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A Review on Fast Disintegrating Sublingual Tablet for Migraine

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ABSTRACT: -

Migraine patients with nausea, vomiting, and light/sound sensitivity can be given sublingual and anti-migraine medications quickly for pain and relief. Headaches that come back easily, especially in women. It usually happens once a week, but can also happen every few years or at shorter intervals. It can last from a few hour to three days, depending on the severity of the pain. Generally speaking, morning headaches affect only one side of the head, usually the forehead. Headaches are very common and can be very painful. These conditions are the most common cause of headaches and account for 95% or more of all headache symptoms. Based on the latest technology, rapidly disintegrating sublingual tablet is a new type of oral drug delivery. When the tablet is placed on the patient's tongue or swallowed quickly, it rapidly disintegrates and dissolves, allowing the drug to be absorbed through the oral mucosa. Derived from the Latin word "sublingual", sublingual (abbreviated as SL) refers to the pharmacological process of drug diffusion into the blood through the sublingual tissue. Demand for rapidly disintegrating sublingual tablets has increased over the last decade due to their potential for emergency treatment. In terms of permeability, the sublingual area of the mouth (i.e., floor of the mouth) is more permeable than the buccal (cheek) area, which in turn is more permeable than the palatal (roof) area of the mouth.

Drug delivery through the oral mucosa is considered a promising method for the oral route. Rapid elimination of sublingual tablets could improve current treatment for special patients such as pediatric patients and the elderly.

Keywords: migraine, rapid disintegration, sublingual drug delivery, technology.[1],[4]

Introduction: -

Sublingual Tablets -

The tablets dissolve easily in the mouth, dissolving quickly and leaving almost no residue. It is a medicine that break down quickly in the mouth and dissolves in the mouth within 1 minute without the need for water. Oral administration is the most commonly used method because it eliminates the pain of taking it, there are many ways to mix different drug candidates, and most importantly, patient compliance. Oral delivery does not require sterilization.

Tablets that break or dissolve quickly in the patient's mouth are suitable for children, the elderly, mentally ill and bedridden people accustomed to dysphagia and hand tremors. dissolving sublingual tablets disperse or dissolve rapidly when placed in the mouth and swallowed in liquid form. When the sublingual tablet is placed under the tongue, the medicine is rapidly or directly absorbed by the sublingual oral mucosa, providing immediate effect. The drug absorbed from the stomach enters the mesenteric circulation by connecting to the portal vein. Therefore, it is absorbed by the oral cavity and does not undergo first pass metabolism. Sublingual tablets are usually small, flat, and slightly compressed to make them soft. The tablet must be dissolved quickly so that the API can be rapidly absorbed. The tablet is designed to dissolve in a small amount of saliva when placed in the mouth under the tongue, patients should not eat, drink, smoke and possibly talk to keep the tablets down.[5],[7]

Sublingual root: -

Sublingual root is newly method of drug administration for systemic drug delivery.

Sublingual root avoids first pass metabolism and affords quick drug entry into the systemic circulation.

Attempts have been made to deliver various pharmacologically active ingredient, such as cardiovascular drugs, analgesics, and peptides, across the sublingual mucosa.

Advantages of sublingual tablet: -

- When sublingual tablets placed under the tongue, it produces immediate systemic effect by enabling the drug absorbed quickly or directly through mucosal lining of the tongue.
- Gets reduces

- Very fast onset action
- Bioavailability improved
- Side effect is less
- More effective in nausea, vomiting, migraine, schizophrenia.
- No need of water for administering tablet.
- Provide the sustained drug delivery
- Sublingual area is more permeable than buccal area.[8],[9]

Disadvantages of sublingual tablet: -

- Area available for absorption is more less.
- No suitable for bitter test drug.
- Less patient's compliance
- Not allowed eating, drinking and smoking.
- Highly ionic drug administration is not allowed.[10],[11]

Mechanism of sublingual absorption:

The absorption potential of the oral mucosa is influenced by the solubility of lipids and thus also the permeability of the solution, ionization potential, ph., molecular weight of the substance. Absorption of some drugs through the oral mucosa increases as the ph. of the carrier increases (more acidic) and decreases as the ph. decreases (more basic). the cell as if wrapped around it). These absorbed particles are usually too large to diffuse through the cell wall. The oral cavity is highly acceptable to patients; the mucosa is relatively permeable with abundant blood supply. It is robust and exhibits short recovery times after stress or damage, and the virtual lack of Langerhans cells makes the mucosa tolerant to potential allergens. These factors make the oral cavity a very attractive and feasible site for systemic drug delivery. In addition to the biochemical properties of the buccal and sublingual membranes, which are responsible for barrier functions and permeability. Various factors of the drug molecule affect the extent of permeation through the membrane-lipid solubility, degree of ionization, drug pka, drug solution ph., presence of saliva, membrane characteristics, molecular weight and drug size. Different physicochemical properties of the formulation and the presence or absence of permeation enhancers affect the absorption and permeation of drugs through the oral mucosa. However, oral administration of drugs has disadvantages such as first-pass metabolism by the liver and enzymatic degradation in the gastrointestinal tract.[12],[13]

Challenges in fast disintegration tablets:

- Development of optimal sublingual formulation includes understanding of drug absorption mechanisms, physical and mechanical properties of drug, performance of formulation excipients and taste masking techniques to improve patient compliance.
- Taste of active ingredients
- Taste is an important parameter in administering drugs orally
- Undesirable teste is important formulation problems that are uncountered with many drugs

Migraine:

A migraine is a type of headache. Symptoms may include nausea, vomiting, and sensitivity to light and sound. Most people only feel a throbbing pain on one side of their head.

Cause - Migraines are caused by abnormal activity in the brain. This activity can be caused by various factors. However, the exact sequence of events remains unclear. Most medical professionals believe that seizures start in the brain and involve chemical and neural pathways. This change affects the blood flow in the brain and surrounding tissues.

Types of sublingual tablets:

Fast disintegrating sublingual tablets

Tablets that quickly disintegrate or dissolve in the patient's mouth are useful for infants, the elderly, patients with swallowing problems (children, the elderly), and situations where drinkable liquid is not available. FDT is defined as a solid dosage form containing a drug. When placed on the tongue, it disintegrates rapidly (within seconds) without water. The drug is released, dissolved, or dispersed in saliva, which is then swallowed and absorbed through

the stomach. FDT generally offers improved convenience and is often preferred over traditional solid oral dosage forms. ODT may lead to significant improvements over current treatment options for specific patient groups, such as pediatric patients. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) says ODT shows promise for children. The potential benefits of ODT formulation can be fully understood by considering the additional requirements of this group. The size and time of disintegration play a very important role in the commercial potential of a formulation. The faster disintegration time reduces the risk of choking and makes it difficult to expel the dose.[14],[15]

Bio adhesive sublingual tablet

The presented new concept of sublingual tablet is based on an interactive mixture consisting of a water-soluble carrier and a bio adhesive component coated with drug micro particles. This approach allows rapid dissolution in combination with maintaining bio adhesion of the drug within the oral cavity.[16]

Lipid Matrix Sublingual Tablets

Lipid Matrix Sublingual Tablets are accessible, rapid, convenient and stable dosage forms suitable for specialized dietary supplements that are often taken orally. Lipid matrix sublingual tablets are formulated using advances in sublingual and liposome technology to create a dosage form that is more rapidly and completely absorbed than traditional oral administration.

Sublingual vitamin tablets

The only sublingual vitamin that all doctors recommend is vitamin B12 (cyanocobalamin). Vitamin B12 is very useful in our body's metabolism.

Technology used in preparation of sublingual tablets:

Various techniques that can be used to formulation sublingual tablets include.

Freeze drying technology, spray drying technology, sublimation method, direct compression technology. Direct compression is considered an ideal method for formulation sublingual tablets because it preserves them along the edges better than other methods.

