



## A Review on Medicated Confectioneries

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### ABSTRACT

Conventional dosage forms like tablets and capsules have good patient compliance but people with dysphagia, pediatrics, and geriatrics found difficulty in swallowing and administering dosage forms with water. These disadvantages can be overcome by confectionery-based dosage forms that are high in market demand and are easily acceptable by pediatrics and geriatrics. Medicated confectioneries are sugar-like soft solid preparations that contain one or more active pharmaceutical ingredients. The medicated confectioneries can be prepared easily and they have many advantages like taste masking, prolonged release, and ease of administration. This article reviews the formulation, method of preparation, characterization, and evaluation of chewing gums, lozenges, jellies, and lollipops.

**Keywords:** Conventional dosage forms, prolonged release, dysphagia, confectionery.

### INTRODUCTION

They are defined as pharmaceutical preparations consisting of a drug mixed with honey or syrup; a soft solid, sometimes used as an excipient for pill masses<sup>1</sup>. Traditional dosage forms are difficult to swallow hence medicated confectioneries overcome this disadvantage and offer better patient compliance. The confectionary dosage forms also have advantages like a prolonged release in the oral cavity, taste masking, etc.

Children like confectionery products a lot. Confectioneries such as chewing gums (CG), lozenges, and lollipops are popular in the food industry and among nutraceuticals. In the past few years, the addition of active pharmaceuticals to these confectioneries has been gaining attention in the pharmaceutical industry and these stand as an alternative to modified drug delivery systems especially, for the pediatric population. These confectionery-based dosage forms have a strong potential to overcome compliance problems and have many advantages.

Medicated confectionery is widely used in the formulation of drugs for many conditions such as minor throat irritations, coughs, colds, respiratory tract congestion, and allergies. Kristian J. Tangso et.al<sup>2</sup> have mentioned that the first confectionary therapeutic product named 'Aspergum', a chewing gum that contains acetylsalicylic acid was officially made available on the market in 1924 and this is still available today.

#### Ideal Characteristics of Medicated Confectioneries:

They should -

- Allow high drug loading and rapid onset of action.
- Be compatible with a pleasing mouth feel.
- Leave minimal or no residue in the mouth after oral administration.

- Allow good taste masking of bitter drugs.
- Be portable without fragility concerns.
- Bypass the first-pass metabolism.
- Exhibit low sensitivity to environmental conditions such as humidity and temperature.

#### Advantages:

- Improved patient compliance especially in the case of bedridden patients, patients with oesophageal problems, patients who were unable to swallow tablets/capsules, and geriatric patients.
- Improved bioavailability and absorption of drugs by pregastric absorption of drugs from the mouth, pharynx, and esophagus along with saliva and bypassing the first-pass metabolism.
- Problems associated with oral administration like choking and suffocation can be avoided by oral medicated jellies.
- Water is not required
- Cost-effective and ease of dose termination.
- Allows high drug loading and rapid onset of action.
- Good chemical stability and rapid drug delivery from dosage forms.
- Taste masking of bitter drugs.
- Oral medicated jellies provide good mouth-feel properties.

#### Disadvantages:

- Expensive production process.
- Poor physical resistance when packed in blister packs.
- Require proper stabilization and safety during storage.



- Oral medicated jellies have fragile, effervescent granule properties.
- They should be stored in a dry place as they are hygroscopic.
- Prolonged chewing causes pain in facial muscles and earache in children.
- Risk of overdosage.

**Drug Selection Criteria for Medicated Confectioneries:**

- Must be able to permeate oral mucosa.
- Must be able to diffuse and partition into the epithelium of the upper GIT.
- Low to moderate molecular weight drugs are preferred.
- Low-dose drugs preferably less than 50mg.
- Drugs should have good stability in saliva and water.
- Very bitter or unacceptable taste and odor drugs are unsuitable for medicated confectioneries.

**Possible Absorption Pathway of Medicated Confectioneries:**

The drug present in the confectioneries gets released and absorbed either through oral mucosa or it may get absorbed through pre-gastric (oral cavity, pharynx, esophagus), gastric (stomach), and post-gastric (small and large intestines) segments of the gastrointestinal tract in diluted, dissolved or suspended form in the saliva. Thus, medicated confectioneries can offer both local and systemic effects and also increase bioavailability with a consequent faster onset of action compared to that of other oral solid dosage forms<sup>2</sup>.

Some of the common medicated confectioneries described in this review are medicated chewing gums, medicated lollipops, medicated lozenges, and medicated jellies.

