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Review on Formulation and Evaluation of Voglibose Mouth Dissolving Tablets

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ABSTRACT:
Mouth dissolving tablets are solid dosage forms which break down in the oral cavity less than one minute without using of water. These dosage forms are placed in the mouth, allowable to diffuse or melt in the saliva. The purpose of this article is to review potential advancements of Oral Dispersible Tablet technology in drug delivery applications.
Mouth dissolving Voglibose tablets offer a convenient and patient-friendly alternative to traditional tablets for the management of type 2 diabetes mellitus. With their rapid disintegration and absorption, these tablets provide a quick and effective way to control postprandial blood glucose levels**.**
Voglibose is alpha glycosidase inhibitor, drug which is used in a treatment of type 2 diabetes mellitus. The blend was evaluated for angle of repose, bulk density, tapped density, Carr's index, Hausner's ratio and IR studies.
The tablets were evaluated for hardness, friability, weight variation, content uniformity test, disintegration test, wetting time.
Key words:voglibose, mouth dissolving tablets, alpha glucosidase inhibitors, super disintegrants.

I. INTRODUCTION:

Diabetes mellitus is a metabolic disorder, in which glucose levels in the blood is much higher than normal [hyperglycaemia] and hence this condition is also commonly referred to as sugar disease. The defect in these conditions is that either the pancreas does not produce enough insulin or it produce sufficient insulin, but the ells of the body are unable to use the insulin properly. Insulin, a hormone released from the pancreas, control the amount of glucose in the body. Glucose in the bloodstream stimulates the pancreas to produce insulin. Insulin allows glucose to move from the blood into the cells. Once insides the cell, glucose is converted to the energy, which is used immediately, or the glucose is stored as fat or glycogen until it is needed. The level of glucose in the blood varies normally throughout the day. They rise after a meal and return to normal within about 2hours after eating. Once the levels of glucose in the blood return normally, insulin production decreases. The variation in blood glucose levels is useful within a narrow range about 70 to 110mg per decilitre [mg/dl] from blood in healthy peoples. If people eat a large amount of carbohydrates, the levels may increase more. People older than 65 years tend to have slightly higher levels, especially after eating. [(1,3)]

There are 2 types of diabetes mellitus There are…,
Type one diabetes [Insulin dependent]
Type two diabetes mellitus [non-insulin]

Drugs used to treat Diabetes
Oral Antidiabetic Medications
Biguanide (Metformin):
It stimulates the use of blood sugar by the body and inhibit generation of sugar from the liver. It should be taken with food to reduce side effects such as nausea, vomiting, diarrhea, gastrointestinal upset and flatulence[5].

Sulphonyl urea (Gliclazide, Glipizide):
They stimulate the production of insulin by the pancreas. Common side effects include abdominal pain, diarrhoea and weight gain.

Alpha-glucosidase inhibitor (voglibose):
It slows down the digestion and absorption of sugar. Common side effects include abdominal pain, diarrhea and flatulence.

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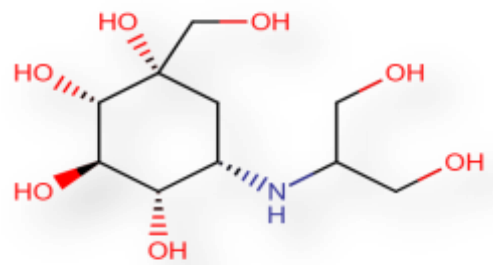
Dipeptidyl peptidase-4 (DPP-4) Inhibitors (Alogliptin, Sitagliptin):
They decrease blood sugar level by regulating the level of a hormone called incretin. Common side effects include headache, abdominal pain and pharyngitis.

Sodium-Glucose Co-transporter 2 (SGLT2) inhibitors (Dapagliflozin):
They promote excretion of sugar in urine. Common side effects include urinary or vaginal infections, dehydration and dizziness.

Voglibose
Voglibose is an oral medication used primarily for managing type 2 diabetes.

Chemistry:



Voglibose is an oral anti-diabetic drug that belongs to the class of alpha-glucosidase inhibitors.Chemical Structureis chemically knownas(2R,3R,4S,5S,6R)-5-hydroxy-2-(hydroxymethyl)-6-[4,5,6-trihydroxy-3-(hydroxymethyl) cyclohex-2-en-1-yl] tetrahydro-2H-pyran-3,4-diol. MolecularFormula: C10H19NO7.MolecularWeight:267.26 g/mol. Voglibose is a white crystalline powder with a melting point of 193-195°C.Voglibose works by inhibiting the enzyme alpha-glucosidase, which breaks down complex carbohydrates into simple sugars. By inhibiting this enzyme, voglibose delays carbohydrate absorption, reducing postprandial blood glucose levels.Voglibose is used in the treatment of type 2 diabetes mellitus, particularly in patients with impaired glucose tolerance or those who have not responded to diet and exercise alone.

