



Research Article

Formulation And Evaluation Of Oral Dispersible Tablet Containing Giloy

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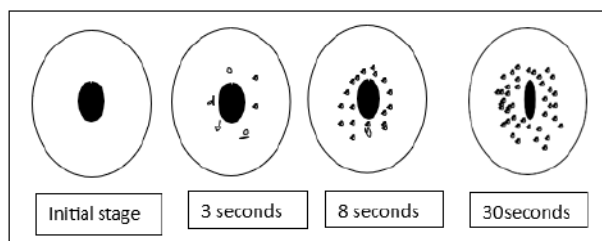
ABSTRACT

Tablets, the most common drug delivery system, provide the opportunity to incorporate new technologies to produce more dosage forms. Orally dispersible drug delivery systems are widely used to improve bioavailability and patient compliance. Orally dispersible tablets (ODT) have been developed for children, the elderly, bedridden patients, and patients without access to water. In fact, swallowing problems develop in young people due to weakening of muscles and nerves. In some cases, such as cold, cough and inability to drink, tablets may be difficult or uncomfortable to swallow. ODT creates a solution by rapidly dissolving or disintegrating in the mouth and provides the final solution to the problem. They also have a pleasant taste. In the preparation of ODT, superdegradants are often added to enhance the release of the drug through complete absorption and thus increase the bioavailability of the drug. The purpose of this article is to review the structure of ODT, identify its advantages and limitations, Challenges in design, use of new technologies, review process, qualification of drugs and supplements, patented technology, throughput and future perspectives.

INTRODUCTION

Oral route of drug delivery method is the easiest management method. The most commonly used oral forms are tablets and capsules. Oral dispersible tablets (ODT) are disintegrate in the mouth. You do not need to drink water orally for a minute. They are also called rapid-acting tablets, oral dissolving tablets, rapid-acting tablets, oral dissolvable tablets, porous tablets, oral tablets . Alternatives to liquids and tablets for adults and

children who have difficulty swallowing food by mouth.



Orally dispersible systems are defined as systems that dissolve within seconds (or minutes) when

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placed in the mouth and do not require swallowing. To improve tablet disintegration, super disintegrating agents such as crospovidone are often added to the formula. Microcrystalline cellulose (MCC), sodium starch glycolate, croscarmellose sodium, crospovidone and other substances are used in the formulation of oral dispersible tablets. A tablet containing an antibiotic that dissolves quickly, usually within a few seconds, when placed on the tongue. ODT is designed to help patients with dysphagia. It is useful for bedridden patients and travelers (where water is not usually readily available) and for bedridden patients. ODT is also useful for children, the elderly, and people with mental illness, as well as patients who have previously avoided taking tablets and capsules due to fear of inhalation. Since drug absorption occurs before the intestine, the dose can be reduced, thus saving more drug from metabolism in the liver. ODT is stable over a long period of time because the drug remains in dosage form until the patient uses it. It combines the advantages of bulk materials and liquid materials in terms of stability and bioavailability. Disadvantages of OTD include the potential for unpleasant odors and/or unpleasant sensations that may remain in the mouth if inappropriate. There are many ways to deteriorate due to the effects of moisture and temperature. Larger doses are more difficult to produce as ODT. Special packaging is required to ensure the safety and security of the product. The challenge in ODT production is that ODT must be strong enough to solve production process and post-production problems. There should be no residue left in the mouth after application. For ease of administration, the tablet should be of a size that is easy to take and hold. Finally, ODT needs to dissolve and dissolve in the mouth without delay. And he was immediately released and released. Recently the European Pharmacopoeia has adopted the term “dispersible tablet”, meaning a

tablet that disintegrates or disintegrates in the mouth within a minute or a second before being swallowed. When synthesized as ODT, it enters pregastric absorption and helps increase the oral bioavailability of the drug. It has good stability, precise dosage and ease of production. Recent market research shows that many patients prefer oral tablets to other types of medications, and most consumers will ask their doctor about them (70%), buy them (70%), or opt for other types of tablets (more than 80%). Or liquid. ODTs are also known as orodispersible tablets, rapidly disintegrating tablets, orodispersible tablets, rapidly disintegrating tablets. The advantages of this new pharmaceutical form have been widely recognized since the appearance of “orodispersible tablets” in the European Pharmacopoeia; This means “tablets for oral use” that are broken before a meal. According to the European Pharmacopoeia, ODT should dissolve or disintegrate within three minutes. The US FDA defines ODT as “a single dosage form containing an antibiotic that acts rapidly, usually within a few seconds, when placed on the tongue.”

