IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Lozenges: An Overview

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Abstract :

Lozenges are one of the very popular and better innovative dosage form and oral confectionary product. Lozenges are solid unit dosage form that contain one or more medicaments containing sweetners excipients and binders Most common and easy way of administration of drug is orally administered Lozenges are one of the widely used dosage form. However, pediatric, geriatric patientsshowless compliance in swallowing tablets and capsules due to difficulties inswallowingand bitter taste of many drugs when formulated as liquid dosage form. The benefits of the medicated lozenges is they increase the retention time of the dosage form in oral cavity which increases bioavailability,reduces gastric irritation and bypasses first pass metabolism . Lozenges provide a palatable means of dosage form position of Lozengein pharmaceutical market owned to its several advantages but it causessome disadvantages. Acceptance for lozenges as a dosage form is high by adults and also more by children. These lozenges contain active pharmaceutical ingredients that are released as they dissolve in the mouth, providing quick and targeted relief. Common uses of medicated lozenges include soothing sore throats, relieving coughs, and treating oral infections. They are also used to manage symptoms associated with colds, flu, and allergies. This review highlights the therapeutic benefits, formulation, and applications of medicated lozenges. The advantages of medicated lozenges over other oral dosage forms, such as rapid onset of action and improved patient compliance, are discussed. Future directions for the development of medicated lozenges, including novel formulations and delivery systems, are also explored. Different types

of lozenges available in market are compressed lozenges, hard lozenges & soft lozengesand their methods of preparation along with ingredients used in their preparation. The present review covers more or less all aspects associated with lozenges and also throws light on the applications of lozenges. It includes various researches performed till date, formulation and evaluation parameters, packaging and applications of lozenges.

Keywords : Lozenge, medicament, Troches, sore throat , cough relief etc.

1. Introduction :

In Lancaster(England)UK 1842 James loft house was born. He openshis pharmacy in Fleetwood on the Flyte coast in 1865 During that time Fleetwood growing fishingportand & homeoftheNorth Atlanticfishing trawlers team with fishermen suffering from various bronchial queries. [Seizing the opportunity, James Make a formulation of anextra strong bronchial mixture containing menthol, eucalyptus oil and capsicum liquorice are designedto be dropped on the sugarcubes and sucked it.]Unfortunately, glass bottles were not the good containersfor thecustomers, who complained thatthe glass bottlebroke in rough seasareaConsequently, he again makes themixtureinto a solid form like a lozenge consisting thesame ingredients dispersed in a sugar and gum base cubes massed with water, which was then rolled, cut into shapes and dried into hot air oven.[Such the popularity of this formulation that give fishermen constantly came into his pharmacy requesting a bag of fisherman's lozenges' –hence the origin of the famous brand name 'Fisherman's Friend' came into the world. henceit is called as fisherman Friends.][(4)]

The word "Lozenge" is derived from French word "Losenge" which means a diamond shaped geometry having four equal sides. Lozenges and pastilles have been developed since 20th century in pharmacy and is still under commercial production. Lozenges are solid preparations that are intended to dissolve in mouth or pharynx. They may contain one or more medicaments in a flavored and sweetened base and are intended to treat local irritation, infection of mouth or pharynx and may also be used for systemic drug absorption.[(1)] They can be made using mouldingor compression techniques, with mouldedpastilles being one type and troches being compacted lozenges . Lozenge is a solid preparation consisting of sugar and gum, the latter giving strength and cohesiveness to the lozenge and facilitating slow release of the medicament..Dispersible tablet conveyance framework ischaracterized by quick deterioration, speedy dissolving, fast delivery and improved patient compliance. Trouble in gulping (dysphagia) is a typical issue of all age gatherings, particularly the old and pediatrics, due to physiological changes.[(2)] Today lozenges contain different category of medicament as follows: analgesics, anesthetics, antimicrobials, antiseptics, antitussives, astringents, decongestants, demulcents and other classes and combinations of drugs .[(3)]

