



Research Article

Development and Characterisation of *Murraya Koenigii* Extract – Loaded Sugar Free Lozenges Using Galen IQ 900

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ARTICLE DETAILS	ABSTRACT
Article history: Received on 12 May 2026 Modified on 16 June 2026 Accepted on 20 June 2026 Keywords: <i>Murraya Koenigii</i>, Ethanol Extraction, Hard Candy Lozenges, Galen IQ 900, <i>In-Vitro</i> Drug Release, Antibacterial Activity.	Sore throat and upper respiratory discomfort are among common reasons patients seek over-the-counter relief and the growing diabetic population has created demand for symptomatic remedies that do not compromise glycemic control. This study aimed to design and characterize a herbal hard candy lozenge incorporating an ethanolic leaf extract of <i>Murraya koenigii</i> within sugar-free excipient systems, producing a throat-soothing dosage form suitable for diabetic patients with bronchitis or upper respiratory tract infection. Curry leaf holds a longstanding place in Ayurvedic practice, its flavonoid and carbazole alkaloid constituents credited with antioxidant, anti-inflammatory and antimicrobial activity. Three candy-base variants, F₁ (sucrose), F₂ (mannitol) and F₃ (Galen IQ 900/isomalt), were prepared by the heating and congealing method and evaluated for appearance, weight uniformity, hardness, moisture uptake, oral mouth dissolving time, content uniformity, <i>in-vitro</i> release, antibacterial activity, release-kinetic modelling and accelerated stability. Among the three, F₃ was the strongest performer, with a crushing strength of $15.30 \pm 0.74 \text{ kg/cm}^2$, drug content of $99.68 \pm 1.50\%$, a 7.5 mm inhibition zone against <i>Staphylococcus aureus</i> and near-complete drug release (99.6%) by 30 min. Its release profile best fit the Korsmeyer–Peppas model, indicating an anomalous, non-Fickian mechanism combining diffusion and matrix erosion. One month of accelerated storage at 40°C/75% RH under ICH Q1A (R2) conditions left F₃'s physicochemical profile unchanged. F₃ is a palatable, safe and mechanistically sound sugar-free herbal lozenge suited to relieving sore throat and respiratory discomfort in diabetic patients, owing to isomalt's negligible glycemic impact and non-cariogenic nature.

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INTRODUCTION

Pharyngitis, cough and general sore throat continue to be a major public health problem worldwide and a significant proportion of consultations and self-medication purchases are made for upper airway conditions each year, with a growing trend towards natural and low-risk OTC products, which has led to an increasing interest in plant derived therapeutic formulations as alternatives to synthetic products. This trend overlaps with another important public health problem: the growing incidence of diabetes mellitus, which has led to a need for dosage forms that provide symptomatic relief without affecting blood glucose control [1-3].

Murraya koenigii commonly referred to as curry leaf is a well-recognized herb in Ayurvedic and traditional medicine of South Asia. Given its rich profile of phytoconstituents, which include flavonoids, carbazole alkaloids and volatile essential oils. The plant is pharmacological characteristics of being mucolytic, anti-inflammatory and antibacterial - the latter of which has been shown to be effective against a number of organisms linked to throat infections, including *Staphylococcus mutans* - make it a good candidate for use in a localized oral drug delivery system [4-9].

Hard candy lozenges are a familiar and well tolerated dosage form that offers the advantages of masking the taste, physical strength and a dosing profile that can be engineered to promote prolonged contact of the pharyngeal mucosa with the medication, while reducing unnecessary systemic exposure [10-17]. The use of Galen IQ

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900 as the structural base of a lozenge thus serves two purposes: it meets the public health drive to reduce the sugar content of the diet and it meets the dietary restrictions of diabetic patients [18].

Keeping this in mind, the present study was conducted to formulate and characterize hard candy lozenges containing ethanolic *M. koenigii* extract with sugar-free candy base with physicochemical quality, *in-vitro* release behaviour, antibacterial activity and storage stability, to establish an evidence base for its use in the management of bronchitis-associated sore throat, especially in diabetic patients [11, 13].

