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Formulation and Evaluation of Albendazole Medicated Lollipop for the Pediatric Use

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Abstract
This research focuses on the formulation and development of a medicated lollipop containing Albendazole, a broad-spectrum anthelmintic widely used for the treatment of helminth infections. Such infections are a prevalent health concern, particularly among school-aged children. Conventional oral dosage forms like tablets, capsules, and syrups often pose challenges for pediatric, geriatric, and bedridden patients due to difficulties in swallowing and the unpleasant taste of the medication. In response to this, novel drug delivery systems are gaining attention for improving patient compliance.
Medicated lollipops offer an alternative dosage form that allows the drug to be held in the oral cavity, thus enhancing retention time and masking the bitter taste. In this study, lollipops were formulated using the heating and congealing method, incorporating Methylcellulose as the polymer matrix. The compatibility between the drug and excipients was assessed using Fourier Transform Infrared Spectroscopy (FTIR). All prepared formulations underwent various physicochemical evaluations, including tests for weight variation, hardness, drug content uniformity, and friability, to ensure quality and consistency.

CHAPTER 1. INTRODUCTION

1. INTRODUCTION

1.1 DRUG: A drug is a chemical substance, typically of known structure, used to treat, cure, prevent, or diagnose a disease or promote wellbeing when administered to living organism.

1.2 MEDICATED LOLLIPOP:

- A medicated lollipop is a lollipop that contains medication, allowing the medicine to be absorbed through the mouth as you suck on it. It's often used for treating sore throat or for patient who have trouble swallowing pills.
- The oral route of medication administration is most often utilized since it is inexpensive, simple to administer, patient complies and offers formulation Versatility. However, patients who are bedridden, elderly or pediatric exhibit trouble swallowing traditional tablets or capsules because they are trouble in swallowing smaller amount of water with the medication they cannot stand the taste of many medications wean they are made in liquid dosage forms, and they have poor patient

complaints.

- Lozenges, sometimes known as lollipops are flavored medicinal dose form that are meant to be sucked and retained in the mouth or pharynx. The typically Include one or more medications in a sweetened foundation/ base. Lollipops are frequently utilize to achieve systemic or local effects via the buccal mucosa. The lollipop has serveral benefits as a dosage form such as increased bioavailability, smaller doses, less stomach discomfort and bypassing the first metabolism.
- The purpose of lollipop is the enhance patient transportation, acceptability and compliance. More patients complaince dose formulation have been in greater demand over the last 20 years. Because of this the demand for their technology has been increasing yearly since designing a new chemical entity is very expensive, pharmaceutical companies are now focusing on creating novel drug delivery method for their current drugs that have better bioavailability and efficacy as well as lower dosages frequency to reduce adverse effect medicated lollipop are hard dosage forms that contains one or more types of drugs in a flavored and coloured sugary base like all lollipops, these are designed to dissolve slowly in the patient's mouth and release their content which may act locally to reduce their content which may act locally to reduce oropharyngeal symptoms or the absorbed through the buccal route and act systematically. Medicated lollipop can contain a veriety of medication such as antibiotics, antitussive and antialgesics for a medication like paracetamol, these kind of formulation help to increase its bioavailability and prevents first pass metabolism.
- Increase patient compliance particularly in children, suitability for patients who have swallowing difficulties reduce production time and expense and dosage reduction are other benefits of this dosage form.

Fig 1: Medicated lollipop

1.3 HISTORY:

The idea of a sweet treat on a stick is a simple one, and it's likely that the lollipop has been invented and reinvented many times throughout history. Early forms of the lollipop, resembling what we know today, can be traced back to the Middle Ages, when the nobility would often enjoy sugar boiled onto sticks or handles. The term "lollipop" itself was first recorded by the English lexicographer Francis Grose in 1796. It is thought that the word might have come from the combination of "lolly" (meaning tongue) and "pop" (a sound similar to a slap). References to the modern-day lollipop can be found in the 1920s, marking the treat's more recognizable form.

