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FORMULATION AND EVALUATION OF MEDICATED CHEWING GUM

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ABSTRACT

Medicated chewing gum (MCG) has emerged as a versatile and patient-friendly oral drug-delivery platform capable of releasing active compounds directly into the oral cavity during mastication. This delivery pathway supports faster onset of action, improved bioavailability, and better patient adherence compared to conventional solid oral dosage forms. Capsaicin, the pungent phytochemical derived from Capsicum species, possesses well-documented analgesic, anti-inflammatory, and sialogogue properties. These therapeutic effects primarily arise from the activation and subsequent desensitization of TRPV1 receptors, making capsaicin particularly suitable for localized oral applications such as mild pain relief, gingival irritation, throat discomfort, and dry-mouth management. However, incorporating capsaicin into a chewing-gum matrix presents formulation challenges due to its strong pungency, hydrophobicity, and sensitivity to humidity. Recent advancements—including microencapsulation, ?-cyclodextrin complexation, and lipid-based carriers—have shown promise in improving solubility, reducing irritation, and ensuring controlled release during chewing. Additionally, the growing demand for convenient, non-invasive, and on-the-go therapeutic formats has further increased interest in capsaicin-loaded MCG. This review compiles and interprets current evidence on formulation strategies, gum-base selection, taste-masking approaches, release-rate optimization, and the analytical evaluation of capsaicin chewing gum. It also highlights in-vitro and in-vivo testing parameters essential for establishing product quality, safety, and performance. Collectively, the literature suggests that capsaicin-based medicated chewing gum is a promising dosage form with

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significant potential in oral-care therapeutics, though further clinical studies and sensory optimization are needed to enhance patient acceptability and therapeutic consistency. [1]

KEYWORDS

Buccal Drug Delivery, Micro encapsulation , taste Masking , Controlled Release Medicated Chewing Gum, Formulation, Evaluation.

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INTRODUCTION

Medicated chewing gum is recognized as a patient-friendly dosage form that provides prolonged retention in the oral cavity, enabling direct mucosal absorption and faster therapeutic response. It offers benefits over conventional tablets, such as improved bioavailability and enhanced acceptability in pediatric and geriatric patients. Capsaicin, the active molecule in chili peppers, activates TRPV1 receptors, causing an initial heating sensation followed by desensitization responsible for analgesic activity. This mechanism makes capsaicin useful for oral discomfort, throat irritation, gingival inflammation, and salivary stimulation. Formulating capsaicin into MCG requires care due to its pungency, hydrophobic nature, and sensitivity to moisture. [1]

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MATERIALS AND METHODS

A structured literature review was performed using Google Scholar, PubMed, ScienceDirect, and SciFinder databases. Keywords included capsaicin medicated gum, buccal delivery, microencapsulation, and oral drug release. Studies from 2000 to 2024 were screened. Articles focusing on formulation, pharmacology, and evaluation of chewing gum were included, whereas non-English, duplicate, or non-scientific papers were excluded. Extracted information was analyzed comparatively and organized into formulation and evaluation sections. This method aligns with typical review-writing guidelines used in pharmaceutical research. [5]

EVALUATION PARAMETERS

PHYSICAL AND MECHANICAL EVALUATION

MCGs are evaluated for uniformity in weight, shape, color, and surface characteristics. Hardness, flexibility, and chewability are tested using texture-analysis instruments to ensure consistent chewing experience. [5]

CHEMICAL EVALUATION

Chemical evaluation includes measuring capsaicin content using HPLC, assessing drug uniformity, moisture content, and checking compatibility between capsaicin and excipients. These evaluations ensure stability and accurate dosing. [7]

IN-VITRO DRUG RELEASE

In-vitro release is measured using a chewing-gum apparatus that mimics jaw movements. Simulated salivary fluid (pH 6.8) is used to study buccal release. Release data are interpreted using zero-order, first-order, and Korsmeyer–Peppas models to determine release mechanism. [9]

SENSORY EVALUATION

Human volunteers assess taste, heat sensation, cooling effect, and overall acceptability. Sensory evaluation is crucial for capsaicin formulations due to its pungency and potential irritation. [4]

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STABILITY TESTING

Stability studies under ICH guidelines evaluate changes in gum hardness, moisture, capsaicin concentration, color, and flavor during storage. This ensures product quality over shelf life. [5]

IN-VIVO CHEWING STUDIES

In-vivo studies involve chewing the gum for a fixed duration and measuring the amount of capsaicin released by analyzing the residual drug in the chewed mass. This provides realistic data on actual release during mastication. [8]

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RESULTS

GUM-BASE

The gum base forms the chewable matrix and determines elasticity, texture, and drug-release behavior. Common gum bases include polyisobutylene, polyvinyl acetate, and synthetic elastomers blended with resins and waxes. Because capsaicin is lipophilic, hydrophobic gum bases allow better incorporation and uniform dispersion. Synthetic gum bases provide stability and consistent chew ability. [1]

DRUG LOADING AND SOLUBILITY IMPROVEMENT

Capsaicin exhibits poor aqueous solubility, making direct release challenging. Techniques such as microencapsulation, ?-cyclodextrin inclusion complexes, solid dispersions, and lipid-based carriers are commonly used to enhance solubility and reduce pungency. Encapsulation also prevents direct contact between capsaicin and the tongue, minimizing irritation during chewing. [6]

TASTE MASKING AND FLAVORING APPROACHES

Taste masking is essential because capsaicin causes a burning sensation. Formulators typically use menthol, peppermint oil, fruit essences, and sweeteners like sorbitol, mannitol, and sucralose to balance the heat sensation. Cooling agents such as WS-3 help counteract irritation and improve mouthfeel. [8]

BINDERS, PLASTICIZERS, AND SWEETENERS

Plasticizers like glycerol and lecithin improve elasticity and chewing properties. Polyols act as sweeteners and texturizers, giving smoothness to the gum. These excipients help maintain the structural integrity of gum during storage and chewing. [5]

ADDITIVES TO REDUCE IRRITATION

Since capsaicin can be irritating, cooling agents and buffering substances are commonly added to reduce burning sensation. These agents improve patient compliance and allow sustained chewing without discomfort. [4]

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DISCUSSION

Capsaicin gum may help in managing oral discomfort, throat irritation, mild pain, and gum inflammation due to its TRPV1-mediated desensitizing effect. It can also stimulate salivary flow, making it useful for individuals with dry mouth (xerostomia). Some studies even note mild antimicrobial effects of capsaicin in the oral cavity. [2]

CONCLUSION

Capsaicin-loaded *medicated chewing gum* offers a promising and convenient platform for local oral therapy. Formulation success depends on selecting suitable gum bases, applying solubility-enhancement techniques, and optimizing taste-masking approaches. With proper evaluation and stability assessment, capsaicin gum can serve as an effective tool for oral pain relief and salivary stimulation, with future expansion toward specialized oral-care products. [1]

ABBREVIATIONS

(Med. Chewing Gum) medicated chewing gum

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CONFLICT OF INTERESTS

author does not contain any conflict

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