MATERIALS AND METHODS

Fresh leaves of *M. koenigii* were collected from the farmers in the nearby area. Food and Pharma Ingredients Pvt. Ltd., from Maharashtra, India, donated a free sample of Galen IQ 900. Mannitol was procured from Merck Specialities Pvt. Ltd., Mumbai, India and sucrose, liquid glucose and corn starch were procured from Nice Chemicals Pvt. Ltd., Kochi, India. Citric acid was obtained from Isochem Laboratories, Kochi, India and menthol crystals were obtained from HiMedia Laboratories Pvt. Ltd., Maharashtra, India.

Preparation of Ethanolic Extract

The authenticated curry leaves were dried under ambient shade to prevent thermal degradation of thermolabile actives followed by coarse grinding. This material was macerated in ethanol at 1:10 drug-to-solvent ratio. The liquid was filtered through Whatman filter paper and concentrated

under reduced pressure at a controlled temperature of 35-55°C to obtain concentrated extract which was kept in sealed containers before use [19].

Determination of Absorption Maximum (λ_{max})

The concentrated extract was dissolved in ethanol to prepare a working solution which was then scanned spectrophotometrically in the range of 200-800 nm. The maximum absorbance wavelength was found using the spectrum [14].

Construction of the Standard Calibration Curve

Concentrated extract was prepared from 100 mg of extract in 100 mL ethanol (1000 $\mu\text{g/mL}$). Working concentrations of 20 - 100 $\mu\text{g/mL}$ were prepared in this stock. At 295 nm, each solution's absorbance was measured [14, 16].

Formulation of Hard Candy Lozenges

The selected candy base for each batch (sucrose for F₁, mannitol for F₂, Galen IQ 900/isomalt for F₃) was dissolved in distilled water and heated on a hot plate at 105-110°C until the syrup thickened. The curry leaf extract, liquid glucose, corn starch, citric acid and menthol were accurately weighed and added to the syrup and thoroughly mixed after an initial 30mins heating period. Heating was then continued for a further 45mins [11, 12, 15]. The complete formulation composition is shown in Table 1 and the preparation sequence is shown schematically in Fig. 1.

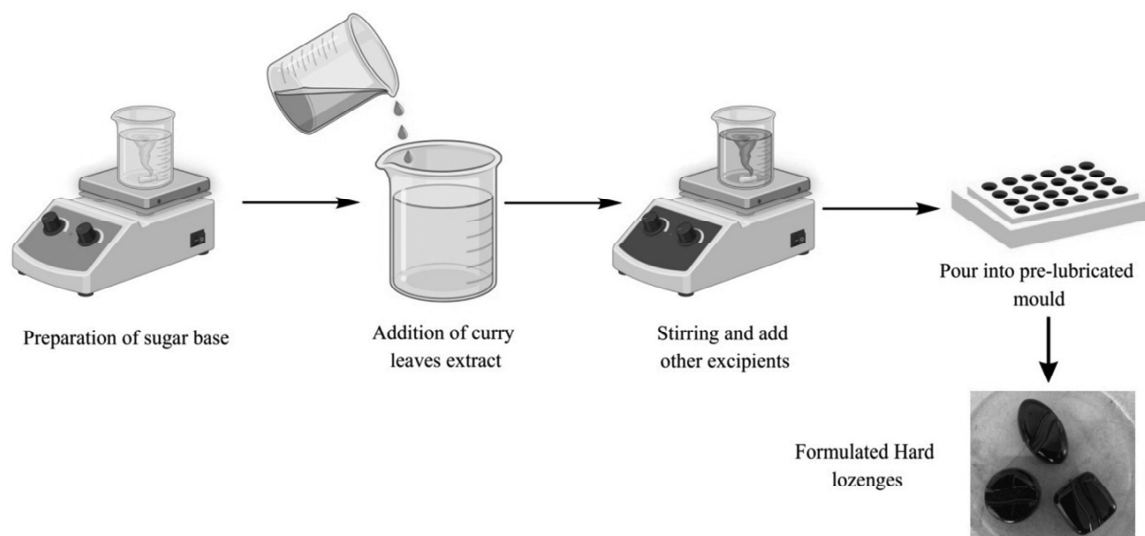


Figure 1: Schematic of the Heating and Congealing Process for Lozenge Preparation

