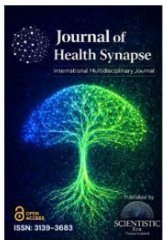
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Development of a Mouth-Dissolving Granule Formulation of Herbal Extract: Formulation Strategies, Evaluation Parameters, Stability and Future Perspectives

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A B S T R A C T

Herbal medicinal products have gained substantial attention in pharmaceutical research owing to their diverse phytochemical constituents, therapeutic potential, and growing consumer preference for plant-derived healthcare. However, translating botanical extracts into effective solid oral dosage forms is frequently challenged by batch-to-batch phytochemical variability, limited aqueous solubility of selected constituents, unpleasant bitter or astringent taste, hygroscopic moisture sensitivity, and difficulties in achieving uniform active distribution. Mouth-dissolving granules (MDGs) represent an attractive orodispersible oral delivery platform engineered to wet, disintegrate, and disperse rapidly upon contact with saliva in the oral cavity without requiring drinking water. This review examines the formulation and development of mouth-dissolving granules incorporating a water-extracted powder obtained from the fruit of Anisophyllea disticha L. (commonly known as Sa Liang), with attention to botanical authentication, marker-compound verification (including 5-hydroxy-2-methyl-4H-pyran-4-one), excipient selection, and granulation methodologies. Key formulation and process variables—such as binder concentration, superdisintegrant level, granule particle size, residual moisture, and drying temperature—are discussed alongside micromeritic flow indices, scanning electron microscopy (SEM) morphology, salivary disintegration versus dissolution behavior, electronic-tongue and sensory acceptability, and ICH Q1A(R2) stability testing. Quality by Design (QbD), ICH Q9(R1) risk management, regulatory compliance, and future research priorities are also addressed, emphasizing that oral-health performance and safety require rigorous analytical and experimental validation.

1. Introduction

Herbal medicines have long occupied a prominent role in traditional healthcare systems and continue to attract contemporary pharmaceutical investigation owing to their structurally diverse secondary metabolites and potential therapeutic or preventive applications [6,37,38]. Converting crude botanical materials into modern pharmaceutical dosage forms requires preserving active chemical integrity while ensuring convenient dosing, physical and chemical stability,

and batch-to-batch reproducibility [37,38,41].

Conventional herbal preparations—such as raw powders, decoctions, syrups, large compressed tablets, and capsules—frequently present practical drawbacks, including swallowing difficulty (dysphagia) in pediatric and geriatric patients, unpleasant bitter or astringent taste, poor dispersibility, dose inconsistency, and limited patient compliance [1,2,4,14]. These limitations have stimulated interest in orodispersible drug delivery platforms—including orally disintegrating tablets (ODTs), orodispersible films (ODFs), fast-dissolving pellets, and mouth-dissolving granules (MDGs) [1,2,12,13]. Mouth-dissolving granules are solid particulate systems designed to rapidly break apart and disperse upon contact with saliva in the oral cavity without requiring water, while offering flexible dose titration, lower compaction stress on sensitive phytoconstituents, and convenient unit-dose sachet or stick-pack packaging [1,4,6].

The present review focuses on mouth-dissolving granules formulated with a water-extracted powder derived from the fruit of Anisophyllea disticha L., locally known as Sa Liang [8]. Background documentation associates fruit material collected from the Maeklong River basin in Thailand (2009) and processed into a water-extracted powder with potential oral cavity cleansing and sweetening applications, alongside references to 5-hydroxy-2-methyl-4H-pyran-4-one; however, these historical and phytochemical attributions require verification against primary authenticated literature and analytical marker confirmation [8,37,40].

