International Journal of Pharmacy and Medicine Sciences
Vol. 2, Issue 7, July 2026 *CAS CODEN (USA): IJPMIY*
ISSN: 3108-009X **DOI:** https://doi.org/10.5281/zenodo.21956539

Open Access RESEARCH

Compounding of Lozenges Containing Biotene® Solution

[1]*Antoine Al-Achi, [2]Trusha Dhanani

[1,2]Campbell University College of Pharmacy & Health Sciences, Buies Creek, North Carolina 27506, USA

***Submission**: July 10, 2026; **Revised**: July 27, 2026; **Published**: July 30, 2026*

Corresponding author:
Antoine Al-Achi
Campbell University College of Pharmacy & Health Sciences, Buies Creek, North Carolina 27506, USA
Email id: alachi@campbell.edu

ABSTRACT

This study aims to include a medicated liquid intended in the treatment of dry mouth in a troche formulation. Lozenges are solid dosage forms made by molding using high heat. Troches (hard lozenges) are commonly prepared to administer drugs in adult and pediatric populations. Blank or medicated lozenges were prepared from sugar, corn syrup, a liquid (water or Biotene®), and a mint flavor. The ingredients (without the flavoring agent) were mixed and heated to 285ºF to produce a melt. After the mixture was cooled to 260ºF, the melt was poured into pre-greased molds. After a period of cooling in the refrigerator, the lozenges were removed from the molds and stored under refrigeration for further testing. Weight variation and dissolution tests were performed on the prepared lozenges. An experimental design was used to establish the best conditions (i.e., amounts of ingredients) that minimized variability in lozenges weight. Troches' weight of and dissolution time of the formed units. The weight of the formed lozenges had a low variability. Lozenges completely dissolved in 6 milliliters of water set in motion at 250 r.p.m. with a magnetic stirrer. The dissolution time was 13.14 min/g (0.14 min/g) for units made with water and 12.34 min/g (0.15 min/g) for the lozenges made with Biotene® liquid. Troches were compounded with low variability for their weight and an acceptable dissolution time to allow proper residence in the mouth cavity for adequate therapeutic action.

Keywords: Lozenges, troches, xerostomia, hyposalivation, compounding.

INTRODUCTION

Traditionally, lozenges are oral dosage forms that have been used to produce a local effect in the oropharyngeal region by administering a topical anesthetic, antibiotics, and even demulcents [1-7]. Lozenges are solid dosage forms of three types: hard, soft, or gummy [1-7]. Hard lozenges (troches) are made from a base of sugars. Soft lozenges (pastilles) use a polyethylene base in their formulations, and the gummy type uses gelatin as a base to form the units [1-7]. All lozenges are made by molding with an appropriate amount of heat applied during the compounding operation. Thus, the final ingredients in the mixture are amorphous (1-7). There is a marked increase in utilizing lozenges to assist xerostomia (dry mouth) and using a liquid form to treat the condition. Although not all people with xerostomia experience hyposalivation, generally, most xerostomia patients experience low salivary production of less than 50% normal [8]. For most part, xerostomia is considered a subjective condition of the sensation of dry mouth [9]. However, xerostomia is associated with medical conditions including mental health disorders, diabetes, allergies, and Sjögren's disease [10]. It also frequently occurs as a side effect of medications like antihypertensives, antipsychotics, and decongestants [10]. The normal unstimulated and stimulated (by chewing paraffin wax) whole saliva secretion rate in adults are greater than 0.25 mL/min and greater than 1.0 mL/min, respectively. These numbers decrease sharply if the patient experiences low or very low saliva secretion. For the very low saliva secretion rate for the

unstimulated and stimulated conditions are less than 0.1 mL/min and less than 0.7 mL/min, respectively [9, 11].

Objectives

This research aimed to prepare compounded lozenges that contain a liquid as an active ingredient, such as Biotene®. The latter contains water, glycerin, xylitol, sorbitol, propylene glycol, poloxamer 407, potassium sorbate, hydroxyethylcellulose, flavor, sodium phosphate, cetylpyridinium, and disodium phosphate, according to the manufacturer (GSK group of companies). Xylitol and hydroxyethylcellulose in the formulation are the primary ingredients that help combat dry mouth conditions. Dissolution rates of the lozenges were studied to obtain data on whether the lozenges formulation provides a sufficient time of contact in the mouth cavity to aid hyposalivation. According to the commercially available lozenges manufacturer, the patient is directed to "Allow lozenge to dissolve in the mouth slowly. Use as needed." Compounding pharmacists can tailor these formulations to meet their patients' needs.

