

Redesigning of *Habb e Adrak* into Lozenges along with its Pharmaceutical Analysis

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ABSTRACT

Traditional Unani dosage forms, despite their proven efficacy, often encounter limitations such as poor palatability, inaccurate dosing, and stability concerns, which can affect patient adherence. This study focused on enhancing the therapeutic acceptability and effectiveness of a classical Unani formulation, *Habb-e-Adrak*, by developing it into a lozenge dosage form and conducting comprehensive physico-pharmaceutical evaluations. Lozenges were selected due to their benefits, including prolonged retention in the oral cavity, improved bioavailability, and ease of consumption. The formulated lozenges underwent detailed assessments covering organoleptic attributes (such as appearance and taste), as well as quantitative tests for weight variation, hardness, thickness, friability, disintegration time in the mouth, drug content uniformity, reducing sugar levels, moisture content, and pH of the solution. Thin Layer Chromatography (TLC) was utilized to identify and analyze the chemical constituents present in the formulation. The findings generated reliable data for establishing quality control benchmarks and suggest that the lozenge form of *Habb-e-Adrak* offers a viable strategy for enhancing patient compliance and therapeutic efficacy in Unani medicine.

Keywords: Thin Layer Chromatography, Traditional Unani, dosage forms, therapeutics.

Introduction

Today, a large number of people around the world depend on herbal medicines to manage their basic health needs. Treatments made from medicinal plants are generally considered safe because they have few or no side effects. A major advantage of herbal medicines is that they can be used by people of all age groups [1]. However, many traditional dosage forms in the Unani System of Medicine are not very user-friendly, which can reduce their acceptance among the general public. For centuries, people have used herbal remedies in forms like *Joshanda* (decoction) and *Khisanda* (infusion) for their healing properties. To improve effectiveness and patient convenience, several Unani dosage forms have recently been modified. For respiratory illnesses, especially throat and upper respiratory tract infections, medicines like *Lauq-e-Sapistan*, *Lauq-e-Khayarshamber*, *Sharbat-e-Tootsiyah*, *Sharbat-e-Adusa*, *Habb-e-Adrak*, and *Habb-e-Gul-e-Pista* are commonly used. However, traditional forms like *Habb* (pills) are still mostly prepared manually and face several problems, such as inconsistent weight, difficulty in dosing, being either too soft or too hard, slow disintegration, easy breakage during handling, poor appearance, and inconvenience for children. These limitations make it necessary to modernize and improve the dosage forms.

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One suitable alternative is converting traditional pills into lozenges, especially for medicines used to treat throat and upper respiratory infections. Lozenges are designed to remain in the mouth for 10 to 15 minutes, allowing the medicine to work locally in the throat. They also provide antibacterial and mild numbing (local anesthetic) effects, which are helpful in throat and mouth conditions [2].

The main advantage of medicated lozenges is their longer contact time in the mouth, which improves bioavailability, reduces stomach irritation, and avoids first-pass liver metabolism. In some cases, the drug may also be absorbed directly into the bloodstream through the buccal or sublingual routes. Therefore, this study focuses on reformulating the classical Unani medicine *Habb-e-Adrak* into a lozenge dosage form. It also includes detailed physico-pharmaceutical evaluation to ensure its quality and effectiveness.

Material and Methods

The ingredients of the test formulation given in table no 1 were procured from the outlet of Dawakhana Tibbya College, Aligarh Muslim University, Aligarh. All the Ingredients were identified and authenticated and the specimens of *Gul-e-Pista*, and *Post-e-Halela Zard*, have been deposited in the museum of Department of Saidla AMU, Aligarh having voucher number D-2019/01/S/AMU and All the chemicals used in the study were procured from registered supplier of the University and of analytical grade.

Formulation of Lozenges from ingredients of *Habb-e-Adrak*

To prepare the lozenges, powdered *Gul-e-Pista* and *Post-e-Halela Zard* were used. Before use, *Post-e-Halela Zard* was detoxified through the process of *Tadheen* (oiling) using *Roghan-e-Badam*. A sugar syrup was prepared by dissolving sugar in water at a temperature of 110°C until a clear, thick syrup was formed. Then, corn syrup was added to this mixture, and the combined syrup was further heated to 160°C until it turned golden yellow in color.