2. Rationale, Objectives, and Literature Context

2.1. Formulation Rationale and Development Objectives

Formulating a water-extracted herbal powder into mouth-dissolving granules addresses key biopharmaceutical and practical limitations of liquid or ungranulated herbal powders [1,5,6]: (i) water-free oral administration improves convenience and compliance; (ii) rapid salivary wetting promotes prompt dispersion in the oral cavity; (iii) solid granulation simplifies handling, transport, and moisture-barrier packaging; (iv) controlled granulation improves active distribution and flow uniformity; (v) sweeteners and flavors mask unpalatable herbal notes; and (vi) dry solid states can reduce hydrolytic degradation when moisture is strictly controlled [9,27,28].

The primary objectives of developing mouth-dissolving granules containing A. disticha fruit extract are to identify compatible orodispersible excipients, select an appropriate granulation process, achieve uniform extract distribution, evaluate micromeritic and physicochemical properties, characterize salivary disintegration and marker dissolution, optimize taste and mouthfeel, establish ICH Q1A(R2) stability, and define reproducible quality control specifications [9,10,39].

2.2. Oral Dissolution Technologies and Herbal Excipient Selection

Orodispersible systems encompass ODTs, ODFs, mouth-dissolving granules, fast-dissolving pellets, orodispersible powders, and effervescent oral preparations [1,2,12,15]. Although US FDA guidance recommends a disintegration time of 30 seconds or less for tablets designated as ODTs, that benchmark applies specifically to compressed tablets and should not be assumed as a rigid regulatory mandate for granules without formulation-specific justification [1,3]. Prior work on herbal granules—such as wet-granulated Orthosiphon aristatus leaf extract granules and plant-derived instant granules—demonstrates that diluent choice, moisture content, and granulation conditions strongly influence flowability, disintegration, dissolution, and sensory taste profiles [5,7,44].

Herbal extracts pose distinct formulation challenges, including seasonal or geographical phytochemical variability, limited aqueous solubility of specific secondary metabolites, bitter or astringent taste, hygroscopic caking, and potential drug–excipient interactions [5,6,37,39]. As summarized in Table 1, rational excipient selection balances mechanical granule strength against rapid salivary breakup and palatability [2,17,22,36].

Table 1. Functional Categories and Representative Pharmaceutical Excipients for Mouth-Dissolving Herbal Granules

Excipient Category	Representative Examples	Primary Functional Role in Granules
Herbal Active Ingredient	Water-extracted Anisophyllea disticha L. fruit powder	Provides target botanical phytochemicals for oral cavity cleansing / application [8]
Diluents / Fillers	Mannitol, lactose, microcrystalline cellulose, maltodextrin	Provides formulation bulk; mannitol imparts pleasant taste and cooling sensation [2,36]
Binders	Polyvinylpyrrolidone (PVP K30), HPMC, HPC, starch paste, natural gums	Promotes particle adhesion for granule integrity; excess delays disintegration [22,36]
Superdisintegrants	Sodium starch glycolate (SSG),	Accelerates capillary water uptake

	croscarmellose sodium, crospovidone	and swelling for rapid granule breakup [17,18,19]
Sweetening Agents	Mannitol, sucralose, aspartame, stevia-derived sweeteners	Improves palatability and masks bitter or astringent herbal notes [27,28,30]
Flavouring Agents	Peppermint, spearmint, mint, orange, lemon flavors	Enhances sensory acceptance and masks unpleasant herbal flavors [27,30]
Lubricants & Glidants	Magnesium stearate, colloidal silicon dioxide, talc	Reduces friction and improves powder flow; hydrophobic lubricant levels kept low [20,21,36]

3. Proposed Formulation Framework and Granulation Process

3.1. Extract Specifications and Proposed Composition

Before formulation trials, raw botanical material must be authenticated with voucher documentation and evaluated for macroscopic/microscopic identity, moisture content, total ash and extractive values, qualitative phytochemical classes (flavonoids, phenolics, tannins, alkaloids, saponins, terpenoids, glycosides), microbial limits, heavy metals, pesticide residues, and HPLC, LC-MS, or spectroscopic marker confirmation [8,37,39–41]. The dried water-extracted powder is also assessed for color, odor, dispersibility, and hygroscopicity.

