IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

A Review: Formulation And Evaluation Of Lozenges.

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ABSTRACT :

Lozenges are solid unit dosage form that contain one or more medicaments containing sweetners excipients and bindersMost common and easy way of administration of drug is orally administered Lozenges are one of the widely used dosage forms. The benefits of the medicated lozenges are they increase the retention time of the dosage form in oral cavity which increases bioavailability, reduces gastric irritation and possess first pass metabolism. Lozenges provide a palatable means of dosage form position of Lozenge in pharmaceutical market owned to its several advantages but it causes some disadvantages too. This dosage form can be applied for local as well as systemic use and a wide range of active ingredient can be incorporated in them. The medicaments which they can be formulated as lozenges include local anatectic, antihistamines, antitussive, antiseptics.

Keywords : Lozenge, Troches, Pastilles, Moldings

INTRODUCTION:

A lozenge is a solid medication that includes a drug and a flavouring agent. Lozenges are solid dosage forms that are intended to be dissolved or disintegrated slowly in the mouth.[They contain one or more active ingredients and are flavoured and sweetened so as to be pleasant tasting. The term "lozenge" originates from the French word for a four-sided diamond shape.][1] They can be made using moulding or compression techniques, with moulded pastilles being one type and troches being compacted lozenges. It is generally used for their topical effect, but may also have ingredients that produce a systemic effect. 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. [They are appropriate for any patient, whatever the age is. Oral

dosage forms have disadvantages as well.][2]They are not the first choice of drugs if the patient suffers chronic vomiting. They are not good choice in case of uncooperative patients as children and infants. [They are not suitable in emergency and for unconscious patients. They are not convenient for a patient with a gastrointestinal disorder such as diarrhoea, constipation, ulceration, hyperacidity in stomach.][1]

[The duration of the lozenge's effect can vary, depending on the individual, but it can last up to 30 minutes.][3] After controlling the rate of dissolution and absorption, the patients can regulate the amount of medication delivered during each time they use a lozenge. Sucking on the lozenge and increased saliva production can lead to dilution and swallowing of the medication. [Lozenges may contain a number of drugs such as analgesics, sedatives, antihistamines, aromatics, astringents, corticosteroids, anaesthetics, antimicrobials, antiseptics, antitussives, decongestants, and demulcents, among others, depending on the specific needs of the patients.][4]

History:

In Lancaster (England) UK 1842 James loft house was born. he opens his pharmacy in Fleetwood on the Flyte coast in 1865 During that time Fleetwood growing fishing port and home of the North Atlantic fishing trawlers team with fishermen suffering from various bronchial queries. [Seizing the opportunity, James Make a formulation of an extra strong bronchial mixture containing menthol, eucalyptus oil and capsicum liquorice are designed to be dropped on the sugar cubes and sucked it.][5] Unfortunately, glass bottles were not the good containers for the customers, who complained that the glass bottle broke in rough seas area Consequently, he again makes the mixture into a solid form like a lozenge consisting the same 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. hence it is called as fisherman Friends.][3]

Advantages:

- Easy to administer to geriatric and paediatric population.
- It can Increase the bioavailability
- It Reduced the dosing frequency
- It may give to those patients who have difficulty in swallowing
- It can be prepared with less equipment or Machinery
- Taste of the drugs can be masked by sweeteners and flavours used in the formulation.
- Lozenge can be withdrawn if dose is not needed
- Less production times
- Less production cost

Disadvantages:

- hard candy lozenge is the high temperature required for their preparation.
- Hard lozenges become grainy
- Some of the drug may not be suitable with aldehyde candy bases e.g., Benzocaine.
- non ubiquitous distribution of drug within saliva for local therapy
- Possibility of draining of drug from oral cavity to stomach along with saliva.
- Lozenges can be use mistakenly by small children's

Classification of lozenges:

- According to the site of action:
  (a) Local effect Ex. Germicides, Decongestants.
  (b) Systemic impact Ex. Nutrients, Nicotine.
- According to texture and composition:
  (a) Chewy or caramel based medicated lozenges
  (b) Compressed tablet lozenges
  (c) Soft lozenges
  (d) Hard sweets lozenges.

