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DEVELOPMENT & CHARACTERIZATION OF MOUTH DISSOLVING TABLET OF VOGLIBOSE

Jayesh R. Tundlayat *, Abhay Kumar D. Sakhare and Kailash R. Biyani

Department of Pharmaceutics, Anuradha College of Pharmacy, Chikhli, Buldhana - 443201, Maharashtra, India.

Keywords:

Mouth dissolving tablets, Super disintegration, Voglibose, Type 2 Diabetes mellitus

Correspondence to Author:
Dr. Abhay Kumar D. Sakhare

Associate Professor,
Department of Pharmaceutics,
Anuradha College of Pharmacy,
Chikhli, Buldhana - 443201,
Maharashtra, India.

E-mail: tundlayatjayesh30@gmail.com

ABSTRACT: The study was aimed at development of voglibose mouth dissolving tablets which can disintegrate or dissolve rapidly once place in the oral cavity. Voglibose is alpha glycosidase inhibitor, drug which is used in a treatment of type 2 diabetes mellitus. The tablets were prepared with different super disintegrant like crospovidone, sodium starch glycolate and lactose at different concentrations. 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. The most satisfactory formulation F6 showed minimum disintegration time of 31 sec and release maximum amount of drug in shortest duration of time in 10 min. it was found to be stable during short term stability studies. Compatibility studies confirmed the absence of any interaction between Voglibose and the selected excipients. The optimized formulation exhibited excellent disintegration time and dissolution profile, meeting the pharmacopoeia requirements for MDTs. Furthermore, sensory evaluation revealed improved palatability compared to conventional tablets. Thus, the developed MDT of Voglibose offers a promising alternative for enhancing patient compliance and convenience in the management of diabetes mellitus.

INTRODUCTION: Mouth dissolving tablet "The mouth dissolving tablets are defined as the solid dosage forms that rapidly get disintegrate and dissolve into saliva in the oral cavity, results into solution without the need of water for administration" [1]. The Oral Cavity is an attractive site of the administration. Various dosage forms like Tablet, Capsules, Liquid preparations are administered.

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By oral route during the last decade, mouth dissolving tablet technologies make tablets disintegrate in the mouth without chewing and additional water intake have drawn a great deal of attention.

The mouth dissolving tablet are also known as, fast melting tablet, fast dispersing tablet, rapid dissolve tablet, rapid melt tablet, freeze dried wafers and quick disintegrating tablet. All mouth dissolving tablets approved by the Food and Drug Administration are an classified as orally disintegrating tablets. The European pharmacopeia to take the term oro-dispersible tablet for a tablet that disperses and disinter grates in less than 3 minutes into the mouth before swallowing, a tablet

disintegrates into the smaller granules and melts in the mouth form hard solid to a gel-like structure, allow easy swallowing by the patients. The disintegration time for the good mouth dissolving tablets varies from several seconds to about a minute [2-4].

The last few years, they have an enhanced demand for more patient friendly dosage forms. The demand for developing modern technologies has been increasing every year. The development cost of a new drug molecules is a very high, efforts are a now being made by pharmaceutical companies to focus on the development of new drug dosage forms for the existing drugs with improve safety and efficacy to with reduces dose frequency, and the production of more cost effectively dosage forms. In addition, patients travel with little and no excess to water. Limit utility of oral administer convectional tablet capsule. Mouth dissolving tablets result in quick dissolved and rapid absorption with provide rapid onset of action. In addition, drug candidates undergo gastric absorption when formulation a mouth dissolving tablet may show high oral bioavailability. It provides good stability exact dosing, and easy manufactured [5].

MATERIALSAND METHODS:

Drug Excipients Compatibility Study: Compatibility studies were carried out to know the possible interaction between voglibose and super disintegrant used in formulation. Physical mixtures of drug and super disintegrants were prepared to study the compatibility. Drug polymer compatibility studies were carried out using IR spectroscopy [6, 7].

Pre-Formulation Study [8-10]: 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.

