JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue
JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)
An International Scholarly Open Access, Peer-reviewed, Refereed Journal

REVIEW ARTICLE ON LOZENGES

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ABSTRACT

Lozenges are one of the very popular and better innovative dosage form and oral confectionary products. Lozenges have been used since 20th century and are still in commercial production. Lozenges have bright future as a novel method of delivering drugs for local action and systemic effect in the oral cavity. The "lozenges are solid medicated, flavoured and sweetened base dosage forms intended to be sucked and hold in the mouth/ pharynx". 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 bypasses first pass metabolism. The acceptance for lozenges as a dosage form is high by adults and also more by children. Different types of lozenges available in market are compressed lozenges, hard lozenges & soft lozenges and their methods of preparation along with ingredients used in their preparation are discussed. 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, Troches, Pastilles, Molding

INTRODUCTION

Lozenges slowly release the drug into buccal cavity for the purpose of yielding the required quantity of drug. Multiple number of drugs or ingredients can be incorporate into lozenges. These are OTC as well as prescription drug which totally depending on its content, it maximizes the local activity of drug and its absorption too, widely they are used for treating the various conditions concerning to the mouth, tongue, throat[20].Lozenges are forms of solid medicinal dosage forms intended to dissolve in the mouth or pharynx[25]. The intraoral route can bethe administration route which is the most favored one, owing to easeof use and quick action. Intraoral dosage types have developed as an alternative to conventional tablets or capsulesamong other liquid formulations. Many intraoral dosage forms areintended to disintegrate, dissolve, or release the drugin oral cavity, allowing local absorption, either partially or fully, and they may, too, be swallowed for*subsequent absorption in the gastrointestinal tract (GIT). TheIts origin of the "Lozenge" is "French Lozenge";which denotes a diamond-shaped four-sided geometric figure. Lozenges and pastilles have been produced in pharmacies since the twentieth century and continue to beare likely to be produced commercially. Lozenges are defined asinclude one or more active ingredients[22].

DEFINITION

"Lozenges are solid dosage form containing the flavourings and sweetening agents that are intended to dissolve or disintegrate slowly in the mouth or oral cavity"[17]. They are most often used for localized effect into oral cavity and can also show systemic effect if it is well absorbed in the buccal lining and pharynx.

TYPES OF LOZENGES

Medicated lozenges.

Non-medicated lozenges.

Classification of lozenges:

I. According to its site of action:

a. Local Effect-

examples: Antiseptics, Decongestant.

b. Systemic Effect-

examples: Vitamins, Nicotine.

II. According to its texture and composition:

a. Chewable-

examples: Vitamins.

b. Hard-

examples: Lollipops.

c. Soft-

examples: Bentalis

d. Compressed-

examples: Troches.

A. chewable lozenges:

The medicaments in chewable lozenges are incorporated into caramel base, hence instead of dissolving it into mouth it is chewed. These lozenges are prepared or formulated by using Glycerin, Gelatin, and Water. They are highly flavourized by fruits[2].

B. hard lozenges:

These types of lozenges are the mixture of sugar and carbohydrates. They are in non-crystalline forms usually in amorphous or glassy state. They are also called as "syrups of sugar[17].

C. Soft lozenges:

Soft lozenges are meant for slow release of drug into mouth, and are prepared by using ingredients like PEG (polyethylene glycol), chocolate base[1]. Some of soft lozenges contain silica gel also in its base acacia. The hero ingredient into these lozenges to achieve the smoothness and texture.

D. Compressed lozenges:

This are heat liable ingredients and heat sensitive ingredients are not possible to formulate by procedure same as that of soft lozenges, hard lozenges. Simply the compression method is applicable for such type of ingredients, same as like compressed tablet[2]. The only difference between them is non-disintegrating and slower dissolution profile. The granulation method is used in compressed lozenges.