**MEDICATED CHEWING GUM (MCG)**

Chewing gum is a popular oral confectionery product that can be chewed for pleasure without being swallowed.

Medicated chewing gum is defined as a single-dose preparation that contains one or more active ingredients and is released by chewing action into saliva which helps in the diffusion of active ingredient from the gum matrix<sup>3</sup>. It is a modified-release drug delivery system that can be used in pain relief medication, smoking cessation, motion sickness, freshness of breath, prevention of dental caries, and vitamin or mineral supplementation<sup>4</sup>.

**Formulation of medicated chewing gum:**

Chewing gum is a mixture of natural or synthetic gums, resins, sweetening agents, coloring agents, flavoring agents, and gum bases that may be water-soluble or water-insoluble.

**ORAL MEDICATED JELLIES (OMJs)**

According to the 17<sup>th</sup> edition of Japanese Pharmacopoeia, jellies are transparent or translucent non-greasy, semisolid preparations meant for internal and external application. Drugs that have a rapid onset of action and absorption sites as the stomach & small intestine are the best choice for the formulation of jelly.

Oral medicated jellies are palatable solid dosage forms administered in the oral cavity that are meant to release drugs in the mouth and have good taste and flavor so that they offer better acceptance of bitter drugs. Oral medicated jellies disintegrate rapidly in saliva in a few seconds without the need for water. Children may accept jelly more easily compared to oral liquid or tablets<sup>5</sup>.

**Formulation of medicated jellies:**

The ingredients added in formulating medicated jelly are gelling agents, sweetening agents, coloring agents, and flavoring agents. (Table 3)

**MEDICATED LOZENGES**

Lozenges are flavored medicated buccal tablet that is held in the mouth or pharynx containing one or more active pharmaceutical ingredient in a sweetened base and are intended for treating local irritation or infection of the mouth or pharynx. Medicated lozenges are used for patients who cannot swallow solid oral dosage forms as well as for medications designed to be released slowly to yield a constant level of drug in the oral cavity or to bathe the throat tissues in a solution of the drug.

**Table 1:** Water-insoluble gum base

Ingredients	Function	Examples
Elastomers	Provide elasticity and gummy texture	Natural- chicle gum, nispero, rosadinha, jelutong, periollo. Synthetic rubbers -PVA, Polyethylene mixtures, polyisobutylene
Plasticizers	Provides desirable texture and consistency properties	Lanolin, palmitic acid, stearic acid, glycerine, propylene glycol monostearate, oleic acid, hydrogenated vegetable oils, paraffin waxes, propylene glycol, fatty waxes, sorbitol monostearate.
Fillers or texturizers	Provide texture, reasonable size of gum lump with low drug dose and improves chewability	Calcium carbonate, aluminum hydroxide, talc, aluminum silicate, magnesium carbonate.



**Table 2:** Water-soluble gum base

Ingredients	Function	Examples
Softeners & emulsifiers	To optimize chewability and mouth feel of the gum	Glycerin, lecithin, tallow, mono/di/triglycerides.
Colorants and whiteners	To improve color and acceptability	Titanium dioxide, natural food colors and dyes used in food, drug, and cosmetic applications.
Sweeteners	For the sweetness of the product	Water soluble sweeteners - xylose, glucose, ribulose, sucrose, galactose, mannose, monellin, fructose, sugar alcohols like mannitol, sorbitol, etc. Water soluble artificial sweeteners - cyclamate salts, sodium or calcium saccharin salts. Protein-based sweeteners- thaumatin I and II. Chlorinated derivatives of ordinary sugar - sucralose.
Antioxidants	Prevents microbial growth	Butylated hydroxytoluene, butylated hydroxy anisole, propyl gallate
Flavoring agents	For acceptability	Essential oils- clove oil, mint oil, citrus oil, peppermint oil, fruit essences, oil of wintergreen Synthetic flavors.
Bulking agent	Used in low-calorie gum	Inulin, polydextrose, oligofructose, Fructo oligosaccharides, guar gum hydrolysate, indigestible dextrin.
Compression adjuvant	For better compression	Magnesium stearate, silicon dioxide, calcium stearate, talc. <sup>3</sup>