Drug excipient profile
Voglibose
Summary:
Voglibose is an alpha-glucosidase inhibitor indicated in the management of postprandial blood glucose in patients with type II diabetes.

Generic Name:
Voglibose

DrugBank Accession Number:
DB04878

Background:
Voglibose is an alpha-glucosidase inhibitor used for lowering post-prandial blood glucose levels in people with diabetes mellitus. It is made in India by Ranbaxy Labs and sold under the trade name Volix.[27]

Mechanism of Action of Voglibose:
The anti-hypoglycaemic action of voglibose results from a reversible inhibition of membrane bound intestines α glycosidase hydrolyse enzymes which hydrolyseoligosaccharides anddisaccharides to glucose and other monosaccharides in the brush border of the small intestine [6,9].

Voglibose

↓

Inhibit alpha glucosidase intestinal brush border

↓

Prevents absorption and delay digestion of carbohydrates

↓

Reduce postprandial blood glucose level [27]

Mouth Dissolving voglibose tablet
Mouth dissolving voglibose tablets are an innovative formulation designed to improve patient compliance and convenience

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Composition:

The composition of a mouth-dissolving tablet of Voglibose typically includes the active ingredient Voglibose along with excipients that help the tablet dissolve in the mouth. While the exact composition may vary depending on the manufacturer, a typical formulation would include:

Active Ingredient:

Voglibose: The primary active ingredient, usually in a dosage of 0.3 mg or 0.6 mg per tablet (but this can vary).

Excipients (inactive ingredients):

Microcrystalline Cellulose,Mannitol, Crospovidone or Sodium Starch Glycolate, Citric Acid, Magnesium Stearate, Hydroxypropyl Methylcellulose, Flavors, Colorants.

Indication

Voglibose is indicated for the treatmentof:

- Monotherapy: As an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus.
- Combination therapy: In combination with other oral anti-diabetic agents (e.g., metformin, sulfonylureas) or insulin to improve glycaemic control in patients with type 2 diabetes mellitus.
- Delaying progression to diabetes: To delay the progression from impaired glucose tolerance to type 2 diabetes mellitus in patients with IGT.
- Insulin resistance: As an adjunct to diet and exercise to improve insulin sensitivity and reduce androgen levels in women with PCOS.

Dosage and Administration:

Dose

- Initial dose: 0.2 mg (1 tablet) three times a day, immediately before meals.
- Maintenance dose: The dose can be increased to 0.3 mg (1.5 tablets) three times a day, if needed, based on the patient's response and tolerance.
- Maximum dose: The maximum recommended dose is 0.3 mg (1.5 tablets) three times a day.

Administration:

- Oral administration: Voglibose OD tablets should be taken orally, immediately before meals.
- No water required: The tablets can be taken without water, as they are designed to dissolve quickly in the mouth.
- Administration with meals: Voglibose OD tablets should be taken immediately before meals to delay carbohydrate absorption and reduce postprandial blood glucose levels.

Side Effects:

- Gastrointestinal symptoms: Diarrhoea, abdominal pain, nausea, vomiting, flatulence, and bloating.
- Gastrointestinal discomfort: Abdominal distension, abdominal tenderness, and gastrointestinal fullness.
- Hypoglycaemia
- Allergic reactions: Skin rash, itching, and urticaria may occur in some patients.
- Headache
- Dizziness

Contraindications:

- Hypersensitivity: Voglibose OD is contraindicated in patients with a history of hypersensitivity to voglibose or other alpha-glucosidase inhibitors.
- Intestinal obstruction: Voglibose OD is contraindicated in patients with intestinal obstruction or those at risk of developing intestinal obstruction.
- Chronic intestinal diseases: Voglibose OD should be used with caution in patients with chronic intestinal diseases, such as Crohn's disease or ulcerative colitis.
- Liver dysfunction: Voglibose OD should be used with caution in patients with liver dysfunction or those at risk of developing liver dysfunction.
- Kidney dysfunction: Voglibose OD should be used with caution in patients with kidney dysfunction or those at risk of developing kidney dysfunction.

