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INHIBITORY EFFECT OF LOZENGES CONTAINING XYLITOL AGAINST STREPTOCOCCUS MUTANS

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ABSTRACT

Streptococcus mutans is considered a major contributor to the development of dental caries and increased risk of developing dental caries later in life. The principal objective of this research is to design and develop xylitol lozenges that treat dental caries. Xylitol plays a major role in treating dental caries that act against Streptococcus mutans at different stages. The compatibility studies were performed using FT-IR and determining the MICs using the broth dilution method aids in the selection of the best formulation to reduce dental caries recurrence. In MIC 2% concentration of xylitol shows 66 % reduction of streptococcus mutans. Lozenges of varying concentrations were developed using starch syrup and tests were performed on the developed formulations. An anti-microbial assay was performed on the optimized formulation and the largest inhibitory zone against microorganisms was observed. Based on the findings of this study, it can be hypothesized that the developed formulation was active at lower concentrations and prolonged release by *in-vitro* drug release studies which reduce dental caries.

Keywords: Xylitol, Lozenges, Streptococcus mutans, MIC, *in vitro* drug release

INTRODUCTION

Dental caries is a chronic infectious disease affecting 2.3 billion people worldwide. It results from the interaction between oral microorganisms in dental plaque, carbohydrate diet, and societal and environmental factors. Streptococcus

mutans, a common cause of enamel caries, has a strong adhesive ability to attach to tooth enamel surfaces, leading to colonization, biofilm formation, and caries development. As Streptococcus mutans multiply in the mouth, they can contribute to

dental caries, plaques, delayed speech, chewing trouble, endocarditis, infections, behavioural issues, socialization, and concentration difficulties [1].

Antimicrobial agents are used to prevent and treat dental caries, such as risk inhibitors, proper tooth-brushing techniques, and salivary flow. However, with the increasing consumption of high carbohydrate and sugar diets, extra measures must be taken to decrease caries progression. Various sugar substitutes like xylitol, sorbitol, mannitol, and erythritol, have been explored for their potential to promote enamel remineralization. This study aims to identify the Minimum inhibitory concentration of xylitol for dental caries in lozenge formulations [2].

MATERIALS AND METHODS

Materials

Xylitol was Purchased from Amazon. Starch syrup, artificial flavours and colours were procured from the local market. All ingredients were pure and analytical grade.

Method

Determination of MIC for xylitol:

The MIC is the lowest concentration which prevents the visible development of a bacterium, after an overnight incubation. The *S. mutans* strain was cultured using Mueller-Hinton Broth and then inoculated with a selected *S. mutans*. The Broth Dilution method was used for determining the MIC of Xylitol. The MIC of different

concentrations was 2% respectively. The lowest concentration of xylitol was chosen for the formulation of lozenges to treat dental caries. Antimicrobial activity is done by using an agar diffusion test. The optimized formulation showed the largest zone of inhibition, indicating its antimicrobial activity in treating dental caries [3, 4].

Drug-Excipient Compatibility Study

An IR spectrum was created by plotting the wave number on the X-axis and the transmittance on the Y-axis. API and Excipient were combined in a one-to-one ratio the physical mixtures were mixed with IR grade KBr in a 1:2 ratio and compressed into pellets using a pellet presser. The pellets were scanned with an FTIR Spectrophotometer [5].

Preparation of lozenges

The lozenges are made using heating and congealing procedures. The syrup foundation was created in a beaker by dissolving the requisite volumes of Xylitol in water and then stored for heating on a hotplate. The temperature was kept between 105 and 110 degrees Celsius until it got thick. Excipients were manually added and well-blended for 30 minutes while being heated continuously. Then above syrup base was poured into a pre-cooled and pre-lubricated mould and the mould was kept aside for 10-15 min. Lozenges had been removed from the mould and air dry [6].

Table 1: Formulation Table for Xylitol Lozenges

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8
Xylitol	19.5	20	20.5	21	21.5	22	22.5	23
Starch Syrup	6.5	7	7.5	8	8.05	8.1	8.15	8.2
Water	10.5	11	11.5	12	12.5	13	13.5	14
Flavour	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
Colour	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

RESULTS AND DISCUSSION:

Evaluation parameters:

Physical parameters:

The medicated lozenges had been tested in phrases of clarity, texture, and consistency. The texture of lozenges in terms of stickiness was evaluated by visual inspection of the product.

Weight Variation Test:

Ten lozenges from each batch were individually weighed in grams on an analytical balance. The mean weight and standard deviation were computed. The individual weight of each lozenge is also calculated using the same average weight. The weight variation should fall within the prescribed limits (generally 10% for lozenge weighing 120 mg or less, 7.5% for lozenge weighing 120 mg to 300 mg, and 5% for lozenge weighing more than 300 mg:

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

Thickness Test:

The thickness in millimeters (mm) was measured individually for 10 pre-weighed lozenges using vernier Callipers. The average thickness and standard deviation are reported.