1.1 Advantages : -

- ★ Easy to administer to geriatric and paediatricpopulation.
- ★ It can Increase the bioavailability
- ★ It may giveto those patientswho have difficulty in swallowing
- ★ It can be prepared with less equipment or Machinery
- ★ Taste of the drugs can be masked by sweetenersand flavours used in the formulation.
- ★ Less production .
- ★ It can increment in bioavailability.
- ★ It can decrease dosing recurrence.
- ★ No disintegration.
- ★ Do not require water forintake.
- ★ Less production time.
- ★ Less production cost.
- ★ Lozenge can be withdrawn if dose is not

1.2 Disadvantages : -

- Some drugs may not be suitable with aldehyde candy bases eg; benzocaine.
- Children having above 6 years of age can use lozenges safely.
- Possible draining of drug from oral cavity to stomach along with saliva.
- The lozenge dosage form is that it mistakenly could be used as candy by children.
- A hard candy lozenge is the high temperature required for their preparation.
- According to the site of action (a) Local effect Ex. Antiseptics[5]

2. Classification :-

2.1 According to the site of action:

(a) Local effect Ex. Germicides, Decongestants.

(b) Systemic impact Ex. Nutrients, Nicotine.

2.2 According to texture and composition:

(a) Chewy or caramel based medicated lozenges

(b) Compressed tablet lozenges

(c) Soft lozenges

(d) Hard sweets lozenges

2.1.1 Chewy or caramel based medicateds lozenges:

These are the dose structure in which medicament is fused into a caramel base which is bitten as opposed to being broken down in mouth. These tablets are regularly exceptionally natural product seasoned and may have a somewhat acidic taste to cover the harsh taste of the glycerin. These tablets are particularly utilized for pediatric patients

extremely viable methods for directing prescriptions for gastrointestinal ingestion and fundamental use. One of the more famous lozenges for pediatric use is the chewable lozenge, or "sticky sort" candylozenges. These gelatin-based pastilles were set up by emptying the dissolve into molds or out onto a sheet of uniform thickness[6,7]

2.1.2 Compressed tablet Lozenges

When the active ingredient is heat sensitive, it may be prepared by compression. The granulation method is similar to that used for any compressed tablet. These tablets differ from conventional tablets in terms of

- Organoleptic property
- Non disintegrating characteristics
- Slower dissolution profiles

The lozenge is made using heavy compression equipment to give a tablethat is hard than usual, as it is desirable for the troche to dissolve slowly in mouthCommercially, the preparation oflozenges by tablet compression is less important.[8]

2.1.3 Soft lozenges

In this soft Lozenges formulation polythene glycol,chocolate or sugar acacia base are used as base, they give soft texture to the lozenges.In this soft Lozenges formulation the Silica Gel and Acacia are used.Acacia is used to provide texture and smoothness. The suspending agents silica gel are used to avoid settling material to the bottom during cooling process. In this Soft lozenges hand rolled method is used to formulate to get desired size and thickness.

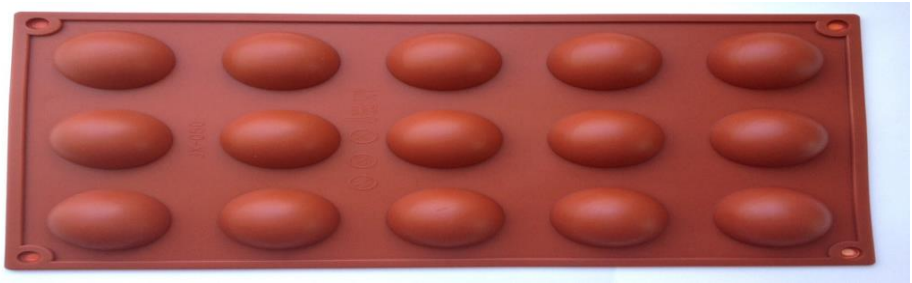
About 50°C heat is required to formulate and hence is only suitable for heat resistance substances. The main disadvantages of these method is that the temperature required for their preparation is high hence heat labile material cannot be prepared.[9,10]

