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FORMULATION STRATEGIES FOR TASTE MASKING OF CHEWABLE SOFTGELS

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ABSTRACT
Chewable softgels offer a convenient and user-friendly dosage form for administering pharmaceuticals and dietary supplements. However, their taste can often pose a challenge due to the presence of bitter or unpleasant active ingredients. Taste masking is crucial to ensure patient compliance and enhance the overall acceptability of chewable softgels. The review encompasses various approaches used to overcome taste issues in chewable softgels, including the utilization of taste-masking agents, flavoring agents, and encapsulation technologies. Taste-masking agents such as sweeteners, flavors, and coating materials play a vital role in reducing the perception of bitterness or unpleasant tastes associated with active ingredients. The selection and optimization of these agents are discussed in detail, taking into account their compatibility with the softgel formulation and their impact on stability and release profiles. In conclusion, this review provides valuable insights into the formulation strategies employed for taste masking of chewable softgels. The comprehensive analysis of taste-masking agents, flavoring strategies, and encapsulation technologies offers a comprehensive understanding of the challenges and opportunities in developing palatable chewable softgel formulations. These insights can aid formulation scientists and researchers in designing effective taste-masking approaches and improving patient compliance and acceptability for chewable softgels.

KEYWORDS: Compatibility; Paediatric patients; Sweeteners; Bitter; Technologies.

1. INTRODUCTION
Chewable soft gelatin capsule typically have a smooth texture upon disintegration, are pleasant tasting, and leave no bitter or disagreeable flavour. They are designed to disintegrate smoothly in the mouth at a reasonable rate with or without actual chewing. Making a successful soft gel formulation requires careful ingredient selection in order to create a durable solid dosage form. Achieving satisfactory manufacturing performance may depend on selecting the right excipient to carry out a particular function in a soft gel formulation, such as disintegration or lubrication. To cover up the unpleasant flavours and simplify paediatric dosing, chewable soft gel formulations frequently contain sweeteners, both manufactured and naturally occurring. They should ideally dissolve in the mouth when chewed, releasing their components as they do so. This reduces the amount of time needed for capsule disintegration before stomach absorption. When an active ingredient is intended to operate locally rather than systemically, chewable soft gels are frequently used and is appealing and can be consumed with little to no water.[1]

Gelatin-based chewable containing APIs have been in development for a while, but there are still issues to be resolved regarding long-term stability, off-taste, and precise dosing. The API should be delivered as suspended, undissolved particles imbedded in the gelatin matrix to achieve the best soft-chew formulation possible. By structurally arresting the API particles in the gel, this will improve chemical stability and prevent API particles from sinking. The amount of off-taste from API will be greatly diminished by keeping the API particles inert during mastication. Soft-chew formulations that keep the API in a suspended, particle form while being arrested in a gelatin matrix were suggested for this use.[2] Gelatin-based chewable containing APIs have been in development for a while, but there are still issues to be resolved regarding long-term stability, off-taste, and precise dosing.

Unpleasant taste is the main obstacle to treating the paediatric population, according to a survey conducted by the American Association of Paediatricians. The success of a final oral dose form depends heavily on taste-masking unless the active substance is tasteless or does not contain any disagreeable flavors. Orally disintegrating tablets, films, and chewable soft gels are examples of specialized dosage forms where the effectiveness of taste-masking is frequently a critical success factor.

The mechanics of taste-masking techniques frequently rely on two main strategies: the first is to mask the unpleasant taste by adding sweeteners, flavors, and taste masking polymers; the second is to prevent the contact of bitter or unpleasant medications with taste buds. By utilising cutting-edge methods and techniques, like hot-melt extrusion and microencapsulation, major advancements in taste-masking have been made in recent years.[3]

1.1 Biology of taste

When anything is placed in the mouth to determine the entire component, a person might communicate their taste impression as a feeling. Four principles of taste are typically present:

- Sweet and salty, particularly near the tongue's tip
- The side of the tongue tastes sour.
- Bitter at the back of the tongue

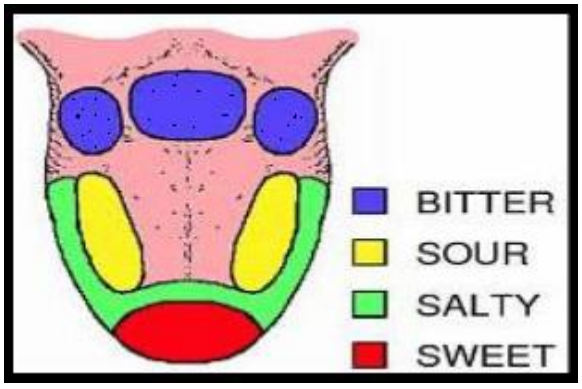

Fig. 1: Taste points in tongue.

