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COMPARATIVE STUDY ON GUM NATURAL GUM BASES USED FOR MEDICATED CHEWING GUM

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01. Abstract:

Medicated chewing gum, a soft, cohesive enjoyable confectionery product loaded with bioactive compounds are chewed to release the bioactive for healing targeted parts. Currently, the production of chewing gum in the global chewing gum market is rapidly increasing from USD 25 billion to an estimated USD 37 billion by the year 2023. The application of chewing gum in drug delivery system has increased compared to pharmaceutical pre-dosage form. However, gum bases are thrown away after chewing which generates non-biodegradable waste causing harmful effects to the environment as well as living organisms. In this research the comparative study of three natural gum base is done and its biodegradability is compared with the synthetic gum base. The gum bases used for this research is Chicle (extracted from Sapodilla Monikara tree), Prolamin (extracted from *Triticum Aestivum* flour) and Zein (extracted from corn). All bases were evaluated for the swelling index, water retention capacity, loss on drying and antimicrobial activity. Thus, this study suggested that the prolamin base showed good results as compared to others and was biodegradable within 2 weeks.

Key words: medicted chewing gum, biodegradable, chicle, prolamin, zein, gum base

02. Introduction:

Medicated chewing gum (MCG) has gained increasing acceptance as a drug delivery system. In this system, drug is buccally absorbed eventually reaching the systemic circulation [1]. When formulating drugs intended to act locally and systemically in the oral cavity, chewing gum should be considered as a potential drug delivery system. Medicated chewing gum is defined by the European Pharmacopoeia and the guidelines for

pharmaceutical dosage forms issued in 1991 by the Committee for Medicinal Products for Human Use (CPMP) as "solid single dose preparations with a base consisting mainly of gum that are intended to be chewed but not to be swallowed, providing a slow steady release of the medicine contained" [2].

Chewing gums were ranked third in the overall confectionary market, after chocolates and candies. Recently, the consumption of chewing gums increased by more than 0.5 MT per annum resulting in the increased growth rate in the global multibillion-dollar industry. It is consumed 70% favorably by children, teenagers, and adults therefore resulting as an important factor in the confectionery industry [6]. The sales value of chewing gums in the world market was recorded at 25 billion dollars in 2014. The European region dominated the worldwide gum market and holds 29.6% of the total market share. Europe is the largest consumer of chewing gums followed by the UK while Switzerland and Poland stand second. A minimum of one billion chewing gums were sold every year in UK and is chewed by one third of the nation.

During the chewing process, the drug in the gum product is released from the mass into saliva and absorbed through the oral mucosa or swallowed reaching stomach for gastrointestinal absorption [3]. Mostly the residue (gum cud) remained after chewing is spit out once the drug is released out. As conventional chewing gum bases are not biodegradable or digestible, the disposal of gum cud is a social problem and causes unsightly litter.

Natural gum bases are more beneficial than synthetic gum bases because of biodegradable and biocompatible nature and easily availability [4]. Chicle is commonly obtained from sapodilla tree (Manilkara zapota L.) belonging to the family Sapotaceae, is one example of the natural gum base having good chewiness. Gliadin, a storage protein of Triticum aestivum (wheat grain) belonging to the family Gramineae, called as prolamin [5]. Zein was first extracted from whole corn or dry-milled corn

(DMC) using a hydroalcoholic solvent. The total protein content of DMC was 6. 8– 8.0% of the milled corn [7]. Zein is a major protein that is found in the endosperm of the corn kernel and it is a class of alcohol- soluble prolamin proteins [8].

03. Material and methods:

Materials:

Natural Rubber Latex was collected from sapodilla tree, wheat and corn was produced from local market and other excipients used were provided by Meher chemie, Mumbai, India.

Methods:

Preparation of Chicle:

First take the rubber latex which is obtained from "sapodilla Monikara "tree/chicle, by inserting a steel/hard glass capillary in smooth trunk of the tree. Attach a small size container at the tip of capillary. The white color sticky gum is start collected in a container. In 24hrs we get 1-3 gm of rubber latex. Take this rubber latex in a clean and dry metal dish and heat or melt the gum base on water bath. Then add in it emulsifier lecithin which is freshly collected from egg yolk by maintaining temperature 60^0C for 45 min. The lecithin get mix with rubber latex and solution which is very sticky is form. Then in it add a glycerol to decrease the stickiness of gum which helps in formation of non-sticky mass of gum. Then add in it Talcum powder as a filler which provides right texture and also provide reasonable size of the gum limp with low dose drug. Pass the above mixture from sieve no 12#, 24#, 100#, store the above gum mixture in Amber colored glass bottle to avoid the degradation and improve stability [9].

