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Review on Medicated Chewing Gum

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Abstract: *Medicated chewing gums (MCGs) represent a unique platform for drug delivery. They have been defined as solid single-dose preparations, which may contain more than one active pharmaceutical ingredient (API) with base consisting primarily of gum that has to be chewed for a certain period of time. Chewing gums are the type of mobile drug delivery systems. The world market for chewing gum is estimated to be 560,000 tons per year, representing approximately US $5 billion. Some 374 billion pieces of chewing gum are sold worldwide every year, representing 187 billion hours of gum-chewing if each piece of gum is chewed for 30 minutes. It is useful by means of administering drugs either locally or systemically through, the oral cavity. The treated chewing gum has through the times gained adding acceptance as a medicine delivery system.*

Keywords: Medicated chewing gum, Oral drug delivery system, Patient compliance

I. INTRODUCTION

Medicated chewing gum as "A solid dose preparation with a base consisting mainly of a gum that are intended to be chewed but not to be swallowed, providing a slow steady release of medicine contained. Medicated chewing gum is a unique dosage form that combines the benefits of oral drug delivery with the convenience of a chewing gum. It typically contains active pharmaceutical ingredients (APIs) for therapeutic purposes, offering advantages such as rapid absorption through the oral mucosa and improved patient compliance. This innovative form of drug delivery is particularly useful for medications requiring quick onset of action or those affected by first-pass metabolism.

History:

Chewing gum as a pass-time has been around for thousands of years with the ancient Mayan Indians chewing chicle sourced from the Sapodilla trees. In 1892, William Wrigley invented his first brand of flavoured confectionary chewing gums "Wrigley's Spearmint", providing the foundations for his thriving business (Rassing, 1996). The concept of chewing gum for medical purposes provides a discrete method for delivery and does not highlight the illness or need for medication for the individual. It can also contribute to delivering medicine on demand during peoples' busy lifestyles. One of the first official oral health gum patents was filed by William F. Semple (in 1869), which stated the use of chewing gum for dental hygiene purposes (Khatun and Sutradhar, 2012). The first gum containing a medicated active was patented in 1924, Aspergum containing acetylsalicylic acid (aspirin) (Biswal and Anantkumar, 2013). One of the most notable recent successes is nicotine replacement gums which have greatly improved the acceptability of medicated chewing gum.

Need of medicated chewing gum:

1. High bioavailability
2. High acceptance by children
3. Local effect
4. Systemic effect
5. Ready for use
6. Pleasant taste

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Advantage

- Very Less first-pass metabolism and improved bioavailability.
- Help improve mood by reducing tension and anxiety.
- High acceptance by children and teenagers
- Good stability against light, oxygen, and moisture.
- Advantageous for patients with difficulty in swallowing tablets.
- Fast onset due to rapid release of active Ingredients in buccal cavity and subsequent absorption in systemic caculation
- Gum does not reach the stomach Hence GIT suffers led from the effects of excipient Fraction of product reaching the stomach is conveyed by saliva delivered continuously and regularly duration of action is increased.
- High bioavailability of drug
- Better and pleasant taste
- The treatment can, if required, be terminated at any time.

Disadvantage:-

- Risk of over dosage with MCG compared with chewable tablets or lozenges thatcan beconsumed in a considerable number and within much shorter period of time.
- Cause pain in facial muscles (due to prolong chewing on gum)
- Produce staining on teeth and tongue.
- Causes earache in children
- Causes side effects when it consumes in more number within short period of time
- Chewing gum has been shown to adhere to differentd0egrees to enamel dentureand fillers.
- Extended chewing of gum may result in pain in facial muscles and ear ache in children.
- Short time of administration due to eating, speaking, and drinking
- Additives in gum like flavoring agent, Cinnamon can cause Ulcers in oral cavity and Liquorice cause Hypertension.
- Allergic reaction to synthetic sweeteners,

Composition:

Composition of Medicated Chewing Gum	Examples
Water insoluble gum base:	It comprises mainly elastomer, resins, fats & oils and inorganic fillers.
Elastomers:- Provide gummy texture and elasticity	Latex, Jelutong, Lechi Caspi, Perillo, Chicle
Plasticizers: Regulate cohesiveness of the product	Glycerol esters, hydrogenated resins, terpenes resins.
Fillers: Improve chew ability, provide reasonably size of the gum lump with low dose drug	Magnesium carbonate, ground lime stone, clay, alumina, talc, titanium oxide, magnesium & aluminium silicate
Water soluble base	It contains bulk well as high intensity sweeteners, flavouring agents, softeners, emulsifiers, colours, and anti-oxidants.
Softeners & Emulsifiers: Provide chew ability & mouth feel of the gum	Glycerine, lecithin, Stearic acid, Palmitic acid, oleic acid, linoleic acid.
Colorants & Whiteners: Provide suitable colour of the gum	FD & C type dyes, fruits and vegetable extracts, titanium dioxide.
Aqueous sweeteners: Used as softeners to blend the ingredients & retain moisture	Sorbitol, corn syrups, hydrogenated starch hydolysate.
Bulk sweeteners: It includes sugar and sugarless	Sucrose, dextrose, maltose, fructose, sorbitol, mannitol,

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components	aspartame,
Flavouring agents: Improve flavour in chewing gum.	Citrus oil, peppermint oil, spearmint oil, mint oil, clove oil.

II. MATERIAL AND METHODS

Medicated chewing is a new drug delivery system for the prevention and treatment of chemotherapy-induced nausea and vomiting (CINV),radiation therapy-induced nausea and vomiting (RINV), and also in post-operative nausea and vomiting (PONV) conditions. Drugs are usually formulated in variety of dosage forms like tablets, capsules, injections, inhalers and ointments etc. The oral drug delivery system is most acceptable route of drug administration due to ease of administration than other dosage forms. In addition to confectionary role, nowadays, chewing gum is also showing best and convenient drug delivery system due to rapid absorption of agents which can be absorbed by oral cavity. Medicated chewing gums are more accepted by the parents for children as comparison to tablets, capsules, or liquids. Medicated chewing gums are used to deliver drug locally or systemically. Drug can be release locally for the oral treatment or may be absorbed rapidly by oral mucosa for systemic conditions, leading to fast onset of action and bioavailability. This avoids first-pass metabolism and also metabolismin gastrointestinal tract

Chewing gum drug delivery system is convenient, easy to administer anywhere, anytime, and its pleasant taste making it most patient acceptable dosage form. Chewing gum usually consists of gum core, which may or may not be coated. There are three methods by which medicated chewing gum can be prepared.

(1) Fusion method,

(2) Cooling, grinding, and tableting method, and

(3) Direct compression.

Manufacturing process

Fusion method

The first step of a typical process for manufacturing chewing gum is to melt and soften the gum base at about 60°C and place it in a kettle mixer, in which blades soften the base, then other ingredients such as sugar, glycerine, sweeteners, taste-masking agent are added to the softened base, lately the flavouring agent is added in the mixing procedure at 40°C, then cooling and rolling steps would be done, and the rolled chewing gum would then be cut into pieces of desired shapes and sizes. To make a coated gum tablet, a coating agent should be sprayed to form a uniform surface.

Second step of this method is somehow different: The primary step of preparation is to set up a mixer (the mixer could be sigma blade or other types of mixers), if a sugar-containing gum is needed, the first step is to add corn syrup to the mixer, and then finely powdered sugar is added gradually. Sugar, used in this step, could be powdered sucrose, dextrose, fructose, corn syrup solids or combination of them.

After adding these sweeteners, plasticizers are added to modify the texture and regulate the cohesiveness. Glycerine is the most preferably plasticizer used. Other components specified in Table 2 could be added to the matrix according to required characteristics, such as fillers, colorants, and flavourings. But it is recommended that flavorants being added to the matrix at the end of procedures when base gum is totally and completely homogenized because most flavorants are relatively volatile.

The proportions of components in the matrix are variable between sources and depend to desired characteristics. But powdered sugar has approximately the most proportion.