Angle of Repose: The angle of repose of mixture of drug and excipients was determined by the fixed funnel method. The funnel was fixed at an of powder sample was passed through the funnel until the apex of the conical pile just touches the tipoff funnel. The diameter of the powder cone was measured and angle of repose was calculated using the following equation:

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

Bulk Density & Tapped Density: Both loose bulk density (LBD) and tapped bulk density (TBD) was determination. A quantity of 6.5 gm of powder from each formulation, previously lightly shaken to break any agglomerates formed was introduced into a 10 ml. measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5cm at 2 sec intervals. The tapping continued until n of urther change in volume was noted. Bulk density is calculated by using formula:

LBD = Weight of the powder / Bulk volume of the powder

TBD = Weight of the powder / Tapped volume of the powder

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

TABLE 1: PRE-COMPRESSION PARAMETER OF VOGLIBOSE TABLETS

Formulation code	Angle of Repose (°) ± S.D.	Bulk Density (gm/ml) ± S.D.	Tapped Density (gm/ml) ± S.D.	Carr's Index (%) ± S.D.	Hausner's Ratio (%)±S.D.
F1	29.003±0.25	0.33±0.008	0.395±0.007	15.87±0.603	1.18±0.01
F2	27.406±1.27	0.35±0.005	0.406±0.006	11.58±062	1.12±0.005
F3	26.29±1.02	0.34±0.006	0.406±0.003	13.606±2.05	1.15±0.02
F4	27.01±0.41	0.36±0.003	0.422±0.013	12.702±1.22	1.14±0.01
F5	27.81±0.30	0.36±0.006	0.42±0.008	13.01±1.38	1.14±0.02
F6	27.9±1.51	0.36±0.003	0.41±0.004	11.31±0.76	1.12±0.005
F7	27.45±0.80	0.35±0.004	0.41±0.003	13.46±1.76	1.15±0.02

F8	28.87±0.65	0.37±0.002	0.42±0.003	11.307±0.603	1.12±0.01
F9	28.09±1.22	0.36±0.006	0.41±0.009	12.48±1.54	1.14±0.02

Reading are average of 3 determination ± Standard Derivation.

Formulation Development: The various formulation of mouth dissolving tablets was developed for Voglibose (Gift sample from Macleods company) by direct compression method using super disintegrant with different concentrations. PVP, Crospovidone and Sodium Starch Glycolate used as super disintegrant, Mannitol used as diluent, Sodium Lauryl Sulphate used as lubricant.

Preparation of Mouth Dissolving Tablets of Voglibose: Mouth dissolving tablets was formulated by direct compression method using the formula shown in **Table 2**. Voglibose, super disintegrant and other excipients except lubricant was passed through #60 sieves separately. The sifted ingredients were blended in a mortar pestle for 15 min through geometric dilution. The blended powder was lubricated with sifted (#60) sodium lauryl sulphate. The lubricated powder was compressed into round tablets with 6 mm standard concave punch using rotatory tablet punching machine.

TABLE 2: FORMULATION OF MOUTH DISSOLVING TABLETS OF VOGLIBOSE

Ingredients (mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Voglibose	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Mannitol	61.38	56.74	52.08	61.38	56.74	52.08	61.38	56.74	52.08
Crospovidone	-	-	-	27.06	32.72	36.36	-	-	-
Lactose	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Sodium Starch Glycolate	-	-	-	-	-	-	27.06	32.72	36.36
Sodium Lauryl Sulphate	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92	0.92
Aspartame	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83	1.83
Poly-Vinyl Pyrrolidone (PVP)	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5	6.5
Total	100	100	100	100	100	100	100	100	100

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 [11].

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 [12].

Friability: Friability is the measured 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 [13].

% 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 analyzed UV spectrophotometrically at 282 nm against buffer solution as a blank [14].

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 [15].

Wetting Time: Five circular tissue paper of 10cm diameter are placed in petridish with 9.8 cm internal diameter. 10 ml of water added to petridish. 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 [16].