MATERIALS AND METHODS

Materials

Granulated sugar, corn syrup (Karo® Corn Syrup, ACH FOOD Companies, Inc.), and mint flavor were purchased from a local store. Olive oil (MP Biomedicals™) was obtained from Thermo Fisher Scientific. Biotene Mouth Moisturizer (8 oz. Liquid, GSK group of companies) was bought from a local pharmacy. Lozenge molds were from PCCA (Houston, Texas).

Methods

Development of hard lozenges: To determine the optimal formulation for the lozenges, initial batches were prepared where the amounts of sugar, corn syrup, and water varied within specified limits (sugar: 42 g to 52 g; corn syrup: 16 g to 18 g; water: 21 mL to 31 mL). Fourteen batches were prepared where the amounts of ingredients vary according to the specified limits (Table 1). Six lozenges were weighed individually from each batch. In addition to observing the lozenges' texture (graining), cohesiveness (2), and variability (relative standard deviation percent; RSD%) were used to select the best conditions for the formulation. Table 2 shows the weights of lozenges from the 14 batches. In addition, the conditions that minimize RSD% were chosen for further compounding.

Table 1. Initial batches with the amounts of sugar, corn syrup, and water varied within specified limits (sugar: 42 g to 52 g; corn syrup: 16 g to 18 g; water: 21 mL to 31 mL)

Batch Number	Sugar	Corn Syrup	Water	RSD%[a]
1	52	16	21	2.09
2	47	17	21	1.67
3	47	17	21	4.66
4	42	17	26	3.55
5	47	16	26	5.15
6	42	18	21	5.71
7	48.7	17.4	27.7	4.42
8	52	16	21	4.30
9	42	16	31	4.64
10	42	17	26	2.70

11	48.7	17.4	27.7	5.28
12	42	16	31	2.49
13	42	18	21	5.81
14	47	16	26	2.23

[a.] Values are from Table 2.

Preparation of hard lozenges: Lozenges were prepared from a formulation containing a base of sugar (42 g), corn syrup (16 g; contains 25% of water), water or Biotene® (21 g), and a mint flavor (3 drops) with and without liquid Biotene®. The ingredients were combined in a glass crucible without the flavor. The mixture was heated to 285ºF (candy thermometers were used to monitor the temperature during compounding). Once the temperature reached 285ºF, the heat was discontinued, and the mixture was cooled to 260 ºF (about 1 minute). The mint flavor was added, and the content was stirred gently. The mixture was then transferred to the molds already greased with a thin film of olive oil. The molds were overfilled slightly to have perfectly shaped lozenges at the end with no contraction due to cooling. After a period in the refrigerator for about 45 minutes to allow the units to harden, the formed lozenges were removed from the mold and placed in glass containers in the refrigerator for further testing. Six or seven batches were prepared with water or Biotene® liquid, respectively. Each batch produced six hard lozenges. The loss of ingredients during processing was due to water evaporation and residuals left on the surface of glassware.

Weight variation: The formed lozenges were individually weighed using an electronic laboratory balance.

Dissolution test: The dissolution profile of one lozenge per batch was obtained by placing a lozenge in a 50-mL glass beaker. A 6-mL volume of purified water was added to the beaker, and the content was stirred using a magnetic stirrer set at 250 r.p.m. The time (hours/minutes/seconds) for the complete dissolution of each unit was recorded. The choice of the volume of purified water (6 mL) used for the dissolution test was based on a low salivary production rate. The low unstimulated and stimulated saliva secretion rates in adults are 0.1-0.25 mL/min and 0.7-1.0 mL/min, respectively (8). The rate of 0.1 mL/min (6 mL/hour) was adopted in this research to simulate low unstimulated hyposalivation conditions.

Statistical analysis: The data were numerically summarized as mean ± standard deviation. A standard least-squares method with a profiler was generated to determine the best formulation that minimized variability in the weight of lozenges. The best formulation was obtained from the profiler where the conditions that minimized variability (i.e., minimized RSD%) were identified. The RSD% was computed from Equation 1:

$$RSD(\%) = \left({Mean}/{Standard\ deviation}\right) * 100 \quad (1)$$

The weights and the dissolution times from various batches with and without Biotene® liquid were compared using an analysis of variance test (One-Way ANOVA). A p-value of less than 0.05 was considered significant. JMP® Statistical Discovery Software, version 15.2.0 (SAS Institute, Cary, NC), was used for the statistical analysis.

RESULTS AND DISCUSSION

The use of lozenges in therapy is common for adult and pediatric populations (12). Compounded lozenges can be made from commercially available molds. This study prepared troches intended for the treatment of xerostomia from a mixture of sugar, corn syrup, water or Biotene® liquid, and a flavor. Six batches of lozenges were made with water, and seven batches were prepared with Biotene® liquid. According to the initial experiments for selecting the optimum conditions that minimize RSD%, the amount of sugar, corn syrup, and water were determined for further experimentation (Tables 1 and 2; Figure 1). The number of lozenges produced per batch varied between six to nine units.