**Table 3:** Formulation of jellies

Ingredients	Characteristics	Examples
Gelling agents	They dissolve in a colloidal mixture resulting in the formation of a weak cohesive internal structure	Sodium alginate, pectin, tragacanth, gelatin, xanthan gum, cellulose derivatives, agar carrageenan.
Sweeteners	Added to mask the bitterness of drug and for good acceptance	Sucrose, dextrose, mannitol, saccharin, sucralose, sorbitol.
Coloring agents	Added to improve the aesthetic appearance, maintain uniformity, and help in product recognition and differentiation.	Natural colors, mineral colors, dyes, and lakes.
Flavoring agents	It is selected depending on its influence on the pharmaceutical and organoleptic properties of the drug and other components.	Orange, lemon, vanilla, chocolate, mint, honey.
Preservatives	Added to avoid any incompatibilities between gelling agents & to retain the shelf life of the product.	Methyl paraben, propyl paraben, benzoic acid, benzalkonium chloride.
Stabilizers	Maintains desirable properties of the product until it is consumed by the customer. Also, prevent jellies from drying.	Propylene glycol, sorbitol. <sup>5</sup>

**Table 4:** Formulation of lozenges

Ingredients	Function	Examples
Candy base sugar Sugar-free vehicles	Sweetening agent and taste masking properties	Sucrose, dextrose, maltose, lactose, PEG 600 & 800.
Fillers	Improve the flowability	Dicalcium phosphate, calcium sulfate, calcium carbonate, microcrystalline cellulose.
Lubricants	Avoid sticking candy to teeth	Magnesium stearate, calcium stearate, stearic acid, vegetable oils, and fats.
Binders	For holding the particles	Acacia, corn syrup, gelatin, sugar syrup.
Coloring agents	To enhance appearance	FD&C colors, water-soluble and alkaline dyes.
Whipping agents	Used in toffee-based confectionaries	Egg albumin, xanthan gum, pectin. Carrageenan.
Humectants	Improve mouth feel properties	Glycerin, propylene glycol <sup>7</sup> .



They are prepared by molding (gelatin and/or fused sucrose and sorbitol base) or by compression of sugar-based tablets. Molded lozenges are sometimes referred to as pastilles, whereas compressed lozenges may be referred to as troches<sup>6</sup>.

#### **Formulation of medicated lozenges:**

The common excipients used in formulating lozenges are sugar bases, lubricants, binders, coloring agents, flavoring agents, whipping agents, and humectants. (Table 4)

#### **MEDICATED LOLLIPOPS**

Lollipops are large sugar-boiled confectionery of various flavors attached to a plastic stick that can be consumed over a long period through licking. The plastic stick is used to hold the confection together. They can be easily swallowed and are gaining in popularity, especially among pediatric patients<sup>8</sup>. Medicated lollipops are defined as hard dosage forms that contain one or more drugs in a sugar base and are meant to be dissolved in the mouth to reduce oropharyngeal symptoms locally or absorbed through the buccal route and act systemically. Most of the lollipop preparations are available as over-the-counter medications.

The components used for the preparation of lollipops were almost the same as those of lozenges. The only difference is the concentration of ingredients used during the preparation of these confectioneries<sup>9</sup>.

#### **METHODS OF PREPARATION MEDICATED CONFECTIONERIES:**

##### **Conventional method:**

This is the most common method used for the preparation of chewing gum. It involves melting the gum components in a kettle mixer and passing through a series of rollers to form thin wide ribbons on to which sugar powder or sugar substitutes are added to increase flavor and to avoid sticking. The gum is cooled for 48 hrs. and is cut into desired size and cooled at carefully controlled temperature and humidity<sup>3</sup>.

##### **Direct compression method:**

This method is used for the preparation of chewing gum and lozenges. This method is suitable when the active ingredient is heat-labile. Free-flowing excipients are allowed to pass from the hopper to the die cavity and compression is made. The diameter of the die cavity and compression force varies from the force involved during the compression of a tablet.

##### **Heating and congealing technique:**

Medicated lozenges, lollipops, and jellies are prepared by Heating and congealing techniques.

The sugar base is prepared by dissolving the required amount of sugar in water and the temperature is maintained at 90-100°C. until the mixture becomes thick. Drug and other excipients are added to the sugar base

except plasticizer and mixed for about 30 minutes for uniform mixing of all the ingredients., the plasticizer is then added and heated for a further 45 minutes. Finally, the syrup base is poured into a pre-cooled and pre-lubricated mold and kept aside for 10-15 minutes to obtain lozenges and lollipops<sup>9</sup>.

In the case of jellies preparation, the syrup base is prepared in the same manner as of lozenges and lollipops but the only difference is the drug solution is added after the incorporation of polymers, gelling agents, and the final weight is adjusted with water, and transferred into molds, cooled at room temperature (25°C) to obtain jellies<sup>10</sup>.

