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Herbal Candies as Novel Oral Dosage Forms: Formulation Strategies, Phytochemical Stability, And Therapeutic Evaluation

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ABSTRACT

Poor aqueous solubility, physicochemical instability, poor oral bioavailability, poor palatability, and patient compliance are common barriers to the use of herbal therapeutics, further amplified by poor palatability and patient adherence in traditional dosage alternatives. This review has put forward herbal candies as a highly developed system of oral/mucosal drug delivery that co-purposes confectionery matrices combined with pharmaceutical design. Scopus, PubMed and Web of Science databases were searched systematically in terms of the formulation strategies, physicochemical characterization, stability and biopharmaceutical performance. It has been found that sugar and hydrocolloid based matrices can be used to achieve controlled dissolution, prolonged oral retention, and partial buccal absorption and hence reduced first-pass metabolism and improved a systemic exposure. Advanced technology like microencapsulation, nanoemulsions, and inclusion complexation are important as they enhance solubility, phytoconstituents are not subjected to thermal and oxidative degradation like in the other methods, and this also controls release kinetics. The quality and reproducibility of the products is ensured by standardized assessment techniques such as dissolution profiling, mechanical characterization, content uniformity and stability investigations all in harmony with the requirements of the International Council for Harmonisation. Nonetheless, the combination of Quality by Design (QbD) and state-of-the-art delivery technologies has high optimization and scalability potential. The bottom line is that herbal candies can offer promising patient-centric drug delivery platform with extensive translational and commercial potential.

I. INTRODUCTION

The existing carrier-based platforms in the market such liposomes, phytosomes, solid lipid nanoparticle, and polymeric nanocarrier have undergone a paradigm shift in the traditional dosage form of the phytoconstituents, including decoctions, powders, and tinctures. A large percentage of plant based bioactives belong to Biopharmaceutics Classification System Class II and IV with a poor aqueous solubility, low permeability and great extent of presystemic metabolism mediated by cytochrome P450 enzymes and efflux transporters such as P-glycoprotein ultimately resulting in low oral bioavailability(1,2). Innovative strategies of state-of-the-art delivery through nanoscale engineering, lipid-based encapsulation, and amorphous dispersion approaches have shown to greatly improve solubilization, stability and pharmacokinetic performance. Nevertheless, traditional oral dosage (tablets and capsules) still exhibits such limitations as dysphagia, low palatability, dose variability, and inconsistent gastrointestinal transit, which consequently leads to the diminished compliance of patients, especially in children and the elderly(3–5).

In this regard, novel interdisciplinary frameworks of confectionery delivery systems comprising pharmaceutical science and food-based delivery systems have developed. Such systems use sugar or hydrocolloid matrices (e.g., sucrose, gelatin, pectin) to create lozenges, gummies and chewable candies that are capable of modulating the release of drugs in the case of diffusion and matrix mediated mechanisms. The long residence time of the oral cavity promotes oromucosal absorption, in part bypassing the first-pass metabolism of the liver, and increasing systemic exposure. The silicy or semi-solid matrix also offers a protective microenvironment that holds labile phytoconstituents stable against oxidative, thermal and hydrolytic degradation as well as effectively masking undesirable taste. The matrix properties including; glass transition temperature, hygroscopicity, and crystal property have critical influence on the kinetics of drug release, the drug stability and the mechanical performance of the drug(6–9).

Also, herbal candy systems provide a patient centered approach that offers better compliance, ease of administration and may offer good results in controlled or sustained release.

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Inclusion complexation, microencapsulation, nanoemulsions are some of the advanced formulation techniques that are used to enhance the solubility, permeability and stability of phytoconstituents. Therefore, this review presents a critical examination of the strategies of formulation, the excipient functionality, the manufacturing processes, the physicochemical characterization, the biopharmaceutical assessment, and regulatory factors of herbal candy-based drug delivery systems, and their potential in translational purposes as scalable, and clinically relevant alternatives in the modern development of phytopharmaceuticals(10–14).

II. PHYTOCONSTITUENTS AND THERAPEUTIC SIGNIFICANCE

2.1 Classification of Phytochemicals

Phytoconstituents can be broadly categorized as alkaloids, flavonoids, terpenoids and polyphenols and each has classified distinct structural frameworks and biofunctional properties. The nitrogen-based heterocycles, the alkaloids, exhibit strong pharmacological actions, but the flavonoids and polyphenols exhibit strong redox activity, with electron donation and metal chelation. Terpenoids are lipophilic isoprenoid derived biomolecules with antimicrobial, anti-inflammatory and analgesic effects, and are therefore a good choice of biomolecules to use as a delivery system in therapeutics(15–17).

