



# International Journal of Pharmacy and Analytical Research (IJPAR)

IJPAR | Vol.14 | Issue 4 | Oct - Dec -2025

www.ijpar.com

ISSN: 2320-2831

DOI : <https://doi.org/10.61096/ijpar.v14.iss4.2025.1068-1083>

## Research

### FORMULATION AND EVALUATION OF HARD CANDY LOZENGES INCORPORATING EMBELIN AND ANTHELMINTIC CLASS DRUG

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	<b>Abstract</b>
Published on:	<p>Lozenges are a common form of dosage widely used in the pharmaceutical industry to treat local problems of throat and oral cavity. Embelin is a naturally occurring para-benzoquinone isolated from dried berries of Embelia ribes plant. Embelin possesses wide spectrum of biological properties like anti-oxidant, anti- tumour, anti-inflammatory, analgesic, anthelmintic, anti-fertility and anti-microbial activity. So, to achieve the anthelmintic property of Embelin and by masking its better taste, hard candy lozenges were formed.</p> <p><b>Keywords:</b> Lozenges, Embelin, hard candy lozenges</p>
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## INTRODUCTION

Lozenges are a type of medication that is designed to be taken orally and dissolve slowly in the mouth. They are commonly used to treat a variety of symptoms, including sore throat, cough, and congestion. Lozenges come in many different types, each with its own active ingredients and intended use. The active ingredients in lozenges vary depending on their intended use. Sore throat lozenges often contain antiseptics or anaesthetics, such as benzocaine or menthol, which can help to numb the throat and reduce pain. Cough lozenges typically contain ingredients such as menthol or eucalyptus oil, which can help to soothe the throat and reduce coughing. Cold lozenges may contain a combination of antiseptics, anaesthetics, and decongestants to reduce inflammation and clear the sinuses. Nicotine lozenges contain a small amount of nicotine, which can help to reduce craving and withdraw symptoms in people trying to quit smoking. Zinc lozenges are sometimes used to help shorten the duration of colds, as zinc is thought to help boost the immune system and reduce inflammation. Lozenges work by slowly dissolving in the mouth, which allows the active ingredients to be absorbed into the bloodstream through the mucous membranes. This allows for rapid onset of action, as the medication is delivered directly to the affected area. The effectiveness of lozenges can vary depending on the type while lozenges are generally safe, they can have side effects.

### **Types of Lozenges**

There are several types of lozenges available on the market, each designed for a specific purpose. Some of the most common types of lozenges include:

**Sore throat lozenges:** - These lozenges are designed to relieve the pain and irritation associated with a sore throat. They often contain anaesthetics, such as benzocaine, which can numb the throat and provide temporary relief. Some sore throat lozenges also contain antiseptics, such as hexylresorcinol or cetylpyridinium chloride, which can help to kill bacteria and reduce inflammation.

**Cough lozenges:** - These lozenges are designed to reduce coughing and soothe an irritated throat. They often contain ingredients such as menthol or eucalyptus oil, which can help to loosen mucus and reduce inflammation. Some cough lozenges also contain antihistamines or decongestants, which can help to reduce nasal congestion and postnasal drip.

**Cold lozenges:** - These lozenges are designed to relieve the symptoms of the common cold, including Sore throat, cough, and congestion. They often contain a combination of antiseptics, anaesthetics, and decongestants to reduce inflammation and clear the sinuses. Some cold lozenges also contain vitamin C or zinc, which are thought to help boost the immune system.

**Nicotine lozenges:** - These lozenges are designed to help people quit smoking by reducing cravings and withdrawal symptoms. They contain a small amount of nicotine, which is slowly absorbed into the bloodstream through the mucous membranes. Nicotine lozenges are available in different strength, depending on the individual's smoking habit.

**Zinc lozenges:** - These lozenges are sometimes used to help shorten the duration of colds. Zinc is thought to help boost the immune system and reduce inflammation. Some zinc lozenges also contain vitamin C or other antioxidants, which can help to support immune function.