Preparation of Mouth Dissolving voglibose tablet

Weigh the ingredients according to the formulation. Mix the ingredients in a suitable container to ensure uniform distribution. Granulate the mixture using a suitablemethod (e.g., wet granulation or dry granulation). Ensure the granules are uniform in size and shape.Dry the granules using a suitable method (e.g., tray drying or fluid bed drying).Ensure the granules are dry and free-flowing.Mill the dried granules into a fine powder using a suitable mill (e.g., hammer mill or pin mill).Mix the powdered granules with magnesium stearate (lubricant) to ensure uniform

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distribution.Compress the mixture into tablets using a suitable tablet press.Ensure the tablets are uniform in size, shape, and weight. Apply a coating to the tablets if desired (e.g., to improve appearance or mask taste).

II. MATERIALS AND METHODS:

In the direct compression method of tablet production, dry ingredients are thoroughly mixed and then compressed into tablets. This eliminates the drying steps associated with the wet granulation method. It also reduces the higher costs involved in wet granulation including increased equipment, labour, time, process validation and energy expenditure.

As a result, direct compression is both efficient and economical, well suited to the production of high-quality tablets, which exhibit hardness, low friability and excellent dissolution rates. As an added benefit, direct compression can improve the physical and chemical stability of tablets as compared to wet granulation

Pre formulating studies:

The Pre-formulation studies are the first step in the rational development of dosage form of a drug substance. The objective of pre-formulation studies is to develop a portfolio of information about the drug substance, so that this information is useful to develop formulation.

Pre-formulation can be defined as investigation of physical and chemical properties of drug substance alone and when combined with excipients.

The powder blends were evaluated for angle of repose, bulk density, tapped density, compressibility index, Hausner's ratio etc. as following

Bulk Density:

Bulk density is defined as the ratio of total mass of powder to the bulk volume of powder. Bulk density is calculated according to the formula which is mentioned below.

Bulk Density = Mass of powder/Volume of powder

Tapped Density:

It is the ratio of total mass of the powder to the tapped volume of the powder

Tapped Density = Mass of powder(mg)/Volume of tapped power(ml)

Angle of Repose: It is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane.

It can be expressed as fallows

tan (è) = h/r

Where, (è) = angle of repose

h = height in cms,

r = radius in cms.

Carr's Index & Hausner's Ratio:

Carr's index and Hausner's ratio measure the propensity of powder to be compressed and the flow ability of powder. Carr's index and Hausner's ratio can be calculated from the bulk and tapped density.

Carr's Index = Tapped density–Bulk density / Tapped density × 100

Hausner's Ratio = Tapped density / Bulk density

Sieving, Mixing & Lubrication:

Voglibose was sieved through mesh 100 (#100); mannitol, microcrystalline cellulose PH 102, croscarmellose sodium and orange DC 100 PH were sieved through mesh 40 (#40). Voglibose was first mixed geometrically with mannitol and then with all other excipients manually in a polybag for 5 minutes.

Magnesium Stearate and Aerosol were sieved through mesh 60 (#60) and lubrication was done with the above mixed powder manually in a polybag for 45 seconds. The moisture content of the lubricated powder was observed in Denever digital moisture analyser at 105°C. The pre-compression parameters of the bulk lubricated powder were performed using Electro lab Tapped Density Tester USP.

The pre compression parameters revealed good flow property of powder for both 0.2 and 0.3 mg of voglibose tablets.

Compression:

After performing the pre-compression parameters, the lubricated powder was subjected for punching using tablet punching machine. The average punch weight of the tablets was 110 mg. The hardness, thickness, weight variation and friability of the punched tablets were maintained in the desired range.[3]

Evaluation of Post Compression Parameters of Voglibose Tablets

Weight Variation:

Twenty tablets were selected at random and average weight was determined then individual tablets were weighted and the individual weighted was compared with an average weight

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Hardness:

The resistance of tablet for shipping or breakage, under condition of storage, transportation and handling, before usage, depends on its hardness, before usage, depends on its hardness. The hardness of tablet of each formulation was measured by Monsanto hardness tester. Six tablets from each formulation were randomly selected and evaluated, and the average values were calculated

Friability:

Friability is the measurement of tablets strength. Roche friabilator was used for testing the friability using the following procedure six tablets were weighted accurately and placed in the plastic chamber that revolves at 25 rpm, dropping the tablets at a reweighted and the percentage loss in weight was determined

% Friability = Initial Weight-Final Weight-Initial weight × 100

Content Uniformity Test:

Ten Tablets accurately weighted and powdered a quantity of the powder equivalent to 10 mg of voglibose was weighted accurately and dissolved in buffer solution. After filtration and sufficient dilution with phosphate buffer solution, sample were analysed UV spectrophotometrically at 282 nm against buffer solution as a blank

Disintegration Test:

Tablets were taken and introduced in each tube of disintegration apparatus, and the tablets rack of the disintegration apparatus in to a 1-liter beaker containing 900 ml of distilled water and the time of disintegration was recorded. The discrimination between disintegration was done at room temperature and disk was not used for the study [24].