Table 1: Composition of *M. koenigii* Hard Candy Lozenge Formulations

Ingredients	Rational	F1 (gm)	F2 (gm)	F3 (gm)
Curry leaves extract	Active Ingredient	0.5	0.5	0.5
Sucrose	Candy base	1.5	-	-
Mannitol	Candy base	-	1.5	-
Galen IQ 900 (Isomalt)	Candy base	-	-	1.5
Liquid glucose	Sweetening agent	0.5	0.5	0.5
Corn starch	Binding agent	0.3	0.3	0.3
Citric acid	Preservatives	0.1	0.1	0.1
Menthol	Flavouring agent	q.s*	q.s*	q.s*
Distilled water	Solvent	q.s*	q.s*	q.s*

q.s*– Quantity sufficient

Characterisation Parameters**Physical Appearance**

Each batch was visually inspected for clarity, surface texture, consistency and any tendency toward stickiness [14].

Weight Variation

Five lozenges per batch were weighed individually on a calibrated analytical balance, and the mean weight with standard deviation was determined in line with IP requirements [13].

Thickness and Diameter

Five lozenges were taken from each batch and their thickness and diameter were measured and recorded in millimeters with a Vernier caliper [10, 13].

Hardness

A Monsanto hardness tester was used to determine the crushing strength of lozenges. Five numbers of lozenges of each batch were tested and the average hardness in kg/cm² was noted [13, 16].

Drug Content Uniformity

Five lozenges were accurately weighed and transferred to a 100 mL volumetric flask and filled with phosphate buffer pH 6.8 to obtain uniformity in the content. The lozenges were allowed to soak for 30 min and the volume was made up to the mark using the same buffer. Appropriate dilutions were made; the absorbance was measured spectrophotometrically at 295 nm [12].

Moisture Content

Each lozenge was weighed, kept in a desiccator for 24 hrs and then re-weighed. % moisture

content was calculated by the difference in weight [13, 16].

Mouth Dissolving Time

The *in-vitro* disintegration time was determined by placing each lozenge in 100 mL phosphate buffer pH 6.8, which was stirred at 50 rpm at 37 ± 0.5°C. The amount of time needed for the lozenge to completely dissolve was measured [10, 11].

In-Vitro Drug Release Study

The study of drug release was conducted using USP <711> paddle-type apparatus. Dissolution medium was 900 ml of phosphate buffer pH 6.8, stirred at 50 ± 5 rpm and maintained at 37 ± 0.5°C. 5 ml aliquots were taken at 5 mins intervals and replaced with fresh medium to keep the medium in sink condition. The spectrophotometric analysis was done at 295 nm and cumulative % drug release was calculated by using the calibration curve for each sample [13, 16].

Antibacterial Assay

Antibacterial activity was assessed using the agar well diffusion technique. Nutrient agar was prepared by dissolving 2.8 gm in 100 mL of distilled water, sterilised by autoclaving at 121°C for 15mins and poured into plates to set. A fresh subculture of *Staphylococcus aureus* was spread evenly across the agar surface and incubated for 24hrs. Three wells were cut into plate and loaded with saline (negative control), chlorhexidine solution (positive control) and the curry leaf lozenge solution. Plates were incubated at 37°C for a further 24hrs, after which the zones of inhibition were measured in millimeters [19, 20].

In-vitro Release Kinetics

For clarity of the mechanism of drug release, dissolution data of the optimized batch were mathematically modeled using zero-order, first-order, Higuchi and Korsmeyer–Peppas model. The model with the largest adjusted R^2 value was chosen as the best fit model. The release exponent 'n' obtained from the Korsmeyer–Peppas equation was used to characterize the transport as fickian diffusion or anomalous transport or Case-II transport [21-23].

Stability Studies

Optimized formulation (F3) was subjected to accelerated stability testing as per the ICH recommendations. The samples were kept at $75 \pm 5\%$ RH and $40 \pm 2^\circ\text{C}$ for a month. The physicochemical properties were evaluated after 0 days and 1 month of storage periods [14].