2.2 Pharmacological Activities

The herbal phytoconstituents have shown multifaceted pharmacological activities including; antioxidant, anti-inflammatory, antimicrobial and immunomodulatory activities which are mediated by several mechanisms such as; reactive oxygen species (ROS) scavenging, pro-inflammatory cytokine inhibition (e.g., TNF-, IL-6, etc.), and modulation of intracellular signaling pathways including; NF-, MAPK, etc. A combination of various phytochemicals also increases the treatment effect due to the additive or potentiation effects(18–20).

2.3 Biopharmaceutical Challenges

Phytoconstituents are also often restricted due to poor aqueous solubility, low permeability, and chemical degradation which again often fits in Biopharmaceutics Classification System Class II and IV profiles. Such limitations cause lack of dissolution, they are prone to enzymatic and oxidative degradation, and lack of systemic bioavailability making them susceptible to enzymatic and oxidative degradation(21–23).

2.4 Criteria of Herbal Actives Selection

The dose feasibility, thermal and oxidative stability, compatibility with excipients and organoleptic properties, i.e. taste and aroma, must be considered as mentioned in **Table 1** when selecting suitable phytoconstituents to use in candy-based delivery systems. Preferred compounds are those with moderate dose needs, acceptable sensory attributes, and acceptable stability characteristics during processing conditions to ensure formulation integrity, patient compliance and effectiveness(24,25).

Table 1: Phytoconstituent–Excipient Compatibility and Selection Matrix for Herbal Candy-Based Drug Delivery Systems(26–31)

Phytoconstituent Class	Examples	Sucrose/ Glucose (Base)	Pectin/Gelatin (Gelling)	Citric Acid (Flavor/pH)	HPMC/ CMC (Release Modifier)	Magnesium Stearate (Lubricant)
Flavonoids	Quercetin, Rutin (antioxidant)	++ (stable, masks bitterness)	++ (forms gel matrix)	- (acid hydrolysis risk)	++ (controls burst release)	+ (minimal interaction)
Alkaloids	Berberine, Caffeine-like (stimulant)	++ (high solubility match)	+ (swells for erosion)	++ (pH-stable at low dose)	+ (prolongs residence)	- (adsorbs, reduces potency)
Terpenoids	Menthol, Gingerol (anti-inflammatory)	+ (volatility preserved)	- (oil separation)	++ (synergistic flavor)	++ (encapsulates volatiles)	++ (non-reactive)

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Polyphen ols	Curcumin , Catechins (anti-microbial)	++ (protects oxidation)	++ (bioadhes ive gel)	-- (rapid oxidation)	++ (pH-independ ent release)	+ (low dose only)
Saponins	Glycyrrhi zin (sweetene r-like)	++ (foaming controlle d)	+ (viscous barrier)	- (precipita tion)	+ (mucoadh esive)	-- (insoluble complexe s)

Essential Oils	Eucalypt us, Clove (analgesi c)	+ (evaporat ion minimize d)	++ (emulsifi es oils)	++ (flavor enhancer)	++ (slow volatilizat ion)	+ (stable)

III. HERBAL CANDY AS A DRUG DELIVERY PLATFORM

3.1 Grade Medicated Candies

Mediated candies may be categorized into categories hard candies, lozenges and soft candy like gummies. Hard candies are generally made of matrices based on sugar and provide a quick release of the drugs, gummies offer a softer bite and a slow release of the drugs(32,33). Lozenges are formulated so as to dissolve slowly in the mouth enabling the drug to be well exposed illustrated in **Figure 1.**