Advantages

- 1.No need for water.
- 2.The drug dissolves and is absorbed rapidly, thus increasing bioavailability
3. Pre-gastric absorption of the drug may increase the oral bioavailability of the drug and reduce the dose.
- 4.It has the same stable medicine as the recommendations of the drug product. First of all, metabolism decreases.
- 5.It is suitable for patients who are not easy to swallow medicine, such as children, the elderly, mentally ill, disabled and uncooperative patients.
- 6.Rapid dissolution and absorption of the drug results in rapid onset of action.
- 7.Pre-gastric absorption may increase bioavailability and improve treatment by reducing side effects due to reduced doses.



Disadvantage

1. Rapidly disintegrating tablets are hygroscopic in nature and must therefore be stored in a controlled environment, for example humidity and temperature.
2. ODT is hygroscopic and should be stored in a dry place.
3. Sometimes it has a mouth.
4. It also shows the characteristics of friable, effervescent granules.
5. ODT must be specially packaged to ensure product stability and safety.

Mechanism of orally dispersible tablets:-

This medicine is a fast dissolving granule and orally dispersible tablets also contain a disintegrant. When saliva in the mouth enters the orodispersible tablet, the solvent swells and produces saliva.

1. Natural super disintegrants :-Because it is versatile, inexpensive, environmentally friendly, softening and non-irritating.
2. Synthetic super disintegrants : for example: cross-linked polyvinylpyrrolidone, Sodium starch glycolate, croscarmellose sodium, chitin and chitosan. How it works:

Instant-dissolving tablets need to dissolve faster, so a super disintegrator is needed when creating ODT. The super disintegrants can be used for further separation, works better on granules and is also effective at low pressure.

1. By Swelling
2. Capillary action (wicking)
3. Deformation Capillary action (suction)

Technology for Preparation of Orodispersible Tablets

The equipment used to produce ODT can be classified as follows:-

1) conventional Technology

2) Patented Technology

1.conventional Technology-

Developed for the preparation of mortal Anti-inflammatory drugs, Many different types of

combinations have been developed, including drying, spray drying, molding, phase change coating process, melt granulation, sublimation, mass extrusion, marshmallow process, direct compression process (Meyers). et al.,1995; Makino et al., 1993).

Direct Compression: The easiest and most effective method of preparing tablets.

Using air compressor with mixed materials but less processing. Microcrystalline cellulose (MCC) and low conversion hydroxypropyl cellulose (HPC) are used for rapid production of tablets.

2.Patented Technology - The rapid disintegration of ODT is mainly due to the rapid penetration of water into the tablet matrix, resulting in rapid disintegration. Various technologies have been developed based on different designs and processes, and the final drug products are evaluated according to mechanical strength, porosity, dosage, stability, taste, mouthfeel, dissolution rate, etc. They differ in terms of many parameters such as. > Bioavailability.

Zydis Technology: Zydis is the first technology for commercial and best known tablets [Nautiyal et al., 2014, Divate et al., 2011]. Once placed on the tongue, the tablets usually dissolve within seconds [Parasha et al., 2012]. Here, tablets are made from freeze-dried or freeze-dried drugs in a gelatin matrix [Ghosh et al., 2011].

Literature Review

Vinita Chaurasia (2016):- Tablets, the most widely used drug, provide the opportunity to create more advanced dosage forms incorporating new technologies. Orally dispersed drug delivery systems are widely used to improve bioavailability and patient compliance. Orally dispersible tablets (ODT) have been developed for children, the elderly, the elderly, and patients who do not have access to water. In fact, swallowing problems develop in young people due to weakening of muscles and nerves.



Jaysukh J Hirani (April 2009): - Drug delivery systems are advancing because scientists better understand electronic and biochemical factors unrelated to their effectiveness. Over the past three years, oral disintegrating tablets (ODT) have gained more attention as an alternative to tablets and capsules due to better patient compliance. ODTs are dosage forms containing drugs that provide a rapid response, usually within seconds, when placed on the tongue. ODT product technology entered the market in the 1980s, demand gradually increased and the product range expanded rapidly.

Priyanka Nagar (2011):- Oral drug delivery is currently the gold standard in the pharmaceutical industry and is considered the safest, most convenient and economical method of administering drugs to most patients. Especially when considering dysphagia in adults and children, the ease of producing verbal information makes patients feel bad. To solve these problems, we have developed a new type of medicine called Orally Dissolved Tablets (ODT), which break down quickly and dissolve in saliva and can then be easily swallowed without water, which is better. Additionally, patients who have difficulty swallowing, severe pain, regurgitation and psychosis prefer this preparation because they cannot swallow much water.