The temperature was then reduced to 90°C, and the powdered herbal ingredients *Gul-e-pista* and *post-e-halela Zard* were mixed into the syrup. After that, *Aab-e-Adrak* (ginger juice), along with a polymer, flavoring agent, and other excipients, were added to the molten mixture. This blend was then poured into pre-greased silicone molds and left to cool. Once cooled and solidified, the lozenges were stored in wide-mouthed, airtight containers in a cool, dry place to maintain their quality [3].

Physico-chemical and pharmaceutical analysis of the prepared Lozenges

Organoleptic Properties

- a. Appearance:** The physical form of the lozenge was observed and noted based on its consistency, such as whether it was solid or semi-solid.
- b. Surface Uniformity:** The surface of the lozenge was inspected visually to check for smoothness and evenness.
- c. Texture:** The texture was assessed through visual observation to determine if the surface appeared smooth or rough.
- d. Color:** The color of each lozenge was observed and recorded.
- e. Odor:** The smell of the lozenge was identified by slowly inhaling the aroma several times.
- f. Shape:** The shape was examined with the naked eye and described accordingly.
- g. Taste:** Taste was evaluated by placing the lozenge in the mouth for five minutes, allowing the taste buds on the tongue and palate to identify the flavor. It was then categorized as slightly bitter, tolerable, acceptable, or pleasant.
- h. Palatability:** Palatability was determined by keeping the lozenge in the mouth for five minutes and noting how it felt in the oral cavity. It was rated as unpleasant, acceptable, good, very good, or excellent.

Table 2: Ingredients of the test formulation *Habb-e-Adrak*

S. No.	Ingredients	Botanical Name	Part used	Quantity
1.	Pista	<i>Pistacia Vera</i> Linn f. Anacardiaceae	Flower (Gul-e-Pista)	6g
2.	HalelaZard	<i>Terminalia Chebula</i> Retz f. Combretaceae	Fruit Rind /Fruit outer skin (Post-e-HalelaZard)	6g
3.	Adrak (Zanjabeel)	<i>Zingiber officinale</i> Rosc. f. Zingiberaceae	Extract (Aab-e-Zanjabeel)	QS

Determination of Weight Uniformity

Weight variation is an important test to check the uniformity of dosage and consistency of the lozenges prepared by the molding method. In this test, ten lozenges were individually weighed using an electronic balance, and their average weight was calculated. The weight of each lozenge was then compared to the average to determine if it fell within the acceptable range. The maximum percentage deviation from the average was also noted. Ideally, the variation in weight should not exceed 5% of the average weight to meet quality standards [4].

$$\text{Average weight} = \frac{\text{weight of 10 lozenges}}{10}$$

Determination of Hardness

Hardness refers to the ability of a lozenge to resist breaking when pressure is applied. To measure this, the lozenge was placed between the fixed and movable jaws of a Monsanto Hardness Tester. Pressure was gradually increased by turning the screw knob until the lozenge broke. The force needed to break it was recorded from the scale on the device, which shows the pressure in kilograms per square centimeter (Kg/cm²) [5].

Determination of Thickness / Diameter

The diameter and thickness of the lozenges were measured using a Vernier caliper. Measurements were taken for five individual lozenges, and the standard deviation was calculated to assess the consistency of size among the samples.

Cooling Checks

Visual inspection was carried out to identify any signs of stress cracks, air bubbles, surface fractures, or black specks, which may occur as a result of rapid cooling, extended mixing, or overcooling during the preparation process [6].

Determination of Friability

The friability test is used to assess how well the lozenges can resist wear and tear during packaging, handling, and

transportation. This test was conducted using a Roche Friabilator, which consists of a rotating plastic drum divided into two sections and operates at 25 revolutions per minute (rpm). A pre-weighed set of lozenges was placed in the chamber and rotated for four minutes, completing a total of 100 revolutions. During each rotation, the lozenges were dropped from a height of six inches, simulating mechanical stress. After the test, the lozenges were reweighed, and the percentage weight loss was calculated to determine the friability [7-8].

The friability (F) is calculated by the formula as under:

$$F = 100 (1 - W/W_o)$$

Where, W_o = Initial weight of the sample before friability test.

W = Weight of the samples after friability test.