Stability Study: Accelerated stability on promising voglibose formulation F1 to F9 was carried out by storing 15 tablets in amber coloured rubber stopped vials at elevated temperature of 30 ± 2°C / 65 ± 5% RH (Stability Chamber, Osworld) over a period of 60 days (2 Month). At intervals of one month, the tablets were visually examined for any physical changes, changes in content and in-vitro dispersion time [17].

TABLE 3: POST COMPRESSION PARAMETERS OF VOGLIBOSE TABLETS

Formulation Code	Hardness ± S.D. (kg/cm^2)	Friability (%)	Weight Variation (mg)	Drug Content (%)	Disintegration Time (sec) ± S.D.	Wetting Time sec (±S.D.)
F1	2.81±0.14	0.22	100.59±0.56	99.18	50.33±1.52	52.48±0.86
F2	3.23±0.44	0.452	100.54±0.72	98.34	41±1	54.15±0.38
F3	3.02±0.01	0.51	100.32±0.75	97.12	44.66±0.57	51.86±0.30
F4	2.82±0.08	0.261	100.93±0.702	96.54	38.33±0.57	54.69±0.49
F5	2.95±0.09	0.412	100.403±0.69	97.73	36.33±0.57	56.54±0.21
F6	2.84±0.17	0.311	100.23±0.66	97.17	31±1	47.47±0.56
F7	3.01±0.11	0.21	100.52±0.68	98.44	53.33±0.57	52.33±0.26
F8	2.97±0.04	0.401	100.61±0.72	99.03	57.33±0.36	51.67±0.71
F9	2.83±0.04	0.367	100.63±0.77	98.78	58±0.37	57.47±0.26

Reading are average of 3 determination ± Standard Derivation.

RESULTS AND DISCUSSION: The identification of pure drug voglibose was carried out and confirmed that the sample passes. The IR spectra and melting point analysis of the drug matched the standard. Voglibose showed maximum absorption at wavelength 282 nm in phosphate buffer pH 6.8 Calibration curve of voglibose in phosphate buffer at 282 nm obeyed the beer's range and when subjected to regression analysis the coefficient was found to be 0.99, which showed near relationship between concentration and absorbance. In order to investigate the possible chemical integration between drug and selected excipients. So, that drug and excipients are compatible. Results are shown in figure 1A-1D. The results of angle of repose were range between 28.09° ± 1.02 to 29.03° ± 0.25 which indicated the flow properties of powder to be sat is factory range, Results are showed in **Table 1**.

The Carr's index values were found to be in the range of 12.48±1.54 to 15.87±0.603%. The bulk density and tapped density values were in the range of 0.332 ±0.008 to 0.379 ±0.002 and 0.395 ±0.007 to 0.427 ±0.003 gm/ml respectively. Results are shown in **Table 1.** These values indicated that the powder mixture of all batches of formulation were in satisfactory range and hence, are suitable for direct compression into mouth dissolving tablets. Hardness of the developed formulation F1 to F9 varied from 2.8 to 0.1 kg/cm^2. The friability of the developed formulation varied from 0.31% which was less than 1% as official requirement of IP. Results are shown in **Table 3**. It was observed that there is decrease in the friability while increase in the hardness of tablets. So, hardness was increased to reduce the friability and the concentration of the disintegrating agent was also increased for the rapid disintegration time. The average weight of 10 tablets were calculated for each formulation which varied from 100.23 ± 0.66 mg to 100.93 ± 0.7 mg and complied with the official requirements as per IP. Results are shown in **Table 3**. The drug content varied from 97.12% to 99.18% and complied with the official requirements as per BP. Results shown in **Table 3**. *In-vitro* disintegrating time of all nine formulations varied from 30 ± 1 to 56 ± 0.5 sec result showed in **Table 3**.