METHODOLOGY

a) Chewable or caramel based medicated lozenges

b) Compressed tablet lozenges

c) soft lozenges

d) Hard Candy Based Lozenges

e) Centre filled hard lozenges

a) Chewable or caramel-based medicated lozenges: - Chewable lozenges have turned out to be successful, especially in the paediatric population, owing to their gummy form.

Manufacturing process: - The candy base is cooked and the cooking is done at a temp. of 95 - 125oC. The cooked candy is then transferred to a sigma blade mixer[10]. The mass is then cooled and cooled till 120oC. The next ingredient is whipped mass, and it is cooled till below 105oC. The medicants can be incorporated when temp. is between 95 - 105oC. The colour can be dispersed in humectants and should be added when temp. is below 85oC. The next ingredient is lubricants, and it can be added when temp. is above 80oC[11]. The chewable lozenges can be made by making them in the form of a thick and desired thickness of rope and then cutting them and packing them in wrappers. This is known as a rope formation process.

b) Compressed tablet lozenges: -

i) Direct compression: - In this method all the ingredients are carefully mixed and directly compressed in to lozenges tablets, Wet granulation method involves grinding of sugar by mechanical agitation and passed through sieve 40-80 mesh size, Medicament is added to sugar mass and then mixed uniformly[2]. Sufficient amount of sugar syrup is added to evenly mixed mass for the granulation and then passed through sieve 2-8 mesh size to obtain wet granules. These wet granules are dried and once again passed through sieve no 10-30 mesh size. Suitable flavour and lubricant are added to granules before compression into required size of tablet lozenges. Sugar is pulverized by mechanical agitator to a fine powder and passed through sieve 40-80 mesh size. Add the medicament and blend the mass. Blend is subjected to granulation with sugar syrup and separated through sieve no 2-8. Drying and milling is carried out and passed through sieve 10-30 mesh size. Flavour and lubricant are added to the mass and compression is carried out[23].

c) soft lozenges: - Soft lozenges may be prepared by the process of hand rolled and then cut into pieces based on their size and thickness. The second process involves the heating of all the ingredients with the medicament at an average temperature of 50oC and then poured into plastic Molds. It should be overfilled with the ingredients if polyethylene glycol is to be used since it contracts as it cools. Soft lozenges with Clotrimazole as an active ingredient may be prepared by the process of moulding with an increasing amount of polyethylene glycol, xanthan gum, or xylitol as an active component of lozenges that enhances hardness in lozenges while carefully observing the amount of active component added to increase the hardness as well as the rate of disintegration[10].

d) Hard Candy Based Lozenges: - i) Heating and Congealing Technique: - Syrup base was prepared in a beaker by dissolving the required amounts of sugar in water and kept for heating on a hot plate and the Temperature was maintained at 105-110 °C till it became thick, later. The drug and other excipients (except plasticizer) were added manually and mixed thoroughly after 30 min with continuous heating. The prepared mass was further heated for 45 min and then plasticizer was added into it. Then above syrup base was poured into pre-cooled and pre lubricated Mold and the Mold was kept aside for 10-15 min[2]. Lozenges were removed from Mold and were kept for air drying. In the case of batches without plasticizer, a step of plasticizer addition was omitted from procedure.

ii) 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[13].

e) Center filled hard lozenges: - Center filled hard lozenges are manufactured by forming a candy base or vehicle comprising sugar, corn syrup, and water, the candy base or the vehicle was heated to remove water there from to obtain a cooked candy base having a residual moisture content ranging from about 0.02% to about 5.0%. Then, subsequent cooling the candy base or vehicle to a soft state and forming the candy base in to a rope. The rope is wrapped around afilling pipe and the powder and semi-liquid centre film was prepared

containing, medicament in a stabilizing base including vegetable oil, and optionally sugar or gelatine, the semi-liquid or the powder center filler was dispensed into the center of the candy base or vehicle in a ratio of about 2 to 50% by weight of the medicament[20].