Determination of Mouth Dissolving Time

The dissolution time of the hard candy lozenges was measured using a USP Disintegration Test Apparatus. Each lozenge was placed in a separate tube of the apparatus, which contained phosphate buffer with a pH of 6.8 maintained at 37°C. The time taken for each lozenge to dissolve completely in the buffer solution was recorded [6].

Drug Content

A few lozenges were randomly selected, weighed, and then crushed into a fine powder using a mortar. An amount of powder equal to the weight of one lozenge was taken and dissolved in 100 ml of phosphate buffer (pH 6.8) in a conical flask. The flask was placed on a rotary shaker to ensure proper mixing. The absorbance of the resulting solution was measured at 193 nm using a UV-Visible spectrophotometer, with the buffer used as a blank. The concentration of the drug was determined using a standard calibration curve, and the total drug content in the lozenge formulation was calculated [7-8].

Percentage of Reducing Sugar

The amount of reducing sugar was estimated using a titration method. For the standard solution, 3 grams of anhydrous dextrose were dissolved in 500 ml of water, boiled for 2 minutes, and then 2 drops of methylene blue indicator were added. This solution was titrated against 25 ml of alkaline cupric tartrate solution (Fehling's solution) until a yellowish-red end point was reached. For the test sample, 10 grams of the candy base were dissolved in 250 ml of water and titrated using 25 ml of Fehling's solution, following the same procedure as the standard. The reducing sugar factor and the percentage of reducing sugar in the sample were then calculated using standard formulas [9].

Reducing sugar factor for 3g dextrose

$$= 3g \frac{\text{Volume of standard dextrose solution consumed by Fehling's solution}}{500}$$

Percentage (%) reducing sugar

$$= \frac{\text{Sample weight}}{250} \times \frac{\text{Reducing sugar factor}}{\text{Volume of sample solution consumed by fehling's solution}} \times 100$$

Determination of Moisture Content

Moisture content was determined using the gravimetric method. A 5-gram sample was accurately weighed and placed in a hot air oven maintained at 105°C until a constant weight was achieved. The loss in weight, calculated by subtracting the final weight from the initial weight, represented the moisture content. The percentage of moisture was then determined using the appropriate formula [10].

$$\text{Moisture Content} = \frac{\text{Initial weight} - \text{Weight after drying}}{\text{Initial weight}} \times 100$$

Determination of pH

Determination of the pH of 1% solution and 10% solution was done by the method [11-12].

Thin Layer Chromatography (TLC)

Thin Layer Chromatography (TLC) was performed using aluminum plates pre-coated with silica gel 60F 254 with a layer thickness of 0.25 mm. A hydro-alcoholic extract of the lozenges was applied to the TLC plates and developed using different solvent systems. The mobile phases used were: (a) Petroleum ether and solvent ether in a 9:1 ratio, and (b) Toluene, ethyl acetate, and a few drops of glacial acetic acid in a 4:1 ratio.

After development, the plates were sprayed with 5% sulfuric acid and anisaldehyde reagent for visualization. The R_f (Retention factor) values of the observed spots were calculated using the standard formula.

$$R_f = \frac{\text{Distance travelled by spot}}{\text{Distance travelled by Mobile phase}}$$

[R_f stands for Retardation factor]

Results

A number of procedures were employed and the significant scientific data have been generated to develop standards for the redesigned formulation. The results of analysis may be used for the purpose of quality control and future reference. All the readings were taken in triplicate and Mean ± SE calculated.

Organoleptic Parameters: The findings are presented in Table 2 and illustrated in Figure 1.

Table 2: Organoleptic features of Lozenges

S. No.	Organoleptic features	Lozenges
1.	Appearance	Solid
2.	Shape	Oval
3.	Surface	Smooth and shiny
4.	Colour	Dark brown
5.	Odour	Agreeable
6.	Taste	Sweet with astringent
7.	Mouth feels	Pleasant



Figure 1. Formulated lozenges of Habb-e-Adrak

Determination of weight uniformity: A random selection of lozenges was taken, and each was weighed individually. The average weight was then calculated, which was found to be 1.87 ± 0.004 grams.

Determination of Hardness, Diameter and Thickness: The hardness was determined for measuring the strength of lozenges. the results are depicted in table 3.

