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Full Length Research Paper

Formulation And Evaluation Of Voglibose Controlled Release Tablets

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ABSTRACT

Voglibose is an oral hypoglycemic drug used effectively in the treatment oftype-2 diabetes mellitus ,itis an alpha glucosidase inhibiter used for lowering postprandial blood glucose level in patients with Type 2 diabetes mellitus. The available of this drug doses are 0.2 and 0.3 mg take a tablet before taking a meal. So, The Objective of Present Work is to reduce the dosing frequency thisdrug in control release tablet and increase its continuous therapeutic effect throughout the day.

.The aim of the work is to design and develop controlled release tablets comprising of this drug by wet granulation method using polymers such as HPMC ,CVP and PVP to carry out the In vitro release studyofthe drug. Formulating Controlled release tablets with good physical strength. There would-be a need of administration of drug once a day with maintaining the drug concentration within the therapeutic range. To improve the patient compliance. The prepared tablets were evaluated for various pre-compression parameters such as bulk density, angle of repose and post-compression, hardness, weight variation, thickness, friability, disintegration time, in vitro dissolution studies.

1. INTRODUCTION

SOLIDDOSAGE FORMS

Oral medicine is a solid dosage with convenient administration. It offers many benefits and has become a common benchmark in the pharmaceutical industry, the mode of administration remains the preferred approach. The oral route is prevalent because to its ease of administration, accurate dosing, cost-effective manufacture, and extended shelf life .

Currently, the majority of new pharmaceuticals are developed and manufactured in oral solid forms, such as tablets and capsules, since they represent one of the most efficacious methods of drug administration. The predominant oral medications available today are of the immediate-release formulation, which facilitate rapid absorption of the drug after administration In contrast. Controlled and sustained drug delivery systems represent the latest advancements in pharmaceutical technology.

TABLETS

Tablets are the most widely used solid dosage form in the pharmaceutical industry. They are unit-dose preparation containing one or more active pharmaceutical ingredients (APIs) along with suitable excipients. Tablets are characterized as solid, flat or biconvex discs ,favored due to their convenience, stability, cost-effective manufacturing and patient acceptability. Depending. On the therapeutic need, tablets can be designed in various forms such as immediate - release, chewable, effervescent, buccal, sublingual, dispersible controlled/ sustained-released formulations. A unit dosage formulation. Their dimensions, mass, and morphology may vary significantly according on the dose and administration route of the medicinal agents. The predominant method of pharmaceutical administration is tablets, making it the most common dosage type. Various ways were used to prepare it. Figure 1 illustrates the three methods: wet granulation, dry granulation, and direct compression.

Diabetes Mellitus (DM):

Diabetes Mellitus (DM) is a persistent metabolic disorder that impacts individuals globally. The micro- and macro-vascular effects lead to significant impairment of various vital human organs and structures, contributing to elevated morbidity and mortality rates.

Estimates indicate that the population of individuals with diabetes in India is projected to increase significantly from 21.7 million to 79.4 million by the year 2030. Nonetheless, considering that numerous individuals remain asymptomatic, unaware of their condition, and thus go undetected, the actual prevalence is probably significantly greater than this estimate suggests. About one-third of the estimated occurrences can be accounted for by this.

Despite the availability of numerous medications for managing type-2 diabetes, achieving normalization of blood glucose levels remains a rare outcome. It is critical to diagnose diabetes mellitus signs early and

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address them promptly to achieve blood normalization, according to recent trials and research.

Another group of people includes those who have impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), which means their glucose levels are higher than normal but not high enough to be classified as diabetes. In the future, these people are more likely to acquire overt diabetes mellitus or have diabetes-related complications. When insulin secretion response is impaired and insulin resistance develops, the outcome is postprandial hyperglycemias (PPHG).

When it comes to diabetes, PPHG is a direct and independent risk factor for the development of CVD or stroke, both of which are caused by early atherosclerosis. High fasting plasma glucose (FPG) levels may cause serious problems down the road if not treated properly.

When it comes to HbA1c levels, PPHG is the major factor to consider. Low HbA levels are a direct result of PPHG reduction.

