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Formulation and Evaluation of Novel Gum Based Medicated Chewing Gum for Toothache

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Abstract:
Chewing gum is a drug delivery system which is going to advance more and more in nowadays researches and it seems to get more standardized in future industry because it can deliver either pharmaceuticals or nutrients which are known as medicated chewing gum (MCG) and non MCG. MCG is supposed to act as an extended release dosage form that provides a continuous release of medicine contained. Ability of chewing gums to release active ingredients into the oral cavity, steady and rapid action, capability of both systemic and local delivery, make it appropriate for extensive use in food and pharmaceutical industries. Oral health is become more and more concerned with appearance, notably the appearance of white teeth. Satins caused by chromogens from food, drink, or smoking can be extrinsic or intrinsic, depending on the source. Oral malodor is caused by anaerobic gram- negative bacteria adhering to the tongue or associated with periodontitis, which produces VSCs such as hydrogen sulfide 3methyl perception.
Chewing gum is a mixture of ingredients either natural or synthetic that comprises water-soluble bulk portion and water soluble bulk portion and water insoluble gum bases. Chlorhexidine, Clove Oil, Poly vinyl acetate, Xanthan, Polyethylene glycol 4000 (PEG-4000), Sorbitol, Peppermint oil, Butylated hydroxytoluene (BHT), Glycerin were used for this preparation. Its prepared by two methods and evaluated by different parameters like Mass uniformity , organoleptic properties, Stickiness , Test for hardness/plasticity etc
Key Words: Chewing gum, Chlorhexidine, Clove Oil, Mass uniformity, organoleptic properties, Stickiness, plasticity.

I. Introduction

Chewing gum is a drug delivery system which is going to advance more and more in nowadays researches and it seems to get more standardized in future industry because it can deliver either pharmaceuticals or nutrients which are known as medicated chewing gum (MCG) and nonMCG. MCG is supposed to act as an extended release dosage form that provides a continuous release of medicine contained. Ability of chewing gums to release active ingredients into the oral cavity, steady and rapid action, capability of both systemic and local delivery, make it appropriate for extensive use in food and pharmaceutical industries.

Oral health is become more and more concerned with appearance, notably the appearance of white teeth. Satins caused by chromogens from food, drink, or smoking can be extrinsic or intrinsic, depending on the source. Oral malodor is caused by anaerobic gram- negative bacteria adhering to the tongue or associated with periodontitis, which produces VSCs such as hydrogen sulfide 3methyl perception. Gums that contain active compounds that target bacteria that cause bad breath have been shown to reduce the amount of VSCs in the mouth. Minor pain treatment can benefit from the use of chewing gum as a drug delivery mechanism because it's rapid onset of action and reduced risk of digestive side effects. Drug absorption rates faster in the liquid form compared to a tablet from with the same dosage of the same medications. Toothaches could possibly be relieved faster if drugs had a faster absorption rate. Gum chewing stimulates the flow of saliva. Mechanical mastication is considered a key element in this boosting effect. Findings show that chewing gum could potentially decrease gingivitis and carious lesions. Additionally calcium containing gums could remineralize incipient caries. Chewing gum could transport Chlorhexidine, Calcium, and

Carbamide based medications such as captopril, nitroglycerin, methadone, antihistamines, and antifungal based compounds as drug carriers.illustrates some of the uses of chewing gum as drug delivery approach for oral health

II. Materials And Methods

2.1 Composition:

Chewing gum is a mixture of ingredients either natural or synthetic that comprises water-soluble bulk portion and water soluble bulk portion and water insoluble gum bases.

Chlorhexidine, Clove Oil, Poly vinyl acetate, Xanthan, Polyethylene glycol 4000 (PEG-4000), Sorbitol, Peppermint oil, Butylated hydroxytoluene (BHT), Glycerin.

Role of Ingredients.

Sr. No.	Name of Ingredients	Role of Ingredients
1	Chlorhexidine, Clove oil	Active Pharmaceutical Ingredient
2	Poly vinyl acetate, Xanthan	Gum base
3	PEG-4000	Softener
4	Sorbitol	Sweetener
5	Peppermint oil	Flavouring Agent
6	BHT	Preservative

Table No. 1 Role of Ingredients

Composition of Chewing Gum

Sr. No.	Name of Ingredients	Quantity Taken
1	Chlorhexidine	6 mg
	Clove oil	1 ml
2	Poly vinyl acetate,	200 mg
	Xanthan	100 mg
3	PEG-4000	73 mg
4	Sorbitol	600 mg
5	Peppermint oil	17 ml
6	BHT	3 mg

Table No. 2 Composition

2.2 Procedure:

2.2.1 Method no: 1

A. 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 beaker, in which blades soften the base.

B. Then other ingredients such as glycerin, sorbitol, and polyethylene glycol are added to the softened base.

C. Now all are ingredients mix with base then add Chlorhexidine and clove oil.

D. Lately the flavoring agent Peppermint oil is added in the mixing procedure at 40°C, then cooling and rolling steps would be done.