Aims and Objectives

Aims of the Study:-

The purpose of this study is to develop and evaluate oral dispersible giloy tablets. The main aim is to obtain a good product by using direct compression technology in cases such as dysphagia, nausea and vomiting in infants and children. The aim is to increase the rate of release of the drug from the oral dosage form by using different super disintegrants, thus improving degradation. The bitter taste of Giloy will help control blood sugar in people with diabetes. Giloy also helps in weight management by improving

overall metabolism. Drinking fresh giloy juice helps improve immunity and can be used to control fever due to its anti-inflammatory properties.

Objectives

1. Giloy ODT is prepared by direct compression using different super disintegrants such as croscopovidone (polyplasdone), croscarmellose sodium (Ac-Di-Sol) and sodium starch glycolate (explotab).

2. Most formulated tablets are evaluated, including safety studies. Develop a single dosage form with a faster onset of action compared to oral dosage forms to increase patient compliance.

Drug Profile

Giloy

The name of *Tinospora cordifolia* is "Guduchi" in Sanskrit and it belongs to the Menispermaceae family. It is a large deciduous climbing tree with many species and green-yellow flowers. It is found in higher areas. The flowering period covers summer and winter months. Various plant compounds such as alkaloids, steroids, diterpene lactones, aliphatic compounds and glycosides have been isolated from the roots, stems, leaves and whole plant parts of plants. Nowadays, plants are more important in research in the preparation of many types of medicines. Due to its medicinal properties such as anti-diabetic, anti-inflammatory, anti-spasmodic, anti-inflammatory, anti-arthritis, antioxidant, anti-allergic, anti-anxiety, anti-leprosy, anti-malarial, hepatoprotective, immunomodulatory and antitumor activity. *Tinospora cordifolia* has many medicinal properties that affect the body. While some of these substances have antioxidant effects, some of them can increase the activity of the immune system. Some drugs can prevent cancer cells in experimental animals. Most research is done in blood vessels or animals.

Excipients Profile

1. Croscarmellose Sodium

BP: Croscarmellose sodium



Synonyms: Ac-Di-Sol; crosslinked carboxymethylcellulose sodium; Explocel; modified cellulose Gum; Nymcel ZSX; Pharmacel XL; Primellose; Solutab; Vivasol.

Chemical Name and CAS Registry Number: Cellulose, carboxymethyl ether, sodium salt, crosslinked and [74811-65-7]

Empirical Formula and Molecular Weight: Croscarmellose sodium is a crosslinked polymer of carboxymethylcellulose sodium And 90,000–7,00,000.

Applications in Pharmaceutical Formulation or Technology:

Croscarmellose sodium is used in oral pharmaceutical formulations as a disintegrant For tablets. In tablet formulation croscarmellose sodium may be used in both Direct-compression and wet-granulation processes. Croscarmellose sodium at Concentrations up to 5% w/w may be used as a tablet disintegrant.

Stability and Storage Condition:

Croscarmellose sodium should be stored in a well-closed Container in a cool, dry place.

Incompatibilities: The efficacy of disintegrants, such as croscarmellose sodium, may be slightly reduced In tablet formulations prepared by either the wet granulation or direct compression Process that contain hygroscopic excipients such as sorbitol.

Safety: Croscarmellose sodium is mainly used as a disintegrant in oral pharmaceutical Formulation and is generally regarded as an essentially nontoxic and nonirritant Material.

2. Crospovidone

BP: Crospovidone

Synonyms: Crosslinked povidone; E1202; Kollidon CL; Kollidon CL-M; Polyplasdone XL; Polyplasdone XL-10; polyvinylpyrrolidone; PVPP; 1-vinyl-2-pyrrolidinone Homopolymer.

Chemical Name and CAS Registry Number: 1-Ethenyl-2-pyrrolidinone homopolymer and [9003-39-8]

Applications in Pharmaceutical Formulation or Technology

Crospovidone is a tablet disintegrant and dissolution agent used at 2–5% concentration In tablets prepared by direct-compression or wet- and dry-granulation methods. It Rapidly exhibits high capillary activity and pronounced hydration capacity, with little Tendency to form gels.

Stability And Storage Condition:

Since crospovidone is hygroscopic, it should be stored in air tight container in a cool and dry place.