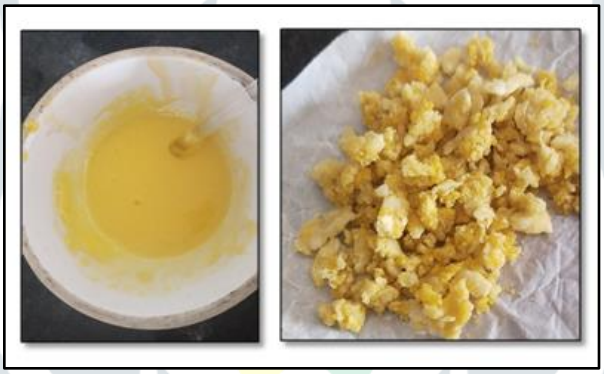


Figure no. 01: Preparation of Chicle

Preparation of Prolamin:

To accurately weigh quantity of Triticum aestivum flour (100 g), 70% ethanol (300 mL) was added, stirred for 2 h, and extracted using a multilayer muslin cloth to remove the marc from the solution. The solution was made concentrated to one fifth of its volume by heating at 50°C to get pure prolamin (gliadin). To this, equal amount of water was added and heated at 70°C until solid gum base was formed [3,10].

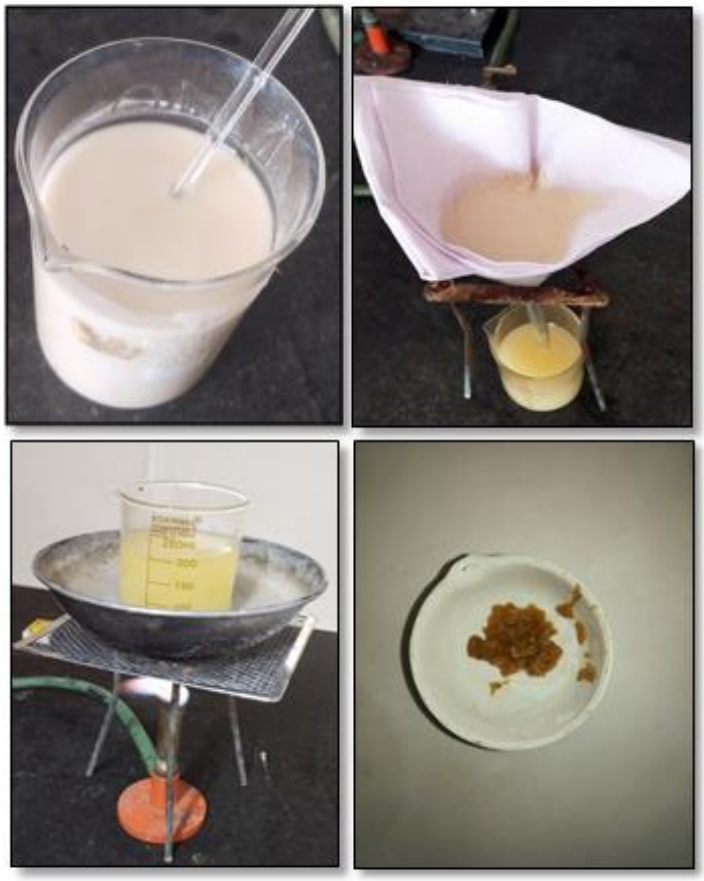


Figure no. 02: Preparation of Prolamin

Preparation of Zein:

The first step in zein manufacture is its extraction from corn or corn gluten meal using a suitable solvent [8]. It is extracted with alcohol in presence of heat and temperature in 1:1 ratio. After extraction the solution is filtered and cooled then the excess solvent is evaporated on water bath. The resultant solid mass obtained is used as gum base [8].

Figure no. 03: Preparation of Zein

Characterization of Isolated Gum Base:

1. **Swelling Index:** To determine the swelling index, previously weighted isolated gum base powder (1 gm.) was transferred to a 10 ml measuring cylinder, initial volume was noted,and distilled water was added .After gentle shaking, the measuring cylinder was kept aside for 24 hours ambient temperature and humidity the volume occupied by the powder sediment was noted [11,12,13].
2. **Water retention capacity:** To determine the water retention capacity, the content remained in the measuring cylinder during the study of the swelling index was filtered through muslin cloth. The water was allowed to water was referred as water retention capacity [111213].
3. **Loss on drying:** Accurately weighted gum base [1.0g] was heated in a hot air oven at 1050c.Gum mass was reweighted and loss on drying was calculated. loss on drying [LOD]was the difference between the initial weight and the final weight of the sample expressed as a percentage.[11,12,13]
4. **Antimicrobial activity:** The antimicrobial activity of the gum base was determined using the cup plate method using selected bacteria Bacillus subtilis and fungus oral candidiasis. The chicle/prolamin/zein powder was dissolved in the dimethyl sulfoxide to get 100 and 1000 µg/ml solution. Nutrient agar media was prepared, sterilized and aseptically poured into sterilized petri plate. Bacterial culture was inoculated into the media under aseptic condition and allowed to solidify. Three cups of 6mm diameter were made with borer at equal distance using sterilized steel borer in each plate. Each cup was filled with 0.1ml test