**Herbal lozenges:** - These lozenges contain natural ingredients, such as Echinacea or ginger, which are thought to help support immune function and reduce inflammation. Herbal lozenges are often used as a natural alternative to Probiotic lozenges.

**Probiotic lozenges:** These lozenges contain beneficial bacteria, such as lactobacillus or bifid bacterium, which are thought to help support digestive and immune function. Probiotic lozenges are often used to help restore the balance of gut bacteria after a course of antibiotics.

It is important to read the label carefully and talk to a healthcare professional before taking any medication, including lozenges.

### **Advantages of Lozenges**

Lozenges offer several advantages over other forms of medication. Some of the key advantages of Lozenges include:

**Localized delivery:** Lozenges are designed to dissolve slowly in the mouth, allowing the medication to be absorbed through the mucous membranes in the throat and mouth. This localized delivery can help to provide rapid relief for symptoms.

**Convenience:** Lozenges are small and portable, making them easy to carry and use when needed. They can be taken without water and are often more discreet than other forms of medication, such as tablets or capsules.

**Reduced side effects:** Because lozenges are absorbed directly into the bloodstream through the mucous membranes, they bypass the digestive system and can cause fewer side effects than other forms of medication. For example, cough or cold medications in liquid or pill form may cause drowsiness or upset stomach, while lozenges designed for the same purpose may not.

**Targeted delivery:** Depending on the type of lozenge, they can provide targeted delivery to specific areas of the

body. For example, sore throat lozenges can help to numb and soothe the throat, while cold lozenges can help to reduce inflammation in the sinuses and airways.

#### **Herbal Lozenges:-**

Herbal lozenges are a type of lozenge that contains natural plant extracts and other natural ingredients. These lozenges are often used to treat minor throat irritations, cough, and other respiratory symptoms. Herbal lozenges can be made from a variety of plant extracts, including peppermint, eucalyptus, ginger, honey, and lemon.

Herbal lozenges are often preferred by individuals who prefer natural remedies over conventional medications. They are typically made from all-natural ingredients, with no added chemicals or preservatives. In addition, herbal lozenges may have fewer side effects than conventional medications, making them a safer alternative for some individuals. Peppermint is a common ingredient in herbal lozenges due to its ability to soothe sore throats and reduce coughing. Peppermint has natural cooling and numbing properties that can help to relieve pain and discomfort in the throat. Peppermint lozenges can also help to improve breathing and reduce congestion by opening up the airways. Eucalyptus is another common ingredient in herbal lozenges, known for its ability to relieve coughs and reduce inflammation in the respiratory system. Eucalyptus lozenges can help to soothe irritated mucous membranes in the throat and nose, making it easier to breathe and reducing coughing. Eucalyptus is another common ingredient in herbal lozenges, known for its ability to relieve coughs and reduce inflammation in the respiratory system. Eucalyptus is another common ingredient in herbal lozenges, known for its ability to relieve coughs and reduce inflammation in the respiratory system. Eucalyptus lozenges can help to soothe irritated mucous membranes in the throat and nose, making it easier to breathe and reducing coughing.

Ginger is another popular ingredient in herbal lozenges, known for its anti-inflammatory and antioxidant properties. Ginger lozenges can help to reduce inflammation in the respiratory system and provide relief for symptoms such as cough, sore throat, and congestion.

Honey is a natural sweetener that is often added to herbal lozenges for its soothing properties. Honey has natural antibacterial and anti-inflammatory properties that can help to relieve throat irritation and reduce coughing. Honey lozenges can also help to boost the immune system and promote healing in the respiratory system.

Lemon is another common ingredient in herbal lozenges, known for its high vitamin C content and natural antibacterial properties. Lemon lozenges can help to soothe sore throats and reduce coughing, while also providing a boost to the immune system. Herbal lozenges are often used to treat minor respiratory symptoms such as cough, sore throat, and congestion. They can be taken as needed throughout the day to provide ongoing relief.