Medicated lollipops are confectionery products infused with medicinal compounds, designed to dissolve slowly in the mouth, thereby delivering therapeutic effects through the oral mucosa. This unique dosage form enhances patient compliance, especially among pediatric and geriatric populations who may have difficulty swallowing traditional tablets or capsules.

The concept of combining candy with medicinal properties dates back to ancient civilizations. Archaeological evidence suggests that ancient Chinese, Arabs, and Egyptians produced fruit and nut confections candied in honey, which served as a preservative, and inserted sticks into them for easier consumption.

The evolution of medicated lollipops as a distinct pharmaceutical dosage form is more recent. These lollipops are formulated to improve patient compliance and increase oral retention time, making them particularly beneficial for pediatric patients who may find it challenging to swallow pills or capsules.

1.4 TYPES OF MEDICATED LOLLIPOPS :

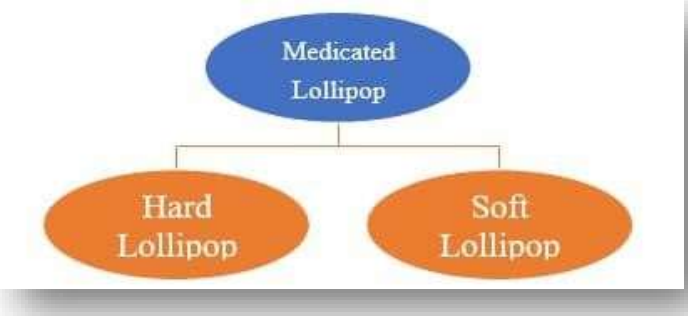


Fig 2: Types of medicated lollipop

A.SOFT LOLLIPOP

B.HARD LOLLIPOP

A.SOFT LOLLIPOP:

Soft lollipop became well known due to their flexibility in providing a variety of medicinal purpose and their simplicity of importance radiance. A variety of PEGS, acacia, or similar substance such glycenol gelatin or an accacia; sucrose base are frequently used as the base.

Depending on how the integrated medications works such lollipops can be coloured, flavored and chewed or slowly dissolved in the mouth.

Fig 3: Soft medicated lollipop

B.HARD LOLLIPOP:

Sugar and other substance are heated together before being poured into mold. Hard candy and hard lollipops are comparable. Actually a lot of the formulations of hard lollipops arevariations of hard candy formulations.There must be the little moisture in the dosing form. Therefore the compound procedure involves heating the sugar mixture to the evaporate the water.

Other carbohydrate combined in an amorphous or glossy state makeup hard candy lollipop. These

lollipop typically contain between 0.5% and 1.5% moisture and can be regarded considered as solid sugar syrup.

There should not be disintegrate but rather dissolve or Erode gradually and uniformly over the period of 5 to 10 minutes. Heart labile material cannot be included in them because of the typically high temperature required for their preparation.

Fig 4: Hard medicated lollipop

1.5 EXCIPIENTS OF MEDICATED LOLLIPOP:

SUGAR: A sugarcane or beet derivative is sucrose, glucose, and fructose disaccharide. The selection of beet or cane sugar is based on availability and geographic factors. Because of their usefulness as neutral sweeteners, their quick solubility, and their ability to act as a "drier" to reduce the confection's load through crystallization, sucrose and its derivatives are used in medicinal lozenges.

CORN SYRUP: Corn syrup is used to control the crystallization of sucrose and dextrose, which can cause crumbling in nearly all confections. When corn syrup is combined with sucrose and dextrose in the right amounts, an amorphous glass is formed, giving the candy the ideal look. The subsequent physical .Density, dextrose equivalent, hygroscopicity, sugar crystallization, viscosity, melting point depression, and pressure are all crucial characteristics of syrup while making medicated candies.

SUGAR BASES: Several excipient manufacturers provide a range of tableting grades for sucrose or compressible sugar, dextrose, mannitol, and sorbitol, which are common sugar bases used in lozengetablets. Although they may be utilized in wet granulation, they are typically designed for applications that call for direct compaction. systems using the binders mentioned above. A natural or synthetic sugar replacement with a sweetness level higher than or comparable to sucrose might be considered a nonnutritive sweetener. Nonnutritive sweeteners include things like invert sugar, xylitol, mannitol, and sorbitol.