Reduced micro vascular and neuropathic consequences of diabetes are related with glycated haemoglobin (HbA1c) levels below 7%, according to the most recent American Diabetes Association recommendations. Implementing this technique promptly after a diabetes diagnosis is also linked to a long-term decrease in macro vascular disease. And hence, many non-pregnant adults should aim for a HbA1c level below 7%.

Furthermore, with every 1% decline in HbA1c levels, the United Kingdom Prospective Diabetes (UKPD) research found that micro-vascular complications reduce by an average of 21%, with a maximum reduction of 35%. Interactions between myocardial cells and abrupt cardiac death were 16% less likely. An 18% drop in fatal and nonfatal cardiac infections correlates to a 1% drop in heart attack cases.

Voglibose:

The α-glucosidase inhibitor(AGI) class includes Voglibose and other competitive inhibitors.α-glucosidasenzyme.

.It was recognized as being produced by Streptomyces hygroscopicies var. limonons in 1981 following its isolation from validamyan on culture medium in Japan. It was made commercially available in Japan for the treatment of DM starting in 1994.

ClinicalPharmacologyandMechanismofAction:

Voglibose exhibits an anti-hypoglycemic effect by reversibly inhibiting the α glycosidase-hydrolyzing enzymes located in the membrane-bound intestines. Enzymes acting at the small intestine's brush border break down oligosaccharides and disaccharides into glucose and other monosaccharide's. The carbohydrate-degrading enzymes are reversibly inhibited by this drug, including sucrose, maltose, and zomaltase, thereby delaying the absorption and digestion of dietary polysaccharides. Consequently, there is a reduction in PPHG.

Figure: VogliboseMechanismofaction

Furthermore, the drug might enhance the secretion of alpha endogenous glycogen-like peptide, which plays a role in inhibiting glycogen and reducing blood glucose levels during fasting. The administration of voglibose has been noted to enhance the production of GLP-1, an insulin tropic hormone recognized for its role in improving insulin sensitivity and secretion.

This drug does not lead to lactose intolerance or diarrhea, as it does not inhibit lactase activity. When used in conjunction with other oral hypoglycemic agents, such as sulfonylurea, it has shown an additive effect. It also reduces the influence of sulfonylurea's on insulin tropic response and weight gain.

2-LITERATURE REVIEW

PravinS.,AyyappanT.andVetrichelvanT.etalreviewed23April2021[1]

Every pharmaceutical formulation, from classic to cutting-edge drug delivery methods, relies on pharmaceutical polymers. The use of polymers in different dosage forms and drug delivery systems allows for the prolonged, extended, modified, controlled, and targeted release of the medication. Polymers may be designed with a variety of pharmaceutical uses in mind by carefully considering bulk and surface qualities. Conventional and regulated drug delivery methods rely heavily on them as pharmaceutical aids (binders, suspending

agents, emulsifying agents, coating agents, adjuvants, etc.), packaging materials, and medical devices. Classification, characteristics, drug release processes, and pharmaceutical polymers' uses in drug delivery systems are all briefly covered in this article.

Ajay S.Dabhi, NikitaR.Bhatt, andMohitJ.ShahetalStudied2013Dec [2]
Diabetes mellitus (DM) is a prevalent and significant health issue affecting individuals worldwide. It may induce complications in both big and small blood arteries. Inadequately controlled postprandial hyperglycemia is the principal cause accountable for these outcomes. Treatment alternatives include alpha-glycosidase inhibitors, including acarbose, voglibose, and miglitol. Voglibose, akin to these other drugs, is efficacious and well-tolerated at comparable doses. The article examines the main properties of voglibose.
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EvangelosKaravas, EmmanouelGeorgarakis,DimitriosBikiarietalstudiedAugust 2006[3]
Developing pulsatile tablet formulations with two layers to prevent ischemic heart diseases was the primary goal of this investigation. The active core was a solid dispersion of FELO/PVP 10/90 w/w, and the stimulus-responsive layer was a coating of PVP/HPMC blends in different proportions; this allowed for modulation of the length of drug release. The interaction between the hydroxyl groups of HPMC and the carbonyl groups of PVP causes these combinations to be miscible throughout all compositional ranges, according to DSC tests. The miscibility of the system allows the blends to outperform pure HPMC in certain applications when it comes to mucoadhesive characteristics. Matrixes were made more wettable and flexible due to the quick breakdown of PVP macromolecules, which allowed for the improvement. The manufactured tablets' coating comes off first when they come into touch with the release medium, and then the active core releases FELO instantly. The swelling and erosion of PVP/HPMC polymer mixes affect the delaying time via a sophisticated method. By modifying the PVP/HPMC blend ratios, the precise release timing of FELO may be fine-tuned mathematically: t = 0.028 C1.5, where C is the concentration of HPMC in the mixture.