#### **Excipients used in Lozenges:-**

**Binders:** Binders are used to hold the ingredients together and ensure that the lozenge maintains its shape and consistency. Some commonly used binders in herbal lozenges include acacia gum, xanthan gum, and gelatine.

**Sweeteners:** Sweeteners are added to herbal lozenges to improve their taste and make them more palatable. Natural sweeteners such as honey, maple syrup, and stevia are often used in herbal lozenges, as they provide a natural source of sweetness without adding additional calories.

**Flavours:** Flavours are added to herbal lozenges to improve their taste and make them more appealing to consumers. Natural flavours such as peppermint, eucalyptus, and lemon are often used in herbal lozenges, as they provide a pleasant and refreshing taste.

**Colours:** Colours are used to enhance the appearance of herbal lozenges and make them more attractive to consumers. Natural colours such as beetroot powder and turmeric are often used in herbal lozenges, as they provide a vibrant and natural color without the use of artificial dyes.

**Lubricants:** Lubricants are added to herbal lozenges to prevent sticking during the manufacturing process and ensure that the lozenges are easy to handle and administer.

**Anti-caking agents:** Anti-caking agents are used to prevent the ingredients in herbal lozenges from clumping together and ensure that the lozenges remain dry and free-flowing. Some commonly used anti-caking agents in herbal lozenges include silicon dioxide and calcium silicate.

#### **EMBELIN**

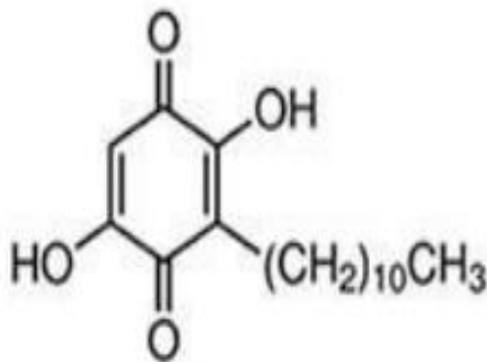
Embelin is a naturally occurring plant compound that is found in the fruit of the *Embelia ribes* plant, which is native to India and other parts of Southeast Asia. It is a yellowish-brown crystalline substance that has a bitter taste and is insoluble in water but soluble in organic solvents.

Embelin has been traditionally used in Ayurvedic medicine for its various medicinal properties, including its antioxidant, anti-inflammatory, and anticancer effects. It is believed to have a wide range of therapeutic benefits and is currently being studied for its potential use in treating a variety of medical conditions.

Embelin works by inhibiting the activity of certain enzymes and signalling pathways in the body that are involved in various physiological processes. For example, it has been found to inhibit the activity of an enzyme called XIAP, which is involved in regulating cell death and survival.



Plant of *Embelia ribes*



Chemical structure of embelin

Figure No.1.1.Plant of Embelin

## PREFORMULATION STUDIES:

### a. Selection of Wavelength:

The Embelin Solution was prepared and scanned from 190-400 nm using a double UV-Visible spectrophotometer.

### b. Calibration curve of Embelin:

Calibration curve for Embelin was constructed by dissolving it in phosphate buffer of pH 6.8 and Series of dilution were made and absorbance was measured at 289 nm.

## 2. Preparation of Lozenges:

Lozenges were prepared by moulding method. Accurately weighed amount of mannitol and lactose were added in sufficient quantity of water and heated at 100°C for form syrup. Embelin and all the other ingredients were added to the syrup and heating was continued to dissolve all solids and crystal clear syrup was obtained. The syrup was added to previously lubricated moulds and dried at room temperature to form lozenges.

## 3. Evaluations:

**a. Organoleptic properties:**

The organoleptic tests were carried out for colour, texture and taste of lozenges.