#### **FACTORS AFFECTING THE RELEASE OF MEDICAMENT FROM MEDICATED CONFECTIONERIES:**

##### **Drug solubility:**

The solubility of the drug in the saliva and the confectionery matrix is very important. Poorly soluble drugs will slow the release rate<sup>10</sup>.

##### **Matrix composition:**

The composition and the amount of excipient used in the confectionery matrix may affect the drug release. The materials present in the matrix may increase or decrease the drug release rate.

##### **Intersubject variability:**

The chewing, sucking, or licking intensity and frequency will affect the drug release from the confectionery and it may vary from person to person. The pH of saliva and the salivary flow rate will also influence the drug release from the confectionery and these factors also may vary from person to person<sup>3</sup>.

##### **Hardness of the confectionery:**

Increased hardness of the lollipops and lozenges will take more time to dissolve and thus slow down the drug release.

##### **Design of the product:**

The size and shape of confectionery may influence consumption and thus affect the release rate of drugs from the product<sup>10</sup>.

##### **Drug particle size:**

The smaller the particle size of the drug faster the release rate of the drug due to the increase in the surface of the drug. Larger particles get slowly released from the confectionery matrix.

##### **pH and ionic strength:**

The salivary pH and the ionic strength of the surrounding environment in the oral cavity will affect the drug ionization which in turn the release rate of the drug.

##### **Contact time:**

Contact time of the medicated confectionery in the oral cavity is important whether it is a local or systemic effect<sup>3</sup>.



## EVALUATION OF MEDICATED CONFECTIONERIES:

### 1) Physical appearance:

Visual inspection is done for jellies, lozenges, and lollipops and observed for any surface cracking, air bubble development, black particles, texture, and consistency present.

### 2) Stickiness and grittiness:

This test is performed for jellies for sticking and gritty properties by rubbing the jelly sample between two fingers and visually inspecting it<sup>11</sup>.

### 3) Moisture analysis:

It is done by gravimetric method to determine the moisture content in lozenges. The gravimetric method involves placing 1g of sample in a vacuum oven at 60-70°C for 12-16hrs and the moisture content is determined by subtracting the final weight from the initial weight.

### 4) Hardness and thickness:

Hardness is tested with Monsanto hardness tester or Pfizer hardness tester and vernier calipers were used to evaluate the thickness of lollipops and lozenges<sup>8</sup>.

### 5) Viscosity:

Viscosity is measured by using a Brookfield Viscometer for oral medicated jellies.

### 6) pH:

The pH of all the jelly is determined by using a digital pH meter. 0.5 gm of the weighed

formulation was dispersed in 50 ml of distilled water and the pH was noted after calibrating the pH meter.

### 7) Weight variation:

This is done for lozenges and lollipops by measuring the weight of about 20 units individually and the average weight is calculated. Each confectionery weight was compared with the average weight to determine the weight variation whether it is in limits or not. This is done by using the following formula –

$$\text{Weight Variation} = \frac{\text{individual weight} - \text{average weight}}{\text{average weight}} \times 100$$

### 8) Friability:

The Roche friability test apparatus was used to determine the friability as it determines the durability of the confectionery during transit. Pre-weighed confectioneries were placed in the apparatus, which was subjected to 100 revolutions and then reweighed. The percentage friability calculated was using the formula.

$$\% \text{ Friability} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100.$$

### 9) Content uniformity:

The content uniformity test is done to ensure every dosage form contains an equal amount of drug substance. A confectionary from each formulation was taken, crushed, and mixed. From the mixture drug equivalent of the mixture was extracted thoroughly with the aid of suitable media. The amount of drug present in each extract was determined using a suitable analytical method.

### 10) Release of drug in saliva:

This evaluation test is carried out for medicated chewing gums by allowing a Panel of volunteers to chew the drug delivery device for a certain period and the remaining quantity of active substance in the residual gum was evaluated.

### 11) Pharmacokinetic studies of medicated chewing gum:

To perform this study, a minimum of four healthy human volunteers were selected. Volunteers are strictly instructed to not take any medicine in the last 48 hours and they are fasted overnight. Sample collection is started from a blank of zero-hour urine or blood and then on from 15 min, 1, 2, 3, 4, 6, 7, 8, 10, 11, 12, 24-hour intervals after administration of medicated chewing gum. The volunteers were allowed to drink water at regular intervals of 30 minutes during the study and the samples collected were analyzed by suitable analytical methods.