The mechanical forces of mixer, that is, compressive and shear and heat can ease the softening process. When no heat is applied, a higher power is demanded. The mixing process continues until a homogenous mass is formed. The mixing process should last about 8 min.

Another way of mixing ingredients is to add sugar gradually till the end of adding other components.

After matrix preparation and completely mixing it, the commercially prepared particles of gum base are added to the chamber all at once. But it is believed that these particles should have been heated and mixed before adding all other ingredients to the mass of gum base. In this stage, mixing will continue for 10-20 min.

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The difference between these almost new methods from the conventional (fusion) method in mixing techniques is wherein the sweetener matrix is first formed then gum base particles as pellets are added, but in conventional (fusion) method, the sweeteners and other ingredients are added to the molten gum base.

This new processing method has advantages over the previous way of processing, that is, the probability of producing sugar lumps is less than before.

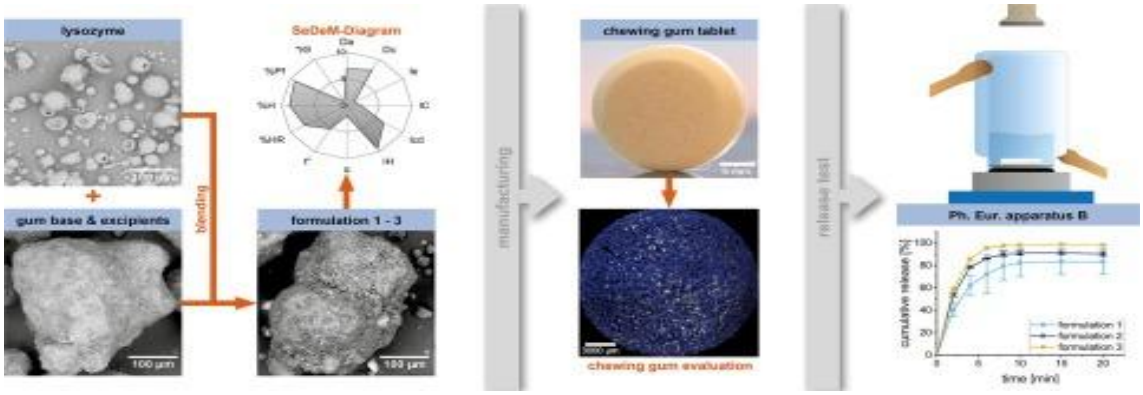

FIG 2: MCG BY FUSION METHOD

Cooling, grinding, and tableting method

One other method to provide a chewing gum with desired taste, colour, and flavour is to mix gum base with favourable and suitable sweeteners, corn syrups, starches, flavouring agents, and colorants, and then refrigerate and cool it by a freezer apparatus or by contacting with a coolant like carbon dioxide to a temperature below −15°C which is therefore crushed and pulverized with a cutter or grinding apparatus to obtain minute particles then these finely ground particles are heated to a temperature which makes them adhere to each other and form a slick and uniform bulk with consistent texture and low specific gravity. If the fragments are such that they do not self-adhere, low pressure would be applied manually or mechanically before they are warmed to the normal room temperature to thereby promote self-adhesion.

The cooling and grinding steps can be combined by cooling the grinding apparatus. After the grinding step, we can let the coolant (if used) evaporate and disappear from our desired composition.

The minute particles may be coated by edible substances or premixed with powdery materials.

For tabularization, compressing punches may be needed but an anti-adherent agent should be applied to avoid sticking to surfaces of punches.