(a) Chewy or caramel based medicated lozenges

Chewy or caramel based medicated lozenges are the dosage form in which medicament is dipped into a caramel base which is chewed instead of being dissolved in mouth. [Most of the formulations are based on the glycerinated gelatine suppository formula which consists of glycerine water and Gelatine. These lozenges are often highly fruit flavoured and may have a slightly acidic taste to cover the taste of the glycerine Its constituent ingredients are the candy base, whipping agent, humectants, lubricants, flavour and of course medicaments incorporated into the lozenges.][6] These lozenges are Mostly used for paediatric patients and are a very effective means of administering medications for gastrointestinal absorption and systemic use. One of the more popular lozenges for paediatric use is the chewable lozenge, or "gummy-type" candy lozenge. These gelatine-based pastilles were prepared by pouring the melt into Molds or out onto a sheet of uniform thickness.

Fig No .01

Manufacturing of Chewy or Caramel Based Medicated Lozenges

[The candy base is cooked at 95-125℃ and transferred to planetary or sigma blade mixer. Mass is allowed to cool to 120℃. This is followed by the addition of whipping agent below 105℃.][7] The medicaments are then added between 95-105℃. Colour is dispersed in humectant and added to the above mass at a temperature above 90℃. [Seeding crystals and flavour are then added below 85 ℃ followed by lubricant addition above 80℃. Candies are then formed by rope forming method.][5]

b) 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 tablet that is harder than usual, as it is desirable for the troche to dissolve slowly in mouth.][8] They are usually flat faced with sizes, weight, hardness, and erosion time ranging between, 5/8-3/4-inch, 1.5-4 g, 30-50 kg inch2 and 5-10 min, respectively

Fig No.02

Manufacturing of Compressed Tablet Lozenges:

Manufacturing of the compressed tablet lozenges can either be direct compression and wet granulation method. In direct compression, ingredients are thoroughly mixed and then it gets compressed.[In wet granulation, sugar content is pulverized by mechanical comminution to a fine powder with (40-80 mesh size). Medicament is added and thoroughly blended.][9] The blended mass is subjected to the granulation with sugar or corn syrup and screened through (2-8 mesh size) screen. [This is followed by drying and milling to 10-30 mesh size. Flavour and lubricant are then added prior to compression.][6]

(c) Soft Lozenges

Soft lozenges have become most popular because of the ease of extemporaneous preparation and applicability to a wide variety of drugs range [They are either meant for chewing or for slow drug release in mouth. It can be can be made from PEG 1000 and PEG 1450, chocolate or sugar-acacia base while some soft candy formulations can also contain acacia and silica gel.][10] Acacia is mostly used to provide texture and smoothness. silica gel is used as a suspending agent to avoid settling of materials to the bottom of the Mold cavity during the cooling of the mould. [formulation requires heating process at about 50°C The improvement in their current use is largely due to the use of polymers (polyethylene glycols) as the matrix for the dosage form.][8] They are easy to use, convenient to carry, easy to store (room temperature), and are generally pleasant tasting. [Polyethylene glycol-based lozenges may have a tendency to be hygroscopic and may soften if exposed to high temperatures.][11]

Fig No.03

Manufacturing of Soft Lozenges:

On the basis of the soft texture of these lozenges, they can be hand rolled and then cut into pieces the warm mass can be poured into a plastic Mold. Mold cavity should be overfilled if PEG is used, and PEG's gets contract as become cool. This is not required in case of chocolate as it does not shrink. [Tuntarawongsa and Phaechamud formulated clotrimazole soft lozenges by moulding method and evaluated the factors that affect the physical properties of lozenge.][12] They found increasing amounts of PEG 1500 and xanthan gum or xylitol increased the hardness of the lozenge. [And also, the disintegration time was found to be increased on increasing number of actives and hardness.][9]

(d) Hard Candy Lozenges:

Hard candy lozenge are combinations of sugar and different starches in an amorphous (nanocrystalline) or smooth state. [The moisture content and weight of hard candy lozenge should be between, 0.5 to 1.5% and 1.5-4.5g respectively the temperature requirements for their preparation are usually high hence heat labile materials cannot be incorporated in them. The ingredients for hard candy lozenges include body agent or base which is corn syrup that is available on Baume basis.][13] A 43° Baume corn syrup is preferred in hard candy lozenges. Sweetening agents such as sucrose, dextrose, maltose and lactose are added. [Acidulants are added to candy base to strengthening the flavour characteristics of the finished product.][3] Commonly used acids are citric, tartaric, fumaric and malic acid. Colours include FD & C colours, orange colour paste, red colour cubes etc while flavours used include menthol, eucalyptus oil, spearmint, cherry flavour etc.[Medicaments up to 2-4% can be incorporated in the hard candy lozenges. Salvage solution can be liquid or solid][14]