Table 3: Hardness, Diameter and Thickness of the Lozenges

S. No.	Hardness (Kg/cm ²)	Thickness (mm)	Diameter (mm)
1.	18	11.28	10
2.	18.8	11.26	10
3.	24.2	11.29	10
4.	19	11.32	10
5.	17.5	11.33	10
Mean ± SE	19.5 ± 1.206	11.29 ± 0.01	10 ± 0.00

Determination of Friability and Mouth Dissolving time: The results were found as per standards and given in table 4.

Table 4: Friability and Mouth Dissolving time of lozenges

S. No.	Friability (%)	Mouth Dissolving Time (Min.)
1.	0.27	22
2.	0.37	25
3.	0.42	29
Mean ± SE	0.35 ± 0.04	25.33 ± 2.02

Drug Content: The average drug content in the formulated *Habb-e-Adrak* lozenges was determined to be 92.06 ± 0.57 .

Percentage of Reducing Sugar: The mean values of reducing factor and percentage of reducing sugar was found to be 0.061 ± 0.002 and $16.1\% \pm 0.15$ respectively.

Moisture Content: Moisture content in the lozenges was measured using the loss on drying method. The average percentage loss in weight was found to be $1.2\% \pm 0.2$.

pH Value of 1% and 10% solution: The mean value of pH in 1% and 10% solution of Lozenges were found to be 5.26 ± 0.07 and 5.71 ± 0.06 respectively.

Cooling Checks: No stress cracking, no surface cracking was found and also there was no excess air bubble formation occurred. All the lozenges passed cooling check.

Thin Layer Chromatography (TLC)

TLC analysis of the lozenges was carried out using two different mobile phases. The first system consisted of petroleum ether and solvent ether in a 9:1 ratio, with 5% sulfuric acid used as the spraying reagent. The second system used toluene, ethyl acetate, and a few drops of glacial acetic acid in a 4:1 ratio, with anisaldehyde as the spraying reagent. No spots were visible under daylight or UV light before spraying. However, after applying the reagents, colored spots appeared on the plates. The number of spots and their respective Rf values were recorded and are presented in Table 5, while the images of the TLC plates are shown in Figure 2.

Table 5: TLC profile of Lozenges of *Hab-e-Adrak*

	Petroleum ether: Solvent ether (9:1) Spraying reagent- 5% H ₂ SO ₄		Toulene: Ethyl acetate: Glacial acetic acid (4:1: few drops) Spraying reagent- Anisaldehyde	
	No. of spots	Rf Value	No. of spots	Rf Value
Day light	--	--	--	--
After Spray	07	0.07, 0.14,0.20,0.31,0.59,0.71,0.81	09	0.12, 0.21,0.25 ,0.37, 0.5, 0.58, 0.75, 0.83,0.91
UV short and long wavelength	-	-	-	-

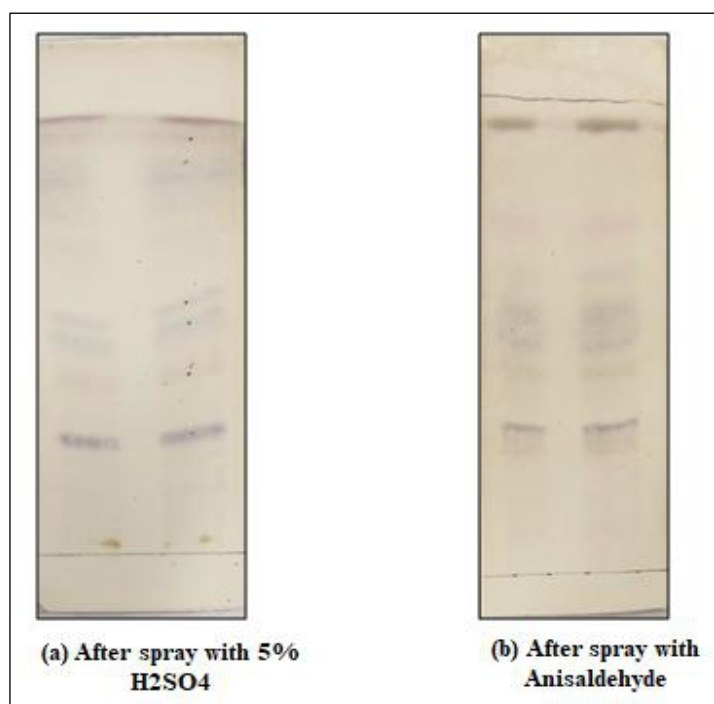


Figure 2: TLC images of Lozenges of *Hab-e-Adrak*

Discussion

Patient compliance plays a vital role in the selection of an appropriate dosage form for effective disease management. In the Unani system of medicine, certain traditional dosage forms often lack patient acceptance due to factors such as unpleasant taste, bulky packaging, inconsistent batch quality, difficulty in dose measurement, and lack of proper quality control. To achieve better therapeutic outcomes and enhance the overall effectiveness of these formulations, it becomes necessary to modernize and reformulate them.