Table 2 outlines the proposed formulation components for A. disticha mouth-dissolving granules; exact excipient proportions must be determined experimentally through screening and optimization studies rather than fixed a priori [2,6,36].

Table 2. Proposed Formulation Components and Functional Roles for Mouth-Dissolving Herbal Granules

Formulation Component	Proposed Material	Formulation Purpose
Active Ingredient	Water-extracted A. disticha fruit powder	Standardized botanical active material [8]
Diluent	Mannitol	Bulking agent providing sweet taste and smooth cooling mouthfeel [36]
Binder	PVP K30 or suitable alternative	Promotes cohesive granule formation during granulation [22]
Superdisintegrant	Sodium starch glycolate (or crospovidone)	Facilitates rapid wetting and granule breakup in saliva [17,18]
Sweetening Agent	Sucralose or stevia sweetener	Enhances sweetness and masks astringent herbal taste [28,30]
Flavouring Agent	Mint or fruit flavor	Improves overall flavor profile and acceptability [27]
Glidant	Colloidal silicon dioxide	Improves powder flowability during blending and filling [20,36]
Lubricant	Magnesium stearate	Reduces inter-particulate friction during processing [21,36]

3.2. Granulation Techniques, Process Variables, and Scale-Up

Granulation converts fine powders into uniform, free-flowing aggregates via wet granulation (binder liquid addition, wet screening, and drying), dry granulation (compaction without liquid binder followed by milling/sieving), or fluid-bed granulation (binder spraying onto air-suspended particles) [23–26]. Wet or fluid-bed granulation is suitable when A. disticha constituents tolerate controlled moisture and drying conditions, requiring optimization of binder concentration, granulating fluid volume, mixing time, granulation endpoint, drying temperature and duration, screen mesh size, and final granule size [23,25,26].

Laboratory-scale trials using analytical balances, sieves, mixers, granulators, fluid-bed or tray dryers, multi-mills, sieve shakers, moisture analyzers, bulk-density testers, and sachet fillers precede pilot scale-up, where binder distribution, drying uniformity, and particle-size consistency must be verified [22,23,26].

4. Physicochemical, Salivary, Sensory, and Stability Evaluation

4.1. Micromeritics, Morphology, Disintegration, Dissolution, and Taste

Powder flowability and packing behavior during handling and sachet filling are evaluated using angle of repose, bulk density, tapped density, Carr's compressibility index (CI), and Hausner ratio (HR) [20,21,22]:

$$\tan\theta = h / r \quad | \quad \rho b = M / Vb \quad | \quad \rho t = M / Vt \quad | \quad CI = [(\rho t - \rho b) / \rho t] \times 100 \quad | \quad HR = \rho t / \rho b$$

where θ is angle of repose, h and r are heap height and radius, M is mass, Vb is bulk volume, and Vt is tapped volume. Sieve analysis and scanning electron microscopy (SEM) assess particle-size distribution, shape, surface roughness, and aggregation, avoiding overly coarse particles that cause a gritty oral feel [7,22].

As illustrated in Figure 1, salivary evaluation in simulated salivary fluid at ~37°C (accounting for limited saliva volume and brief contact time) should distinguish three non-interchangeable processes: disintegration (granule breakup into smaller particles), dispersion (particle distribution across the medium), and dissolution (molecular release of soluble constituents, quantified via validated HPLC or UV-visible spectrophotometry as % Release = [Qt / Q0] × 100) [7,19,31, 69]. Marker release from a complex extract does not necessarily represent release of every minor phytochemical [6,39,70-76]. Sensory testing—using ethically approved human panels and electronic tongue taste profiling—evaluates sweetness, bitterness masking, flavor, cooling mouthfeel, grittiness, aftertaste, and mucosal comfort [7,29].