RESULTS AND DISCUSSION

λ_{max} and Calibration Curve

The ethanolic extract of *Murraya koenigii* had its UV spectral scanning result showing a wavelength of maximum absorbance at 295 nm,

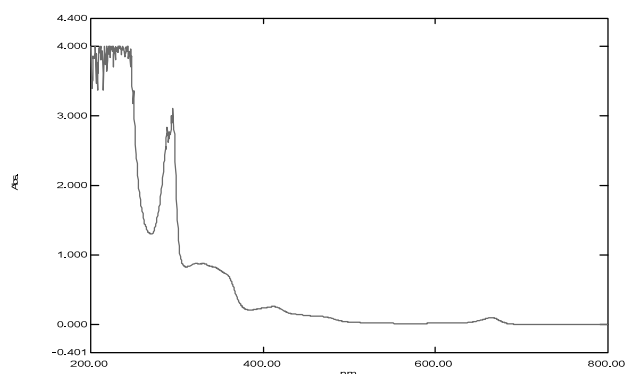


Figure 2: UV Absorption Spectrum of the Ethanolic curry leaf Extract

which was used for further analysis. The method was suitable for quantitative determination as a calibration curve was plotted in the concentration range of 20–100 $\mu\text{g/mL}$ with good linear correlation.

Physical Appearance

All three batches appeared smooth and translucent on visual inspection. F_1 and F_2 exhibited slight surface stickiness and a relatively dense tactile sensation, which is probably due to their moisture attracting properties with ambient storage. F_3 (isomalt-based), by contrast, had a clean, non-tacky surface and good optical clarity, as generally reported for isomalt.

Post-Formulation Physical Parameters

The physicochemical evaluation data of the three batches are summarized in Table 2 and 3. No significant deviations were observed between batches of any of the parameters measured and the pharmacopoeia limits.

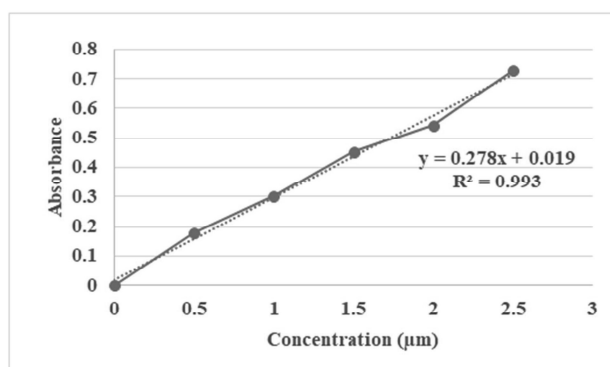


Figure 3: Calibration curve of the Ethanolic curry leaf Extract at 295 nm

Table 2: Physical Parameters of *M. koenigii* Lozenges

S.No.	Formulation	Weight Variation (gm)	Hardness (kg/cm^2)	Thickness (mm)	Diameter (mm)
1	F_1	2.72 ± 0.20	11.28 ± 0.63	10.7 ± 0.75	21.5 ± 1.00
2	F_2	2.62 ± 0.15	10.42 ± 0.19	10.56 ± 0.39	21.34 ± 0.29
3	F_3	2.50 ± 0.02	15.30 ± 0.74	10.45 ± 0.25	21.42 ± 0.92

$\pm$ - Standard deviation

Table 3: Moisture content, mouth dissolving time and drug content

S.No	Formulation	Moisture Content (%)	Mouth Dissolving Time (mins)	Drug Content (%)
1	F_1	2.1	7.06 ± 0.43	94.84 ± 3.85
2	F_2	1.19	10.16 ± 0.51	93.13 ± 2.32
3	F_3	0.83	30.28 ± 0.75	99.68 ± 1.50

$\pm$ - Standard deviation

The variation in weight remained relatively low in all three batches, which was a result of using the same moulds, which provided a consistent fill volume, with F₃ having the narrowest spread (2.50 ± 0.02 gm) indicating a high degree of manufacturing consistency. The hardness of F₃ (15.30 ± 0.74 kg/cm²) was significantly higher than that of F₁ (11.28 ± 0.63 kg/cm²) and F₂ (10.42 ± 0.19 kg/cm²), which is due to the mechanical strength afforded by the isomalt to the candy matrix. This will provide extra strength to the F₃ and make it more resistant to the physical stresses of handling, packaging and transport.

The moisture uptake of F₃ was also the lowest (0.83%) compared to F₁ (2.1%) and F₂ (1.19%) which is an important characteristic for a hard candy dosage form for long term durability.

All three batches met the IP standards and F₃ performed the best again with $99.68 \pm 1.50\%$ of the drug content distributed evenly throughout the candy matrix. The time required for the tablets to dissolve in the mouth was also found to be similar, with F₃ dissolving in 30.28 ± 0.75 mins, while F₁ and F₂ took 7.06 ± 0.43 mins and 10.16 ± 0.51 mins, respectively. The longer the residence time in the oral cavity is beneficial

to the lozenge concept, as the longer the contact with the oral cavity, the longer the active constituents will be released at the mucosal surface and the more powerful the local therapeutic effect.