Table 1: Specific area of tongue and threshold concentration for primary taste sensations.[13]

Taste	Region of tongue	Limitation of concentration
Sweet (Sucralose)	Tip of tongue	0.5%
Salt (NaCl)	Tip and sides of tongue	0.25%
Sour (HCl)	Sides of tongue	0.007%
Bitter (Quinine)	Back of tongue	0.00005%

1.2 Elements which are required into consideration throughout the taste covering formulation procedure[5]

- The extent of bitter taste of the API
- The dose
- The drug's ionic properties and solubility
- Finished product's dissolution and disintegration.
- In-depth bioavailability

1. General formulation factors[7]

There are numerous components that go into the creation of chewable softgels. Organoleptic features of the active pharmacological ingredients are the main concern here, although other formulation aspects including flow, lubrication, disintegration, compatibility, and stability are also important. Regular (Swallowed) and chewable capsules share these characteristics. A formulator may employ one or more strategies to come up with a formula and process combination that yields a product with favourable organoleptic qualities. An adequate level of flow, compressibility, and stability must be present in such a substance.

- **Taste and Flavours**

A chemical stimulus to the taste receptors on the tongue causes a sensory response known as taste, according to biology. There are four primary flavours: bitter, sweet, sour, and salty. Ionising chemicals in the solution are what give foods their salty or sour flavours. Despite possibly being unable to ionise in an aqueous media, many organic therapeutic chemicals cause a bitter reaction. The majority of saccharides, disaccharides, some aldehydes, and a small number of alcohols have a sweet flavour. Tasteless is a term used to describe a substance that cannot stimulate the senses. The word "flavour" often describes a particular combination of taste and scent. For instance, honey has a characteristic fragrance in addition to having a sweet taste, whereas sugar only has a sweet taste.

- **Aroma**

Aromas are typically used to refer to pleasant odours. For instance, a properly made chewable capsule with orange flavour should have the distinctive sweet-sour flavour and aroma of a fresh orange.

- **Mouth-feel**

This word refers to the kind of taste or touch that a capsule makes when it is chewed in the mouth. As a result, it has nothing to do with the chemical stimulation of taste or olfactory nerves. The overall mouthfeel of a composition is crucial for its success, though. In general, gritty, or sticky textures (like calcium carbonates) are undesired, but smooth textures with calming and cooling effects (like mannitol) are favoured.

- **After effects**

The most frequent side effect of several substances is aftertaste. As an illustration, some irons impart a "rusty" aftertaste, and saccharin in large doses often has a bitter aftertaste. Another frequent side effect is a section of the tongue and mouth's surface feel numb. Promethazine hydrochloride and Pyribenzamine hydrochloride are examples of bitter antihistamines that are typical of this family of medications.

Assessment of the problems regarding formulation

Whenever possible and practical, obtaining a thorough profile of the active medication is the first step in the manufacture of capsules. As the medicine typically influences the choice of carriers, sweeteners, flavour compounds, and other product modifiers, this usually results in the formulation of a stable and quality product that is most effective. Ideally, the medication profile would include details on the following:

- **Physical characteristics**

Physical shape, such as crystal, powder, amorphous solid, oily liquid, etc. Melting temperature, moisture content, flavour, aftertaste, and mouthfeel. Active medication stability and aqueous solubility.

- **Chemical characteristics**

Chemical composition and class, significant reactions, significant incompatible chemicals, and drug dosage. The use of excipients that would physically, chemically, and organoleptically complement the drug the best would result from the elimination of possibly incompatible excipients, tastes, and other ingredients. Excipients and other product modifications should be chosen while considering both their cost and functionality. Utilising excipients that are low in calories and free of sugar may have marketing benefits, particularly for customers who are concerned about their calorie consumption and dental caries.[8]

Need for the development of chewable capsules

Due to patients' poor compliance and acceptance of current delivery regimens, improved absorption and bioavailability, rapid onset of action, as well as the demand for non-invasive delivery systems continues.[9]

Patient related factors

Approximately one-third of patients require immediate therapeutic effects from drugs, which results in poor adherence to conventional medication therapy and decreased overall therapeutic efficacy. A brand-new dose form called instant release tablets has been created, and it combines the benefits of dosing simplicity with dosing convenience. These pills are made to deliver the medication at a faster rate. Patients who find it uncomfortable to swallow regular pills and capsules with an 8-oz glass of water are well suited to chewable dose forms.