Fig No.04

Manufacturing of Hard Candy Lozenges:

[The candy base is cooked by dissolving desired quantity of sugar in one third amount of water in a candy base cooker. This is continued till the temperature rises to 110℃.][7]Corn syrup is added and cooked till the temperature reaches 145-156℃. candy mass is removed from the cooker and transfer to a lubricated container mounted onto a weight checking scale where the weight of the mass is checked and followed by colour or addition in form of solutions, pastes and colour cubes. [The mass is transferred to a water-jacketed stainless steel cooling table for mixing and the flavour, drug and ground salvage is added.][2] The mass is either poured in Mold or pulled into a ribbon while cooling and then cut to desired length. The obtained lozenges are packaged.[Cocaine voice tablet lozenges and pastilles were developed in late 1800's and were indicated in Extra Pharmacopoeia, 1888.][15]They were used by singers and public speakers for the remedy of vocal huskiness and hoarseness.

Raw Material use for making lozenges

1. Sucrose
2. Invert sugar
3. Corn syrup
4. Is malt
5. Colorants
6. dyes and other colorants
7. acidulants
8. flavours
9. salvage

Formulation of lozenges:

SR. NO	INGREDIENTS	EXAMPLE	ROLE
1	Sugar free vehicles	Dextrose, sucrose, maltose, lactose. Mannitol, sorbitol, PEG 600 & 800.	These are the used as sweetening agent and impart the taste masking properties.
2	Lubricants	Magnesium stearate, calcium stearate, stearic acid and PEG, vegetable oils and fats.	These are the used to avoid sticking of candy to the teeth
3	Fillers	Di calcium phosphate, calcium sulphate, calcium carbonate, lactose, microcrystalline cellulose	These are the used to Improve the flowability
4	Binders	Acacia, corn syrup, sugar syrup, polyvinylpyrrolidone, gelatine, tragacanth, and methylcellulose	These are the used to hold the particles
5	Colouring agents	Water soluble and lanoline dyes, FD & C colours, orange colour paste, red colour cubes, etc.	These are the used to enhance appearance and organoleptic properties of dosage form
6	Flavourings agent	Menthol, eucalyptus oil, spearmint, cherry flavour, etc	These are the used to give a taste
7	Humectants	Glycerine, propylene glycol and sorbitol	They improve chew mouthfeel properties
8	Whipping agent	Milk protein, egg albumin, gelatine, xanthan gum, starch, pectin, algin and carrageenan	These are the used in toffee-based confection.
9	Salt	Butterscotch, maple, nutty,	Saltnes in the taste

Sugar:

As it with beets provide sugar, but it which is which consists of carbohydrate with ethanol. [Beet or natural sweetener selection is based in physical considerations as convenience. Because glycol but glycol products

function for balanced role of neutral sweeteners, they dissolve easily, while they may work like a "drier" in decreasing the mass of the sweet by formation of crystals, they serve a purpose within sealed shells.][5]

Lubricants:

[Lubricants are used to avoid sticking of candy to the teeth and improve flow of final troche mixture and include magnesium stearate, calcium stearate, stearic acid and PEG, etc.][16]

Binders:

[Binders are generally used for compressed tablet that are intended to hold the particles of mass as discrete granules which include acacia, corn syrup, sugar syrup, gelatine, polyvinylpyrrolidone, tragacanth and methylcellulose, HPMC, etc.][16]

Corn syrup:

Corn syrup is used in almost every type of confection to control sucrose and dextrose crystallization, which may lead to crumbling. [Corn syrup in appropriate proportion with sucrose and dextrose allows the formation of an amorphous glass and produces a candy with the desirable appearance.][1] The following physical properties of corn syrup are extremely important in the preparation of medicated candies: density, dextrose equivalent, hygroscopicity, sugar crystallization, viscosity, freezing point depression, and osmotic pressure

Flavouring agents:

Flavors used in medicated lozenges must be compatible with the drug and excipients and capable of withstanding the rigors of the manufacturing conditions. [Flavors consist of numerous chemicals that may interact with excipients or. Aldehydes, ketones, and esters may react with drugs.][17]A classic example of flavour–drug interaction is that of a primary amine drug (benzocaine, phenylpropanolamine) with aldehyde containing flavour components like cherry, banana, etc., resulting in the formation of a Schiff base, drug decomposition, and loss of efficacy. [Adjustment of lozenge base pH to accentuate certain Flavors (e.g., citrus) may also result in incompatibility with some medicaments][8]

Colouring agents:

Prescribed sachets contain coloration additives to help with recognizing the goods, aesthetics, with bodily concealment. [Their major objective of additives is giving prescription pill tablets a unique look. When making a decision-making, that ought carefully to research the compatible nature of blues as well as other natural hues using drugs, preservatives, as well as manufacturing parameters because they might breakdown under sunlight or warmth through oxidation, hydrolysis, photo oxidation, etc various actions. procedures.][10]

Acidulants:

Acidulants are generally added to medicated lozenges to fortify and strengthen their flavour profile. Organic acids such as citric, malic, fumaric, and tartaric acids are most commonly used. Citric acid alone or in combination with tartaric acid is the most common. Another use of acids in medicated lozenges is to alter the pH to maintain the integrity of the drug.

Preservatives:

Since hard candy lozenges are hygroscopic, the water content may increase and bacterial growth may occur if they are not properly packed. The presence of water would dissolve some sucrose; the resulting highly concentrated sucrose solution is bacteriostatic in nature and would not support bacterial growth

Different shapes of moulds:

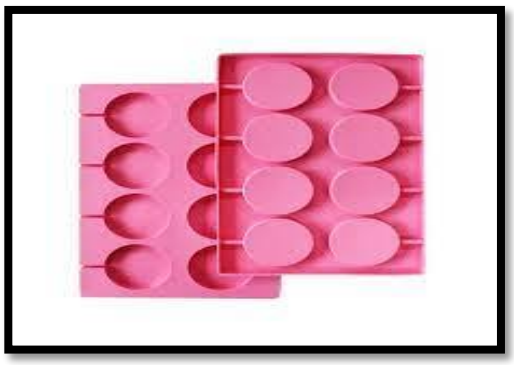

Fig No.05 Circle mould

Fig no.06 Square mould

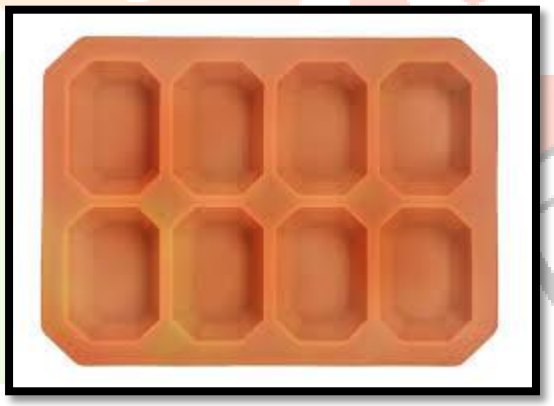

Fig No.07 Octagonal mould

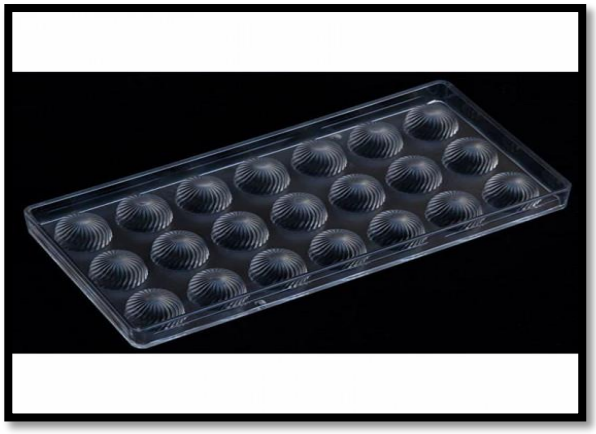

Fig No.08 Dome shaped mould

Evaluation and quality control of lozenges:

Physical and chemical testing:

Hardness:

Hardness of the lozenges is determined by Pfizer or Monsanto hardness tester. [The resistance of lozenges to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness][6].