BINDER: Acacia, corn syrup, sugar syrup, gelatin, polyvinylpyrrolidone, methylcellulose, and tragacanth are examples of binder materials that are frequently used for compressed tablets that are employed as distinct granules to preserve particles of mass.

LUBRICANTS: Stearate of calcium, stearate of magnesium, stearic acid, and PEG are among the lubricants that are used to improve the flow of the final troche mixture and keep the candy from adhering to the teeth.

COLORANTS: Colorants are added to medicinal lozenges for attractiveness, product identification, and to cover up physical degradation. Because dyes and other organic colorants can oxidize, hydrolyze, photooxidize, and undergo other degradations when exposed to heat or light, their compatibility with medications, Before using, excipients and process conditions should be examined.

ACIDULANTS: Medicated lozenges frequently utilize acidulants to strengthen and improve their flavor character. The organic acids that are most frequently utilized include tartaric, fumaric, malic, and citric acids. The most often used is citric acid, either by itself or in conjunction with hydroxy acid. Medicated lozenges' pH is frequently altered with acids to maintain The legitimacy of the substance.

PRESERVATIVES: Preservatives are usually not required because these dose forms are solid. But because hard candy lozenges are hygroscopic, improper packing may result in larger particles and the development of germs. Because some sugar may dissolve in the current water, the resultant extremely concentrated .A bacteriostatic solution of sucrose will prevent the growth of bacteria. We should talk a little bit about the effects and flavors of preservatives.

FLAVORS: Medicated lozenges' flavors need to be acceptable under production conditions and compatible with the drug and excipients. Many compounds that make up flavors can interact with excipients or pharmaceuticals, and they break down when exposed to heat or light. Drugs can react with ketones, esters, and aldehydes. When aldehyde-containing flavorings like cherry, banana, etc. are combined with primary amine drugs (benzocaine, phenylpropanolamine), a Schiff base is formed, the medication decomposes, and its effectiveness is reduced. This is a typical example of a flavor-drug interaction. The pH of the lozenge base may be changed to highlight specific tastes (like citrus) at the expense of some medications (like benzocaine) .

TABLE 1: TYPES OF EXCIPIENT USE IN MEDICATED LOLLIPOP AND THEIR ROLE:

Sr.no	Ingredients	Example	Role/Function
1	Candy-based, sugar-free vehicles	Ingredients include maltitol, dextrose, sucrose, maltose, lactose, mannitol, sorbitol, and PEG- 600/800.	They are used to make desserts and to mask desserts.
2	Lubricants	Vegetable oils and fats such As PEG, calcium, magnesium, and stearic acid.	These are used to prevent sugar from remaining on your teeth
3	Binders	corn syrup, sugar syrup, gelatine, methylcellulose, tragacanth and polyvinylpyrrolidone.	These are used as holders for objects.
4	Humectants	Trimethylopropylene glycol, sorbitol, and glycerine.	They enhance the digestive tract.
5	Whipping- agent	Egg, albumin, milk protein, gelatine, xanthan gum, starch, pectin, algin, and carrageenan.	They are utilised in candy confections.
6	Flavourings; agent	Ingredients include menthol, eucalyptus oil, spearmint, cherry taste, among others.	You are meant to taste these.
7	Colouring- agent	Orange coloured pastered colour cubes, FD and colourants, water soluble and lakolene dyes, etc.	They would produce stunning beauty. paper dosage's sensory characteristics.

1.6 METHOD OF PREPARATION:

The process of heating and congealing involves:

1. Preparing the syrup base by dissolving the necessary amount of sugar by heating it to 110 °C.
2. Adding the base syrup by increasing the temperature to 160 °C.
3. Cooling to produce the plastic mass.
4. Adding the drug, polymer, color, and flavor while mixing.
5. Roping the materials in a moving roller after they have dried.
6. Wrapping them in polyethylene wraps and wrapping them.

To calculate the weight of the lozenge using the specific base of interest, molds used to produce lozenges and troche must be calibrated.