**b. Moisture Content:**

For Karl Fischer titration, 20ml of dehydrated methanol was added to the titration vessel and was titrated to the electrometric end point using Karl Fischer reagent. Prescribed amount of substance was weighed accurately and quickly transferred to the titration Vessel. Lozenges were crushed in pestle mortar, weighed 4-5 times and then added in the KF reagent to attain a moisture percent value.

**c. Hardness:**

The Pfizer hardness tester was used to measure the lozenges hardness in terms of kg/cm<sup>2</sup>. Hardness of lozenge is the measurement of force which is applied across the diameter of the lozenge in order to break it as chipping or breakage during storage and handling always depends on the hardness.

**c. Thickness:**

The thickness of lozenges was measured by vernier calliper and it is a significant feature in reproducing appearance. The average thickness for lozenges was measured in mm and presented with standard deviation.

**d. Friability:**

It is a measure of mechanical strength of tablets and was determined using Roche Friabilator. Ten lozenges were preweighed and then they were placed in the Friabilator. The lozenges were then rotated at 25 rpm for 4 minutes (100 rotations) and then the lozenges were re-weighed. Loss in the weight of lozenges is the measure of friability and is expressed as:

$$\% \text{ Friability} = [(W1 - W2) / W1] \times 100 \text{ Where}$$

W1 = Initial weight of 10 lozenges

W2 = Weight of the 10 lozenges after testing

**e. Disintegration time:**

Disintegration time is defined as the time interval required for complete disappearance of a tablet or its Particles from the tester net. Disintegration test apparatus was used to determine the disintegration time using phosphate buffer, pH 6.8 at 37 °C.

**f. Weight Variation Test:**

Twenty lozenges from the formulation were randomly selected and weighed together the tablets were then weighed individually. The batch passes the test for weight variation test if not more than two of the individual

lozenge weight deviated from the average weight by more than the percentage according to IP limits shown In table.4.1

**Table 4.1: Weight Variation Limits according to IP**

Average weight of tablet (mg)	% Deviation
Less than 80	10
80-250	7.5

More than 250	5
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**f. % Drug Content:**

5 mg lozenge powder was dissolved in 100 ml of phosphate buffer of pH 6.8 and Absorbance was measured at 289 nm using UV visible spectrophotometer. % Drug Content was determined by using following formula;

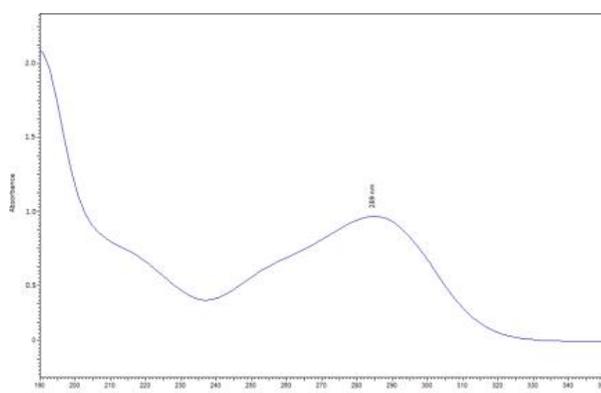
$$\% \text{ Assay} = \text{Sample Absorbance} / \text{Standard Absorbance} \times 100$$

**g. In-vitro dissolution study:**

USP apparatus II (paddle type) was used for the study. Accurately weighed formulations of lozenges were placed in 900 ml phosphate buffer of pH 6.8. The temperature was kept up at 37°C and mixed at a speed of 50 rpm. At every time interval, a 5 ml aliquot of the sample was withdrawn and the volume was replaced with an equal measure of plain buffer kept at 37°C. The obtained samples were filtered through 0.45 µm filter and measured at 289 nm using UV visible spectrophotometer.

**h. Stability Study:**

The lozenges of optimized batch F5 were stored at 40°C and 75% Relative humidity for 1 month and evaluated for all the physicochemical parameters like Colour, Odour, Taste, Moisture, Thickness, Weight Variation, Hardness, Disintegration time, Friability and % Drug Content.