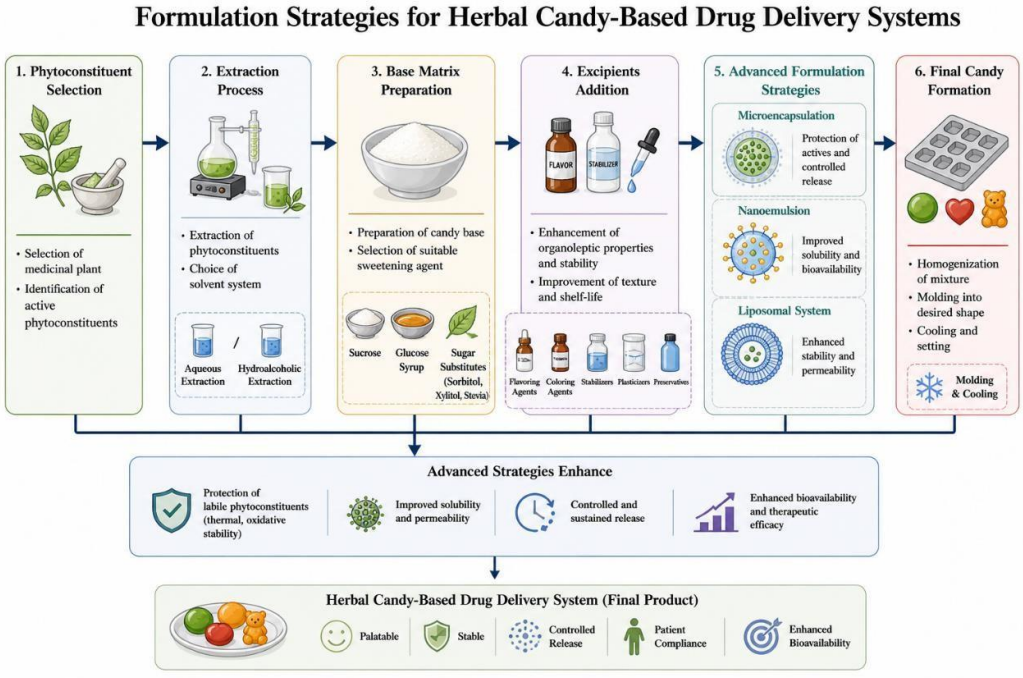

Figure 1: Herbal Candy Drug Delivery Mechanism

3.2 Release and Absorption Mechanisms of Drugs

The action of drugs being released by herbal candy is done by the active compound being liberated by the action of saliva and diffusion of the active compound. There are some incidences whereby it is absorbed via the buccal mucosa or the sublingual mucosa bypassing the initial metabolism process(32,34,35). The compositions of the matrices, the particle size and the active compound solubility are some of the factors which influence the release kinetics illustrated in **Figure 2.**

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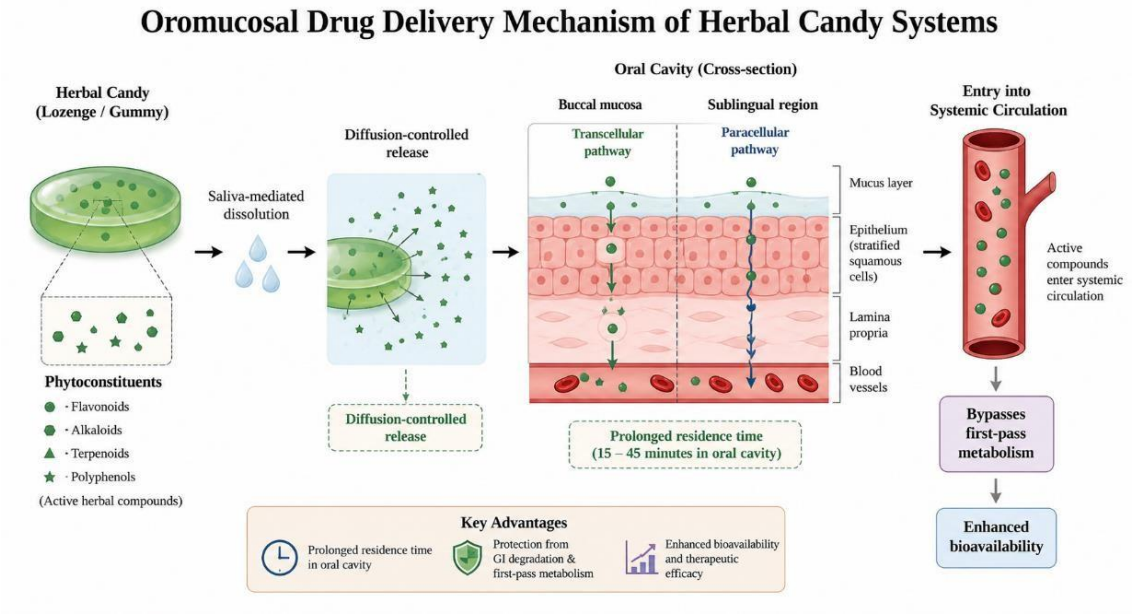