The following is one way to do this.

1. Get the lozenge mold ready and make sure the cavities are dry and clean.
2. Get enough lozenge foundation and melt it to fill six to twelve molds.
3. Fill the molds, let them cool, then trim them if needed.
4. Weigh the lozenges after removing them.
5. To find the average weight of each lozenge for this kind of specific base, divide the total weight by the quantity of blank lozenges made.

1.7 ADVANTAGES OF MEDICINAL LOLLIPOP :

1. Having a formulation that can be patiently specific and easily modified.
2. Patient with spelling difficulties can be given a lollipop.
3. It requires less time and equipment to prepare.
4. Do not need water intake in order to administer parenteral is a non invisive technique.
5. It prolongs the duration of drug presence in oral cavity to produce Pacific result.
6. It has pleasant test and prolong the amount of time at drug remains in the oral cavity to provide the healing effect, Additional pharmacist may spontaneously manufacture lollipop with little equipment and time.

1.8 DISADVANTAGES OF MEDICATED LOLLIPOP:

1. Medication with low level of bitterness is suitable.
2. It is appropriate to use heat stable medication.
3. Due to high temperature needed for preparation Heat labile medication cannot be utilised in this formulation.

1.9 EVALUATION PARAMETERS:

1. DISINTEGRATION TEST:

Disintegration is the process where tablets break down into small particles in a liquid medium.

2. HARDNESS:

Hardness is a material's resistance to permanent deformation or indentation.

Fig 5: Monsanto hardness tester

3. FRIABILITY TEST:

A friability test measures how much a tablet breaks or crumbles when subjected to mechanical stress

%Friability = Initial weight –final weight x 100 Initial weight

Fig 6: Roche friabilator

4. WEIGHT VARIATION:

The weight variation statistical quality control test is used to confirm uniformity of the dosage unit and therefore also to support product safety, identity and quality.

% weight variation = Average weight –individual weightx 10

Average weight

CHAPTER: 2. LITERATURE REVIEW

2. LITERATURE REVIEW :

1. J.HORTON ET.AL.,(2000):

The history, pharmacology, effectiveness, and safety of the anthelminthic medication albendazole in humans are covered in this review. For a number of illnesses, including as hookworm, Ascaris lumbricoides, Trichuris trichiura, and Enterobius vermicularis, it displays cure and egg reduction rates. With more than 100 million patient exposures over a 20-year span, the medication has an impressive safety record. Very few adverse effects have been documented in the literature; only gastrointestinal side effects exist, and they only happen "1%." Because of its broad-spectrum action, albendazole has enhanced child growth and general population health, including nutrition.

2. PURUSHOTHAM RAO K ET.AL.,(2012):

This research explores the development of medicated lollipops containing Ketoconazole for treating oral thrush caused by Candida albicans. The study highlights the advantages of lozenges, such as increased bioavailability, reduced gastric irritation, and bypassing first-pass metabolism. Using a sucrose base, the lollipops were prepared using a heating and congealing method and evaluated for physical properties like hardness, content uniformity, and weight variation. The formulations showed good stability over six months and effective drug release, with formulation K0 releasing 99.43% of the drug in just 7 minutes. Antimicrobial studies confirmed the effectiveness of the lollipops against the target pathogens, and preclinical trials on healthy volunteers ensured their safety. Overall, the research offers a promising alternative for treating oral thrush in pediatric patients, combining ease of use with rapid drug absorption and minimal side effects.

3. LAURA MARTINEZ-MARCOS ET.AL.,(2012):

This research explores the use of hot-melt extrusion (HME) to improve the dissolution properties of albendazole (ABZ), a poorly soluble drug, by creating amorphous solid dispersions with polyvinylpyrrolidone (PVP K12). Formulations with ABZ content of 1%, 5%, and 10% w/w were prepared, and several analytical techniques were employed to assess the results. Scanning Electron Microscopy (SEM) provided insights into the morphology, Micro-computed Tomography (μ-CT) visualized the internal structure, X-Ray Powder Diffraction (XRPD) confirmed the amorphous nature of the drug, and Differential Scanning Calorimetry (DSC) assessed thermal properties. The dissolution profiles showed that HME significantly improved the dissolution rate of ABZ. This study demonstrates the potential of HME in enhancing the bioavailability of poorly soluble drugs.