**Figure 4.1: UV Scan of Embelin from 190-400 nm**

**a. Construction of Calibration Curve:**

Calibration curve of Embelin was constructed by plotting Standard concentration (µg/ml) and Absorbance. Results of the calibration curve are given in Table 4.2

**Table 4.2: Results of Calibration curve of Embelin**

Conc. (ug/ml)	Absorbance
0	0.000
20	0.197
40	0.405
60	0.595
80	0.803
100	0.975

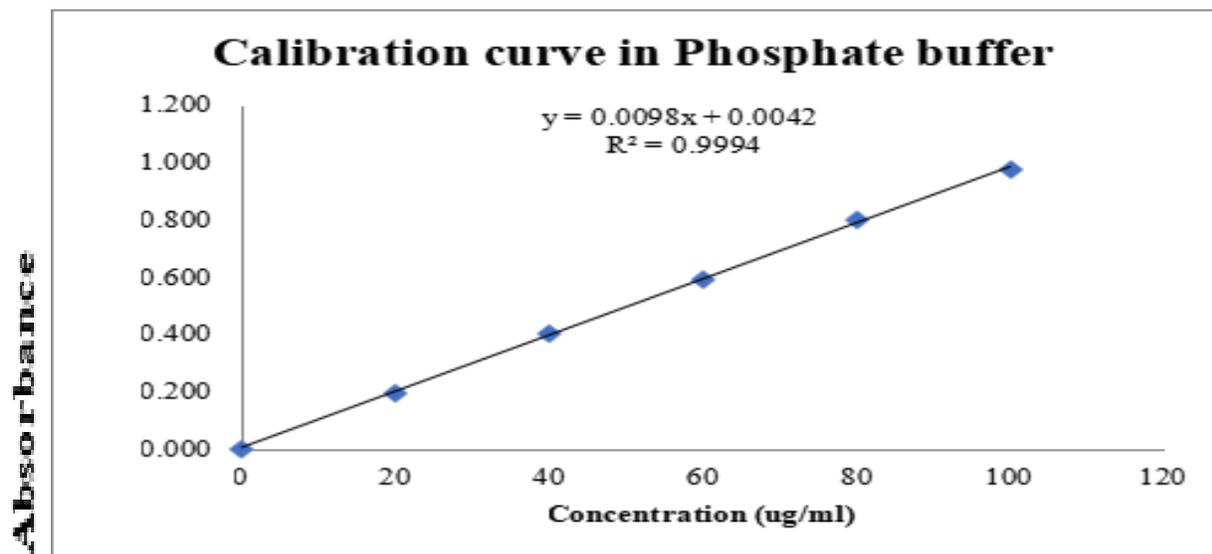


Figure No.4.3 Standard Calibration Plot of Embelin

**Preparation of Lozenges:**

The preparation of Lozenges was done by Moulding method. Various trials were done by changing the concentration

of Mannitol and Lactose. In Table 4.3, the various formulation trials are given.

**Table 4.3: Formulation of Lozenges**

Formulation	F1	F2	F3	F4	F5	F6

Embelin (mg)	5	5	5	5	5	5
Stevia (mg)	10	10	10	10	10	10
Mannitol (mg)	200	180	160	140	120	100
Lactose (mg)	300	320	340	360	380	400
Glycerine (mg)	100	100	100	100	100	100
Citric acid Monohydrate (mg)	300	300	300	300	300	300
Colouring agent (mg)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Flavour (mg)	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Water	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Total (mg)	920	920	920	920	920	920

**7.1 Evaluation of Lozenges:**

**a. Organoleptic properties:**

The results of organoleptic evaluations are given Table 4.3. All the lozenge batches had light orange colour and had smooth texture. The tastes of all six batches were sweet with no bitter taste of Embelin confirming successful taste masking.