The rapid disintegration was seen in the formulation (F6) containing crospovidone. This is due to rapid uptake of water from medium, swelling and bursting effect. The formulation F6 is the most satisfactory formulation, as it showed rapid disintegration within 30 sec. the average wetting time of all formulations was obtained in the range of 47.47 ± 0.5 to 57.47 ± 0.2 sec. The maximum wetting time of 57.4 sec showed by formulation F1 and the minimum wetting time of 47.7 showed by formulation F6. The release of voglibose from mouth dissolving tablets varied according to the proportions of various super

disintegrant. After 10 min dissolution studies of formulations F1 to F9, the drug release varies from 98.94 ± 0.1%. Results are shown in **Fig. 2**. *In-vitro* drug release represents, formulation F6 is the most satisfactory formulation. As it showed maximum drug release of about 98.94% when compared with other formulations. Stability studies was carried out the most satisfactory formulations F6 at 30 ± 2°C / 65±5% RH for two months to assess their stability, after two months of storage of formulation F6, they were checked periodically for hardness, drug comtent, disintegration time. Results are shown in **Table 4**. There is no significant change in results obtained after stability studies.

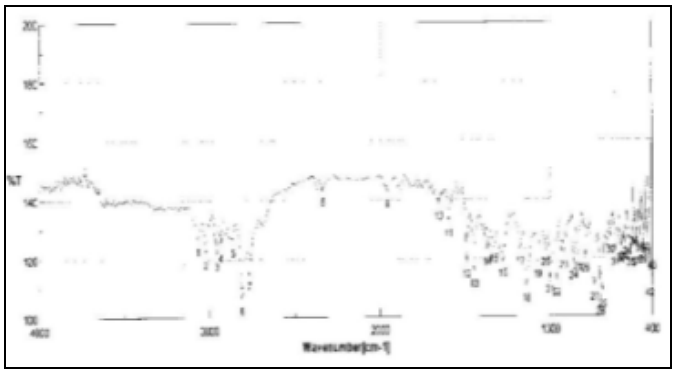

FIG. 1A: IR SPECTRA OF VOGLIBOSE

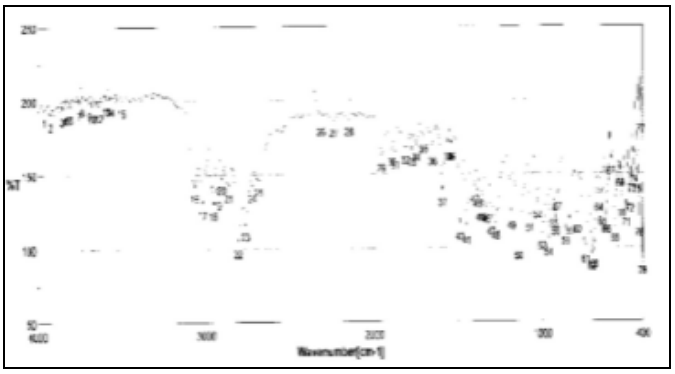

FIG. 1B: IR SPECTRA OF VOGLIBOSE & SODIUM STARCH GLYCOLATE

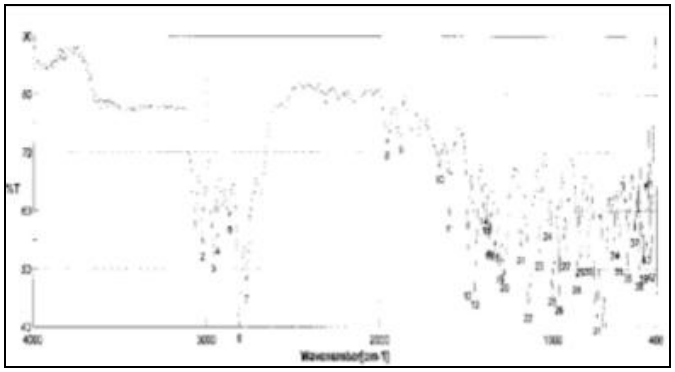

FIG. 1C: IR SPECTRA OF VOGLIBOSE & CROSPOVIDONE

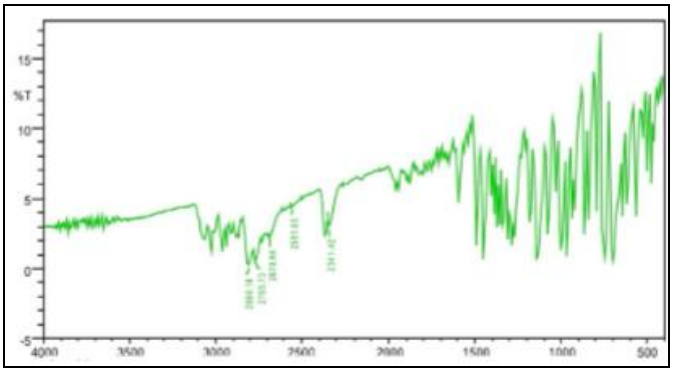

FIG. 1D: IR SPECTRA OF VOGLIBOSE & LACTOSE

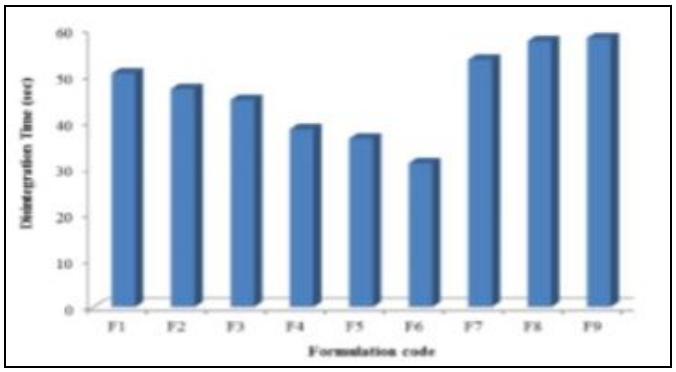

FIG. 2: DISINTEGRATION TIME OF F1 TO F9

Stability Study:

TABLE 4: STABILITY DATA OF F6 FORMULATION AT 30±2°C/65±5% RH

Time in days	Physical changes	% Drug content ±S.D.	*In-vitro* dispersion time ±S.D.
1st day (Initial)	--	94.36±0.20	22.16±0.92