E. The rolled chewing gum would then be cut into pieces of desired shapes and sizes.

F. To make a coated gum tablet, a coating agent should be sprayed to form a uniform surface.

2.2.2 Method no: 2

A. Second type 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.

B. After adding these sweeteners, plasticizers are added to modify the texture and regulate the cohesiveness. Glycerin 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 flavorings. 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.

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

D. 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.

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

F. 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.

III. Results and Discussion.

Mass uniformity

Twenty MCGs are selected randomly and weighed, not more than two single mass should vary the average mass.

Evaluation of organoleptic properties

Organoleptic properties refer to those which affect sense, taste and feelings of people who use a product, so the vital role of these properties should not be disregarded because they impress acceptance by individuals and even marketing. The organoleptic characteristics of prepared gums comprise softness/stiffness, adherence to teeth, taste, bulk volume and perdurability of taste. A Latin-square designed should be held on 10 volunteers to score their points of view. The Latin-square design is a statistical method; this means that testing units (volunteers and formulations) are divided into two blocking factors. For differentiation, we allocate rows to volunteers and columns to formulations or contrariwise. In this case no testing unit should be repeated in each row and column.

1	2	3
2	3	1
3	2	1

Stickiness

On plain surface, medicated chewing gum was placed, it is subjected to Collide with Teflon hammer with mass of 250 g for a period of 10 min. Hammering frequency was 30/min. After specified time, amount of Mass stick to hammer was observed and reported.

Test for hardness/plasticity

There is no one reported method for the determination of hardness; Hence, it was decided to use Pfizer type hardness tester for the Determination of hardness/plasticity of all MCG formulations.

IV. Factors affecting release rate and amount

In vivo and in vitro release of drug from MCG is dependent not only to formulation factors but also to active ingredients' portion and individual chewing characteristics.

A. Water solubility:

When the active ingredient is water-soluble, the release of drug gets to the end rather than other active ingredients with slight water-soluble properties, and lipid-soluble drugs face further release problems than others because they are bound to lipophilic substances and gum bases and slowly released into oral cavity

B. Formulation factor:

Mixing of active ingredients with hydrophilic compounds or hydrophobic compounds affects the release of the drug. Sometimes faster release does not mean more complete release of drug; rather formulations with slower release profiles often show more complete release of drug.

C. Physicochemical properties:

Ingredients more soluble in saliva will be immediately released within few minutes of chewing, but highly lipid-soluble ingredients are first released into gum base then into saliva. Stability of gum base and its components to salivary enzymes, molecular mass, and ionization play an important role in release and absorption of drug through mucosa.

D. Individual characteristics:

Speed, intensity, frequency, and type of chewing characteristics of different individuals affect the release of active ingredients; EP recommends 60 chews/min for appropriate release of active ingredients. But these numbers of chews depend also on the retention time of MCG in the mouth, which in clinical trials, the ordinary and suitable time is about 30 min of chewing. These differences lead to variable results of drug release.

E. The problem of adhering of many lipophilic ingredients to gum base and other lipophilic compounds and, therefore, slow release of the drug into saliva may be solved by encapsulation of active ingredients or coating them with appropriate substances.

F. Stability

Chewing gum is a very stable product due to its low moisture content and less reactive nature than that of other oral ingredients.

V. Conclusion.

According to the benefits of chewing gum as a novel drug delivery, like concurrently supporting both local and systemic delivery, protection against acids and enzymes, low first pass metabolism, elevating alertness and cognitive function, good stability and a lot more; we can conclude that chewing gum will be much more

familiar to patients and market in the next few years. However, their new and old applications prove our statement as it can be seen that there are treatments for motion sickness, pain, smoking, dental caries, tooth decay, otitis media, GI problems, oral fungi, inflammatory problems etc., by formulating efficient chewing gums that contain at least one drug as active agent.

The technology to bring chewing gum to market and health system as a reliable alternative for different kinds of tablets has not been ready and fully understood yet because there are much more information and knowledge to be explored for manufacturing chewing gums. But, fortunately, the progress of this procedure is admissible.

Scientists and researchers should also consider new formulations for chewing gums for increasing variations of chewing gum due to patients' different styles and providing appropriate release pattern for chewing gums containing drugs.

Gum-driven drugs could be introduced as promising candidates for treating oral diseases. This is due to their ability to deliver the proper local dosages of active ingredients, short contact time, biocompatibility, biodegradable chemical structures, and ability to maintain a state of eubiosis. These benefits have spurred many people to research to make a lot of different kinds of medicated chewing gum commercials.

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