- An eight-year-old with allergies who wants a more convenient dosage form than antihistamine syrup.
- Very elderly individuals who might not be able to swallow a daily dose of antidepressant.[10]

Effectiveness factors

One of the main claims made for these formulations is increased bioavailability and quicker onset of effect. Pre-gastric absorption can be quite advantageous for medications that undergo a lot of hepatic metabolisms since it prevents first pass metabolism. Additionally, for medications that significantly increase the production of hazardous metabolites through first-pass liver metabolism and stomach metabolism.[8]

Manufacturing and Marketing related factors

Regardless of their size, pharmaceutical firms must create innovative drug delivery technologies and use them in product development to thrive. It is typical for pharmaceutical companies to create a certain drug entity in a new and enhanced dosage form as a drug approaches the end of its patent life. A novel dosage form enables a firm to give its patient population a more practical dosage form while extending market exclusivity, distinctive product differentiation, value-added product line expansion, and patent protection.[12]

2. Strategies available for taste-masking formulations

Taste masking is the lowering of an unpleasant taste that would otherwise be present. Taste masking can be accomplished with the aid of sweeteners, particular flavours, and taste masking agents. Sweeteners are necessary to finish the experience and generate a tasty outcome. This is one of the main impediments to the development of oral dosage forms with disagreeable tastes. The two main strategies for solving this issue are flavour masking and processing methods. Additions of flavour, sweetness, fat, and acids are frequently used to disguise flavours.[14]

For the most part, chewable dosage forms provide more difficulties in taste-masking because to the increased contact surface area and residence time in the mouth, which heighten any disagreeable taste and/or lingering aftertaste. In these situations, it is frequently required to put something between the API and the taste buds, like a particular taste-mask coating, to increase palatability and promote compliance.

3. Techniques for taste masking[15]

Before formulation, there were certain typical issues like terrible mouthfeel and taste. The desired product should have a flavour and sweetener that are appropriate, a decent mouth feel. It should also prevent or minimise stimulation of the taste buds. These issues are resolved using the subsequent methods:

1. Conventional method

1. Use of flavour enhancer
2. Uses of sweetener

Recent method

1. Granulation
2. Prodrug
3. Ion exchange resin
4. Solid dispersions
5. Organoleptic method
6. Hot melt Extrusion
7. Spray drying
8. Inclusion complex
9. Microencapsulation
10. Coating.

3.1 Taste masking with Sweeteners and Flavours[16]

- **Flavouring agents for taste masking**

Natural or synthetic sources can be used to create flavourings and fragrances. Fruit juices, aromatic oils like lemon and peppermint, herbs, spices, and their distilled fractions are examples of natural products. They can be purchased as syrups, spirits, alcoholic or water-based solutions, concentrated extracts, or extracts.

Table 3: Flavour selection.[16]

Taste sensation	Recommended flavor
Salt	Butterscotch, apple, apricot, peach, vanilla,
Bitter	Wild cherry, walnut, chocolate, mint, Grape
Sweet	Fruit and berry, vanilla
Sour	Citrus flavors, licorice, root beer, raspberry

- **Sweeteners[16]**

In addition to their crucial function in taste masking, sweeteners are commonly used in pharmaceutical formulation for a number of functions. Three types are nutritive sweeteners, polyols, hydrogenated starch hydrolysates, and high-intensity sweeteners. Since no single sweetener is suitable for everyone, they each have unique organoleptic and functional characteristics. This can be avoided by employing a combination of sweeteners that reduces the rate at which one particular sweetener is consumed. As an illustration, Aspartame is 500 times sweeter than sugar, but has the potential to cause cancer.

Table 4: Relative sweetness of commonly used sweeteners.