solution [A=1000 µg, B=100 µg].Standard and control petri plates were prepared by similar method .Petri dishes were kept in the refrigerator for 30 min to allow the diffusion of sample to the surrounding agar medium. All the plates were incubated at 37^0C for 24 hour in an incubator. After 24 hours, zone of inhibition was measured [11, 12, 13].

04. Result and Discussion:

Parameter	Chicle	Prolamin	Zein
Color	Yellow	Brown	Yellow
Swelling index	No swelling was observed	No swelling was observed	134.78
Water retention capacity	1.2±0.5ml	1.3±0.1ml	1.4±0.9ml
Loss on drying	0.71%	0.57%	0.78%
Solubility	Insoluble in water, soluble in ethanol, methanol, Dil. HCL and NAOH	Insoluble in water, soluble ethanol, methanol, Dil. HCL and NAOH	Insoluble in ethanol, methanol, Dil. HCL and NAOH
Antibacterial activity	1.2cm[100µg/ml],1.5cm[1000µg/ml]	1cm[100µg/ml],1.3cm[1000µg/ml]	1.3cm[100µg/ml],1.5cm[1000µg/ml]
Antifungal activity	1cm[100µg/ml],0.99cm[1000µg/ml]	0.92cm[100µg/ml],1.2cm[1000µg/ml]	1cm[100µg/ml],1.2cm[1000µg/ml]

