Sore Throat Treatment: Formulation and Evaluation of Cobalamin Lozenges

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Abstract

The current research aims to create and assess sore throat lozenges with nutrition B12. One of the eight B vitamins, vitamin B12, is also known as cobalamin. It assists the body in converting food—carbohydrates—into glucose, which is used as an energy source, in conjunction with other B vitamins. These B vitamins, often called B Complex vitamins, help the body metabolise fat and protein. Cobalamin Lozenges have been formulated with powdered sucrose, corn syrup, purified water, flavoring and coloring agents utilizing a congealing method and heat. The created lozenges have been evaluated for their diameter, thickness, weight variation, hardness, friability, in vitro testing, and drug content. Fourier transform infrared spectroscopy tests confirmed that there was no interaction between the selected drug and excipients. In PH 6.8 phosphate buffer, cobalamin lozenges with in vitro drug release have been effectively manufactured; for all formulations, over 90% of the medication was released in less than 30 minutes. In vitro research has been the main source of optimization for the lozenges. Based on current research, cobalamin lozenges are regarded as a suitable transport mechanism for the medication that keeps your body's blood and nerve cells healthy and produces DNA, which is the genetic material found in every cell in your body.

Keywords: Lozenge, Cobalamin, Warmness and Congealing Method, Nerve Cells

1. Introduction:

Vitamin B12 is essential for neurological function, blood cell production, and overall health. It is found in low concentrations in blood serum and its deficiency can lead to severe health disorders, especially in vegetarians [1]. In addition to being necessary, vitamin B12 is essential for the synthesis of DNA and RNA, the body's genetic material in maintenance of healthy nerve cells. It collaborates closely with vitamin B9, commonly referred to as folate or folic acid, to support the body's synthesis of red blood cells and improve the way iron functions. S-Adenosylmethionine (SAMe), a chemical important in mood and immune response, is created when folate and vitamin B12 interact. The American Heart Association recommends that adults consume 2.4 micrograms of B12 daily. It is important to note that vitamin B12 is a vitamin that dissolves in water and is not stored by the body, and any excess is eliminated through urine [2]. Vit B12 plays a vital role in gestational diabetes, with significant associations found between Vit B12 deficiency, homocysteine levels, lipid metabolism, and increased risk of gestational diabetes mellitus [3]. Among a few other management ways, the method of ingestion is the recommended course of action because in some beneficial aspects like ease of ingestion, adaptability, and mostly affected person compliance. The major drawback of this approach is for young and elderly patients who have trouble swallowing [3]. Nearly 35 percent, people particularly the old and young, report having health problems related to swallowing difficulties, which leads to a high prevalence of resistance and insufficient treatment. Children frequently experience difficulty swallowing because of their underdeveloped muscular and neurological systems [4]. Individuals who may also experience difficulty swallowing traditional oral dosages include those who suffer from nausea, non-causable sufferers, mentally disabled individuals, and patients with tremors in their extremities. To triumph over those issues along with problem between eating and circumstances which includes formulators have made great efforts to develop a one dose form for tablets intended for oral use—that is, one that dissolves—in order to alleviate sore throats rapidly in saliva, removing the need to swallow the whole dosage form. It will enhance assimilation and initiate a scientific impact since multiple companies have unique combinations of ingredients and solutions [5]. As a medicine breaks down faster, assimilation and the start of scientific effects also happen faster. Various manufacturers of lozenges have one-of-a-kind mixture of components and numerous blends of fixings.

1.1 Merits

- Both children and geriatric patients can easily receive it.
- It tastes good and will extend the duration and volume of time that the drug remains in the oral cavity to cause localized action.
- Drugs may be able to enter the systemic circulation through the buccal cavity.
- The formula's sweets and flavors may hide the taste of the drug.

1.2 Demerits

- Parents need to be advised about confusing medications with sweets and to keep the product out of their children's reach.
- Paediatrician’s, inadvertently utilize it as candy.

- Certain medications, such as benzocaine, may not work well with aldehyde sweet bases.
- Children older than six years old can utilize lozenges appropriately.

2. Materials:

API was procured as a gift sample. The chemicals and reagents used are AR grade, and standard laboratory equipment was utilized. Along with the medication, it also contains sugar, corn syrup, taste, and colorant.

1. **S**ugarcane or beetroot provide sucrose, a disaccharide composed of glucose and fructose. The selection between cane and beet sugar is mostly determined by availability and regional factors. Medicinal lozenges use sucrose and sucrose derivatives as natural sweeteners because they are inexpensive, highly soluble, and can function as a "drier" by transforming and lowering the weight of the confection.
2. Almost all confections contain corn syrup to prevent crumbling can also result from the crystallisation of sucrose and dextrose. The correct ratios of corn syrup to sucrose and dextrose can result in an amorphous glass and a candy with the desired appearance.
3. Flavorants are utilized in medicated lozenges ought to be well suited with the drug and its additives, as well as resilient to the challenging production circumstances.