30th day (1 month)	No Changes	93.35±0.11	22.36±0.12
60th day (2month)	NoChanges	93.12±0.13	22.60±1.15

CONCLUSION: Voglibose is an alpha glucosidase inhibitor used in the treatment of diabetes mellitus type II Voglibose showed maximum absorption when analyzed UV-spectrophotometrically at wavelength of 282 nm in phosphate buffer solution. The value of correlation coefficient was found to be 0.99, which showed linear relationship between concentration and absorbance. Pre-formulation study for drug excipient compatibility by IR spectroscopy gave confirmation About their purity and showed no interaction between drug and selected super disintegrant Nine formulation of mouth dissolving tablets were prepared by direct compression technique by using of super disintegrant like crospovidone, sodium starch glycolate and lactose. Along With their additives. Developed mouth dissolving tablets gave satisfactory results for various Physicochemical parameters like hardness, friability, weight variation, drug content, *in-vitro* Disintegration time, *in-vitro* drug release study and wetting time. The disintegration time of Mouth dissolving tablets depends on concentration of the super disintegrants. The disintegrants time was rapid in formulation containing crospovidone as compared with the other formulations. Formulation F6 showed 99.43% drug release at about 10 min & it showed minimum disintegration time 31 sec as compared to other formulations. So, it was selected as the most sat is factory formulation. The most sat is factory formulation F6 Showed no significant change in physicochemical properties, drugcontent, *in-vitro* disintegration and *in-vitro* dissolution pattern after storage 30 ± 2°C / 65 ± 5% RH stability The present work of formulation oro-dispersible tablets of voglibose by using super dis-integrant like crospovidone, sodium starch glycol-late and lactose have been achieved

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