In-vitro Drug Release

The release profiles of the three formulations are summarized in Table 4. F₁ released 95.38% of its drug load in 10mins and F₂ achieved 98.6% release in 15mins. The dissolution of F₃ was a much more gradual process, with 99.6% dissolution occurring at 30 mins, consistent with its longer dissolution time in the mouth.

Table 4: Cumulative % drug Release from the medicated lozenges

Time (mins)	F ₁ (%)	F ₂ (%)	F ₃ (%)
0	0	0	0
5	80.5	56	30.4
10	95.38	78.5	45.2
15	-	98.6	68.1
20	-	-	82
25	-	-	94.3
30	-	-	99.6

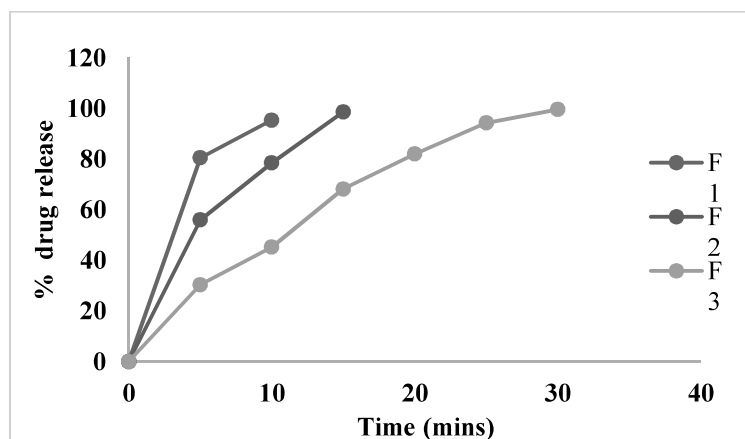


Figure 4: In-Vitro Drug Release Profile of the Formulations F₁, F₂, F₃

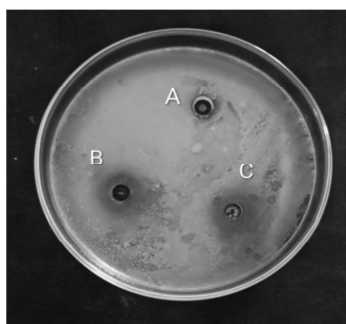


Figure 5: Comparative Zones of inhibition - (A) Saline (B) Chlorhexidine solution (C) Curry leaf lozenge solution

Antibacterial activity

The curry leaf lozenge solution gave a zone of inhibition of 7.5 mm against *Staphylococcus aureus* which is greater than the zone of inhibition of chlorhexidine positive control (5 mm) and saline negative control (0 mm) indicating the validity of the assay design and presence of carbazole alkaloids, other secondary metabolites has been frequently correlated with this activity.

In-Vitro Release Kinetics of Optimized Formulation (F₃)

The modelling of the dissolution data of F₃ gave the best fit with the Korsmeyer–Peppas equation ($R^2 = 0.9985$). The derived release exponent, $n = 0.6987$, falls in the range of 0.5 – 1.0, indicating that the release mechanism is anomalous (non-Fickian). At the practical level, this implies that

the movement of the drug from the isomalt matrix is controlled by both molecular diffusion and progressive dissolution of the matrix in the saliva. A reasonably good correlation was also achieved with the zero-order model ($R^2 = 0.959$) indicating that the contribution of matrix erosion to the overall release process is significant, which is generally desirable for a lozenge dosage form.