Figure 1. Saliva-Triggered Wicking, Superdisintegrant Swelling, Dispersion, and Release Mechanism of Herbal Mouth-Dissolving Granules

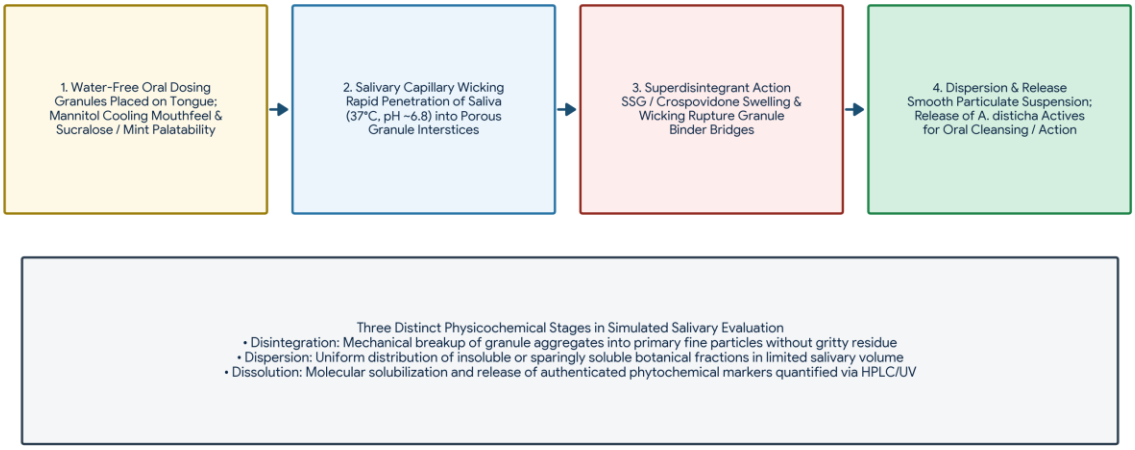


Figure 1. *Saliva-triggered wicking, superdisintegrant swelling, dispersion, and marker dissolution mechanism of Anisophyllea disticha mouth-dissolving granules.*

4.2. Stability, Bioavailability, QbD Risk Assessment, and Regulation

Stability studies under ICH Q1A(R2) monitor appearance, color, odor, moisture content, caking/aggregation, flowability, disintegration time, dissolution, marker content, and microbial limits in moisture- and light-protective single-dose sachets or laminated stick packs [9,36]. Rapid oral disintegration aids local mucosal contact—relevant for an oral cavity cleansing concept—but does not by itself guarantee systemic bioavailability, which depends on solubility, dissolution rate, stability, membrane permeability, and metabolism [4,63-68].

Applying Quality by Design (ICH Q8(R2)) and Quality Risk Management (ICH Q9(R1)) defines the Quality Target Product Profile (QTPP), Critical Quality Attributes (CQAs), Critical Material Attributes (CMAs), and Critical Process Parameters (CPPs) [10,11,32,33]. As shown in Figure 2 and detailed in Table 3, Failure Mode and Effects Analysis (FMEA) prioritizes formulation and manufacturing risks and establishes targeted control strategies [11,32]. Regulatory compliance requires authenticated botanical sourcing, heavy-metal, pesticide, residual solvent, and microbial testing, excipient safety, good manufacturing practices, and substantiated oral-care or health claims aligned with applicable pharmaceutical, food, or traditional medicine regulations [6,8,37,40].