### 12) Buccal absorption test of MCG:

Human volunteers were allowed to swirl a fixed volume of drug solution of known concentration at different pH values of 1.2, 5, 6, 6.5, 7, 7.5, 7.8, and 8, in the oral cavity for 15 min and then expelled out. The expelled saliva is analyzed for drug content and back-calculated for buccal absorption<sup>3</sup>.

### 14) In-vitro Dissolution Study:

An *in-vitro* dissolution study is performed by the USP basket apparatus using a suitable dissolution medium. The temperature of the medium is maintained at about 37 °C ± 0.5° C and the rotation speed is about 50 rpm. The samples are withdrawn for 10, 20, 30, 40, 50, and 60 minutes and replaced with fresh media. The Samples were analyzed for drug release using a suitable analytical method<sup>10</sup>.

### 15) In-vitro drug release from MCG:

#### Official modified dissolution apparatus:

In this apparatus, in addition to the pair of horizontal pistons ('teeth'), the chewing chamber contains a vertical piston ('tongue') working alternately with the horizontal pistons, which ensures that the gum is always positioned in the correct place during the mastication process. s. If required, it is possible to construct the machine in such a way so that at the end of the chew the horizontal pistons rotate in opposite directions around their axis to each other to attain maximum mastication. The temperature of the chamber is maintained at 37±0.5° C and the chew rate varies. Other maintenance settings include the volume of



the medium, the distance between the jaws, and the twisting movement. As per European Pharmacopoeia, 20 ml

of the unspecified buffer is used in 40 ml of the chewing chamber and the chew rate is about 60 strokes per minute.

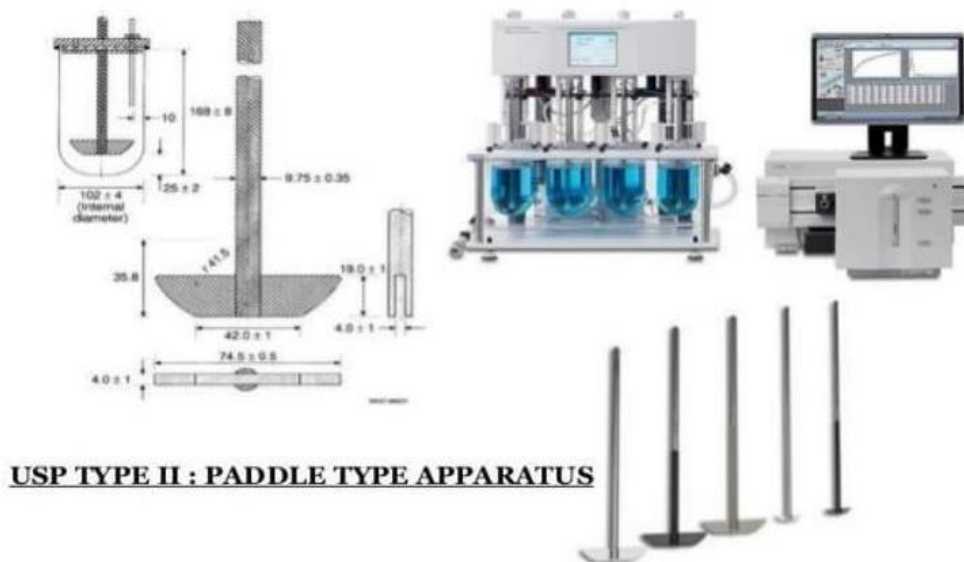


Figure 1: Official modified dissolution apparatus

**Wintergreen chewing apparatus:**

One of the unofficial apparatuses for performing dissolution studies of MCG was designed by the scientist Wintergreen. This apparatus consists of a two-piston and temperature-controlled reservoir for the dissolution medium. The upper jaw has a flat surface which is parallel to the central part of the lower surface. The small brim of the lower surface is angled upwards (45 degrees) in such a way that the lower surface functions as a small bowl with a flat bottom and it prevents the chewing gum from sliding during mastication. During one cycle of chewing, one piston on each side shifts towards the other. When they get together, they press the MCG between them and then make a twisting association before returning to the preliminary point. To perform a drug release test, chewing gum of known weight is placed in a 20 ml volume of dissolution medium, and temperature is maintained at 37 degrees. The chewing is maintained at about 60 strokes per minute. e. At specified time intervals, i.e., 3, 5, and 10 min, samples are collected and analyzed to determine the percentage of drug release<sup>3</sup>.