4. JAYALAKSHMI KAMATH ET.AL.,(2012):

The research paper explores the development of medicated lollipops containing Levamisole, a synthetic drug used to treat helminthiasis, particularly in pediatric patients. Helminthiasis, prevalent in developing countries, leads to conditions like undernourishment, anemia, eosinophilia, and pneumonia, which is why effective treatment is crucial. The study addresses the challenge of making bitter-tasting drugs palatable for children through taste masking techniques. In this case, the medicated lollipops were formulated using various polymers such as Sodium carboxymethyl cellulose, Methyl cellulose, and Hydroxypropyl methyl cellulose, with some formulations having no hydrocolloids. The researchers used the heating and congealing technique for the preparation of the lollipops. Among the different formulations, the lollipop with Methyl cellulose showed the best drug release properties and stability, making it a promising option for improving the oral administration of Levamisole in pediatric care. This study highlights an innovative approach to improving drug delivery in children, especially in regions with high rates of parasitic infections.

5. KALPESH PATI ET.AL.,(2017):

This research focuses on the development of medicated lollipops as an effective dosage form for both local and systemic effects. The study highlights advantages such as increased retention time in the oral cavity, improved bioavailability, and reduced gastric irritation by bypassing first-pass metabolism. Fexofenadine HCl, a bitter antihistamine, is used in the formulation, with saccharides like sucrose and dextrose added to improve taste and patient acceptability. Methylcellulose and citric acid are used as polymers, and plasticizers like glycerin enhance texture and stability. The results show that formulations containing methylcellulose and a combination of saccharides provide better drug release and stability. This research offers valuable insights into the design of patient-friendly, effective oral dosage forms.

6. ONYEKA IFEANYI PETER.,(2017):

This study focuses on developing Albendazole microcapsules for colonic drug delivery to overcome its poor solubility and extensive metabolism in the intestine and liver. Six batches of microcapsules were prepared using polymers like Eudragit RS-100, chitosan, and HPMC via the solvent evaporation method. The formulations were evaluated for drug content, incorporation efficiency, and dissolution profile.The results showed that all batches had high drug content, with batch MC6 achieving the highest incorporation efficiency (96.48%). The maximum drug release was also observed in batch MC6 (90.18%), indicating its potential for sustained colonic delivery. In conclusion, Albendazole microcapsules show promise as a safe and effective system for sustained drug delivery, potentially enhancing the therapeutic efficacy of Albendazole.

7. PERUMALLA JAGADEESH ET.AL.,(2017):

Flavored dosage forms for local or systemic effects, medicated lollipops have benefits such a higher onset of action, decreased gastrointestinal discomfort, bypassing the first pass metabolism, and enhanced bioavailability. Commonly utilized for elderly, pediatric, and bedridden patients, these preparations have the potential to be very successful commercially for the drug business, patients, and doctors.

8. HATEM A. HEJAZ ET.AL.,(2020):

The study aims to improve the administration of paracetamol for pediatric, geriatric, and bedridden patients by developing sugar-based medicated lollipops. The researchers use sucrose and corn syrup to enhance the acceptability and ease of use for patients with dysphagia. The lollipop formulations are designed to be pleasant for patients, avoid risks like choking, and bypass first-pass metabolism, leading to improved bioavailability and therapeutic outcomes. The study conducted physicochemical tests to ensure the quality of the lollipops, confirming their stability and effectiveness. The study presents paracetamol medicated lollipops as a promising solution for improving drug delivery and patient compliance, particularly in pediatric and geriatric populations.