While traditional Unani preparations are known for their therapeutic value, they may lose their appeal because of substandard organoleptic properties and poor-quality assurance.

In this study, a traditional and pharmacopoeial Unani formulation, *Habb-e-Adrak*, known for its expectorant properties and effectiveness in treating productive cough, was reformulated into a lozenge dosage form. Lozenges are solid, candy-like oral dosage forms that are designed for local action in the oral cavity. Attractive organoleptic characteristics—such as taste, color, texture, and smell—are critical, as they create the first impression for the consumer and also reflect the overall quality and acceptability of the product [11].

To establish the physical standards for the lozenges, several evaluations were conducted. Weight variation and average weight were assessed, as accurate and consistent weight is essential for hard candy lozenges, which should fall within the range of 1.5 to 4.5 grams [12]. The average weight of the lozenges was found to be 1.87 ± 0.004 g, indicating consistency. Diameter and thickness uniformity was also evaluated, which largely depends on the mold used. While lozenges can vary in shape and size, they are typically round or oval with flat or biconvex surfaces [13]. The average diameter and thickness of the lozenges were recorded as 10 mm and 11.29 ± 0.01 mm, respectively.

Mechanical strength tests such as hardness and friability were performed to assess the lozenges' ability to withstand stress during manufacturing, packaging, and transport. The hardness was recorded as 19.5 ± 1.206 Kg/cm², and friability was found to be $0.35 \pm 0.04\%$, both within acceptable limits.

The disintegration or mouth-dissolving time is a key indicator of how quickly the active ingredients are released and absorbed. Faster dissolution may enhance bioavailability and result in a

quicker onset of action, especially for ingredients that can be absorbed through the mucosal linings of the mouth, pharynx, and esophagus [14]. The average disintegration time for the lozenges was 25.33 ± 2.02 minutes, aligning with pharmacopeial standards.

Uniformity in drug content is essential for ensuring each lozenge delivers the correct therapeutic dose. The mean drug content of the lozenges was found to be 92.06 ± 0.57 , indicating reliable consistency across samples. Moisture content, which influences stability, shelf life, and microbial safety, was evaluated using the loss on drying method. The moisture content was determined to be $1.2\% \pm 0.2$, which falls within the recommended range of 0.5–1.5% for hard candy lozenges [15].

The pH of the lozenge solution provides information about its acidity or alkalinity, which is important for both stability and safety. Excessively acidic formulations can lead to tooth erosion by dissolving calcium and phosphorus and are associated with dentin damage (Grenby, 1995; Delgado et al., 2018). The pH of 1% and 10% solutions of the lozenges was found to be 5.26 ± 0.07 and 5.71 ± 0.06 , respectively.

All physicochemical parameters tested were within acceptable limits, making the formulation suitable for quality control purposes and future reference. A cooling check was also conducted to detect any defects such as surface cracks, air bubbles, brittleness, or breakage, which may result from rapid or excessive cooling, prolonged mixing, or low reducing sugar content [16–18]. All lozenges passed this test and were found to be physically stable. Thin Layer Chromatography (TLC), a rapid and reliable method for the identification and separation of compounds in drug formulations, was also used as part of the quality assessment. This technique plays an important role in confirming the identity and purity of the formulation components. Overall, the results confirmed that the lozenge formulation met all necessary quality standards and can be recommended for further development and quality assurance purposes.

Conclusion

The studies suggest that the “Lozenge” dosage form of “*Habb-e-Adrak*” is much more convenient, compatible, and has better compliance of the patient and the tests applied for standardization and analysis of the Lozenge of *Habb-e-Adrak* shall be considered as standard quality control parameters to avoid batch to batch variation and can be used for future references.

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