Figure 2. Quality by Design (QbD) and FMEA Risk Control Architecture for Anisophyllea disticha Mouth-Dissolving Granules

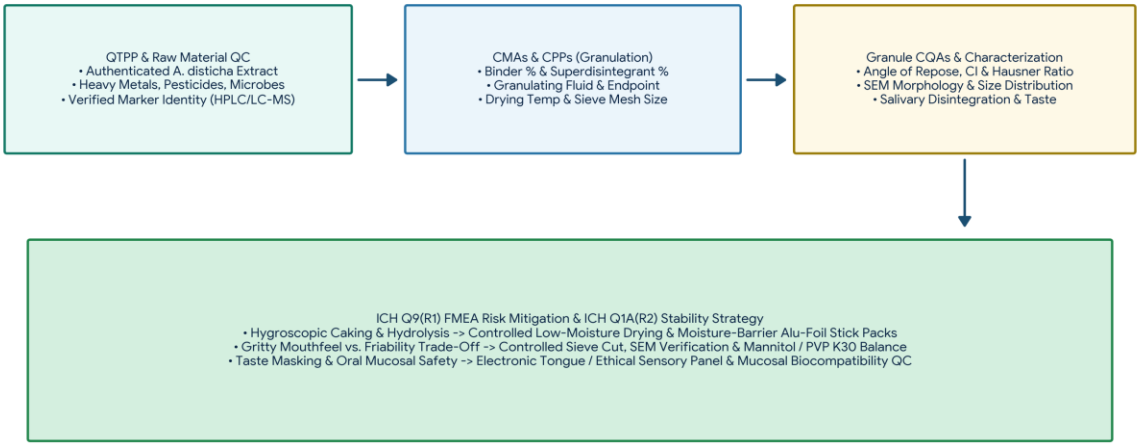


Figure 2. *ICH Q8(R2) Quality by Design (QbD) and ICH Q9(R1) FMEA risk control architecture for Anisophyllea disticha mouth-dissolving granules.*

Table 3. Major Failure Modes, Potential Impacts, and Risk Control Strategies for Herbal Mouth-Dissolving Granules

Potential Risk	Possible Impact	Control Strategy
Herbal Extract Variability	Inconsistent potency, color, or taste	Botanical authentication and HPLC/LC-MS marker standardization [8,37]
Excessive Moisture	Granule aggregation, caking, or degradation	Controlled drying, low moisture targets, and moisture-barrier stick packs [9,36]
Excessive Binder	Delayed salivary disintegration	Binder concentration optimization via DoE screening [10,22]
Poor Flowability	Non-uniform sachet or capsule filling	Particle-size control and glidant optimization [20,21,36]
Unpleasant Taste	Reduced palatability and patient acceptance	Sweetener/flavor taste masking and electronic tongue evaluation [27,29,30]
Large Particle Size	Gritty mouthfeel in the oral cavity	Sieve-cut particle-size optimization and SEM morphology checks [7,22]
Marker Degradation	Loss of chemical quality during storage	Stability-indicating assay and protective packaging [9,11]

5. Discussion, Future Perspectives, and Conclusion

Mouth-dissolving granules offer a practical way to convert A. disticha fruit extract into a convenient, water-free solid oral formulation, provided wet or fluid-bed granulation avoids excessive moisture and thermal stress on sensitive phytochemicals [5,6,8,23]. Balancing granule mechanical integrity against rapid salivary dispersion—using diluents such as mannitol, superdisintegrants such as sodium starch glycolate or crospovidone, binders, and taste-masking excipients—while distinguishing physical dispersion from marker dissolution remains central to formulation design [6,7,17,36]. Because experimental literature specifically on A. disticha mouth-dissolving granules is currently limited, this platform represents an early-stage research opportunity rather than an established oral healthcare product [57-62].

Future research should prioritize botanical authentication, analytical marker verification, excipient compatibility, DoE process optimization, oral mucosal tolerability, and comparative in vitro/in vivo performance studies [6,8,10,45–56]. In conclusion, mouth-dissolving granules represent a promising platform for delivering standardized herbal extracts such as water-extracted A. disticha fruit powder, contingent upon systematic excipient and granulation optimization, micromeritic, salivary dissolution, sensory, and ICH Q1A(R2) stability evaluation, and QbD/FMEA risk control.

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