2.2 Processing and Excipients:

Cobalamin lozenges can be processed using tablet-processing strategies such direct compaction, dry granulation, or moist granulation. Nonetheless, the lozenges ought to dissolve gradually without crumbling; wet granulation is ideal as it typically provides greater control. It is necessary to define the amount of soaking and the rate of drying. Over-wetting undoubtedly results in harder granules that may have detrimental compression properties, making the medication weaker and more friable and unsuitable for use as lozenges. These granulations give medications a grainy taste in the mouth. Because the drying cycle is not adjusted to compensate for the overwetting, the drying process takes longer to reach the required moisture stage or better moisture level. To design a system with the optimal dissolution rate, moist binders that delay dissolution must be used appropriately. In order to achieve gradual disintegration, smoothness, and superior mouthfeel, careful excipient selection and suitable process development are needed to ensure that the regulating variables are effectively managed. The performance characteristics of the final product depend heavily on the fundamental components of lozenge tablet manufacturing. Lozenge capsules are usually made to be larger than 1.5 mm in diameter, flat on the front (with a bevelled edge), heavy (>700 mg), and robust (>15 kg). These physiological characteristics facilitate oral use and support the desired slow disintegration. The existence of a high power, dissolution retarding binder and the lack of a fall apart are the formula factors that influence dissolution, hardness, and mouth sensation.

Figure 1: COBALAMIN LOZENGES

2.3 Formulation:

Table 1: Composition of Lozenges

INGREDIENTS	QUANTITY
Drug	1gm
Powdered sugar	42 gm
Corn syrup or honey	16 ml or 16 gm
Water	24 ml
Mint extract	1.2ml

2.4 Evaluation of Cobalamin lozenges:

2.4.1 Determination of Organoleptic Properties:

Visual evaluation of the shape, color, and look of the lozenges has been used to assess the organoleptic qualities.

2.4.2 Uniformity of Weight

A random selection of ten lozenges was made from each batch. Ten lozenges were weighed, and the average and variation were determined. When the weight of the batch deviates from the average weight by no more than two lozenges, the batch passes the test.

% of weight variation = average wt.–average wt. individual wt. / average wt×100

Thickness

From each batch, six lozenges are chosen at random, and a vernier calliper is used to test their thickness.

Hardness

The pressure needed utilising a Monsanto hardness tester, breaking a lozenge in a diametric compression is known as hardness, or breaking energy (Fo). The lozenges are held between the tester's pair of jaws along their diagonal axis. Pressure should start out at 0 kg/cm2. After that, the knob is rotated continuously until the lozenge breaks. At this stage, the pressure was expressed in kg/cm2.

Diameter

The selection of molds determines the lozenges' diameter, size, and form. Lozenges are usually round and have a flat or biconvex face, though they can be organised in many shapes and sizes.

Dissolution

The paddle-style USP Dissolution Equipment Type II was used to conduct an in vitro dissolution research. The 900 cc PH 6.8 Phosphate Buffer was added to the dissolution vessels. Once the temperature reached 37°C, the Cobalamin Lozenges formulation was added and rotated at a rate of fifty revolutions per minute. After 10 minutes, a 10-milliliter aliquot of the sample was removed, and the same amount of buffer that had been kept at 37°C was added. Using a UV-Visible spectrophotometer, the samples were filtered and analyzed at 278 nanometers.

Friability

The Roche Friabilator was utilised to evaluate the friability of lozenges. The equipment is run for four minutes @ 25 rpm. The lozenges that were initially weighed are in the friabilator. The lozenges were weighed again and cleaned off after the revolution. There shouldn't be any more than 1% weight noticed. The formula used to calculate friability is as follows:

% friability = (1- Wt. / W) × 100

Were, W= Initial weight of lozenges

Wt.= Weight of lozenges after revolution.

Results and Discussion

All the formulations showed good appearance. The diameter of all the lozenges was found to be 1.4cm. The thickness changed into in range of 0.3mm to 0.6 mm. All the formulations had excellent hardness and passed drug content uniformity. Accordingly, it is concluded that each of the formulation passed physicochemical assessment. which is given in the below table.

TABLE 2: PHYSIOCHEMICAL PARAMETERS OF COBALAMIN LOZENGES

PARAMETERS	**L1**	**L2**	**L3**	**L4**	**L5**	**AVERAGE AND SD**
Thickness	0.6	0.4	0.5	0.4	0.3	**0.44 ±0.11**
Hardness	13	15	13	14	15	**14 ± 1.2**
Weight variation	0.74	0.70	0.79	0.89	0.72	**0.76 ± 0.07**
Diameter (cm)	1.4	1.4	1.6	1.5	1.4	**1.46 ± 0.08**
Disintegration	13 min 20sec	13 min 45sec	13 min 19 sec	13 min 28 sec	13 min 30 sec	**13 min28sec**
Cumulative drug release %	70.86754	67.9875	78.542495	76.9834256	69.84321	72.8448341