Table 2. The weight (g) of individual lozenges from the initial formulations.

	Batch #													
Lozenge #	1	2	3	4	5	6	7	8	9	10	11	12	13	14
1	5.413	5.396	5.262	4.986	5.769	5.561	5.818	5.573	5.650	5.517	5.068	5.347	4.938	5.245
2	5.570	5.420	5.552	5.122	5.388	5.413	5.854	5.091	5.911	5.596	4.703	5.356	5.455	5.400
3	5.359	5.537	5.289	5.153	5.187	4.736	5.225	5.461	5.656	5.306	Damaged lozenges	5.481	5.333	5.561
4	5.379	5.541	5.896	4.926	5.102	5.087	5.518	5.420	5.801	5.511		5.704	5.194	5.483
5	5.347	5.648	5.801	5.290	5.488	5.015	5.788	5.478	5.749	5.207		5.484	5.815	5.565
6	5.224	5.488	5.519	4.790	5.042	5.253	5.820	5.012	5.156	5.456		5.371	5.637	5.400
Total number of lozenges made	9	8	8	8	6	6	6	8	6	6	6	6	7	8
Average	5.382	5.505	5.553	5.044	5.329	5.178	5.670	5.339	5.654	5.432	4.886	5.457	5.395	5.442
Standard deviation	0.112	0.0918	0.259	0.179	0.274	0.296	0.250	0.230	0.263	0.147	0.258	0.136	0.314	0.121
RSD%	2.09 %	1.67%	4.66 %	3.55 %	5.15 %	5.71 %	4.42 %	4.30 %	4.64 %	2.70 %	5.28%	2.49 %	5.81 %	2.23 %

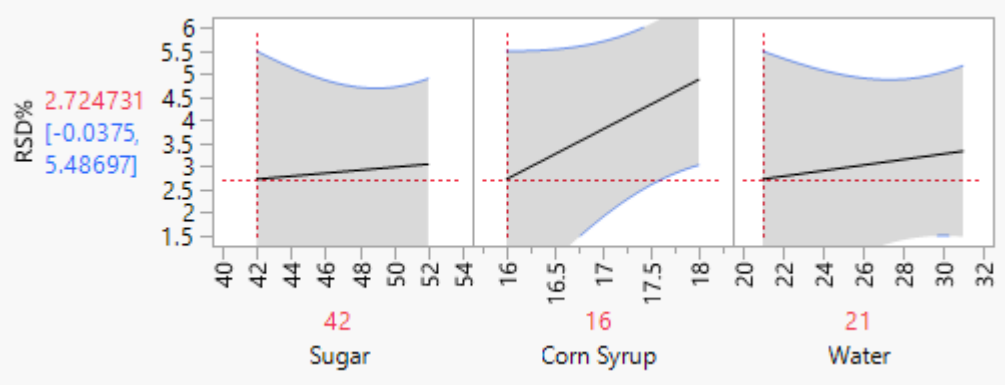

Fig 1. The profiler: the conditions (amounts of ingredients) that result in minimizing RSD%.

According to the initial experimental results, the amounts (percent in the formulation) of ingredients in the formulation that minimized variability in weight were 42 g of sugar (53.2%), 16 g of corn syrup (20.3%), and 21 mL of water (or Biotene® liquid) (26.6%). Subsequently, six batches of lozenges containing water and seven

batches containing Biotene® liquid were prepared. The weights of units in the batches are shown in Tables 3 and 4. As shown from the results, the formulation of lozenges produced six units per batch; for the units made with water or with Biotene® liquid, the variability was relatively low for both types (RSD% = 1.92%-5.86% for water units; 1.37% to 3.03% for Biotene® liquid units). Incidentally, the weight of the initial blank units prepared with water was 5.4 ± 0.27 g (overall average for all 14 batches of 80 units; RSD% = 5%) (Table 2) was higher than generally expected for a hard lozenge (1.5-4.5 g) (3-5). The compounded troches in this study were outside the range for weight which may relate to the high density of the study's formulation containing a large percentage of granulated sugar. Regardless of the weight of the lozenge, the size of the unit is determined by the mold being used. Generally, if smaller-sized lozenges are desirable, then smaller cavity molds should be used.

Table 3. The weight (g) of lozenges made with water.