Components of Lozenges: -

1. Sugar: - Sucrose is a disaccharide composed of glucose and fructose and is obtained from either sugarcane or sugar beet. The selection of cane or beet sugar depends largely on availability and geographical factors. Sucrose and sucrose-based products are widely used in medicated lozenges because they act as neutral sweeteners, dissolve readily, and function as drying agents by promoting crystallization, which helps reduce the overall weight of the confection[10].

2. Corn syrup: - Corn syrup is used in nearly all types of confectionery to control the crystallization of sucrose and dextrose, which can otherwise result in crumbling. When combined with sucrose and dextrose in appropriate proportions, corn syrup promotes the formation of an amorphous glass, producing candies with a desirable appearance and texture[17]. The following physical properties of corn syrup are particularly important in the preparation of medicated candies: density, dextrose equivalent, hygroscopicity, tendency toward sugar crystallization, viscosity, freezing point depression, and osmotic pressure.

3. Sugar bases: - Sugar bases commonly linked with the use of the above-mentioned lozenge tablets include the use of compressed sugar, which includes those of the above compositions along with an assortment of excipient sources. They find widespread use as a directcompression material. Even the use of the above binders in wet granulation techniques is possible. A non-nutritive sweetener is an artificial or natural sugar substitute whose sweetness is greater than or equal to that of sugar[10]. Non-nutritive sweeteners – xylitol, mannitol, sorbitol, invert sugar.

4. Binders: - These are generally intended for compressed tablet that are used to hold the mass as isolate granules and include acacia, corn syrup, sugar syrup, gelatin, polyvinyl-pyrrolidone, tragacanth and methylcellulose[17].

5. Lubricants: - they 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[17].

6. Colorants. Colorants are incorporated into medicated lozenges for appearance, product identification, and masking of physical degradation. Dyes and other organic colorants may degrade by heat or light via oxidation, hydrolysis, photo oxidation, etc and their compatibility with drug, excipients, and process conditions should be studied before selection[22]. Suppliers of colours are excellent sources of information on current regulatory status of colorants.

7. Acidulants: - Acidulants are generally added to medicated lozenges to strengthen the flavour profile. Organic acids such as citric, malic, fumaric and tartaric acids are most commonly used[10]. 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.

8. Preservatives: -These are solid dosage forms; there usually is no need to incorporate preservatives. However, since hard candy lozenges are hygroscopic, the water content may increase and bacterial growth may occur if they are not packaged properly. Since the water that is present would dissolve some sucrose, the resulting highly concentrated sucrose solution is bacteriostatic in nature and would not support bacterial growth[23]. A few comments are in order concerning the flavors and effects of preservatives.

9. Flavours: -As far as hard lozenges are concerned, the major focus is on the gradual, uniform release of the medicine, directly onto an affected mucous membrane[17]. This is yet another problem to be solved by the compounding pharmacist—how best to blend a mixture of flavors that adequately conceals unpleasant principles that are caused by the medicine, as well as maintaining a smooth surface texture to a hard lozenge that is disintegrated by the gradual dissolve effect. In a situation where medicine is odourless, taste is no problem. In a situation where a medicine must be made, special effort must be made to eliminate taste, to increase patient compliance. Flavour is a very complex phenomenon, being composed of components that are

combinations of taste, touch, olfaction, eye, and ear sensations[10]. The first, taste, is composed of four specific tastes—sweet, bitter, sour, and salty.

EVALUATION OF LOZENGES

1. Diameter and thickness**:** For the lozenges to be uniform in size, their diameter is crucial. Vernier Calliper's can be used to measure the diameter[2]. The degree of deviation of the lozenge's diameter is from ± 5% of the reference value.

2. Hardness: It was determined by using tablet hardness tester. The test was performed by using three lozenges and standard deviation was calculated. [2]The hardness of lozenges can be measured by using Monsanto hardness tester. The hardness was measured in terms of kg/cm2.