Incompatibilities:

Crospovidone is compatible with most organic and inorganic pharmaceutical ingredients

Safety : Crospovidone is used in oral pharmaceutical formulations and is generally regarded as A nontoxic and nonirritant material. Short-term animal toxicity studies have shown no Adverse Effects associated with crospovidone.

3. Sodium Starch Glycolate

BP : Sodium Starch Glycollate

Synonyms: Carboxymethyl starch, sodium salt; Explosol; Explotab; Glycolys; Primojel; starch Carboxymethyl ether, sodium salt; Tablo; Vivastar P.

Chemical Name and CAS Registry Number: Sodium carboxymethyl starch and [9063-38-1].

Stability And Storage Condition: Tablets prepared with sodium starch glycolate have good storage properties. Sodium Starch glycolate is stable and should be stored in a well closed container in order to Protect it from wide variations of humidity and temperature, which may cause caking.

Incompatibilities: Sodium starch glycolate is incompatible with ascorbic acid.

Safety: Sodium starch glycolate is widely used in oral pharmaceutical formulations and is Generally regarded as a nontoxic and nonirritant material. However, oral ingestion of Large quantities may be harmful



4. Mannitol

BP: Mannitol

Synonyms: Cordycepic acid; C*Pharm Mannidex; E421; manna sugar; D-mannite; mannite; Mannogem; Pearlitol.

Chemical Name and CAS Registry Number: D-Mannitol and [69-65-8.]

Applications in Pharmaceutical Formulation or Technology

In pharmaceutical preparations it is primarily used as a diluent (10–90% w/w) In tablet formulations, where it is of particular value since it is not hygroscopic And may thus be used with moisture-sensitive active ingredients.

Stability and Storage Condition:

Mannitol is stable in the dry state and in aqueous solutions. The bulk material should be stored in a well-closed container in a Cool, dry place.

Safety: Mannitol is a naturally occurring sugar alcohol found in animals and plants, it is present in Small quantities in almost all vegetables. Laxative effects may occur if Mannitol is consumed Orally in large quantities.

5. Sucrose

BP: Sucrose

Synonyms: Sugar, Saccharose, Beta-D-Fructofuranosyl-alpha-D-glucopyranoside

Chemical Name and CAS Registry Number: A-D-glucopyranosyl-(1→2)-β-D-fructofuranosand [57-50-1]

Applications in Pharmaceutical Formulation or Technology: -

Sucrose is used as an intense sweetening agent in pharmaceutical preparations Including tablets, powder mixes, and vitamin preparations.

Stability And Storage Condition:

Store sugar in a cool, dry location (not the refrigerator).

Safety:

Ingestion of large amounts may cause gastrointestinal irritation. Expected to be a low

ingestion hazard. Inhalation: Low hazard for usual industrial handling. Excessive inhalation may cause minor respiratory irritation.

6. Microcrystalline Cellulose (MCC)

BP : Microcrystalline cellulose.

Synonyms: Avicel PH, cellulose gel, emcocel, fibrocel, tabulose..

Chemical Name and CAS Registry Number: Cellulose. And [9004-34-6.].

Applications in Pharmaceutical Formulation or Technology: Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a Binder/diluent in oral tablet formulations where it is used in both wet Granulation and direct compression processes.

Applications in Pharmaceutical Formulation or Technology

Microcrystalline cellulose is widely used in pharmaceuticals, primarily as a binder/diluent in oral tablet and capsule formulations where it is used in both wet granulation and direct compression processes. In addition to its use as a binder/diluent, microcrystalline cellulose also has some lubricant and disintegrant properties that make it useful in tableting.

Stability and Storage Condition:

Microcrystalline cellulose is a stable though hygroscopic material. The bulk material Should be stored in a well closed container in a cool, dry place.

7. Talc

BP: Purified talc

Synonyms: Altalc; E553b; hydrous magnesium calcium silicate; hydrous magnesium silicate; Luzenac Pharma; magnesium hydrogen metasilicate; Magsil Osmanthus; Magsil Star; Powdered talc; purified French chalk; Purtaalc; soapstone; steatite; Superiore.

Chemical Name and CAS Registry Number: Talc and [14807-96-6.]



Functional Category: Anticaking agent; glidant; tablet and capsule diluent; tablet and capsule lubricant

Applications in Pharmaceutical Formulation or Technology: Talc was once widely used in oral solid dosage formulations as a lubricant and diluent. In topical preparations, talc is used as a dusting powder, although it should not be used to dust surgical gloves. Talc is additionally used to clarify liquids and is also used in Cosmetics and food products, mainly for its lubricant properties.