Figure 2: Formulation Strategy of Herbal Candy

IV. FORMULATION STRATEGIES

The rational choice of the base materials, excipients and advanced delivery methods are used to develop herbal candy systems to obtain optimal stability, palatability and drug release performances. The base matrix usually includes sucrose and glucose syrup, which provide structural integrity, desired glass transition behavior, and release kinetics. Sugar substitutes, like sorbitol and xylitol, are usually included in the base matrix to create low-glycemic, or diabetic-friendly, formulations that directly affect the texture, hygroscopicity, and release kinetics. Excipients are critical functional components, whose flavouring and colouring agents make organoleptic acceptability, the action of preservatives keeping microbial stability, the effect of plasticiser to increase elasticity and chewability, and the influence of stabilizer to stop degradation of the phytoconstituents(36–38). The incorporation of herbal extracts can be done through mixing, coating or encapsulation processes, with the policy of extraction methods (aqueous or hydroalcoholic) being obtained based on the solubility and stability pattern, with standardization of bioactive markers being fundamental in ensuring batch-to-batch consistency and therapeutic efficacy. Careful formulations, such as microencapsulation, nanoemulsions and liposomal systems are utilised to improve solubility, protect labile compounds against thermal and oxidative degradation, and enhance controlled or sustained release behaviours. Statistical methods to optimize the formulation parameters include Design of Experiments (DoE) and Response Surface Methodology (RSM), to enable a systematic evaluation(39–42) of the critical variables and establishment of robust, reproducible formulations consistent with the ideas of modern pharmaceutical development as described in **Table 2.**

Table 2: Functional Role of Excipients in Herbal Candy Formulations and Their Influence on Critical Quality Attributes (CQAs) and Drug Release Behavior(43–48)

Excipient	Functional Role	Key CQAs Affected	Influence on Drug Release Behavior
Sucrose/Glucose Syrup	Bulking agent, sweetener, crystallizing base	Hardness (↑), friability (↓), content uniformity (↑)	Rapid initial dissolution via solubility (80-100% in 10min saliva); osmotic trigger
Pectin/Gelatin (Herbal gums e.g., Acacia)	Gelling/suspending agent, mucoadhesive	Viscosity (↑), stickiness (↑), disintegration time (↑)	Sustained release via gel erosion/swelling (60-90%

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			in 30min); prolongs residence >15min
Citric Acid/Tartaric Acid	pH modifier, flavor enhancer, solubilizer	pH stability (↓ risk oxidation), taste acceptability (↑)	Enhances phytoconstituent ionization for faster release (burst <5min); but risks instability

HPMC/CMC (or Xanthan Gum - herbal alt.)	Release retardant, film-former, thickener	Swelling index (↑), erosion rate (↓), hardness (↑)	Diffusion-controlled (fickian, 20-50% in 15min, full in 60min); pH-independent
Magnesium Stearate/Talc	Lubricant, glidant, anti-adherent	Friability (↓), ejection force (↓), flowability (↑)	Minimal direct effect; hydrophobic coat may slow wetting (delay 2-5min onset)
Sorbitol/Glycerin	Humectant, plasticizer, sweetener	Moisture content (↑ controlled), flexibility (↑), hygroscopicity (↑)	Improves wettability for uniform release; plasticizes matrix for erosion
Natural Flavors (Menthol, Licorice)	Taste masker, penetration enhancer	Palatability (↑), sensory score (↑)	Enhances permeation via membrane fluidization; faster systemic uptake (Tmax ↓20%)

V. MANUFACTURING AND PROCESS DEVELOPMENT

5.1 Conventional Heating Method

The traditional heating process includes the formation of a super-saturation system of sugars by heating the solutions of sucrose-glucose to 120-150 C (~=90-95 O Brix, hard crack phase), wherein the viscosity and rate of crystallization of final texture are determined. The cooling process (80-90 0 C) is used to incorporate the herbal extracts during the cooling session to reduce the degradation of the heat sensitive phytoconstituents during the cooling process. Controlled mixing and de-gassing give uniform distribution and structural integrity with parameters in the process critically affecting clarity, hardness and dispersion of the drug(49–51).

5.2 Vacuum Cooking Technique

Cooking under vacuum conditions concentrates the sugar matrix under a reduced pressure (0.05-0.2 bar), making possible evaporation below 100 C as well as preserving thermolabile compounds, e.g., polyphenols and terpenoids. Minimization of oxidative degradation through reduced exposure to oxygen and control of processing through reduced caramelization and better color stability. The method is useful in maximizing phytochemical yields and maintaining sexual consistency in moisture levels and viscosity(52–54).

5.3 Molding and Cooling

The molten mass of candy is then poured into molds (silicone or starch) in order to obtain homogenous geometry/dosing. Controlled cooling (25 /15 C, 40/50 % RH) controls the crystallization process and avoids crystal/stickyness defects or cracking. Cooling Proper cooling to promote stable amorphous or microcrystalline structure, which is important to mechanical strength and predictable dissolution behavior(55–57).

5.4 Scale-Up Considerations

Scale-up involves a very narrow control of heat transfer, mixing and cooling to ensure uniform crystallization and drug distribution. Process Analytical Technology (PAT) like NIR monitoring can be used to support(58) real-time control, whereas pilot-scale validation can be used to ensure that the results are reproducible in batch as described in **Table 3**.