Sweetening agents	Relative sweetness	Comment
Aspartame	200	Not very stable in solution
Glycerrhizin	50	Moderately expensive
Lactose	0.16	Large amount required
Saccharin	450	Unpleasant after taste
Sucrose	1	Most commonly used
Sucralose	600	Synergistic sweetening effect

3.2 Granulation

Granulation is a rapid, easy, and scalable flavour masking technique. As granulating agents, polymer, flavour, and waxes have all been used to mask the bitter taste of medicine. Waxy liquids with low melting points, such as hydrogenated castor oil, glyceryl palmitosterate, and glyceryl behenate, are employed. During granulation, the practical coating could not be complete. On the other hand, matrix swelling can lessen the bitter active's diffusion. As a result, a swellable polymer can offer more taste masking in granulation as compared to a non-swellable polymer.[3] The process is routine in the production of tablet dosage forms. Several saliva insoluble polymers are used as a binding agent. Because these polymers are less soluble in saliva, the flavour of granules composed of them is subdued. Granulation decreases the productive surface area of the bitter chemical that comes into touch with the tongue during oral ingestion.[18] It is possible to create chewable and quickly dissolving tablets or cpasules from taste-masked granules manufactured from saliva-insoluble polymer. In the granulation process, low melting point liquids and waxes such glycerol palmitate stearate, glyceryl behenate, and hydrogenated castor oil are frequently used to generate the taste-mimicking effect.[19]

3.3 Prodrug

They are pharmaceutically active parent metabolics that are released from medicinal compounds after biotransformation, not withstanding their inert moieties. One approach to achieving bitter taste masking is to design prodrugs that are stable in the oral cavity but readily convert to the active drug in the gastrointestinal tract or bloodstream. This can be accomplished by attaching a specific chemical group to the drug molecule, which is subsequently cleaved or metabolized in the body to release the active drug. The taste-masking prodrug should be chemically stable, non-toxic, and have good bioavailability.[20]

Table 6: Prodrug for bitter taste masking.[16]

Parent molecule	Reversible modification
Chloramphenicol	Palmitate or phosphite ester
Clindamycin	Alkyl ester
Lincomycin	Phosphaye or alkyl ester
Tetracyclin	3,4,5-Trimethoxy benzoate salts

3.4 Ion exchange resin complexes:

Pharmaceutical scientists have shown a lot of interest to ion exchange resins (IER) because of the many different ways they can be used as drug delivery systems. The development of novel drug delivery systems and other medicinal applications has heavily explored IER over the past few years. For immediate release and sustained release applications, a number of ion exchange resin formulations for oral and peroral delivery have been developed. Bitter medications can be successfully removed from solution during transit through the mouth by being absorbed onto ion exchange resins. At salivary pH 6.7, the drug remains in complete form, rendering it tasteless.

Table 7: Common ion exchange resins.[16]

Type	Functional group	Polymer backbone	Commercial resins
Strong anion	$-N^+R_3$	Polystyrene-DVB	Amberlite IR 400, Dowex 1
Weak anion	$-N^+R_2$	Polystyrene-DVB	Amberlite IR 4B, Dowex 2
Strong cation	$-SO_3H$	Polystyrene-DVB	Amberlite IR120, Dowex 50
Weak cation	-COOH	Methacrylic acid-DVB	Amberlite IRC50, Indion 204, 234, tulsion 335, 339

3.5 Solid dispersion

They are solid-state dispersions of one or more active ingredients in an inert matrix or carrier. Insoluble or bland matrices may be used to cover the flavour of bitter medications. Povidone, polyethylene glycols, hydroxypropyl methylcellulose, urea, mannitol, and ethyl cellulose are some of the carriers employed in solid dispersion systems. The following is a description of various methods for creating solid dispersion.

- **Melting technique:** Using heat, the medication or drug combination and a carrier are melted together. In an ice bath, the melted mixture quickly cools and congeals while being stirred ferociously. Crushed and ground up till it becomes a solid mass.
- **Solvent method:** This technique involves dissolving the active substance and the carrier in a typical solvent, allowing the solvent to evaporate, and then recovering the solid dispersion.
- **Melting-solvent method:** In this technique, a molten mass of polyethylene glycol is mixed with a medication in solution without the solvent being removed at a temperature below 70^0C.

3.6 Organoleptic methods

The easiest method to conceal your taste is to do it this way. An assortment of sweeteners and tastes are employed to cover up the unpleasant flavour of mild to moderately bitter active ingredients. Effervescent chemicals may also be used to enhance mouthfeel. Some remedies may contain a bitterness blocking agent to mask the tart flavour.[22] Sweeteners like sucralose and xylitol and some bitter masking flavours like grape, wild cherry can be used to make the formulation palatable.