3. Weight Variation: The USP weight variation test is done by weighing 20 lozenges individually, calculate the average weight and compare the individual weights with the average weight[5].

4. Drug excipients interaction studies: Analysed by FTIR. Fourier Transform Infrared (FTIR) Spectroscopy is generally known for being an "instantaneous," non-invasive form of analysis that detects the presence of different compounds by seeing how the compounds take infrared light. By "seeing the fingerprint," FTIR can both identify and quantify compounds by detecting the various types of vibrating molecules within the composition[5].

5. Friability: Determined by using Friabilator operated at 25rpm for 4min[11].

6. Moisture content: By Gravimetric method, one gram of sample is weighed and placed in desiccators for 24 hours[16].

Moisture Content = Initial weight - final weight

7. Drug content: In a 50ml volumetric flask, the lozenge is crushed to a powder, dissolved in 5ml of a good solvent, and then the solution is diluted to 50ml with 6.8 pH phosphate buffer. In a 50ml volumetric flask, 1ml of the solution is prepared, a quantity of 6.8pH phosphate buffer is added to the solution, sonicating for 30 minutes, and then filtered through the filter papers, absorbance of the solution is determined by using spectrophotometry.

8. In vitro mouth Dissolving Time: The mouth-dissolving time of each of the batch formulations was determined by using a USP Disintegration apparatus. In this apparatus, one lozenge was placed in each of its tubes. The time taken for lozenges to dissolve completely was then determined. The lozenge's dissolving time was determined using 100ml of pH 6.8 phosphate buffer at 37°C[2]. The processes were done three times. The average dissolving time for the Lozenges was calculated and shown together with the standard deviation.

9. In-vitro drug release: This is carried out using USP II paddle type dissolution apparatus.USP Apparatus II It is the same as the standard dissolution test equipment. It uses a rotating paddle to test the drug product. Solid dosage forms are placed at the bottom of the vessel filled with the medium. A rotating paddle travels at a fixed speed to produce fluid flow. USP states the paddle should be placed 25 ± 2 mm above the bottom surface[23]. Volume: 500 to 1000 mL. Most frequently: 900 mL. Example: water, 0.1N HCl, phosphate buffer. Must be deaerated. Temperature: 37 ± 0.5 degrees C. Typical RPM: 50 RPM or 75 RPM.

10. In vitro buoyancy studies: The rate at which the drug dissolved from the lozenges was considered to determine the rate of drug absorption[20]. Therefore, the effectiveness of the lozenges could be directly related to the rate of dissolution and bioavailability. The pH 6.8 phosphate buffer dissolution media, 100 ml, was added into the beaker containing the lozenges and stirred at 100 rpm using the magnetic stirrers. Every 5-minute interval, a 5ml aliquot sample was withdrawn and immediately replaced with an equivalent amount of fresh new fluid, simulating saliva[1]. Each diluted aliquot was analysed by UV visible spectrophotometer.

CONCLUSION

Lozenges have been seen as an important drug dosage form in the drug industry that has gained popularity through their easy administration, pleasurable taste, and ability to use drugs therapeutically in the treatment of

human ailments. The prolonged time of contact of the drug with the tissues in the mouth helps in enhancing therapeutic efficacy in disease states such as sore throats, mouth ulcers, etc. The drug formulation has been seen as having total patient acceptance, especially in paediatrics, as lozenges can easily be consumed by those who often complain of difficulty in swallowing the common drug dosage forms that have been in use in modern drug therapeutics. The drug formulation has been seen as having significant potential in modern drug therapeutics following the introduction of drug innovations concerning lozenges. The drug formulation has become significant in modern therapeutics based on current research findings in pharmaceutical science that focus on the production of new lozenge drug combinations that have been seen as useful in therapeutic management in modern drug therapeutics. Based on current research findings, the drug formulation is seen to be significant in modern drug therapeutics; thus, lozenge drug formulation is expected to be very useful in future therapeutics.

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