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Table 3: Comparative Analysis of Advanced Formulation Strategies in Herbal Candy Systems: Impact on Solubility Enhancement, Stability, and Oral Bioavailability(59–62)

Strategy	Descripti on in Candy Context	Solubilit y Enhance ment	Stability Impact	Oral Bioavaila bility	Advanta ges	Limitatio ns
Solid Dispersio n (SD)	Phytos. dispersed in molten sugar/PE G matrix, rapid cooling to amorpho us state	5-20x (amorpho us supersatu ration)	↑ (polymer inhibits recrystalli zation; >12 months)	2-4x (faster dissolutio n in saliva)	Simple hot-melt extrusion; masks taste	Recrystal lization risk if moisture ↑
Micro/Na noencaps ulation	Spray-dried phytos. in gum arabic/ma ltodextrin shells within candy	10-50x (particle size ↓ to <5µm)	↑↑ (protects oxidation /volatiles; 18-24 months)	3-5x (mucoadh esive prolonge d release)	High load (20%); controlle d burst	Scale-up cost for spray-drying
Cyclodex trin Complex ation	Inclusion complexe s (β-CD) kneaded into gelling base pre-casting	10-100x (host-guest cavity solubiliza tion)	↑ (shields from light/heat)	2-6x (enhance d permeatio n)	No toxicity; improves palatabilit y	CD cost; bitterness if excess
Lipid-based (SEDDS-like)	Self-emulsifyi ng oils (e.g., clove oil) in gelatin emulsion candies	20-50x (micelle formation in GI)	+ (lipid barrier vs. hydrolysi s)	4-10x (lymphati c uptake bypasses first-pass)	For lipophilic terpenoid s	Oil separatio n in storage
Nanosusp ension	Milled phytos. (<200nm) suspende d in syrup, molded	50-200x (surface area ↑)	↑ (stabilizer s like Tween prevent agglomer ation)	3-8x (improve d absorptio n)	High potency low dose	High-energy milling equipmen t
Conventi onal (Plain Matrix)	Direct blend in sugar/pec tin without mods	1-2x (baseline)	Baseline (6-12 months)	1x (referenc e)	Low cost/simp le	Poor for BCS II/IV herbals

5.5 Quality by Design (QbD) Approach

Quality by design (QbD) aims at defining critical material attributes (CMAs) and critical process parameters (CPPs) to assure uniform quality of the products. A strong design space is risk assessment and statistical design, which is in tandem with International Council for Harmonisation of a robust design space in terms of improved control and compliance.

VI. CHARACTER(63)IZATION AND QUALITY EVALUATION

6.1 Organoleptic Properties

Trained sensory panels are used to analyse the scent, flavour, colour and texture of the food that have a direct impact on patient compliance. The hedonic scale ranging to 9 is commonly used to measure attributes including; sweetness, masking of bitterness and mouthfeel. Uniformity of colors is determined through the use of Lab colorimetric analysis and the volatile aroma compounds may be

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profiled using gas chromatography(64–66). The subjective and instrumental assessment of features such as chewability and hardness is made to guarantee that there is an acceptable level of sensory performance without impairment of drug release properties as mentioned in **Table 4.**

Table 4: Comprehensive Characterization, Quality Evaluation, and Stability Assessment Parameters of Herbal Candies Aligned with ICH Guidelines and Pharmaceutical Standards(55,67–69)

Category	Parameter	ICH/WHO/Pharmacopeial Reference	Rationale for Herbal Candies
Physical Characterization	Appearance/Color /Odor	USP <711>, WHO herbal QC	Detects degradation (browning from oxidation).
	Weight Variation	USP <905>, ICH Q6A	Ensures dose uniformity for potent phytos.
	Hardness	USP <1217>	Balances suckability vs. brittleness.
	Friability	USP <1216>	Prevents powdering/loss during handling.
	Thickness/Diamet er	USP <2040>	Molding consistency.
Chemical Evaluation	pH	WHO stability herbal	Affects mucoadhesion/stability of alkaloids.
	Assay (% Phytoconstituent)	ICH Q1A, Q2(R1) validation	Quantifies actives (e.g., flavonoids >95%).
	Impurities/Degrad ation	ICH Q3B	Monitors oxidation/hydrolysis products.
	Moisture Content	USP <921>	Hygroscopicity control prevents microbial growth.
Dissolution/Disintegration	Dissolution	USP <711>, ICH Q6A	Buccal release profile for local/systemic action.
	Disintegration	USP <701>	Ensures timely erosion in mouth.
Microbiological	Microbial Limits	USP <61>/<62>, WHO	Prevents contamination in natural extracts.
Stability Assessment (ICH Q1A)	Long-term	ICH Zone II/IV (India humid)	Real-time shelf-life prediction.
	Accelerated	ICH Q1A(R2)	Arrhenius extrapolation for expiry.
	Photostability	ICH Q1B	Protects light-sensitive polyphenols.
	Packaging	ICH Q1E evaluation	Extends stability in tropical climates.