2.1.4 Hard sweet lozenges:

Hard sweet lozenges are in glass state , it is mixture of sugar and carbohydrate. They can be also referred as solid syrups. 0.5 to 1.5% moisture content is necessary to hard sweet lozenges. Weight of hard sweet lozenges about 1.5 to 4.5g Temperature requirement for their preparation is usually high and hence heat labile material cannot be use in their preparation. Sucrose, dextrose maltose and lactose are used as sweetening agents.

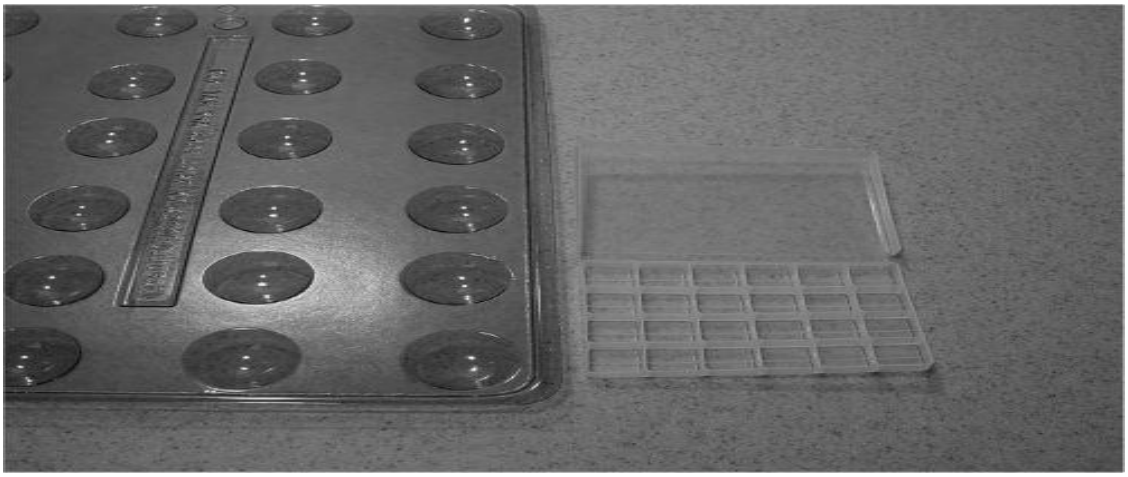
Commonly used acids are citric acid, tartaric acid, fumaric acid , malic acid. The undergo slow and uniform dissolution over 5 to 10 min. The corn syrup is also included in hard sweet lozenges .[11,12,13]

3.Different Shapes of lozenges : -



Dome shape Mould

Sqaure shape Mould



Circle shape Mould

4.Formulation of Lozenges : -

Ingrediant	Example
a] Sugar b] Sugar free vehicle c] Filers	Dextrose, Sucrose, Maltose, Lactose. Mannitol, Sorbitol, Poly Ethylene Glycol (PEG) 600 and 800.Di calcium phosphate, Calcium sulfate, Calciumcarbonate, Lactose, Microcrystalline cellulose.
Bindaers	Acacia, Corn syrup, Sugar syrup, Gelatin, Polyvinyl pyrrolidone,Tragacanth and Methylcellulose.
Lubricants	Magnesium stearate, Calcium stearate, Stearic acidand PEG, Vegetable oils and Fats.
Whiping agent	Milk protein, Egg albumin, Gelatin, Xanthan gum,Starch, Pectin, Algin and Carrageenan.
Cloring agent	Water soluble and Lakolene dyes, FD & C colors, Orange color paste, Red color cubes, etc.
Flavoring agent	Menthol, Eucalyptus oil, Spearmint, Cherry flavor,
Humactent	Glycerin, Propylene Glycol and Sorbitol.
Presevative	Methyl paraben, Propyl paraben.