Stability and Storage Condition: Talc is a stable material. Talc should be stored in a well-closed container in a cool, dry place.

Safety: Talc is used mainly in tablet and capsule formulations. Talc is not absorbed Systemically following oral ingestion and is therefore regarded as an essentially Nontoxic material.

Method of preparation

Procedure of Wet Granulation

Step 1: Weighing of API and Excipient

Step 2: mixing of all API and Excipient. Then make starch paste .

Step 3: prepare damp mass and then form granules.

Step 4: Drying the granules in Hot air oven

Step 5: granules pass through sieve for uniformity of granules.

Step 6: Last step in which the tablet is fed into the die cavity and then compressed.

Evaluation methods

1.pre formulation study

2.post compression study

1.pre formulation study-

a. Organoleptic evaluation: These are preliminary characteristics of any substance, which is useful in identification Of specific material. Following physical properties of API were studied.

For Giloy:

Appearance: creamy white or grey.

Colour: White

Odor: characteristic

b. Loss on drying:

0.5g of sample of Giloy was accurately weighed and the powder was kept in a Metter Toledo apparatus for 5 minutes at 105°C and the moisture content was calculated (USP 39/NF 34, 2015).

C. Melting Point:

The determination of melting point during pre-formulation studies is important since it is a simple test gives valuable information regarding thermal properties of the material. Melting point was determined by capillary melting method (Electro lab Apparatus). Seal capillary from one end and fill the drug sample about 10% of capillary volume. Tie the capillary to thermometer and dipped into Thiele's tube and heated and melting point was noted.

Angle of repose -The height of the pile (h) and the radius of the base (r) were measured and angle of repose was calculated using the following equation. (USP 30 NF 25, 2007)

$$\tan\theta = h/r$$

Where, tan θ the angle of repose, h and r are the height and radius of the powder cone.

pH Dependent Solubility Study of API: pH of Giloy in 10% solution (water) was found to be slightly acidic.

2.post compression study

Hardness:-Hardness of the tablet was determined by using Monsanto tablet hardness tester. Hardness or tablet crushing strength (fc), the force required to break a tablet .The upper Plunger is then forced against a spring by turning a threaded bolt until the tablet Fractures. Hardness of tablet is expressed in kg / cm².

Friability

The friability test for tablets was performed to assess the effect of abrasion and shocks.

Roche Friabilator was used for the percent friability of the tablets. This device subjects



the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. The percentage friability was measured by using the following formula.

$$\% F = \frac{W_{\text{initial}} - W_{\text{Final}}}{W_{\text{initial}}} \times 100$$

Where

% F = Friability in percentage, W initial = Initial weight of tablet

W final = Final weight of tablet.

Thickness

The thickness of tablets was measured by using Vernier caliper. Five tablets from each batch were taken randomly and thickness was measured and average values were calculated. Thickness is expressed in mm.

Disintegration Time:

It is determined by using USP device which consist of 6 glass tubes that are 3 inches long, open at one end and held against 10 mesh screen at the bottom end of basket rack assembly. To test for disintegration time, one tablet is placed in each tube and the basket arch is positioned in a 1 liter beaker of water at $37^{\circ}\text{C} \pm 2^{\circ}\text{C}$. A standard motor driven device is used to move the basket assembly up and down (USP39/NF34). To be in compliance with the USP standard, all tablets must disintegrate and all particles must pass through the 10 mesh in the time specified.

CONCLUSION

From the present study carried out on Giloy Oral dispersible tablet using by Direct compression method, the following conclusion can be drawn. The total weight of MF5 batch was 500 mg contained Giloy-8.33%, croscarmellose sodium-6.66%, Microcrystalline cellulose-41.66%, aspartame-5.41%, magnesium stearate-0.83%, talc-1.25%, flavor-0.83%, mannitol-34.18%. Likewise The Preformulation study gives the

Following information of optimize batch Angle of Repose-28.50(θ), Bulk density-0.520, Tapped density-0.627, Compressibility Index-16.08 good to flow, Hausner ratio-1.205. Post parameter evaluation of tablets Hardness-1.96, Friability-0.788, Thickness-2.590, Weight variation-240.11±, Dispersion time-32 sec, Water absorption ratio-61.65, Disintegration time-26 sec, Content uniformity-99.80%, and 99.04% In-vitro drug Release studies- in 3 min. Formulation MF5 gives the quick disintegration and better drug release. Hence it can Be concluded that the formulation MF5 is a stable and effective for quick action and it Is alternative to the conventional tablets.

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