6.2 Physicochemical Properties

Physicochemical characterization comprises PH, moisture level, solubility, and composition of sugars that determine the stability and release behavior. pH is evaluated in an aqueous dispersion (usually maintained at 4.5 by keeping the aqueous pH approximately the same as the solid pH), whereas moisture content is assessed using loss on drying or Karl Fischer titration, with levels less than 5 percent to prevent microbial growth and stickiness. Sugar profiling Sugars and sugar crystals Sugars are carbohydrates containing simple sugars, such as glucose and fructose, as their components.Sugar profiling Sugars and sugar crystals Sugars are carbohydrates that include simple sugars, e.g. glucose and fructose, within

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them(70).

6.3 Mechanical Properties

The structural integrity is taken care of through mechanical evaluation during handling and storage. The hardness is ascertained on the basis of texture analyzers or Monsanto testers to determine compressive strength and thickness and diameter are determined using digital calipers to ensure that there is dimensional uniformity(70–72). Friability testing depends on a Roche friabilator to test resistance to abrasion with acceptable limits usually being less than 1% to ensure durability and consistency in action illustrated in **Figure 3.**

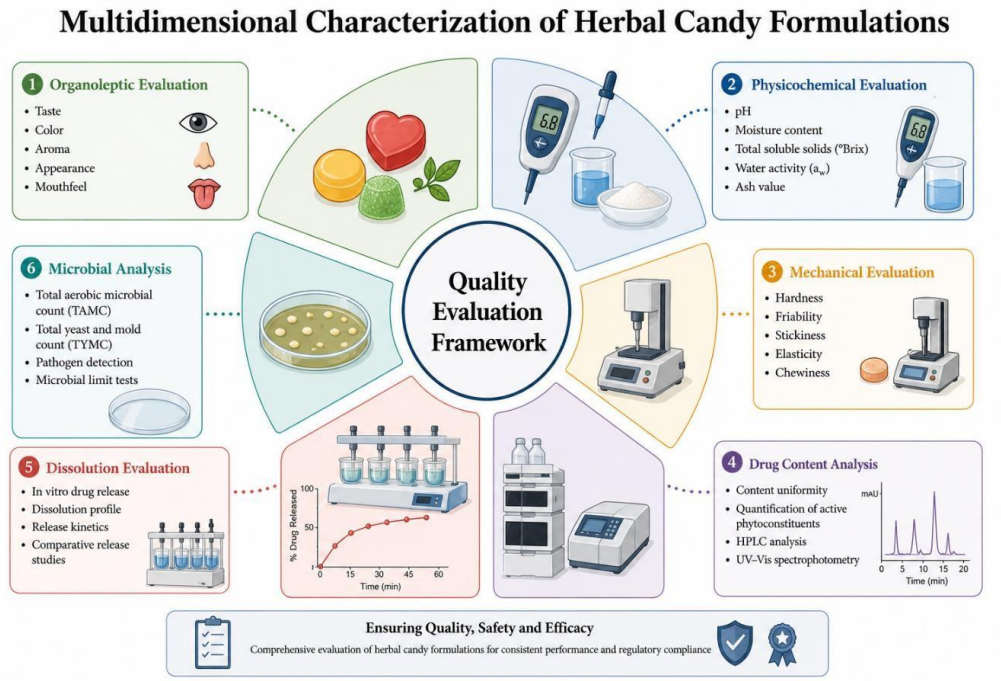

Figure 3: Characterization & Evaluation Workflow

6.4 Drug Content and Uniformity

Uniformity and drug content will play a crucial role in determining the accuracy of the doses and consistency of the therapy. To determine the amount of active constituents UV-vis spectrophotometry or HPLC is used in which the candy is dissolved in a suitable solvent and analyzed using UV-vis spectrophotometry or HPLC. The homogeneity of content across various units is enforced within 90 -110 percent of the labeled statement, with low relative standard deviation, so that the content is homogeneously distributed, and as well as possible the variability in the content due to mixing inefficiencies or by phase(73,74).