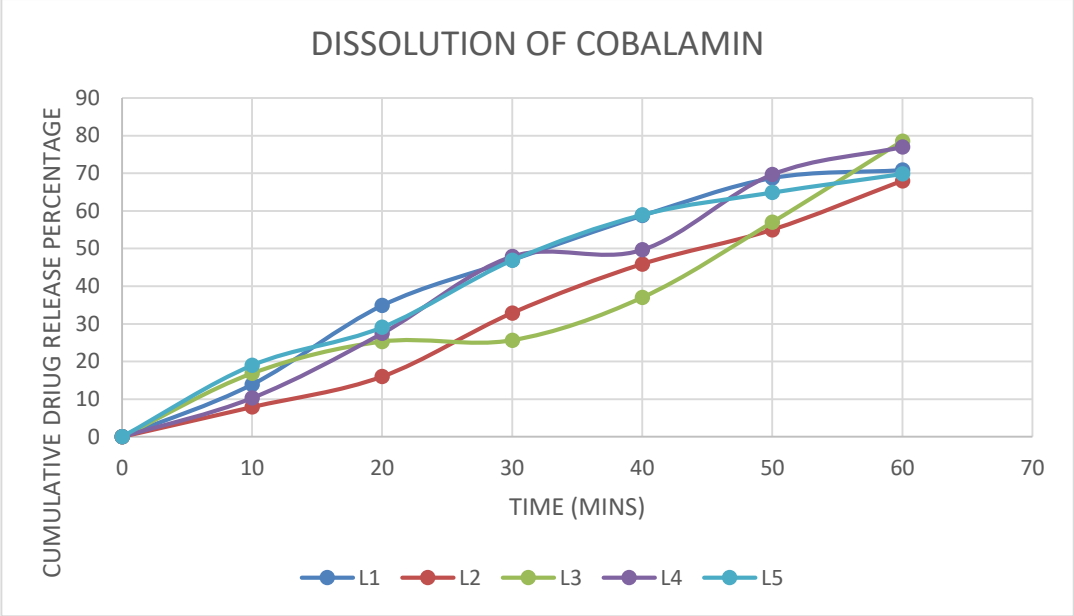

FIG 1: DISSOLUTION GRAPH OF LOZENGES – COBALAMIN

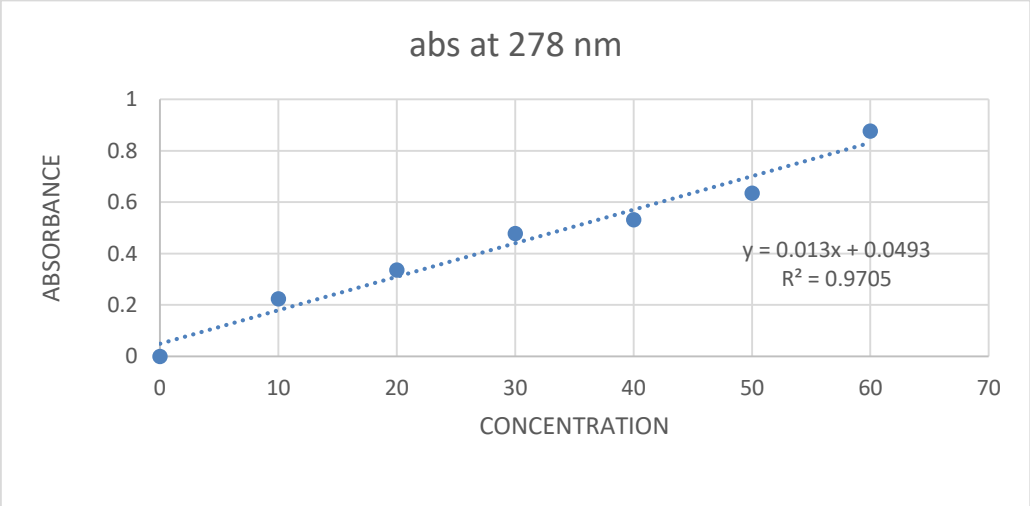

FIG 2: LINEARITY GRAPH OF COBALAMIN LOZENGES

TIME	L1	L2	L3	L4	L5
0	0	0	0	0	0
10	13.8976	7.89065	16.8473077	10.28987	18.976543
20	34.8764	15.9856432	25.2934615	27.457809	29.086759
30	46.98963	32.8759	25.655	47.897543	46.879056
40	58.76439	45.876521	36.980765	49.654827	58.976543
50	68.7653	54.988742	56.987345	69.6763425	64.897534
60	70.86754	67.9875	78.542495	76.9834256	69.84321

TABLE 3: CUMULATIVE DRUG RELEASE PERCENTAGE OF COBALAMIN

Evaluation Parameter	Result (Mean ± SD)
Friability	**0.3 ± 0.2%**

TABLE 3: FRIABILITY OF LOZENGES

CONCLUSION:

The organoleptically preferred formulation of these cobalamin lozenges is both easy to administer and effective for both pediatric and elderly patients. They are among the most straightforward prescription formulas. It may be smooth, patient friendly and produce systemic effect in the course of administration. These lozenges can accommodate a variety of active ingredients, making them versatile in the drug market. Enhanced formulations that meet regulatory standards, such as those outlined in the Indian Pharmacopoeia (IP). They seem to offer a promising solution for managing medication effectively in these specific patient populations.

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