3.7 Hot-melt extrusion

A revolutionary method of drug masking called hot-melt extrusion (HME) has a number of drawbacks, including the absence of an organic solvent, fewer processing steps, continuous operations, and scale-up potential. In dry conditions, the bitter active is mixed with additional ingredients to mask the flavour. The mixture is placed in a hopper and then moved, mixed, and melted by an extruder. The ingredients go through a heating process with a lot of mixing to create the taste-masked extrudates. After that, it is micronized to create granules that have been taste-masked before being added to the right dosage form.[22]

3.8 Spray drying[19]

Spray drying offers an alternative to flavour masking by utilising a physical barrier coating.

The bitter drug is either dissolved or mixed with a polymer in an appropriate solvent before being spray dried.

The process typically involves three steps:

1. Turning feed into a spray via atomization
2. Spray air before drying.
3. Separating dry goods from the atmosphere.

3.9 Formation of inclusion complexes:

In the process of creating an inclusion complex, the drug molecule nestles inside the host molecule, which functions as the complexing agent, to create a stable compound. The complexing agent has the ability to cover up the medicine's bitter taste by either lowering the drug's oral solubility upon consumption or lowering the amount of drug particles exposed to taste receptors, which lessens the bitter taste's perception. For inclusion type complexes, beta cyclodextrin is the most commonly employed complexing agent. By creating a 1:1 complex

with cyclodextrin, the strong bitter flavour of carbapentane citrate syrup was decreased to about 50%.[24]

3.10Microencapsulation technique:

Small solid particles, liquid droplets, and dispersion are covered with a comparatively thin coating by the process of microencapsulation. This technique is commonly utilised in the pharmaceutical industry to improve bioavailability while also masking the taste of harsh medications. In microencapsulation, coating agents such gelatin, povidone, HPMC, ethyl cellulose, carnauba wax, acrylics, and shellac are used. This process involves encapsulating bitter medications to create free-flowing microcapsules, which are subsequently combined with excipients and crushed into tablets. Air suspension, coacervation, phase separation, spray drying and congealing, pan coating, solvent evaporation, and multiorifice centrifugation are techniques used to create microencapsules.[25]

Table 9: Taste masking of bitter drugs by microencapsulation.[16]

Technique	Drug	Coating agent	Dosage form
Wurster fluid bed coating	Acetaminophen	Croscarmellose	Dispersible tablet
	Caffeine	Eudragit RL 30D, RS30D Eudragit NE30D/RL30D, HPMC	Chewable tablet
	Levofloxacin	Eudragit E100, cellulose acetate	Suspension
Top spray fluid bed coating	Sildenafil citrate	Eudragit NE30D, E-100	Mouth melt tablet
	Chlorpheniramine maleate	Ethyl cellulose	
Tangential spray fluid bed coating	Acetaminophen	Eudragit E-100, Cellulose acetate	Chewable tablet
	Theophylline	Eudragit NE30D, Guar gum	Dry suspension
Spray drying	Ampicillin	Sodium CMC	Powders
	Nizatidine	Eudragit E-100	Sprinkels
	Roxithromycin	Eudragit RS100/ RL100	Suspension
Spray congealing	Clarithromycin	Glyceryl monostearate, Eudragit E-100	Powders
Coacervation phase separation	Chloroquine diphoshphate	Eudragit RS100	Powders
Solvent evaporation	Metronidazole	Eudragit E, Fattibase	Dry suspension

3.11 Polymer coating of drug:

For a variety of pharmaceutical applications, coating is a very helpful approach. It is feasible to totally cover up the taste of a bitter medicine while maintaining the targeted drug release profile by using the proper sort of coating material. Any nontoxic polymer that is soluble at acidic pH levels but insoluble at pH 7.4 is a suitable substitute for taste masking. Drug particles are coated using a variety of inert coating agents, including starch, povidone, gelatin, methylcellulose, and ethyl cellulose. The fluidized bed processor is one of the most effective ways to coat medication particles. This method fluidizes powders as tiny as 50 m in an expansion chamber using heated, high velocity air, and then coats the drug particles with a coating solution that is typically supplied from the top as a spray through nozzle. With heated air, the coated grains are dried.[26]

4. Gneral methods for manufacturing of chewable soft gelatin capsules

The Chewable soft gels are prepared by using the following methods.

1. Plate process
2. Rotary die process
3. Reciprocating die process
4. Accogel process
5. Seamless gelatin capsules

5. Formulation considerations during manufacture of softgels[27]

Manufacturers should keep the followings in mind when producing soft gelatin capsule.