6.5 In Vitro Release Studies of Drugs

USP dissolution equipment (Type II paddle) is used to perform in vitro dissolution studies under the influence of simulated salivary conditions (pH at 6.8, at 37 at 0.5, C). Samples are then regularly withdrawn at set intervals and the samples are analyzed to calculate cumulative release of the drug. The mathematical equations used to model release kinetics include zero-order, first-order and Higuchi provides an insight into the diffusion and erosion processes. These researches are critical in forecasting in vivo performance, and optimization of formulation design(75–77).

6.6 Analysis Having Moisture and Sugar Content

Moisture analysis has been shown to be important in determining hygroscopicity, shelf-life prediction, sugar content is important in determining the sweetness, texture and glycemic response. The Karl Fischer titration is a precise method to quantify moisture, whereas the sugar composition is determined by using the Karl Fischer titration, HPLC or enzyme testing. The manipulation of these parameters is crucial in product stability, the absence of microbial growth, and preferred

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organoleptic characteristics(78–80).

6.7 Microbial Quality Assessment

Microbial analysis is undertaken to help ascertain the safety of products as well as the adherence to pharmacopeial requirements. Aerobic plate count (TAMC) and yeast and mould plate count (TYMC) are determined in plate count methods in the presence of controlled conditions. Organisms (Escherichia coli and Salmonella) are tested to ensure there is no contamination. The upkeep of microbial limits is very essential in order to guarantee the safety of products and also their compliance with the regulations(81,82).

VII. STABILITY/SHELF-LIFE STUDIES.

7.1 Stability Study Design

Stability studies are also done at a controlled environmental condition to determine the impact of temperature, humidity and light over time on the quality of the product. The long-term and accelerated stability experiments are conducted basing on the guidelines of the International Council for Harmonisation, which allow to predict the behavior of the products in various conditions under which they are kept(83,84).

7.2 Phytochemical Stability Analysis

The assessments of the stability of active phytoconstituents are determined through the analytical processes information using the HPLC and LC -MS to identify the degradation products and provide a quantitative analysis of the active content. It is these studies that can shed some light on degradation pathways, such as oxidation, hydrolysis, and photodegradation, having potential effects on therapeutic efficacy(85,86).

7.3 Shelf-Life Estimation

Kinetic modeling techniques like Arrhenius equations which can be used to relate the rates of degradation to temperature are used to determine shelf-life. Time to decomposition (t90) is the time taken to reach 10 percent degradation. Time to estimate expiration time Time to break Time to establish expiration time: It is calculated time to break, and based on the time to break, expiration time is estimated(87–89).

VIII. BIOPHARMACEUTICAL AND CLINICAL EVALUATION

Biopharmaceutical analysis integrates in vitro, in vivo, and clinical strategies to describe the absorption, the pharmacokinetics as well as the performance of the phytoconstituents administered through herbal candy systems. The use of Franz diffusion cells and Caco-2 monolayers as models of the oral mucosal and intestinal barriers, respectively, has been proven to model apparent permeability coefficients (Papp) and predict bioavailability(90,91) llustrated in **Figure 4.** In vivo pharmacokinetic and animal model In vivo pharmacokinetic studies with animal models are used to quantify the following parameters (Cmax, Tmax and AUC): Insight into systemic exposures and extent of first-pass metabolism bypass through

buccal absorption. A randomized controlled trial provides clinical assessment of therapeutic agent efficacy, onset of action and patient compliance, especially with respiratory and oral health purposes. Safety evaluation, done as per OECD guidelines includes acute and subchronic and chronic toxicity tests, and irritation and allergenicity tests, and ensures overall biocompatibility and clinical safety(92).

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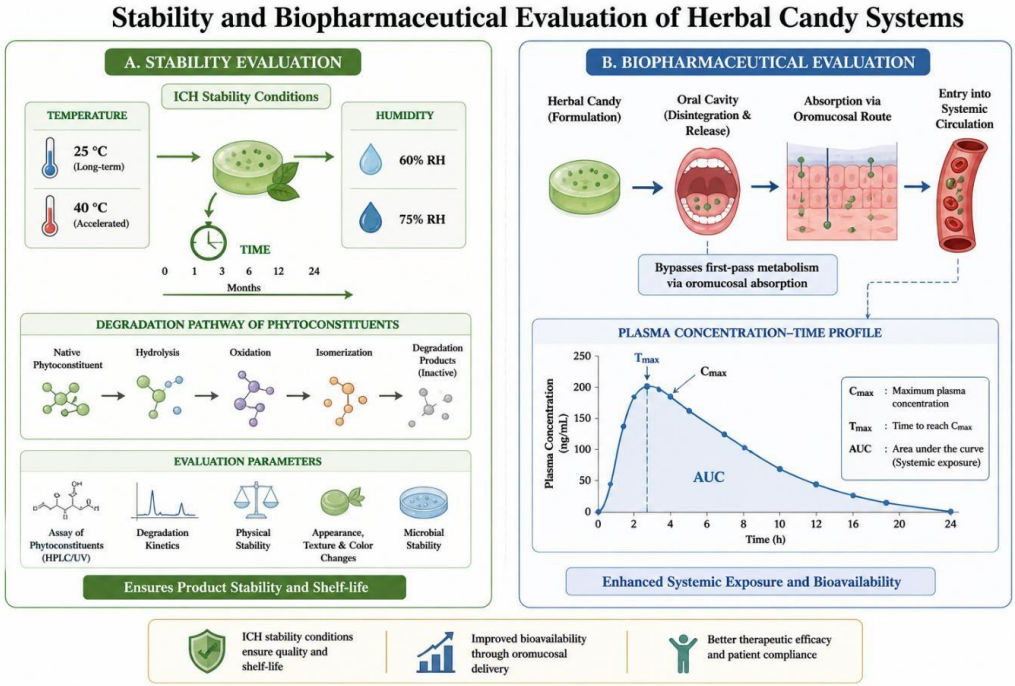