**Unofficial single module chewing apparatus<sup>30</sup>**



Figure 2: Wintergreen chewing apparatus

**APPLICATIONS OF MEDICATED CONFECTIONERIES:**

- 1. Cough Relief:** Medicated lozenges and cough drops often contain ingredients like menthol, honey, or herbal extracts that can help soothe irritated throats and suppress coughing. They provide temporary relief from coughing and throat discomfort.
- 2. Sore Throat Soothing:** Lozenges and throat drops with ingredients like benzocaine or pectin can help numb the throat and alleviate soreness. They provide a soothing effect and temporary relief from throat irritation.
- 3. Throat Lubrication:** Some medicated confectioneries contain ingredients like glycerin that help keep the throat moist, reducing dryness and irritation.
- 4. Vitamin and Mineral Supplementation:** Medicated gummies or candies can be formulated to include vitamins, minerals, and dietary supplements. They offer a tasty way to deliver essential nutrients and can be particularly useful for individuals who have difficulty swallowing pills.
- 5. Nausea Relief:** Ginger-flavored confectioneries are sometimes used to help alleviate nausea and motion sickness. Ginger has natural anti-nausea properties.
- 6. Pain Relief:** Medicated lollipops or gummies containing analgesic (pain-relieving) ingredients like ibuprofen or acetaminophen
- 7. Nutritional Support:** Medicated confectioneries can be designed to include certain nutrients that are beneficial for specific health conditions. For instance, products enriched with fiber for digestive health or antioxidants for immune support.
- 8. Herbal Remedies:** Some confectioneries incorporate herbal extracts known for their potential health benefits. For example, Echinacea for immune support or elderberry for cold and flu relief.

**9. Smoking Cessation:** Medicated candies can be designed to help people quit smoking. They may contain ingredients that reduce nicotine cravings or alter the taste of cigarettes.

**10. Vitamins for Kids:** Medicated confectioneries formulated for children can make taking essential vitamins and minerals more enjoyable, encouraging compliance with daily supplementation.

**11. Throat Infections:** Medicated confectioneries with antibacterial or antiseptic ingredients can help combat bacterial infections in the throat.

**12. Sleep Aid:** Some confectioneries may include ingredients like melatonin, which can aid in promoting sleep. These are often used as a more pleasant alternative to traditional sleep aid pills.

**Table 5:** Marketed formulations of medicated confectioneries

<b>Marketed MCG'S:</b>		
<b>Local therapy</b>		
<b>Therapeutic effect</b>	<b>API</b>	<b>Trade name</b>
Dental hygiene and tooth whitening.	Calcium as tricalcium phosphate	Orbit white, Happy Dent white, Trident white.
Antibacterial agent- preventing tooth decay & treating gingivitis.	Chlorohexidine	VitaFlo CHX, HEXIT
Prevention of dental caries	(Fluoride)sodium fluoride	Fluogum
<b>Systemic therapy</b>		
Pain relief- in treatment of minor headaches, pains	Aspirin	Aspergum
Smoking cessation	Nicotine	Nicorette, Nicotnelle, Niquitin cq.
General Health	Vitamin C	Stamil, endykey
Enhanced brain activity	DHA & CCE	Brain
Symptomatic relief from post-menopausal syndrome	Extracts of dong quai root, black cohosh root, damiana leaf, Mexican wild yam root	Zoft menopause gum <sup>4</sup> .
<b>Marketed lozenges</b>		
Sore throat	Benzocaine, menthol	Cepacol
Sore throat	Menthol	Vicks
Oral thrush	Clotrimazole	Clotrimazole lozenge
Sore throat and blocked nose	Amyl meta cresol, di chlorobenzyl alcohol	Strepsils
Common cold and flu	Zinc Gluconate	Therazinc <sup>7</sup> .
<b>Marketed jellies:</b>		
Treats Erectile dysfunction	sildenafil	Kamagra
Provide half the number of vitamins required per day	Vitamins and minerals	Calorie mate <sup>5</sup> .

## CONCLUSION

Medicated confectioneries in the pharmaceutical industry are increasing day by day as they serve numerous advantages like they increase the shelf life of the incorporated drugs, and offering better bioavailability bypassing the first-pass metabolism. They are used in the treatment of various ailments such as dental caries, throat infections, otitis media, and oral inflammatory problems. Hence, we can conclude that medicated confectioneries are best suitable for pediatrics and geriatrics and will be more popular in the market in the next few years.

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