- **Compatibility of the drug with gelatin (and shell components)**
  Soft gelatin capsules can contain solids, solids in liquid, solutions or suspensions, mixtures of miscible liquids, or just a straightforward liquid composition. The only acceptable fill materials are those that don't interfere with the gelatin shell or other parts of the shell.
- **Stability of the drug with moisture**
  Compared to hard gelatin capsules, soft gelatin capsules plasticized with glycerol have a significantly higher moisture content. Therefore, moisture-sensitive medications should not be formulated in soft gelatin capsules in order to guarantee the chemical stability of the medication.
- **Stability of the drug at temperature 35°C to 40°C**
  This is another important consideration in the development of soft gelatin capsules. During encapsulation, fill materials may be heated up to 35°C. Hence, highly thermolabile drugs may not be encapsulated in soft gelatin capsules.
- **pH of the fill material**
  Extreme pH values should be avoided since gelatin tends to hydrolyze at pH values below 2.5, which

might cause leaks. Additionally, aldehydes and fillers with a pH higher than 9 tan the gelatin. Crosslinking of gelatin during the tanning process causes the shell to harden. When exposed to water, the shell becomes insoluble and difficult for trypsin and chymotrypsin to break down.

- **Migration of drug substances into the shell:** Making sure that there is little to no interaction or migration between the liquid fill matrix and the softgel shell is one of the most crucial parts of the formulation of soft gelatin capsules. Drug compounds' water solubility and the partition coefficient between water and the nonpolar solvent have both been linked to their ability to migrate from an oily vehicle into the shell. Packaging topical medications in gelatin capsules that resemble soft tubes must take drug migration into the shell into account since it may alter the amount of the drug in the ointment after application. When drug migration occurs in other products, such as oral capsules or suppository capsules, it is necessary to assess the drug content of both the shell and the contents.

6. Evaluation parameters for chewable capsule[28]

In-process organoleptic assessment

This assessment happens at numerous points during the creation of a chewable tablet. These are listed below:

- **Analyses of the drug:** It entails characterising and evaluating the substance either in absolute terms or in comparison to a recognised reference standard.
- **Evaluation of a coated medicine:** This process compares the coated drug to the pure drug and takes different coating treatments into account.
- **Evaluation of the unflavoured base formulation:** It entails comparing various vehicles, the percentage of vehicles, or other formulation factors when the drug is coated. Comparison of several flavoured formulations is required for the evaluation of the baseline flavour formulation.
- **Evaluation of the chosen option and the product acceptance test:** This involves examining two formulations or competitors.

i. Chemical evaluation: It involves the following:

Assay of drug content, Dosage uniformity, In vitro and In vivo Evaluation.

ii. Physical evaluation: It involves the following:

Capsule physical appearance, Disintegration.

7. Application of chewable capsules[28]

- The use of chewable capsules for local therapy allows for the regulated release of an active ingredient over an extended period of time, resulting in a more pronounced local effect.
- Discomfort: Rapid absorption of therapeutic quantities of the active component is necessary for the effective treatment of minor pains, headaches, discomfort from a cold, muscular aches, allergies, etc. When buccal absorption produces a rapid beginning of action and lowers the risk of gastrointestinal side effects, chewable capsules as a medication delivery mechanism may be helpful in treating mild discomfort.
- Chewable capsules, particularly those in which the active ingredient is absorbed through the buccal mucosa, are advantageous for systemic drug delivery in systemic therapy.
- Clinical trials have been conducted on chewing gum formulations including nicotine, lobeline, and silver acetate as cessation aids.
- Obesity: There are several chewing gum formulations available that contain caffeine, guarana, or chromium. Guarana and caffeine are centrally stimulating anorectic substances that have been shown to speed up metabolism.

8. CONCLUSION

In conclusion, a range of taste-masking technologies are already accessible and used in the pharmaceutical sector, and new platforms are always being investigated and created. The chosen technology is mostly determined by the physical and chemical characteristics of the pharmacological ingredient as well as the preferred final dose form. Recent advancements in taste-masking technology have allowed the pharmaceutical industry to offer commercial products with improved patient acceptability and compliance, especially with paediatric and geriatric populations, as well as enhanced convenience for patients on the go. To enhance their product portfolios for oral dosage forms, more businesses are relying on taste-masking expertise.

9. Acnowlwdgmwnt

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Conflict of interest

None to declare.

Ethical approval

None to declare.

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