9. ASHWINI S. PUNDKAR ET.AL.,(2024):

The research explores the development of a medicinal lollipop for pediatric patients, addressing the limitations of traditional dosage forms like tablets and syrups, which can be inconvenient for children. The lollipop, formulated with a polyherbal blend of Sitaphal powder, bamboo, pepper, cardamom, and cinnamon, is designed for children with coughs, particularly those caused by bronchial infections. Notably, honey is used as a base instead of sugar syrup, making it suitable for diabetic children.The study evaluates the lollipop's quality using parameters such as hardness, friability, weight variation, and moisture content, all of which meet the required standards. This innovative formulation offers a promising, palatable alternative for pediatric medication delivery, especially for diabetic children, and could inspire further development of child-friendly pharmaceutical products.

10. SHASHANK LAVKUSH SHUKLA ET.AL.,(2024):

Lollipops as a drug delivery system offer a unique way to administer medications, particularly for local effects in the mouth or throat. By using a sucrose base, these lollipops provide several advantages, including enhanced bioavailability, reduced dosage, and avoidance of the first-pass metabolism. This can improve patient compliance, especially in pediatric populations. The physical properties of the lollipops, such as thickness (12-13.2 mm) and hardness (10-11.5 kg/cm^2), are essential for ensuring proper drug release. In vitro studies show that formulations like L3, L6, and L10 release the drug efficiently within 30 minutes, with L3 being the most effective. Stability tests over 90 days indicate no

significant changes, further supporting the potential of lollipops as a reliable drug delivery method. Overall, this approach appears promising for treatments like mucolytic therapy in children.

CHAPTER:3 NEED OF STUDY

3. 1 NEED OF STUDY:

3.1.1 Prevalence of Helminth Infection :

Highlight the widespread issue of helminth infection of particularly in children and their impact on health such as malnutrition and anemia

3.1.2 Challenges of conventional dosage form :

Discuss the limitations of traditional albendazole formulations like tablets and syrups, including their bitter taste and difficulty in administration, especially for pediatric and geriatric patients.

3.1.3 Advantages of medicated lollipop :

Explain how medicated lollipop can improve patient compliance by offering a palatable and easy to administer alternative. emphasize their potential to increase oral retention time ,which may enhance drug absorption .

3.1.4 Research Gap :

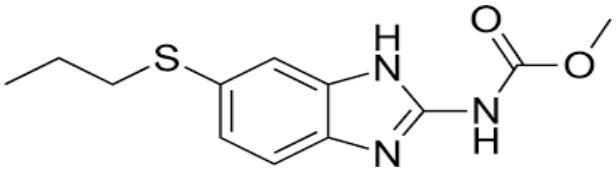
Point out the lack of sufficient studies on medicated lollipops as a drug delivery system for albendazol. Highlight the need for the innovative approaches to improve treatment outcome for helminthiasis.

3.1.5. Objectives of study :

Conclude by stating the purpose of research, which is to design and evaluate medicated lollipop containing albendazol to inhance patient compliance and therapeutic efficacy.

CHAPTER: 4. DRUG PROFILE

4.1 DRUG PROFILE:

NAME	ALBENDAZOLE
Category	Anthelmintic
Molecularformula	$C_{12}H_{15}N_3O_2S$
Structure	
IUPAC Name	Methyl5-propylthio-1H-benzimidazole-2-yl-carbamate
Molecularweight	265.3
Solubility	Soluble instrong acids,strong bases,and dimethyl sulfoxide.
Meltingpoint	208^0C-210^0C
Description	A white to pale buff coloured powder
Modeof action	Inhibitory effect on tubuline polymerization which result in loss of cytoplasmic microtubules

Assay	Dissolve 0.5g in 80ml of anhydrous glacial acetic acid.Titrate with 0.1M perchloric acid, using crystal violet solution as indicator. Carry out blank titration. 1ml of 0.1perchloric acid is equivalent to 0.02653g of $C_{12}H_{15}N_3O_2S$
Dose	Nematodal infestation, 400mg as a single dose Cestodalinfestation 400mg daily for three consecutive days Strongyloidiasis 400 mg daily for three consecutive days
Storage	Store protected form light

FORMULATION AND EVALUATION OF ALBENDAZOLE MEDICATED LOLLIPOP FOR PEDIATRIC USE

CHAPTER: 5. AIM AND OBJECTIVE

5.1 AIM:

"Formulation and Evaluation of Albendazole Medicated Lollipop for Pediatric Use"

5.2 OBJECTIVE:

1. To formulate albendazole medicated lollipops:
2. To determine the optimal concentration of albendazole.
3. To evaluate the physicochemical properties of the lollipop.
4. To study the release profile of albendazole.
5. To test the palatability of the lollipop.
6. To assess the stability of the lollipop formulation.
7. To evaluate the efficacy of the albendazole medicated lollipop.
8. To compare the medicated lollipop with conventional albendazole dosage forms.