Weight variation:

Twenty lozenges were randomly selected and individually weighed using an electronic balance. [The average weight and standard deviation of 20 tablets was calculated or initial weight is compared with the calculated average weight.][17]

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]

Friability:

Fryolator is used for the determination of friability of lozenges. Apparatus is rotated at 25 rpm for 4min. [Initial weights of lozenges are taken and they are placed in fryolator. After the revolution the lozenges were de-dusted and weighed again. The observed value not be more than 1%. Friability is calculated by following formula % friability = (1- Wt. / W) × 100 Where, W= Initial weight of lozenges Wt.= Weight of lozenges after revolution][16]

Disintegration:

USP Disintegration apparatus is used to determine the disintegration time of lozenges. [Disintegration time is noted in pH 6.8 phosphate buffer or artificial saliva at 37ºC.In- vitro drug dissolution study. Rate of drug absorption is determined by the rate of drug dissolution of the lozenges. Rate of dissolution and bioavailability is directly related to efficacy of lozenges.][15] This study is carried out by using USP II Dissolution type apparatus (paddle type). Dissolution study was carried out in 900 ml of buffer pH 6.4 or use artificial saliva by USP II paddle method at 100 rpm.[Samples were withdrawn at 5 min time interval and replaced immediately with an equal volume of fresh buffer or artificial saliva and were analysed spectrophotometrically. Temperature 37OC ± 2OC maintain between dissolution studies.][9]

Moisture content analysis:

Moisture content in the final candy is determined by using Helium moisture balance apparatus. [The sample was weighed and crushed in a mortar from this one gram of the sample was weighed and the moisture content is determined by the moisture balance apparatus.][18]

Mouth dissolving time test:

[The time taken by the candy to dissolve completely was determined by the USP Disintegration apparatus, where hard boiled candy lozenges were placed in each tube of the apparatus and time taken for the lozenges to dissolve completely was noted by using phosphate buffer of pH 6.8 at 37 ◦ C.][4]

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][13]. Stability Testing Stability testing of lozenges is carried out under following conditions:

- →1-2months at 60℃
- → 3-6months at 45℃
- →9-12months at 37℃
- → 36-60months at 25 and 40℃

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 analysed UV spectrophotometer.][15]

Drug content:

Drug content is done by taking an appropriate number of lozenges being crushed and dissolved in a suitable solvent and the absorbance of the solution is measured spectrophotometrically. [As the candy base manufacture is commenced, a check on following parameters is performed: Corn syrup and sugar delivery gears; temperature, steam pressure and cooking speed of precoders and temperature, steam pressure, cooking speed and vacuum of candy base cookers][11]

Stability Testing:

Lozenges are subjected to stability testing under following conditions: 2 months at 60℃, 3-6months at 45℃, 9-12 months at 37℃, 36-60 months at 25℃ [1]. [Lozenges in their final packs are subjected to the following conditions for stability testing: 25℃ at 80% relative humidity (RH) for 6-12 months, 37℃ at 80% RH for 3 months, 25℃ at 70% RH for 6-12 months][16]

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][17].

Packaging:

Hard candies are hygroscopic and frequently 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.][10][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.][18] If a disposable Mold with a cardboard sleeve is used, it is best to slip this unit into a properly labelled, sealable plastic bag. Packaging should be proper and attractive or colourful.

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.

Discussion:

The formulation of lozenges is an easy and time saving process. It is a formulation which is more organoleptically accepted particularly by the paediatrics patients. Medicated Lozenges will be ideal dosage forms for paediatric patients. These will have additional advantages of patient compliance, convenience and comfortless for efficient treatment including low dose, immediate onset of action, reduced dosage regimen and 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.

CONCLUSION:

Drugs are chewed over a butterscotch core that produces chewy even marshmallow-like medicinal dressings, versus dissolving by spit. Most these mixtures rely from the instructions using glycerinated agar tablet, which requires lactic solvent with proteins. Many pills are fairly fruity, while several might look a little vinegary for covering up the graininess of the material. The ingredients that comprise what is being sold include the fragrance, moisturizers, grease, foundational sugar, or, of course, the medicines combined inside the vials. Dimethicone pills are generally utilized for babies and kids enabling provide a reasonable method of administering medications for belly absorption and worldwide distribution. One of an the most popular types of medications to feed administering to babies is the consumable variety.

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