**b. Moisture Content:**

The moisture content of all lozenges was between 0.5- 1.5 % given a hard candy consistency to the lozenges. The % Moisture content of F5 batch was least amongst all the batches i.e. 0.58%. The results of % moisture content are given in table 4.4

**Table 4.4: Organoleptic evaluation of Lozenges**

Batches	Colour	Taste	Texture
F1	Light Orange	Sweet	Smooth
F2	Light Orange	Sweet	Smooth
F3	Light Orange	Sweet	Smooth

F4	Light Orange	Sweet	Smooth
F5	Light Orange	Sweet	Smooth
F6	Light Orange	Sweet	Smooth

**c. Hardness:**

The Hardness results are given in Table 7.4. The hardness for Lozenges was found to be between 8-12 kg/cm<sup>3</sup>. Batch F5 was found to have the hardness of 11.3 kg/cm<sup>3</sup>. The variation in the Hardness was found to be due to varying concentration of lactose.

**d. Thickness:**

The Thickness of the lozenges varied from 6-8 mm. The variation in the thickness was found to be due to varying concentration of lactose. The lowest thickness i.e. 6.26 mm was found to be of Batch F5. The various results of thickness are mentioned in Table 7.

**e. Friability:**

The intactness of the Lozenge during transportation can be evaluated from the Friability test. The Results of friability is given in table 4.4. The Friability of all the Lozenges batches was less than 1.0% which complies to the IP Limits.

The least Friability was found to be 0.21% of Batch F4.

**f. Disintegration time:**

The Disintegration time shows the intactness of Lozenges in the mouth. All the Batches showed the disintegration time between 15-25 min. Such a short time of disintegration is enough to give better effect. The Results of Disintegration time is given in Table 4.4.

**g. Weight Variation:**

As per the IP Limits, all the batches of Lozenges passed the weight variation test showing that the variation in the Weight was less than 5% of average weight. The Results of weight variation is mentioned in table 4.4.

**Table 4.5: Physicochemical Evaluation of Lozenges**

Batches	Moisture content (%)	Hardness (kg/cm <sup>2</sup> )	Thickness (mm)	Weight Variation	Disintegration Time (min.)	Friability (%)	% Drug Content
F1	0.92±0.03	8.4 ± 0.2	7.79±0.06	Passes	17 ± 0.5	0.43±0.03	97.75
F2	0.73±0.04	10.2±0.4	7.21±0.02	Passes	18 ± 0.1	0.71 ±0.01	98.24

F3	0.67±0.02	8.8 ± 0.3	6.48±0.02	Passes	20 ± 0.4	0.98±0.03	96.48
F4	0.94±0.07	9.5 ± 0.3	6.98±0.04	Passes	18 ± 0.2	0.21±0.04	97.36
F5	0.58±0.06	11.3±0.1	6.26±0.03	Passes	19 ± 0.6	0.54±0.04	99.63
F6	0.94±0.01	9.8 ± 0.1	7.15±0.05	Passes	24 ± 0.6	0.95±0.07	98.42

**h. % Drug Content:**

The Embelin Lozenges showed above 95% drug content in all the formulations indicating the amount of drug incorporated during the formulation was performed accurately. The results of Drug content are given in Table 4.5

**i. In-vitro dissolution Study:**

The Results of in vitro dissolution study are given in Table 4.6. The dissolution study was performed for 30 minutes. Phosphate buffer pH 6.8 was used as Dissolution media. Batch F5 showed maximum release of 94.27% at 30 minutes. Lowest release was found to be of Batch F6 with 73.18% at 30 minutes.