- No water or heat required during mixing.
- Economical compared to other methods
- Reduction of production process and equipment
- Reduces labor cots
- Low power consumption
- Low process validation
- Involves tableting by slugging or roll compaction to avoid high compaction pressure
- Greater stability of tablets on aging
- Prime particle dissociation each primary drug particle is released from the tablet mass and is available for dissolution disintegrate rapidly into elementary particle sizes.
- Elimination of the granular process.
- No pretreatment of powder mixture is required
- Eliminate variations in wet granulation process [15]

Direct compression

One of these techniques requires the inclusion of a superdisintegrant in the formulation or use of highly Water-soluble excipients to achieve rapid tablet disintegration. Direct compression is suitable for chemicals With flow able and viscous properties. Direct compression is the ideal method for heat-labile drugs.[16]

Fast melting technology

It is recognized as one of the most innovative methods in oral drug delivery system a rapidly growing Area of drug delivery. The initial success of the FMT formulation led to the development of various Techniques. these technologies, however, still have some limitation. FROSTA-new technology used

FMT techniques can be classified as follows-

- Freeze drying
- Molding / sublimation

- Compression

Regardless of the technology used, the important properties of successful FMT are rapid absorption of water into the core of the table followed by rapid disintegration of the respective particles into Separate components.[17],[18]

Sublimation

The basic principle involved in preparing fast-dissolving tablets by sublimation technique is to add a volatile salt to the tableting ingredient to obtain a substantially homogeneous mixture and a volatile salt. Removal of the volatile salt creates pores in the tablet, which helps achieve faster disintegration when the tablet comes into contact with saliva. Tablets were subjected to vacuum at 80ºC for 50 min to remove volatile components and thus create pores in the tablet; volatile salts like camphor, ammonium bicarbonate, naphthalene, urea etc.; Also used as sublimable ingredients to prepare porous tablets.[19],[20]

Lyophilization

It is one of the most common processing methods to remove moisture from biopharmaceuticals and also enhances the stability, tolerability and shelf-life of these products. It is one of the well-established processes in the industry.

Evaluation of sublingual tablets

General appearance

General appearance and overall elegance of a tablet is very important for consumer-acceptance. So organoleptic

Properties like color taste shape and size should be evaluated properly.

Hardness

Tablet hardness can be determined using Monsanto hardness tester [cad match] . the tablet is placed diagonally

Between the 2 plungers of the tablet hardness tester; and then pressure is applied until the tablet break into two pieces;

And noted the reading on the scale.[21]

Friability

Friability can be determined using the ARoche FibrillatorE Friability is a measure of the mechanical strength

Of a tablet. 10 or 20 Prevease tablets are placed in the fibrillator and then rotated at a speed of 25 rpm for 4 minutes.

Finally, the % wt. loss should be calculated. wt. loss should not exceed 1%

%FRIABILITY = loss in wt. /initial wt. 100 [22]

Uniformity of weight

It can be determined with the help of a digital weighing balance. the weight of a tablet can be determined from the

Collective weight of all the tablet. Individual tablets are weighed on a digital weighing balance and then compared to average weight.[23]

Thickness

It can be measured with the help of Vernier calipers or micrometer. the thickness should be controlled 50%

Variation of the standard value.[24]

Wetting time

In this test, a circular tissue paper is placed in a Petri dish and a tablet is placed on the paper. A certain amount of

Distilled water is added and the time required to cover the entire surface of the tablet is recorded as the wetting time.[25]

Water absorption ratio

It can be calculated using the following equation water absorption ratio=[wlastt-wfrist]/w first. Where, first stands for dry sublingual tablet and Wlast for entirely wet sublingual tablet [26]

Disintegration test:

Sublingual tablets are one of the most suitable candidates for oral drug delivery such as proteins and peptides that have limited bioavailability when administered by conventional tablets. Injections are not used by patients unless facilitated by advanced automated injection. The development of an

ODTS-enhanced oral protein delivery technology that can deliver these drugs into the oral cavity is promising for the delivery of high molecular weight proteins and peptides.

Conclusion:

Due to its ease and avoidance of hepatic metabolism, the bidirectional route offers a promising alternative to overcome the limitations of conventional oral drug delivery and parenteral administration. Dual products have been developed to overcome the difficulty of swallowing conventional tablets in children and geriatric patients. The target population is distributed to those who want a convenient dose of water at any time. The peak blood level of most products administered twice is reached in 10-15 minutes; Often, this drug works faster than when taken orally. The sublingual route offers efficient absorption and a rapid onset of action.

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