Wetting Time:

Five circular tissue paper of 10cm diameter are placed in Petri dish with 9.8 cm internal diameter. 10 ml of water added to Petri dish. A tablet is carefully placed on the surface of the tissue paper. Time required for water to reach upper surface of the tablet was noted as wetting time [25].

List of tablet defects

1. Capping
2. Lamination
3. Chipping
4. Sticking
5. Picking
6. Cracking
7. Binding / Binding in the die
8. Edging / Flashing of tablet
9. Mottling
10. Weight Variation
11. Hardness Variation
12. Aging of tablets/ Loss of hardness
13. Uneven Breakage
14. Double Impression
15. Black Spot
16. Inconsistent Thickness
17. Twining.

1. Capping:

Capping is a term used to describe the partial or complete separation of the top or bottom crowns of a tablet from the main body of the tablet. In other words, capping is a laminar splitting along the edge of the crown or band of a compressed tablet. Generally, capping is a common tablet defect during tablet manufacturing [15].

Causes:

- Air-entrapment in the granular materials.
- Too dry granules.
- High quantity of fine powder materials in the granules.
- Presence of too much lubricant.
- Too soft granules

2. Lamination:

Lamination is the separation of a tablet into two or more distinct horizontal layers. It is a tablet defect in which a tablet splits or separates into layers [17].

Causes:

- High quantity of fine powder materials in the granules.
- Oily, elastic, or waxy excipients in granules.
- Air-entrapment in the granular material
- Presence of too much lubricant.

3. Chipping:

Chipping is the breaking of tablet edges during the pressing process or during the subsequent handling and coating [18].

Causes:

- Too dry granules.
- Too much or too low binding.
- Sticking on punch faces

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4.Sticking:

Sticking is a defect of the tablet where the tablet surface sticks to the punch face or adhesion of tablet material to the die wall during compression. Simply, sticking is the adherence of material to the faces of tablet press punches or dies after compression. In sticking, the tablet surface sticks to the lower punch face but a small portion of the tablet surface is not detached or the pitted surface will not occur [19].

Causes:

- Excess moisture in granules.
- Inadequate lubrication.
- Too much binder.
- Too much hygroscopic excipients.
- Too much hygroscopic excipients.
- Sticky API or sticky excipient.

5.Picking:

Picking is the term used when a small amount of material from a tablet is sticking to and being removed from the tablet surface by a punch [1]. In other words, the removal of material from the surface of the tablet, and its adherence to the face of the punch is called picking [12].

Causes:

- Inappropriate dried granules**.**
- Inadequate lubrication.
- Too much binder.
- Too warm granules when compressing.

6.Cracking:

Cracking is a defect of tablets where small, fine cracks are observed on the upper and lower central surface of tablets, or very rarely on the sidewall. Easily visible in the tablet that contains pigment or dye [11].

Causes:

- Large size of granules**.**
- Too dry granules**.**
- Inadequate binder.
- Rapid expansion of tablets.
- Elastic excipients in granules.
- Granulation too cold.

7.Binding / Binding in the die:

Binding is a tablet defect where a tablet adheres, seizes, or tears in the die, or a film is formed on the die area and hindered the ejection of the tablet or splits during the moulding/pressing process. The powder adheres to punch edges and dies punches may bind in dies difficult ejection [4].

Causes:

- Too moist granules.
- Excessive binder.
- Inadequate lubrication.
- Too hard granules for the lubricant to be effective.
- Granular material very abrasive and cutting into dies.
- Use of hygroscopic IngredientsUse of Hygroscopic Ingredients

8.Edging / Flashing of tablet: Edging is a defect of tablets in which burrs (raised edges)/ sharp edges appear on the final compressed tablet. This type of tablet defect also known as collaring of the tablet or flashing.

Causes:

- Waxy or elastic API or excipients in formulation.
- Moisture in granules.
- Higher compression pressure
- Poor design punch or wear punch.

9.Mottling

Mottling is the term used to describe an unequal distribution of color on a tablet, with light or dark spots standing out on an otherwise uniform surface. This type of tablet defect occurs in tablet formulation with a dry colouring agent. Simply, mottling is a tablet defect where dark and light patches on the tablet surface occur.