CHAPTER: 7. EXPERIMENTAL WORK

7.1. MATERIAL AND INSTRUMENTS:

7.1.1. MATERIALS:

The drugs used for the present investigation were obtained from Lasa superhenerics ltd. Ratnagiri

A.DETAILS OF PURE DRUG:

Drug	Supplied by	Quantity	Purity (Assay)
Albendazole	Lasa superhenerics ltd. Ratnagiri	40 g	99.62

Table.No.2. Details of API

B.REAGENTS AND CHEMICALS:

All reagents and chemicals used were for medicated lollipop.

1. Sucrose
2. Citric acid

3. Dextrose
4. Corn syrup
5. Carboxyl methyl cellulose sodium salt
6. Water

7.1.2. INSTRUMENTS:

Sr. No	Instrument	Model
1	UV-Visible Spectrophotometer	Double beam carry-07 Bio
2	Friabilator	EF-2L Friability tester
3	Monsento Apperatus	Vinsytst manual tablet hardness tester
4	Balance	Mettler Toledo Analytical Balance

Table.No.3. Instruments used

FORMULATION AND EVALUTION OF ALBENDAZOLE MEDICATED LOLLIPOP FOR PEDIATRIC ANTHELMINTICS THERAPY

7.2. METHOD DEVELOPMENT STRATEGY:

7.2.1. SELECTION OF DRUG:

The selection of Albendazole was based on its proven therapeutic efficacy in treating and its suitability for research objective.

7.2.2. SELECTION OF EXCIPIENT:

For the preparation lollipop excipient were selected to enhance stability efficacy and patient acceptability of the formulation.they play key role as dilutent, binder, disintegrants or solubulizing agent, colouring and flavouring agent.

- **PROCEDURE:**

1. PREPARATION OF SYRUP BASE:

Preparation of Syrup base was prepared by dissolving required amount of sucrose in purified water at 110^0C and continously stirring for 30 min.

2. PREPARATION OF MEDICATED LOLLIPOIP:

Medicated lollipoip were prepared by heating and congealing technique. The base was prepared in a beacker dissolving sucrose while heating and stirring at 110^0C for about 20 min. Followed with corn syrup addition and stirring continously for 30 min. While Raising the temperature to 160^0C. The material was left to cool and temperature brought down at 90^0C till the semiplastic mass was obtained drug colouring and flavouring agent were added and mixed material for 10 min. After mixing all ingredients the mixture was poured into silicon mould that have diameter and thickness then it was wrapped with alluminium foil and left to solidify at room temperature.

3. FORMULAS OF PREPARATION OF ALBENDAZOLE LOLLIPOP:

Sr.no	Ingredients	F1	F2	F3	F4	F5	F6
1	Sucrose	66.6gm	44.4gm	70gm	133.2gm	80gm	144gm
2	Dextrose	-	22.2 gm	-	-	-	-

3	Corn syrup	27.7	25.7	25gm	55.1gm	14g	44g
4	Albendazole	400mg	400mg	400mg	400mg	400mg	400mg
5	Citric acid	-	1g	-	-	1g	-
6	Methyl Celluose	1g	1g	1g	1g	1g	1g
7	Flavoring agent	0.67g	0.67g	-	0.67g	-	0.67g
8	Colouring agent	0.03g	0.03g	0.03g	0.03g	-	0.03g
9	Purified water	100ml	100ml	100ml	200ml	100ml	200ml
10	Total weight	100g	100g	100g	200g	100g	200g

4. EVALUTION PARAMETER

1. GENERAL APPEARANCE:

Colour ,Odour ,Taste ,Shape , Touch

2. DRUG EXCIPIENT INTERACTION STUDY:

For analyzing drug excipients interaction the FTIR study is done.