Table 1. Excipient used

Salt	Butterscotch, Maple, Nutty, Buttery
Bitter	Spice Wild Cherry, Licorice, Chocolate Mint, Grapefruit, Coffee, Cherry, Peach,
Acrid	Raspberry, Orange, Lemon, Lime
Sour	Raspberry, Fruits, Berries, Acacia
Oily	Syrup
Sweet	Peppermint, Anise, Wintergreen
Acrid	Fruit, Berry, Vanilla

Table 2. Flavouring agent(14)

4.1 Sugar :

Sucrose, a disaccharide of glucose andfructose, is gotten fromsugarcane or beet. Thedecision of beet or natural sweetener depends onaccessibility and geological contemplations.Sucrose and sucrose items are utilized in curedcapsules in view of their significance as unbiasedsugars, their dissolvability properties, and theircapacity as a "drier" to lessen the mass of the sweetthrough crystallization.

4.2 Corn syrup:

Corn syrup is utilized ineach sortof dessert to control sucrose and dextrosecrystallization, which mayprompt disintegrating.Corn syrup insuitable proportion with sucrose anddextrose permits the arrangement of a formlessglass and builds up a candywith the alluringappearance. The accompanying actual properties ofcorn syrup are critical in the arrangement ofmedicated candies: thickness, density, dextroseequivalent, hygroscopicity, sugar crystallization,consistency, edge of freezing point depression, andosmotic pressure. Sucrosecrystallization isexperienced in different food and drug applications.In sucrosecrystallization,dispersion of the sucrosefrom the mass answer forprecious stone surfaceand combination of the sucroseatom into the gridstructure are the average rate-restrictingsteps.Numerouselements can influence the developmentrate, including temperature, supersaturation, disturbance ,and pollutants.

4.3 Binders:

Binders are generally used forcompressed tablet that are intended to hold the particles of mass as discrete granules which includeacacia, corn syrup, sugar syrup, gelatin polyvinylpyrrolidone, tragacanth and methylcellulose, HPMC, etc.

4.4 Lubricants:

Lubricants are used to avoidsticking of candy to the teeth and improve flow of final troche mixture and include magnesiumstearate, calcium stearate, stearic acid and PEG, etc.

4.5 Coloring agents:

Coloring agents areincorporated into medicated lozenges for productidentification, good appearance and masking ofphysical degradation. Colorants are mainly used toimpart a distinctive appearance to thepharmaceutical dosage forms.Dyes and otherorganic colorants may degrade by heat or light viaoxidation, hydrolysis, photo oxidation, etc. andtheir compatibility with drug, excipients, andprocess conditions should be studied beforeselection.

4.6 Flavoring agents:

Flavor refers to a mixedsensation of taste, touch, smell, sight and sound.Flavors are composed of different organicchemicals, such ashydrocarbons, alcohols,aldehydes, ketones, acids, esters or lactones. Thelow volatility and lowmolecular weight, usually lower than 400 Daltons, are responsible for a rangeof sensorial sensations attributed to the flavors.

4.7 Preservatives:

Since hard candy lozenges are hygroscopic, thewater content may increase and bacterial growthmay occur if they are not properly packed. Thepresence of water would dissolve some sucrose; theresulting highly concentrated sucrose solution isbacteriostatic in nature and would not support bacterial growth .[15]

5. Methods of preparation

5.1 Candy Based Lozenges

5.1.1 Heating and Congealing Technique

Syrupy base was prepared in a beaker by dissolving the required amounts of sugar in water and kept for heating on a hot plate.Temperature was maintained at 105-110 °C till it became thick. The drug and other excipients (except plasticizer) were added manually and mixed thoroughly after 30 min with continue process of heating. The prepared mass was further heated for 45 min and then plasticizer was added into it. Then above syrupy base was poured into pre-cooled and prelubricated mold and the mold was kept aside for 10-15 min. Lozenges were removed from mold and were kept for air drying. In the case of batches without plasticizer, a step ofplasticizer addition was omitted from procedure.[16]