Causes:

- The unequal particle size of the colouring agent or pigment.
- A coloured drug used along with colourless or white-coloured excipients.
- A dye migrates to the surface of granulation while drying.
- Improperly mixed dye, especially during ‘Direct Compression’.
- Too small amount of colorant.
- Preferential absorption of soluble dye by component of mix.

10.Weight Variation

Weight variation is a common defect of tablets that occurs during tablet manufacturing where the average or individual weight of the tablet may be outside of the accepted limit.

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Causes:
- Poor or erratic flow of granules from the hopper.
- Improper amount of glidant
- Particle size ranges too wide.
- Improper drying.
- Abnormal uniform mixing of all excipients.
- Particle segregation as press RPMs increase
- Particle size not suitable for die diameter
- Improper tool setting of the machine. Hi-speed running of the machine.

11.Hardness Variation:

Tablet hardness does not remain constant but it has a range. Hardness variation is a common defect of tablets where individual hardness of tablets may be outside the accepted limit. Unlike weight variation, the hardness variation limit is determined by a prototype trial of that tablet.

Causes:
- Over-blending.
- Weight variation in granules filled in die.
- Improper mixing of lubrication
- Uneven die-fill

12.Aging of tablets/ Loss of hardness

It is a tablet defect where the hardness of the tablet decreases with time.

Causes:
- Over-lubrication.
- Tablets with microcrystalline cellulose (MCC) lose some hardness with time at high humidity, but most of the hardness is quickly regained at normal humidity.
- Compression force (pressure) too low
- Granulation too soft
- Moisture content too high

13.Uneven Breakage

Many tablets are designed to be broken into smaller dosages with functional score-line / break lines. It is a tablet defect where the tablet breaks unevenly into two parts.

Causes:
- Coarse granules.
- Improper mixing.
- Air-entrapment in the granular materials.
- Unequal sizes of granules.

14.Double Impression:

Double impression is one of the most common tablet problems. This defect is characterized by the presence of two or more imprints on a single tablet. It occurs when the tablet material is subjected to multiple impressions during compression, resulting in overlapping or duplicated markings.

Causes:
- The punches are not properly aligned within the die cavity.
- The rotation of lower punches is not properly controlled.
- Clearance between the punches and dies is not properly adjusted.

15.Black Spots:

Black spots on tablets refer to the dark or black-coloured specks or dots on the tablet surface. These spots are considered defects and can negatively impact the appearance and quality of the tablets.

Causes:
- Foreign particles or impurities are in the raw materials used for tablet manufacturing.
- The equipment, compression tooling, and manufacturing environment are poorly cleaned.
- Inadequate lubricant mixing results in agglomeration.
- The tablet formulation is not properly granulated.
- Oxidation of formulation components or exposure to unfavourable conditions causes the formation of black spots or discoloration.

16.Inconsistent Thickness:
- Inconsistent thickness is one of the most common defects in tablets.
- It refers to variations in the tablet thickness within a batch or across different tablets.
- Inconsistent thickness can impact the overall quality, functionality, and appearance of the tablets.

17.Twining:

Twinning is one of the common tablet problems. It presents as two distinct tablets fused together. Twinning occurs when two tablets stick together during the compression process.

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Causes:

- The tablet material and the punches and dies are not adequately lubricated.
- Formulations are not properly granulated, resulting in tablets with excessive porosity.
- Tablets with flat or parallel faces are more likely to experience twinning.
- Inconsistent compression force causes tablets to merge instead of being individually formed.
- The ejection mechanism of the tablet press is not functioning optimally.[17]

III. CONCLUSION:

Mouth dissolving Voglibose tablets represent a promising innovation in the management of type 2 diabetes mellitus. With their unique formulation and rapid absorption, these tablets have the potential to improve patient outcomes, enhance patient compliance, and expand treatment options for healthcare providers.

Mouth dissolving Voglibose tablets offer a convenient and patient-friendly alternative to traditional tablets for the management of type 2 diabetes mellitus. With their rapid disintegration and absorption, these tablets provide a quick and effective way to control postprandial blood glucose levels.

About one of the third paediatric and geriatric population have difficulty to swallow the tablet, but orally disintegrating tablet is convenient for paediatric and geriatric populations to swallow the tablet easily without need of water

These tablets are planned to be dispersed quickly in the saliva within 60 seconds. Many drugs can be added in ODT mainly unpalatable drugs.

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