Figure 4: Stability & Biopharmaceutical Evaluation

IX.CURRENT MARKETED PRODUCTS AND APPLICATIONS

The international market of herbal candy formulations is based on compounds with local (and also systemic effects) such as menthol, eucalyptus oil, glycyrrhizin, and polyherbal extracts. These products have wide applications in respiratory relief, immune-enhancing products, oral hygiene, gastrointestinal support, and leveraging oromucosal deliveries to achieve rapid changes in action. The marked growth in the market has largely been contributed by the increasing consumer preference to natural dosage forms that are palatable and conveniently administered; especially in the pediatric and geriatric populations. Nevertheless, sugar composition, labeling transparency and clinical validation are also key reasons of consumer acceptance and sugar-free formulations and evidence-based products positioning have to be developed(31,37,93–96).

X.REGULATORY AND QUALITY FRAMEWORK

Their classification that spans the border between pharmaceuticals, nutraceuticals, and functional foods makes it complex to regulate with, as these regulatory issues can lead various systems across the world onto different regulatory tracks. These products are regulated by the World Health Organization (providing general information on the safety and quality of herbal products) and the U.S. Food and Drug Administration (regulating these products based on the intended use; (97,98)some being regulated as either DSHEA (1994) or OTC monographs). In India, there is regulatory separation between AYUSH and the nutraceutical regulation, sacrificing the unity of regulation. Advanced analytical methods (HPLC, LC Dachs Mass, HPTLC) are used to provide phytochemical uniformity, whilst compliance to a set of Good Manufacturing Practices and International Council for harmonisation requirements (Q8, Q9, Q10) help provide control over key quality attributes and process parameters. In spite of these frameworks, the weakness of lack of harmonization and still diverse evidence requirements remains to be the primary challenge resulting in the discrepancy between the development of regulatory frameworks and risk management(99,100).

XI. CONCLUSION

A patient-centered but scientifically sound platform: Herbal candy-based drug delivery systems represent a robust scientifically based platform that addresses the crucial limitations related to the conventional phytopharmaceutical formulations including poor solubility, instability, and less than optimal bioavailability. The combination of

confectionery matrices with pharmaceutical design by enabling the control of dissolution, prolongation of oromucosal residence, and partial incorporation of phytoconstituents by the body, suggests an increased systemic exposure to phytoconstituents (Clark et al, 2010). Other sophisticated formulation practices like microencapsulation, nanoemulsion structures, as well as inclusion complexation have shown a lot of promise as far as the enhancement of solubility, the stability of bioactives against thermal and oxidative degradation, and the tuning of release rate, are concerned. Moreover, reproducibility, scalability, and regulatory compliance, as required by the International Council of Harmonisation guidelines, can be ensured by systematic control of critical quality attributes, as well as process parameters. Detailed physicochemical, mechanical, and biopharmaceutical analyses confirm that herbal candies can attain a consistent drug content, desired drug release profile, and acceptable drug stability parameters due to the presence of plant-based ingredients. Nonetheless, this has been hampered by such challenges as dose loading limitations, sensitivity to moisture, glycemic

issues and regulatory ambiguity which continue to be key barriers to widespread clinical translation. Incorporation of improved nanotechnological systems, improved excipient systems and standardized regulatory frameworks will be necessary in future development. Taken together, herbal candies represent one of the most promising futures where the science of nutraceuticals and pharmaceuticals converge, offering a great deal of potential over the next few years, to both improve the overall outcomes of therapeutic interventions, to increase patient compliance, and to expand the applicability of herbal medicines in contemporary healthcare infrastructures.

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