5.1.2 Melting and Mold Technique

PEG was melted on water bath and mixed with the other ingredients to form a homogeneous mixture. Subsequently, the mixture was poured into the desired shape & size stainless steel mold to forming a candy.[17,18]

5.2 Compressed Tablet lozenges

Method 1: Wet Granulation*

1. Weigh and mix API, base, binding agents, and fillers.
2. Add solvent (water or alcohol) to create a damp mass.
3. Granulate the mixture.
4. Dry the granules.
5. Mix with lubricants.
6. Compress into lozenges.

Method 2: Dry Granulation

1. Weigh and mix API, base, binding agents, and fillers.
2. Granulate the mixture using a slugging or roller compaction process.
3. Mix with lubricants.
4. Compress into lozenges.

Method 3: Extrusion

1. Weigh and mix API, base, binding agents, and fillers.
2. Add solvent (water or alcohol) to create a damp mass.
3. Extrude the mixture through a die.
4. Cut into lozenges.
5. Dry the lozenges.[19]

6. Evaluation of Medicated Lozenges

The prepared lozenges were evaluated for parameters like drug content uniformity, hardness, thickness and diameter, weight variation, friability and in vitro dissolution test, drug content, moisture content analysis and stability studies by

6.1 pharmaceutical standard methods.

6.1.1 Diameter

The thickness and diameter of lozenges were determined using vernier callipers. Three lozenges from each batch were used and average values were calculated. The extent to which the diameter of the lozenges deviated from ± 5 % of the standard value.

6.1.2 Weight variation:

The weight variation was conducted by weighing 20 lozenges individually and calculating the average weight and comparing the individual lozenges weight to the average value.

Weight Variation = Average Weight- Initial Weight/ Average Weight

6.1.3 Hardness:

The hardness of the lozenges was determined by using Monsanto Hardness tester, where the force required to break the lozenges wasnoted. The hardness was measured in terms of (kg/cm2).

6.1.4 Moisture content analysis:

Moisture content in the final candy is determined by using Helium moisture balance apparatus.

6.1.5 In-vitro drug dissolution studies:

The rate of dissolution possibly is related to the efficacy of the tablet lozenge. Dissolution study was carried out in 800 ml of phosphate buffer of pH 6.8 by USP II paddle method at 150 rpm. Samples were withdrawn at 5 min interval and replaced immediately with an equal volume of fresh buffer and were analyzed UV spectrophotometer.

6.1.6 Stability studies:

The stability studies were performed to assess physical as well as the chemical stability of the drug, which may possibly affect the organoleptic properties of the lozenges. Accelerated stability study was conducted as per ICH guidelines (zone IV) at 45°C and 75% relative humidity over a period of seven weeks. Sufficient number of optimized formulations were packed in amber coloured screw capped bottles and kept in incubator maintained at 37°C. Samples were taken at intervals of 15 days to estimate the drug content and to evaluate organoleptic properties.

6.1.7 Storage :-

These preparations should be stored away from heat and out of the reach of children. They should be protected from extremes of humidity.Depending on the storage requirement of both the drug and base,either room temperature or refrigerated temperature is usually indicated.