	Batch #					
Lozenge #	1	2	3	4	5	6
1	6.265	5.165	5.657	5.749	5.980	5.338
2	5.884	5.714	5.369	5.540	5.657	5.500
3	5.493	5.519	5.536	5.575	5.780	5.326
4	5.560	5.350	5.401	5.749	5.938	5.310
5	5.693	6.080	5.875	5.830	5.840	5.435
6	7.120 (damaged)	5.377	5.524	5.578	5.529	5.561
Average	6.00 (with damaged unit) 5.779 (without damaged unit)	5.534	5.560	5.670	5.787	5.412
Standard deviation	0.614 (with damaged unit) 0.310 (without damaged unit)	0.324	0.186	0.120	0.171	0.104
RSD%	10.23% (with damaged unit) 5.36% (without damaged unit)	5.86%	3.34%	2.12%	2.96%	1.92%

Table 4. The weight (g) of lozenges made with Biotene® liquid.

	Batch #						
Lozenge #	1	2	3	4	5	6	7
1	5.420	5.386	5.593	5.421	5.401	5.432	5.621
2	5.387	5.196	5.234	5.236	5.338	5.279	5.469

3	5.252	5.438	5.650	5.606	5.723	5.601	5.702
4	5.568	5.386	5.501	5.605	5.339	5.605	5.571
5	5.388	5.382	5.603	5.701	5.451	5.469	5.622
6	5.279	5.390	5.461	5.475	5.603	5.521	5.617
Average	5.382	5.363	5.507	5.507	5.476	5.484	5.600
Standard deviation	0.113	0.084	0.151	0.167	0.156	0.122	0.077
RSD%	2.10%	1.57%	2.74%	3.03%	2.84%	2.23%	1.37%

In addition, the lozenges were subjected to a dissolution time test. Each unit was dissolved in a 6-mL volume of purified water, and the time for the complete dissolution of the unit was observed. The dissolution time of the lozenges from the batches is shown in Table 5. On average, it took 73.65 ± 2.59 and 66.52 ± 1.09 minutes for the water- and Biotene®-containing lozenges to completely dissolve. The difference in dissolution time between the two types of lozenges was statistically significant ($p = 0.0001$). The average weight (± SD) of the randomly selected units from the water batches was greater than that of the Biotene® lozenges (5.61 ± 0.15 g vs. 5.39 ± 0.14 g; $p = 0.0309$). Even when the dissolution time was adjusted for the weight of the lozenges, the time for complete dissolution remained different (dissolution time (minutes) per gram of lozenge was 13.14 (0.14) for units made with water and 12.34 (0.15) for the lozenges made with Biotene® liquid) ($p < 0.0001$). The difference in dissolution time indicates that lozenges made with water took 48 seconds/g longer on average to dissolve completely. It is postulated that water afforded high cohesiveness in the structure of lozenges. The Biotene® liquid does not have as much water, and its other ingredients do not provide the same structural viscidity for the formed troches; thus, a longer dissolution time was observed with water-containing compounded units.

Table 5. The dissolution time (minutes) of water-and Biotene®-containing lozenges.

	With Water			With Biotene®		
Batch #	**Weight of lozenge (g)**	**Time (minutes)**	**Dissolution time (min) per unit weight (g) of lozenge**	**Weight of lozenge (g)**	**Time (minutes)**	**Dissolution time (min) per unit weight (g) of lozenge**
1	5.493	70.95	12.92	5.279	65.01	12.31
2	5.519	72.25	13.09	5.386	66.45	12.34
3	5.524	72.75	13.17	5.603	67.87	12.11
4	5.749	76.60	13.32	5.236	65.73	12.55
5	5.840	77.20	13.22	5.339	66.48	12.45
6	5.508	72.15	13.10	5.521	67.60	12.24
Average	5.606	73.65	13.14	5.394	66.52	12.34
Standard deviation	0.150	2.59	0.14	0.142	1.09	0.15
RSD%	2.68%	3.52%	1.07%	2.63%	1.64%	1.22%

Overall, the data from the weight of individual lozenges and the dissolution time had low variability, as evident by the values of the relative RSD% (Tables 3 and 4). A low RSD% indicates higher precision and better reproducibility of the compounded units. Therefore, low variability in the compounded units can lead to more consistent therapeutic outcomes, which in turn can result in better compliance by the patient in adhering to the medication schedule.

It is logical to assume that the dissolution time in vitro would correlate well with that observed in the mouth cavity. Thus, the dissolution time for the Biotene®-containing lozenges with an average dissolution time of 12.34 min/g reflected a projected prolonged contact with local tissues in the mouth, which could aid better with xerostomia hyposalivation symptoms.

CONCLUSION

In summary, this work provides a methodology for preparing compounded troches from a liquid active ingredient. The lozenges made from an over-the-counter xerostomia aid liquid product had an appropriate dissolution time that reflects the ability of the units to maintain a residency of the drug within the mouth cavity to achieve an optimal therapeutic outcome.

CONFLICT OF INTEREST

Authors declare for none conflict of interest.

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