**Table 4.6: Results of Dissolution study**

Time (min.)	F1	F2	F3	F4	F5	F6
0	0.00	0.00	0.00	0.00	0.00	0.00
5	15.39	14.05	13.08	12.98	14.33	11.52
10	28.77	28.94	27.48	26.66	30.37	23.35
15	44.28	43.62	44.89	40.63	46.97	35.76
20	59.31	55.97	54.78	52.33	62.62	45.38
30	91.75	85.14	86.53	82.11	94.27	73.18

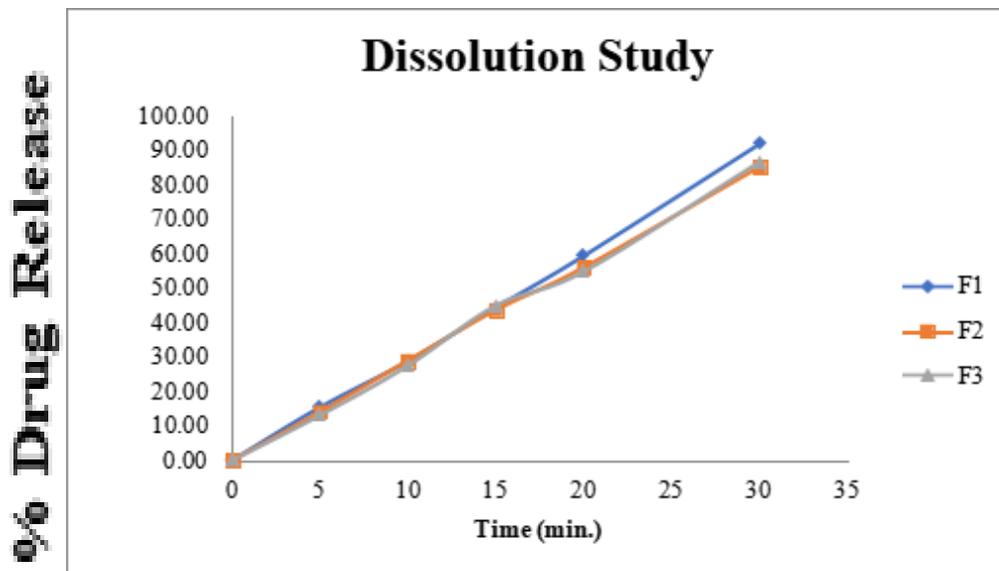


Figure No.4.4: Dissolution Study of Batch F1, F2 and F3

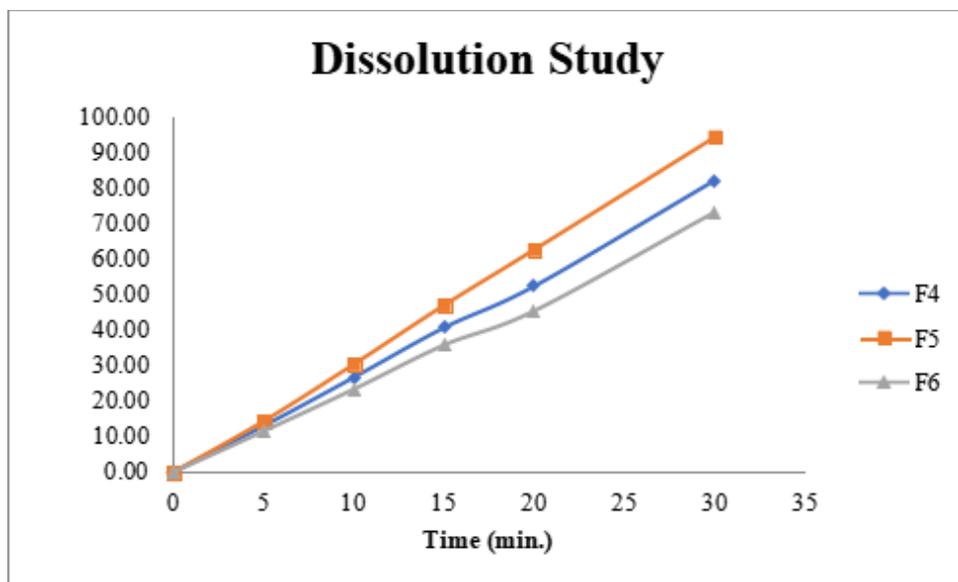


Figure No. 4.5: Dissolution Study of Batch F4, F5 and F6

**j. Stability Study:**

Table 4.7: Results of Organoleptic evaluations at Stability

Interval	Colour	Taste	Texture
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T0	Light Yellow	Sweet	Smooth
T1	Light Yellow	Sweet	Smooth