6.1.8 Packaging :-

Hard candies are hygroscopic and usually prone to absorption
of atmospheric moisture. Considerations must include the hygroscopic nature of the candy base, storage conditions of the lozenges, length of time they are stored and the potential for drug interactions. These products should be stored in tight containers to prevent drying. This is especially true of the chewable lozenges that may dry out excessively and become difficult to chew. If a disposable mold with a cardboard sleeve is used, it is best to slip this unit into a properly labelled,
sealable plastic bag.[20,21,22]

6.1.9 Microbial Test for Lozenges:

Microbial test for lozenges is performed to check the presence of any bacterial, [Mold or spore contamination in raw materials, cooling tunnels, finished products, machinery, environmental conditions and storage drums. Laboratory microbial testing should include the various counts such as total plate, total coliform, yeast and Mold, E. coli, Staphylococcus and Salmonella][27]

7. Applications : -

Lozenges are employed for the treatment of local as well as systemic disorders. [A variety of drug candidates can be incorporated in them for the treatment of and relief from conditions of oral as well as throat infections such as oral thrush, sore throat, cough, gingivitis, pharyngitis, decongestant, etc.]16 Moreover, these also have been used to deliver the drug systemically for smoking cessation and pain relief.[23]

8. Discussion / Conclusion : -

The formulation of lozenges is an easy and time saving process. It is a formulationwhich is more organoleptically accepted particularly by the pediatrics patients.MedicatedLozenges will be ideal dosage forms for pediatric patients. These will have additional advantages of patient compliance, convenience and comfortness for efficient treatment including low dose, immediate onset of action, reduced dosage regimenand economic. This will offer better innovative dosage form. Lozenges enjoy an important position in pharmacy and will continue to remain at the same in future.[24,25,26] Lozenges are medicated confections that have been developed about 20th century ago and are still under commercial production. Most of the preparations are available over the canter products and are very economic dosage forms. They are designed for local as well as systemic therapy. A wide range of actives can be incorporated within their structure. Lozenges enjoy an important position in pharmacy and will continue to remain so in future.

9. References :

1. Pothu, R. and Yamsani, M.R., 2014. Lozenges formulation and evaluation: A review. Ijapr, 1, pp.290-294

2. Mishra, K.K., Tasneem, K., Jain, V. and Mahajan, S.C., 2017.Formulation and evaluation of herbal lozenges. Journal of Drug Delivery and Therapeutics, 7(7), pp.87-90

3.Choursiya, S. and Andheriya, D., 2018. Review on lozenges.Journal of Drug Delivery and Therapeutics, 8(6-A), pp.124-128.

4. Kadirvel, V., Vasuki, M.T., Narayana, G.P. and Kulathooran, R., 2022. Formulation and evaluation of medicated lozenges using traditional herbs to treats to throat infection. Journal of Food Processing and Preservation,46(10), p.e16903.

5. Khaladkar, A.S., Avalaskar, A., Bharati, P. & Honkalas,K.,2019. Formulation and evaluation of Adhulsa lozengesforpediatric patients. Journal of Drug Delivery and Therapeutics, 9(2-s), pp.115-117.7.

6. Loyd. V. Ansel Pharmaceutical Dosage forms &Drugdelivery System. Chewable Lozenge. 8thedition. NewDelhi (India) Pvt.Ltd. 2007;246

7.Aulton E. M. Aulton pharmaceutics. Compressed lozenges. 3rdedition.Elsevier. 2007; 457.

8. Rachana Maheshwari, Vikas Jain. A review on Lozenges . BBB.2013. [1] [1], 035-043

9. Madhusudan Rao Yamsani*, Shravan kumar Y, Sandeep P, Naresh Naomula, formulation nd evaluation of Lidocaine lozenges, International Journal of Innovative Research In Science, Engineering And Technology, 2015; IV: 11640-11646.

10.K Purushotham Rao, Girish Katti, Ajay Kartik, P Manjunath, design of medicated Lozenges for paediatrics, International journal of research in medical and health sciences, 2013; II: 14-22.

11.Vidyadhara, S., Sasidhar, R.L.C., Lakshmi, B.S., Lal, M. and Nithin, P., 2021. Formulation and evaluation of amoxicillin trihydrate oral lozenges for treating upper respiratory tract infections.Current Trends in Biotechnology and Pharmacy,15(1), pp.62-69.