Hardness Test: [7]

The hardness of lozenges was measured by Monsanto Hardness Tester. The crushing strength of the 10 lozenges with the known weight and thickness of each batch was recorded in kg/cm² and the average hardness and the standard deviation were reported.

Drug Content Uniformity: [8]

The content uniformity was tested by measuring weight equivalent to one lozenge by dissolving the content in a 100 ml volumetric flask containing 50 ml of 6.8 phosphate buffer. The diluted sample absorbance was recorded at 272 nm. Three replications of each test were analysed for mean and standard deviation. For most of the larger-dose drugs in lozenge form, the official potency range permitted is not less than 90% and not more than 110% of the labelled amount.

Moisture Content:[9]

By gravimetric method, one gram sample was weighed and placed in a desiccator for 24 hrs. The final weight was subtracted from the preliminary and the distinction in moisture content was calculated:

$$\% \text{ Moisture content} = \frac{\text{Initial weight} - \text{Final weight}}{\text{Initial weight}} \times 100$$

***In-vitro* Drug Release [10]**

The modified dissolution test apparatus USP type II (paddle) was used for 250 ml of phosphate buffer pH 6.8 was placed in the beaker containing the lozenge and stirred at 100 rpm. Five ml aliquot samples were taken at 5 min intervals and replaced immediately using an equivalent volume of a new medium i.e., phosphate buffer pH 6.8. Each aliquot was diluted and analysed with the aid of a UV-visible spectrophotometer. The quantity of drug release was calculated.

Accelerated stability studies:

Stability testing was performed on the optimised formulation before it was filled into the sterile container. For one month, the preparation was placed in a stability chamber at $40 \pm 2^\circ\text{C}$ and $75 \pm 5\%$ RH [11].

Compatibility Study (FTIR):

FTIR studies were conducted to reveal the excipient compatibility with the drug.