MalleshKurakula and G.S.N.KoteswaraRao et. alStudied2020Dec
The process of polymerization of the monomer N-vinylpyrrolidone yields the water-soluble polymer known as polyvinylpyrrolidone (PVP). A non-toxic and durable polymer, PVP can withstand fluctuations in both temperature and pH. It works well for encapsulating hydrophilic and lipophilic medicines due to its biocompatibility and biodegradability. Because of its many useful properties, PVP is being considered as an excipient for many different types of controlled delivery systems, both old and new. DNA delivery, orthopaedic implants, and tissue engineering all rely on PVP due to its malleable properties. Various molecular weights and modified forms of PVP may produce PVP with a wide range of chemical properties and exceptional beneficial attributes. The coupling of PVP with pharmaceuticals that are not very soluble may be achieved using graft copolymerization and other methods. This increases the medications' bioavailability and allows for the creation of the swelling profile needed for controlled or sustained release. From conventional to controlled delivery systems for pharmaceuticals, genes, and cosmetics, this study covers the chemistry, mechanical and physicochemical characteristics, assessment factors, and manufacturing techniques of PVP derivatives. Given its long history of use and current popularity, PVP is an attractive polymer candidate for enhancing the properties and functionality of modern medicinal dosage forms.

William B. Liechty, David R. Kryscio, Brandon V. Slaughter, and Nicholas A. Peppas[5]
A key component of modern drug delivery systems, polymers allow for the cyclic, controlled release of medicinal substances over long periods of time at constant concentrations. Medication administration and controlled release, including both water-soluble and water-insoluble formulations. Chemical engineers have been instrumental in the field's meteoric rise from its humble beginnings using commonplace materials. Modern advances in medication distribution rely on carefully engineered polymers that can carry out targeted biological functions. The mathematical foundations of the most important drug delivery systems are discussed in this overview, together with the physiological challenges that these systems face. This study takes a look at the fundamentals and applications of polymer therapies, such as polymer-protein and polymer-drug conjugates, as well as stimuli-responsive polymer systems. This review aims to shed light on research areas that are pushing the frontiers of drug delivery by examining the most current breakthroughs in polymers that aid in molecular identification or guide intracellular administration.

Moussa , F. Siepmann , M.P. Flament, Y. Benzine , F. Penz , J. Siepmann , Y. Karrout[6]
When making controlled release tablets, hydroxypropyl methylcellulose (HPMC) is a typical matrix former to use. It is suggested to add freely water-soluble lactose in order to change the target medication release kinetics. Propranolol HCl loaded matrix tablets, namely HPMC:lactose mixes, were the subject of this investigation because of the importance of the production method. Here are the

procedures that were used to produce the tablets: (i) physical blends consisting of the medication, HPMC, and lactose were compressed directly; (ii) spray agglomerated HPMC:lactose blends were compressed directly; and (iii) wet granulation was practiced. Notably, although the physical HPMC:lactose blends and the co-processed HPMC:lactose particles showed similar water absorption kinetics and medication release rates, the former showed better flowability and compactability. The drug release kinetics were also similar when the granulation was done in a moist environment. As a result, controlled release matrix tablets made with co-processed HPMC:lactose provide significant technological advantages without sacrificing system performance.