**Table 4.8: Results of Physicochemical evaluations at Stability**

<b>Interval</b>	<b>Moisture content (%)</b>	<b>Hardness (kg/cm<sup>2</sup>)</b>	<b>Thickness (mm)</b>	<b>Weight Variation</b>	<b>Disintegration Time (min.)</b>	<b>Friability (%)</b>	<b>% Drug Content</b>
T0	0.67±0.06	11.3±0.1	6.26±0.03	Passes	11 ± 0.6	0.54±0.04	99.63
T1	0.65± 0.03	11.2±0.3	6.18±0.05	Passes	12 ± 0.3	0.58±0.04	99.68

The Stability study of conducted for F5 batch and later was evaluated for various organoleptic and physicochemical parameters which showed that the batch F5 was stable for 1 month at 40°C and 75% Relative Humidity. The results of stability study are given in Table 4.7 and 4.8

## SUMMARY AND CONCLUSION

### Summary:

Embelin is a naturally occurring para-benzoquinone isolated from dried berries of *Embelia ribes* plant. Embelin possesses wide spectrum of biological properties like anti-oxidant, anti-tumour, anti-inflammatory, analgesic, anthelmintic, anti-fertility and anti-microbial activity. So, to achieve the anthelmintic property of Embelin and by masking its better taste, hard candy lozenges were formed.

Embelin Lozenges were prepared by moulding method. The Lozenges were prepared by dissolving mannitol and lactose in sufficient water and heated at 100°C to form the syrup. Later Embelin and other ingredients were dissolved in to the syrup and was continuously heat to form crystal clear syrup and were transferred to the pre-lubricated mould and allowed to cool at room temperature to obtain the lozenges.

The Prepared lozenges were evaluated for its organoleptic properties like Colour, Taste and Texture. The Colour of all the prepared lozenges was light orange and taste was sweet with no bitter taste of Embelin. The Texture of the lozenges was smooth.

The prepared lozenges were also evaluated for its physicochemical parameters likes Moisture content, Hardness, Thickness, Friability, Disintegration time, Weight Variation, Percent Drug Content and In-vitro Dissolution Study. The Moisture content of lozenges was found to be less than 1.0%. Hardness of prepared lozenges was found to be between 8-12 kg/cm<sup>3</sup>. The Thickness of the lozenges was found to between 6-8 mm. The Friability of the all the prepared lozenges was less than 1%.

The prepared lozenges pass the Disintegration time and weight variation test as these confirms the IP Limits for Lozenges. The Percent drug content was also found to be above 95% for all the batches.

In-vitro dissolution test was also performed for all the prepared lozenges for 30 minutes using phosphate buffer pH 6.8 to replicate the oral mucosal condition. Batch F5 showed the maximum drug release of 99.63% within 30 minutes. Hence, Batch F5 was found to be the optimized formulation. Stability study of Batch F5 was performed at 40°C and 75% Relative humidity for 1 month. After stability, the Batch F5 was evaluated for all the organoleptic and physicochemical parameters and it was confirmed from all the evaluation parameters that the Lozenges were stable.

### Conclusion:-

An attempt was made to formulate and evaluate the Embelin Lozenges due to its antihelmintic properties. The Formulation was prepared by using moulding method. The prepared lozenges were evaluated for its organoleptic properties like colour, taste and texture and physicochemical evaluations like Moisture content, Hardness, Thickness, Friability, and Disintegration time, Weight Variation, Percent Drug Content and In-vitro Dissolution Study. From the evaluations, Batch F5 was confirmed to be the optimized formulation to delivery Embelin. Hence, it can be concluded that Lozenges are a potential candidate for the delivery of Embelin.

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