IR Spectra of Xylitol

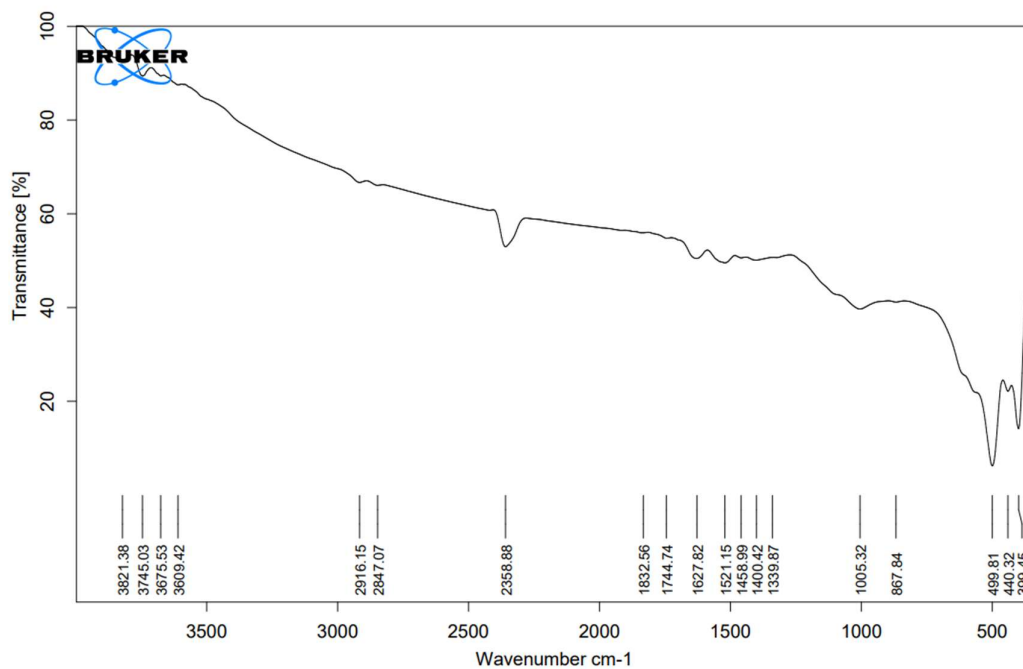


Figure 1: IR Spectra of Xylitol

IR Spectra of Drug + Excipients

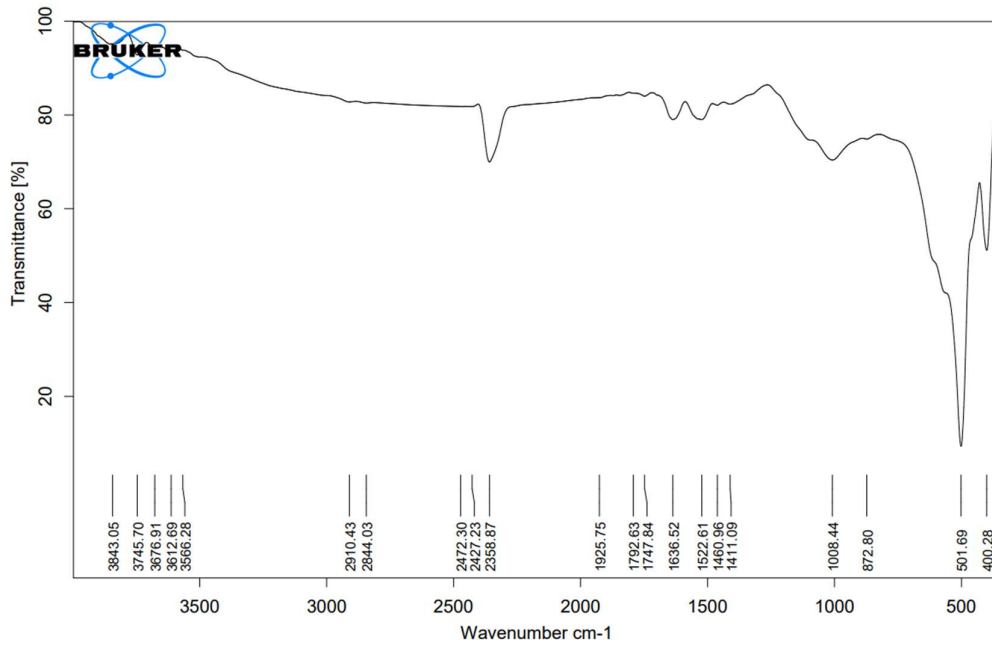


Figure 2: IR Spectra of Drug + Excipients

Observation:

Table 2: FTIR spectral interpretation of Xylitol with Starch

Functional group	Characteristic bands(cm ⁻¹)	Observed bands of Xylitol(cm ⁻¹)	Observed bands of For optimized formula(cm ⁻¹)
Amide N=H	3700-3500	3675	3676
Alkyl C-H	2950-2850	2916	2910
Alkyl C-H	2950-2850	2847	2844
Ester C=O	1750-1735	1744	1747

Compatibility results from DSC studies:

DSC for xylitol:

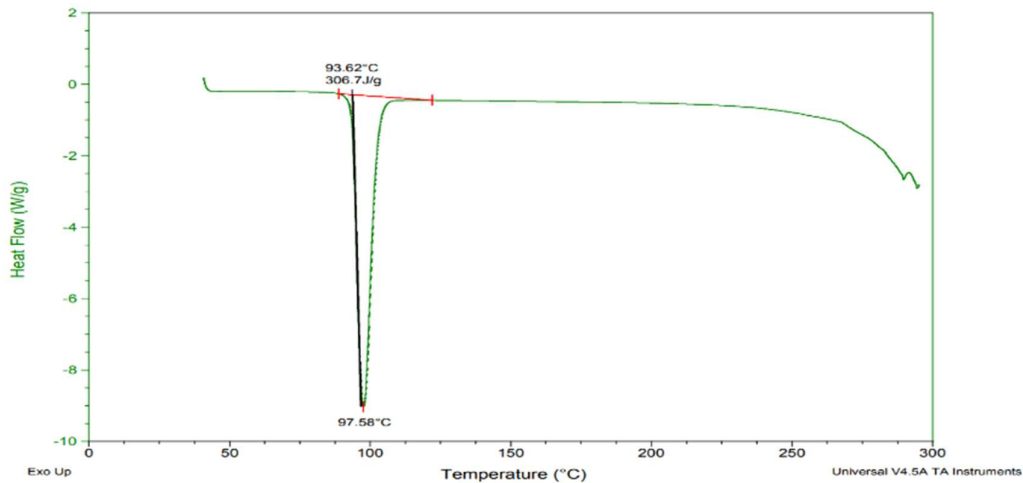


Figure 3: DSC for xylitol

DSC for xylitol and excipient:

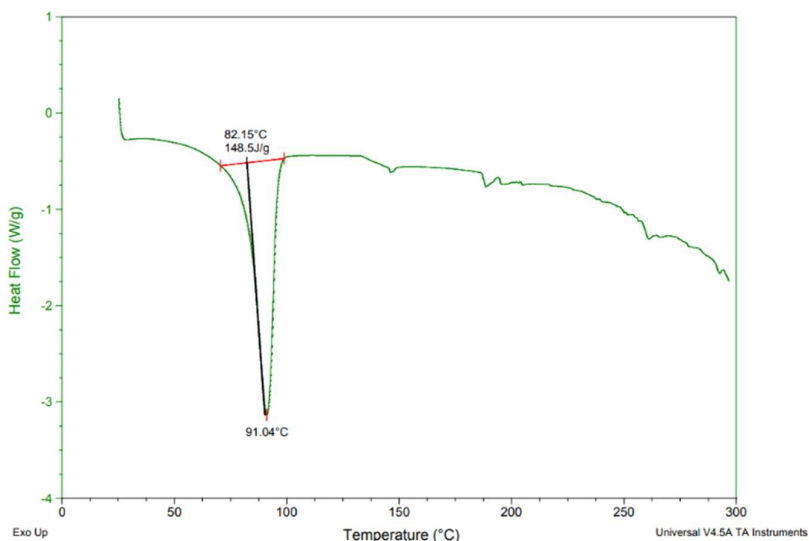


Figure 4: DSC for xylitol and excipient

Table 3

Formulation code	Weight of (gms)	Hardness (Kg/cm ²)	Thickness of (mm)	Drug content (%)	Moisture content (%)
F1	2.473	11.5	6.42	96.9	0.91
F2	2.517	10.65	7.6	98.6	0.93
F3	2.519	7.4	7.25	97.5	0.89
F4	2.725	10.45	6.9	98.48	0.98
F5	2.407	11.65	6.9	95.89	0.82
F6	2.489	10.65	6.8	97.25	0.93
F7	2.548	11.25	7.56	95.25	0.86
F8	2.706	9.45	7.85	96.59	0.82

Table 4: Percentage cumulative drug release of formulations F1-F8

Time (min.)	PERCENTAGE DRUG RELEASE (%)							
	F1	F2	F3	F4	F5	F6	F7	F8
0	0	0	0	0	0	0	0	0
5	4.7	4.52	6.75	13.5	7.52	7.8	5.36	10.88
10	6.8	7.35	13.5	21.85	10.87	11.5	11.8	20.5
15	18.4	19.25	28.5	40.2	29.5	27.5	29.8	39.2
20	37.2	35.26	39.2	60.2	42.5	45.2	45.8	65.27
25	63.2	69.35	68.2	79.5	78.5	62.8	64.87	78.6
30	97.2	94.25	95.8	99.79	93.5	91.8	98.5	95.02

Stability Studies

Table 5: Evaluation parameters after the stability studies

Evaluation parameter	Optimized formulation(F4)	Stability Studies after 1 Month	Stability Studies after 3 Months
Weight variation(gm)	2.725±0.028	2.507±0.026	2.402±0.023
Hardness (Kg/cm ²)	10.45±0.62	10.15 ±0.08	09.52±0.05
Thickness (mm)	6.93±0.054	6.89 ± 0.16	6.68±0.12
Moisture Content (%)	0.98	0.93	0.89
Mouth dissolving (min)	12:50±0.19	13:61±0.98	13.58±0.92
Content uniformity (%)	98.48±2.3	96.48±1.20	95.78±1.02
Drug release (%)	99.79	99.2	98.85

SUMMARY

The present study aimed to formulate and evaluate Xylitol hard lozenges against *Streptococcus mutans* through the buccal absorption by the addition of polymer.

- ✓ Pre-formulation study was done to identify the interactions between the Xylitol and excipient by using FT-IR spectroscopy.
- ✓ Minimum inhibitory concentration of Xylitol was determined by using broth dilution techniques
- ✓ Evaluation tests such as weight variation, content uniformity, *in vitro* drug release etc were studied.
- ✓ Microbial studies were performed by anti-microbial assay in which the zone of inhibition determines the effectiveness of the optimized formula from microbial attack.
- ✓ Accelerated stability studies performed for the optimized formula at conditions of i.e. 40°C /75% RH for one month revealed the better performance of the formulation.

CONCLUSION:

To treat Dental Caries, Xylitol lozenges were developed and formulated using Starch Syrup by varying their concentrations. FTIR studies concluded that there is no interaction between the Xylitol and starch syrup. The evaluation studies like Weight variation, hardness, thickness, and *In vitro* studies for optimized formula (F4) were done. The *in vitro*

showed the % drug release for optimized formula 99.79%. Anti-microbial studies confirmed that there was no microbial growth observed for the optimized formulation. The formulation showed the largest zone of inhibition which indicates it shows more activity when compared to the standard. Accelerated stability studies conducted at 40 ± 2°C and 75 ± 5% RH for the optimized formula showed that there was little change in the Hardness, Thickness, Weight variation and drug release.

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