Table 5: *In-Vitro* Drug Release Kinetics Data for the Optimized Formulation (F₃)

Time (mins)	Square root of Time	Log Time	% Cum. Release	% Cum. Remaining	Log % Remaining	Log % Release	% Remaining
0	0	∞	0	100	2	∞	4.64
5	2.24	0.699	30.4	69.6	1.843	1.483	4.11
10	3.16	1	45.2	54.8	1.739	1.655	3.80
15	3.87	1.176	68.1	31.9	1.504	1.833	3.17
20	4.47	1.301	82	18	1.255	1.914	2.62
25	5	1.398	94.3	5.7	0.756	1.974	1.78
30	5.48	1.477	99.6	0.4	0.398	1.998	0.797

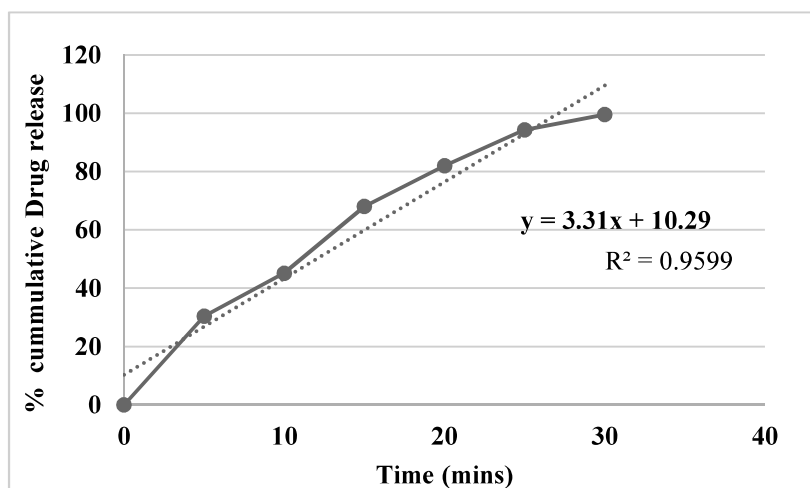


Figure 6: Zero Order Release Plot

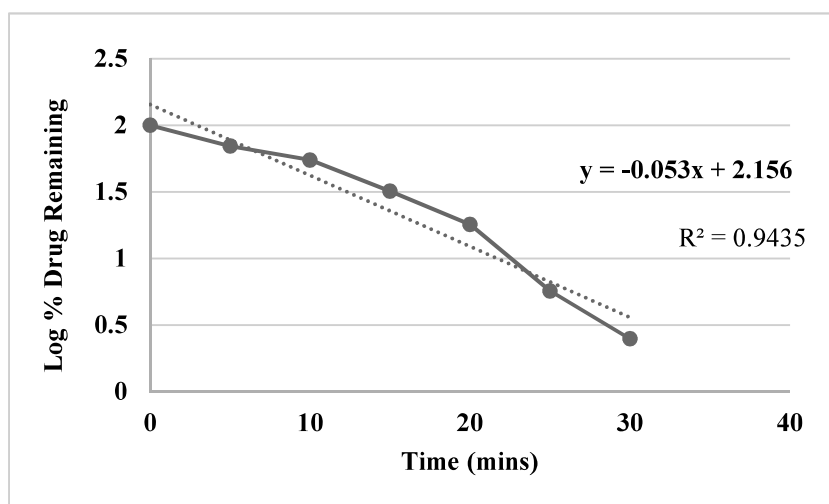


Figure 7: First Order Release Plot

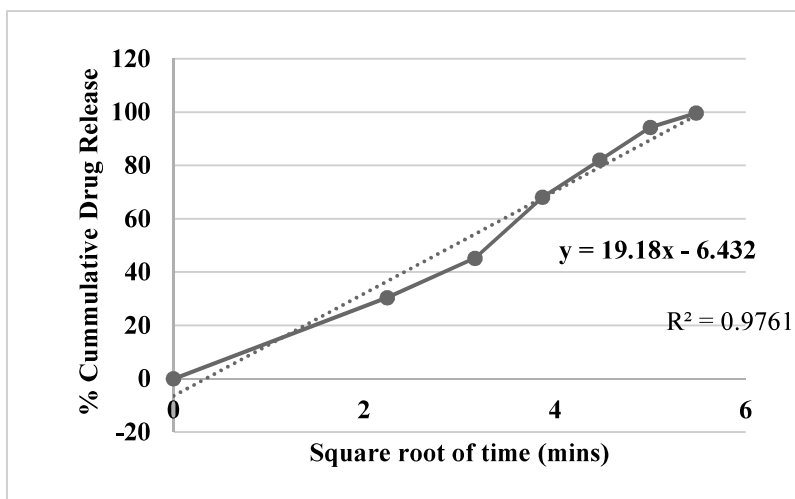


Figure 8: Higuchi Model Release Plot

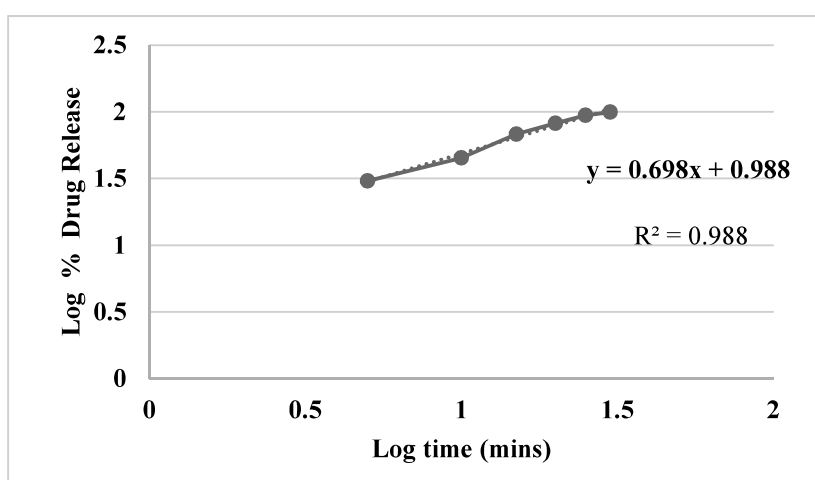


Figure 9: Korsmeyer – Peppas Model Release Plot

Table 6: Physicochemical evaluation of F₃ before and after accelerated stability testing

Evaluation Parameter	F ₃ (Initial)	After 1 Month Stability (40°C / 75% RH)
Weight Variation	2.50 ± 0.02 gm	2.51 ± 0.03 gm
Hardness	15.30 ± 0.74 kg/cm ²	15.10 ± 0.80 kg/cm ²
Thickness	10.45 ± 0.25 mm	10.46 ± 0.27 mm
Diameter	21.42 ± 0.92 mm	21.43 ± 0.94 mm
Moisture Content	0.83%	0.89%
Mouth Dissolving Time	30.28 ± 0.75 mins	30.45 ± 0.80 mins
Content Uniformity	99.68 ± 1.50 %	99.12 ± 1.55 %
% Drug Release	99.6 % in 30 mins	99.1 % in 30 mins

± - Standard deviation

Stability Studies

After accelerated storage for 1 month at 40°C/75%RH (ICH Q1A (R2)), no significant decrease was observed in any of the physicochemical parameters of F₃. The remaining parameters (weight variation, hardness, dimensions, moisture content, mouth dissolving time, content uniformity and drug release) were within acceptable limits at the end of the storage

period, which indicates that the isomalt-based lozenge is physically and chemically robust and is expected to have an acceptable shelf life for F₃.

CONCLUSION