12. Bhandarkar, A., Alexander, A., Bhatt, A., Sahu, P., Agrawal, P., Banjare, T., Gupta, S., Sahu, H., Diwedi, S.D., Sahu, S.K. and Yadav, P., 2018. Formulation and Evaluation of Ascorbic acid Lozenges for the treatment of Oral Ulcer.Research Journal of Pharmacy and and Technology, 11(4), pp.1307-1312.

13.Esimone, C.O., Okoye, F.B.C., Odimegwu, D.C., Nworu, C.S., Oleghe, P.O. and Ejogha, P.W., 2010. In vitro antimicrobial evaluation of lozenges containing extract of garlic and ginger.International Journal of Health Research,3(2), pp.105-110.

14 .Abhijeet Sunil kukde, Varsha M.A REVIEW STUDY ON -MEDICATED LOZENGES AS AN EFFECTIVE DOSAGE FORM.WJPPS. April 2020.Vol9, Issue 5,669-682.

15. StephenO.Majekodunmi.AREVIEW ON LOZENGES. AJMMS.2015.5(2):99-104.

16. Modyala D., Srinivas P. Formulation, Evaluation and Characterization of Itraconazole Lozenges. International Science and Research Journal of Pharmceutical, Bioscience. 2014; 9(3):86-94.

17.Phaechamud T and Tuntarawongsa S. Clotrimazole Soft Lozenges Fabricated with Melting and Mold Technique. Research Journal of Pharmceutical, Bioscience. & Chemical. Science. 2010; 1(4):579- 587.

18. Patel M. Dasharath, Patel J. Rahul, Shah R.M., Patel N. Chhagan. Formulation and Evaluation of Diphenhydramine hydrochloride Lozenges for Treatment of Cough. World. Journal of Pharmaceutical Science. 2014; 3(5):822-835.

19.Shinde G., Kadam V., Kapse G.R., Jadhav S.B., Zameeruddin Md., Bharkad B.A:Review on lozenges. "Indo American Journal of Pharmaceutical Research. 2014; 4(1):566-571.

20. Kini R., Rathnanand M., Kamath D. Investigating the Suitability of Isomalt and liquid glucose as sugar substitute in the formulation of Salbutamol Sulfate hard candy lozenges. Journal of Chemical and Pharmaceutical Research. 2011; 3(4):69-75.

21.Nagoba S.N. Studies on candy Ketoconazole based Paedriatic tablet lozenges. International Journal of Research in Ayurveda & pharmaceutics. 2011; 2(1):239 243.

22. Rao K., Reddy V., N. Nagoba Shivappa, Ayshiya S., Zakaullah, Saran S V. Medicated lollipops for the treatment of Oral thrush in children."International Journal of Life Science & Pharmceutics. Research. 2012; 1(1):95 -102

23. Gopale, O., Jethawa, S. and Shelke, S., 2022. Medicated lozenges: a review.Asian Journal of Pharmaceutical Research and Development,10(2), pp.129-134.

24..Maheshwari R., Jain V., Ansari R., Mahajan S.C., joshi G. A Review on lozenges. British Biomedical Bulletin. 2013; 1(1): 35-43.

25. Pothu R., Rao Y. Lozenges Formulation and Evaluation. International Journal of Advances in Pharmaceutics. Research.2014; 5(5):290 – 298.

26. Kaur R., Kaur S. Role of polymers in drug delivery. Journal of Drug Delivery and Therapeutics, 2014; 4(3):32-36. https://doi.org/10.22270/jddt.v4i3.826

27. Vidyadhara, S., Sasidhar, R.L.C., Lakshmi, B.S., Lal, M. and Nithin, P., 2021. Formulation and evaluation of amoxicillin trihydrate oral lozenges for treating upper respiratory tract infections.Current Trends in Biotechnology and Pharmacy,15(1), pp.62-69.