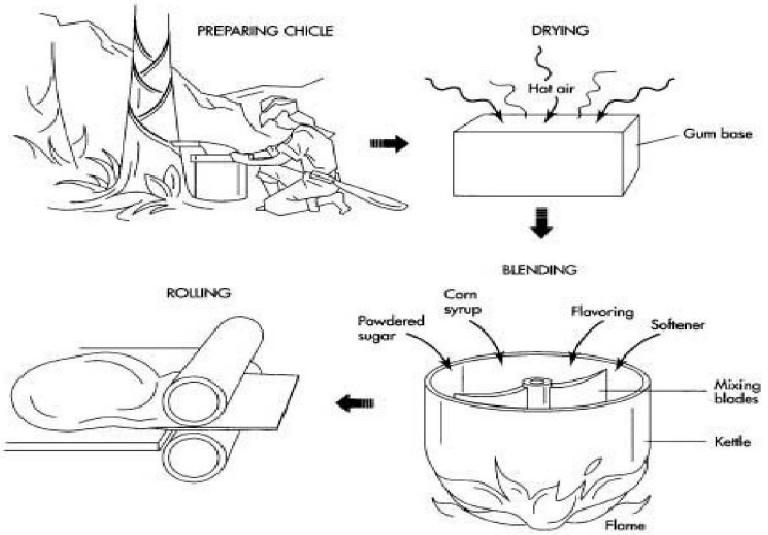

FIG3: MCG by Cooling, grinding, and tableting method

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Direct compression

A new technology to make a chewing gum tablet is direct compression and tableting at high-speed standard machine, but as explained in a patent, this way of forming chewing gum tablets provides a quickly dissociable chewing gum, but after a few seconds of chewing, particles adhere together to form a uniform and homogenous mass. In this method; we need a granulating agent, most preferably that is sorbitol which can also act as a sweetener. A lubricant such as magnesium stearate, talc, stearic acid, hydrogenated vegetable oils, and sodium stearyl fumarate is added to formulation before tableting. First step of this method is dry mixing of gum base, granulating agent and at least one processing material then adding active ingredient, sweeteners, and other needed ingredients to the formulation in free flowing form of materials then directly compressing the chewing gum into tablets. In the first step, the temperature should not raise higher than the melting point of the gum base. After obtaining a uniform and slick mass, the temperature would lower to add other ingredients.

The compressed tablet is capable of releasing the active ingredient into the mouth cavity, after 2-10 chews dissociation reaches to maximum

We can formulate many sensitive active substances in model of compressed chewing gum that is advantage over previous methods, other significant benefits are:

Fast release, fast absorption, andhigh content uniformity. Bi-layered compressed chewing gum tablets are now found in new pharmaceutical products.

Fig4: MCG by Direct compression

Problems associated with manufacturing chewing gums

Capping, lamination, picking, and sticking are the most common processing problems.

In the first method, one of the problems is that the inordinate content of moisture in the matrix may cause a low viscosity which reduces the shear and compressive forces, indeed more gum base particles are more likely to dissociate and float

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Heating and melting can make controlling the accuracy and uniformity of the drug difficult.It is hard to provide sanitary conditions to make MCGs.

In the second method, moisture content of chewing gum may cause the gum jam to the blades and punches of apparatus, screens, surfaces, and chamber's wall.

In the second method caking and balling of the gum prevent formation of gum fragments

In the third method, ejection of final compressed mass from the mixer is difficult and may stuck up into the tubes and stick to punches.

Forming a low calorie chewing gum has resulted in a gum with hard chew, poor texture, and bad taste or off-taste.

Bad smell and undesired taste of ingredients applied in the compound.

Sugar spots or lumps may appear in the final texture and cause undesired feeling.

Some ingredients and active agents can irritate mucosa.

High temperature to facilitate the mixture of gum base, leads to spoil other ingredients.

Water elimination from final formulation requires advanced techniques to avoid the hardness of gum

FIG 5: Problems associated with manufacturing chewing gums.

III. CONCLUSION

There is still a lot of information and knowledge to explore regarding chewing gum manufacturing. Scientists and researchers should consider new chewing gum formulations to increase chewing gum variations for different patient styles and to provide appropriate release patterns of chewing gum and drugs. They are suitable for the local and systemic delivery of remedies that target pain headache, migraine, cough, anxiety, allergy, and digestive conditions. Currently, nicotine gums, antihistaminic motion-sickness gums, nutraceutical and multivitamin gums, and weight management gums have established a foothold in the market. In the next few years, new formulations will be introduced and chewing gum will become a more widely used drug delivery system.

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