The herbal hard candy lozenges were successfully formulated and characterised in this study using an ethanolic extract of *Murraya koenigii*. The overall performance of the three

candy bases tested was best for the isomalt based F₃. pharmacotechnical performance: it showed excellent hardness, lowest moisture content, high content uniformity (99.68 ± 1.50%), controlled release profile (99.6% within 30mins), inhibition zone (7.5 mm) greater than that of the chlorhexidine standard and stable performance after 1 month of accelerated storage. The longer it remains in the mouth, the more time it will have to come in contact with the mucosa, potentially increasing the amount of active phytoconstituents available locally. F₃ is especially suitable for diabetic patients due to the fact that isomalt does not have any glycaemic burden and does not cause dental caries. The release from this formulation was found to be following Peppas type diffusion-erosion mechanism and all the parameters measured were found to be within the Indian Pharmacopoeia specifications. All the results suggest that the isomalt-based curry leaf lozenge (F₃) is a safe, effective, palatable and stable herbal dosage form for the treatment of sore throat, bronchitis and upper respiratory tract complaints.

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CONFLICT OF INTEREST

The authors declare no conflict of interest in connection with this work.

FINANCIAL ASSISTANCE: Nil

AUTHOR CONTRIBUTION

M. Surenthiran contributed to methodology development, wrote the original draft and participated in manuscript review and editing. I. Naveen and K. A. Chittesh assisted with data collection, conducted the investigations and performed graphical data interpretations. S. Vanitha and Dr. R. Sambath kumar conceptualized the study and supervised the experimental work. All authors have read and approved the final manuscript.

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