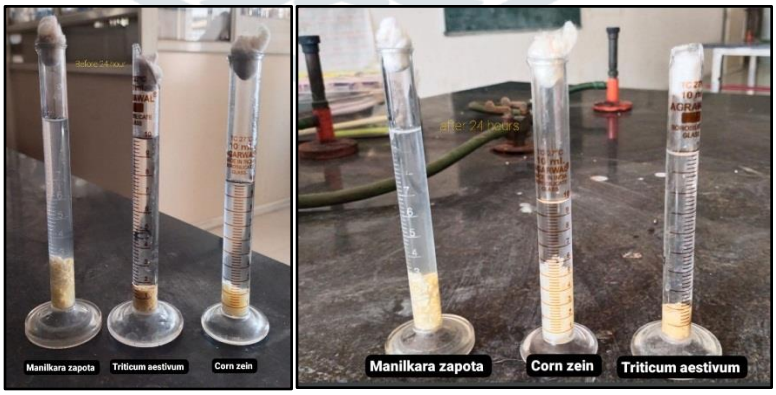


Figure no. 04: Swelling Index and water retention capacity

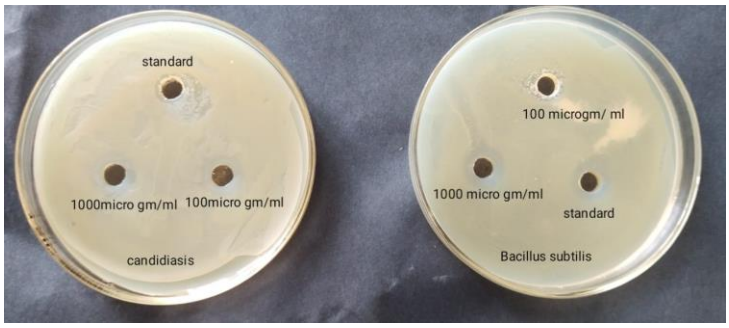


Figure no. 05: Antimicrobial and antifungal activity of Chicle

Figure no. 06: Antimicrobial and antifungal activity of Zein

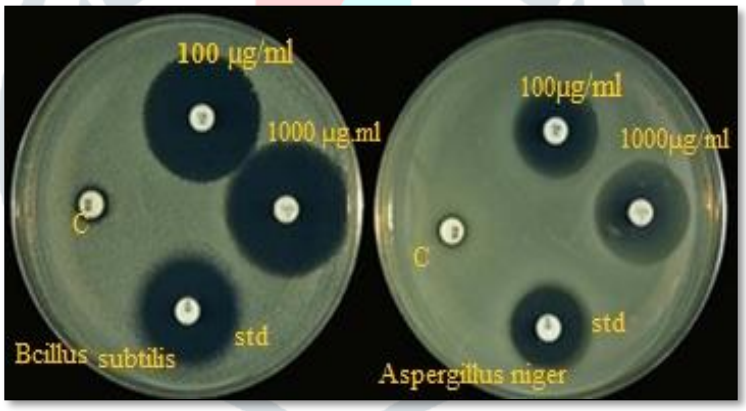
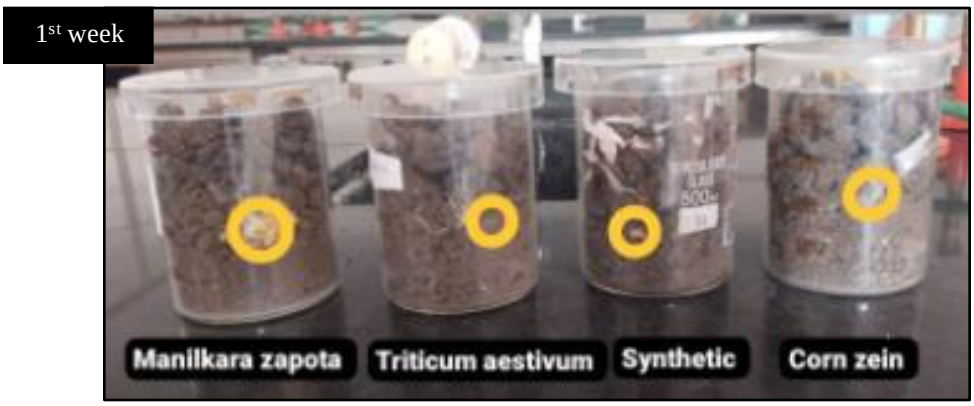


Figure no. 07: Antimicrobial and antifungal activity of Prolamin



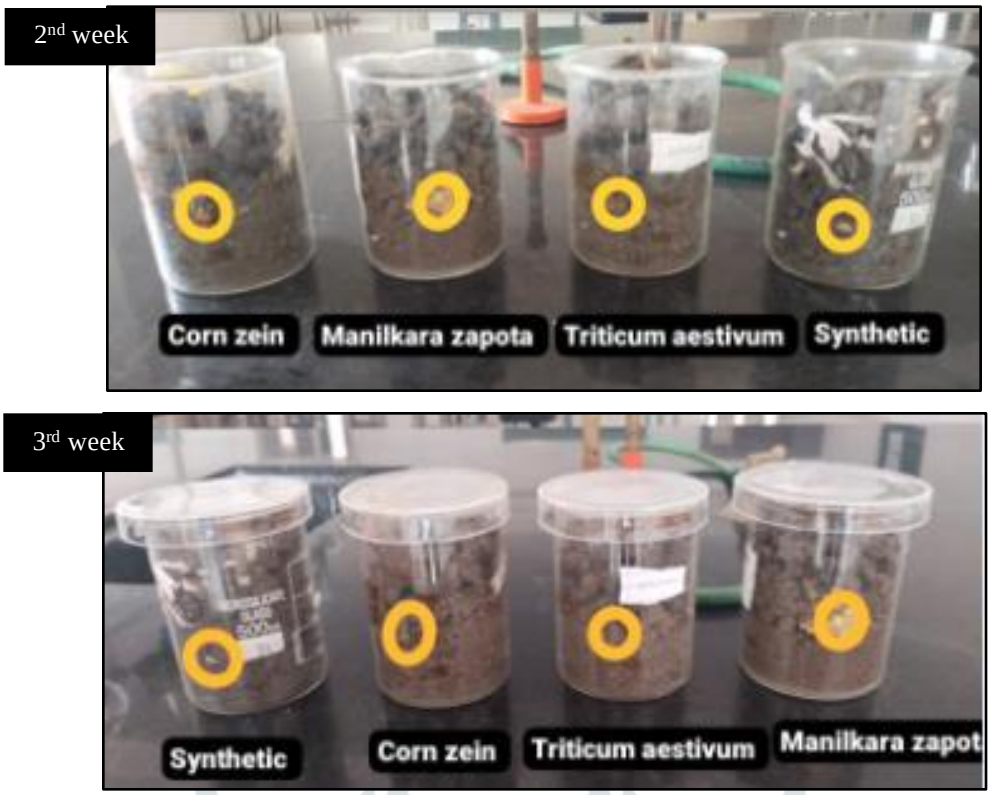


Figure no. 08: Biodegradability of gum bases

05. Conclusion:

Chile, Zein and Prolamin can be used a natural gum base for chewing gum formulation. The synthetic gum base are non-biodegradable so the introduction of natural gum base is very important in the market as the market for chewing gum is very wide. Various tests were done to determine whether the gum base is suitable for formulation or not, among them few tests are swelling index, water retention capacity, loss on drying, solubility, antimicrobial, antifungal and finally their nature to biodegrade was checked. The results showed that Prolamin shows better results as compared to zein and chicle and also it is biodegradable within 3 week.

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