3. WEIGHT VARIATION TEST:

- Lollipop were randomly cheacked for the uniform weight of lollipop. Where 5 lollipop is selected to perform weight variation test, then average weight of lollipop for each batch is calculated and also deviation.
- Two lollipop from average weight is greater than acceptance limit shall be accepted.

a) ACCEPTANCE CRITERIA:

- Individual weight should not more than ±5% from average weight.
- Maximum 2 lollipop can be deviated but it should not more than ±10%

b) FORMULA:

$$\% \text{ Deviation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

4. HARDNESS:

Five lollipop are randomly taken. It is bases on the principle of an ordinary plier. Pfyzer lollipop hardness tester is a plier fitted with a pressure dial. The lollipop is placed between the jaw of the plier and pressure is applied by pressing the handles with hand unit until the tablet breaks. The reading of the dial indicates the pressure needed to break the lollipop.

Fig 7: Pfyzer

5. FRIABILITY TEST:

Normally during the course of compression of lollipop a sufficient pressure is applied on the granules, so that the lollipop can withstand the wear and tear during transportation and handelling. But inspite of observing all the precaution, the lollipops show considerable powedering after normal handling, giving an undesirable appearnace. Friability test is performed to evaluate the ability of the tablet to withstand wear and tear in packing, handling and transpoting. The apperance used to perform this test is known as "Friabilator".

6. THICKNESS:

The thickness of a lollipop is the only dimensional variable related to the process.Thickness of an individual tablets may be measured by a vernier caliper.

Fig 8: vernier caliper.

6. DISSOLUTION TEST:

Place 1000 ml of phosphate buffer and previously warmed t 37.5^0 into the vessel. Place the lollipop in the basket. Start the motor and adjust the rotation speed to 100 rpm. Withdraw the volume of solution from vessel after 5 minutes. Filter and determine the amount of active ingredient present in it by UV spectroscopy. Repeat the comolete operation 5 times upto 30 min.

7. DRUG CONTENT:

5 lollipops were selected randomly and powdered. A quantity of these powder corresponding to 400mg of Albendazole was dissolved in 100ml of phosphate buffer pH 6.8 in a 100ml volumetric flask(stock

solution "A"). From(stock solution "A") 1ml is diluted with phosphate buffer pH 6.8 upto 100ml volumetric flask(stock solution "B"). From(stock solution "B") 1ml is diluted with phosphate buffer pH 6.8 upto 10ml volumetric flask(stock solution "C") and absorbance will be recorded at 291 wavelength in UV spectroscopy.

% DRUG CONTENT : Absorbance of test sample ×100

Absorbance of test standard

8. STABILITY STUDIES:

Stability research for the lollipop were finished at 30^0C at 65p.c Rh as in line with ICH pointer (Q1A). For every 15 days the parameter like physical look weight variant, hardness, drug content and in vitro dissolution have been determined.

FORMULATION AND EVALUATION OF ALBENDAZOLE MEDICATED LOLLIPOP FOR PEDIATRIC USE

CHAPTER:9. CONCLUSION

CONCLUSION:

The development of medicated lollipops is a relatively simple and time-efficient process. These lollipops offer an appealing and innovative alternative for delivering medications, particularly for managing pain in pediatric patients. Among the various methods of drug delivery, the oral route remains the most favored due to its convenience, patient compliance, ease of administration, and adaptability in formulation. Medicated lollipops serve as an excellent dosage form for children, providing a user-friendly and effective means of treatment. This form of drug delivery represents a forward-thinking approach and is expected to maintain its significance in the field of pharmacy well into the future.

In our study Batch 4 was found to be optimized.

Result for batch 4 are as follows:

In weight variation it gave the result 7 ± 0.35 having deviation -4.2%.

In hardness test, hardness was found to be 11.5 ± 0.575.

Thickness of lollipop was found to be 11 ± 0.055.

In Friability test result is found to be 0.48%.

Drug content found to be 90.07%.

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