three tablet and each tablet is placed vertically on the monsanto hardness tester to determine the strength of the tablet. The hardness of the tablet is measured in kg/cm^2. Thickness of the tablet is determined by using vernier calliper.

3.3.2.2.4. Friability

Friability is used to assess the tablet's durability during packing and transportation. The friability is evaluated by placing 10 tablets in a Roche friabilator for 4 minutes at 25 rpm [37]. The percentage of weight loss is calculated using the following formula

% Friability = W1 – W2/W1 × 100

Where, W1 = Initial weight of tablets

W2 = Final weight of tablets

3.3.2.2.5. Disintegration Test

The disintegration of the tablet is evaluated using the USP disintegration apparatus, which consists of six glass tubes, each 3 inches long, open at the top and positioned against a 10-inch screen at the bottom end of the basket rack assembly. A tablet is placed in each tube, and the basket is then immersed in a beaker containing 1 liter of water, maintained at 37 ± 2°C. The basket is positioned 2.5 cm above the bottom of the beaker. The test is run, and the time taken for the tablet to completely disintegrate is recorded.

3.3.2.2.6. Wetting Time (Wt) and Water Absorption Ratio (R)

The wetting time of the tablet is determined by placing the Whatman filter paper, folded once diametrically in a petri dish with a diameter of 8.5 cm. A small amount of water (8 mL) containing the water-soluble dye Rhodamine B (0.1 g) was added to the filter paper inside the Petri dish at the initial time =0 hrs the tablet is placed on the paper after complete wetting the time is recorded. The emergence of dye on the tablet surface indicated the point of complete wetting [38].

After the complete wetting the tablet is reweighed and determined the absorption ratio by the following equation

R=wa-wb/wbx100

Wa = Weight of the tablet after absorption (after it has fully absorbed water)

Wb = Initial weight of the tablet (before water absorption)

3.3.2.2.7. Taste/Mouth Sensation Test

Orally disintegrating tablet needs to be plays a major role on the taste masking to enhance the patience compliance especially for paediatrics and geriatrics accetabilty, where the mouth feeling test can be determined by choosing the healthy volunteers by placing the tablet different batches on the tongue for 30 seconds [39]. and determine the sensation of the patients ratings like 0= good 1= tasteless 2= slightly bitter 3= bitterness 4= Terrible .

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3.3.2.2.8. Moisture Uptake

This test is performed to determine the stability of the formulation by placing 10 tablets on the dessicator (37° C, 1 d)and weighed after that the tablets are placed at 75% RH (25° C, 15d). reweigh the tablet as result the amount of moisture uptake by the tablet is determined [40,48].

3.3.2.2.9. Invitro Disintegration Study [41]

It is determined by dropping the tablet of batches in the beaker containing 50ml of ph buffer 6.8. in that 3 tablets are randomly selected from each formulation and the dispersion time of the tablet is recorded

3.3.2.2.10. In-Vivo Disintegration Test

This test is performed on healthy volunteers by placing 2 or 3 tablets in the mouth and measuring the time, in seconds, until the tablet completely disintegrates [49].

3.3.2.2.11. In-Vitro Dissolution Test [42]

Invitro dissolution study was carried out by using usp II type dissolution apparatus is used where the dissolution medium is filled with phosphate buffer ph.6.8. and maintains the temperature level at 37±0.5°C. After the test started a 5ml aliquot of dissolution medium was pipette out from the medium at the time interval of 2 minutes and replace it with phosphate buffer. The pipette out liquid is filteres and diluted with suitable solvents analysed to determine the amount of drug released from the formulation is determined.

3.3.2.2.12. Drug Content

For drug content analysis, accurately weigh 20 tablets and crush them into a fine powder. Weigh a sample of the powder equivalent to the required amount of active drug (in mg) and dissolve it in a suitable solvent. The solution should then be filtered through a 0.45 µm millipore filter to remove any impurities [43,44]. Finally, the filtered solution is analyzed using a UV spectrophotometer to determine the drug content.

3.3.2.2.13. Stability Study

As per ich guidelines the stabilty study was carried out to determine the stability were 20 tablets are packed in each 10 mL high-density polyethylene (HDPE) bottle and sealed thermally, then placed in a humidity chamber (45 ± 2° C and 75% ± 5% RH)[45][46]. for three months at each month the tablets are evaluated that each formulation is remains under the mentioned specification means passes and no significant changesin the formulation.

4. Conclusions

Currently, the preparation and evaluation of Siddha drug dosage forms (Tablets) primarily rely on basic evaluation methods such as friability and disintegration. However, there is a growing need for more comprehensive evaluation parameters that better reflect the unique characteristics and challenges of herbal medicines. In the future, an increasing number of researchers will likely focus on the development of novel herbal dosage forms, driven by the rising global interest in natural medicine. The inclusion of additional evaluation parameters, along with defined ranges, will significantly contribute to enhancing the quality and standardization of herbal products. This will not only improve the efficacy and safety of herbal medicines but also promote the widespread acceptance and growth of the herbal market, making these treatments more accessible and reliable for patients worldwide.

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Abbreviations

The following abbreviations are used in this manuscript:

ODT	Orally Disintegrating Tablet
API	Active Pharmaceutical Ingredients
BD	Bulk Density
TD	Tapped Density

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