ShaileshT.Prajapati, AmitN. Patel, and Chhagan N.Patelet alStudied2011

In this work, a 32 complete factorial design is used to investigate the effects on the formulation of controlled-release tablets for Zolpidem tartrate using varied concentrations of PEG 6000 as a melt binder and different ratios of HPMC K4M to PVP. As independent variables, we found the HPMC K4M/PVP K30 ratio (X 1) and the melt binder concentration (X 2), and the drug release at Q1, Q4, Q8, the diffusion coefficient (n), and the release rate constant (K) were determined to be the dependent variables. The melt granulation process was used to manufacture the tablets, which were then tested for several evaluation criteria. There was a strong relationship between the melt binder content and Q1, Q4, n, and K. The ideal binder concentration was found to be 25% w/w. There was a solid correspondence between the predicted pharmacological profile and the improved formulation (F 7). While X 1 had no discernible effect on the dependent variables, X 2 had a statistically significant influence on them.

Zhisu Sun,Huicong Zhang,Huiyang He,Lingling Sun,Xiaorui Zhang,Qun Wang,KexinLi, and Zhonggui Heet al Studied 2018 Sep [8]

When it comes to medications that don't dissolve well in water, solid dispersion devices have proved a lifesaver. During the formulation process and scaling-up techniques simultaneously, HPMC E5 was used to address the constraints associated with polyvinylpyrrolidone (PVP) dispersions. Nimodipine (NMP) and its tablet counterparts were prepared for this investigation utilizing solvent extraction and a one-step fluid bed granulating procedure, respectively. Consistent dissolution results were achieved by using selective dissolving media. During this period, we studied SD stability by keeping them in an environment with high temperatures and humidity. Also, in order to find out how carriers affected the SDs, we tested their solubility. Characterization of the preparations was carried out using DSC, PXRD, and FTIR methods. The novel combination of the two polymers significantly improved the rate of NMP dissolution. In contrast to the rapid degradation of the single NMP/PVP-SDs in water, the binary NMP/PVP/HPMC-SDs showed a constant release profile. Similar to the commercial NimotopTM tablets, the fluid-bed tablets (FB-T) dissolved slowly. It seemed from the characterisation patterns that our SDs included NMP in an amorphous form. In addition, the results of the stability tests showed that the binary SDs were more stable. Regarding the dissolving properties of NMP SDs and tablets, a novel cooperative effect of PVP and HPMC was discovered; this finding might have future applications to other medications. Using NimotopTM as a reference, the bioavailability of FB-T was evaluated in beagle dogs. According to the results, FB-T had a greater AUC0-12h value.

Patil harshal santoshrao , Patel Nikhil bhai Dilip bhai, Patil Vinay S., Bhushan R. Rane, Nayan A. Gujrathiand Sunil P. Pawar et al reviewed 2014[10]

There has been a sharp drop in the number of novel pharmaceuticals developed recently. Furthermore, the misuse of antibiotics and other current drugs is causing a major problem with resistance. Accordingly, making little changes to the operation is an appropriate and optimum way to increase the drug's efficacy. One potential method for lowering medication side effects is sustained release, which works by maintaining a steady therapeutic concentration of the drug in the blood. Learn the basics of sustained-release formulations and the several kinds that are linked to them in this article.

ArijitDuttaet alReviewed 2023[11]

The α-glucosidase inhibitor voglibose is useful for the management of hyperglycemia and type II diabetes mellitus, and it also has anti-obesity and anti-diabetic effects. The production, pharmacology, and action mechanisms of Voglibose have all been the subject of substantial research. The article's writers zero emphasis on the several analytical methods used to estimate Voglibose in pharmaceutical formulations. This study covers a range of analytical methods for the analysis of Voglibose in both single and multicomponent dose forms, including UV-Visible spectroscopy, HPLC, UPLC, and LC-MS.

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N.Mallikarjuna Rao,J.Bagyalakshmi1 and T.K.Ravi1etalStudied2010[12]

There are UV-Spectrophotometric methods that can reliably quantify Voglibose in pharmaceutical formulations in a fast, accurate, and efficient manner. Because Voglibose absorbs UV light only in the low wavelength range, it is not very sensitive when detected. Voglibose analysis requires specialized detection techniques. Mixing voglibose with taurine and sodium periodate is the only way to get reliable data from a number of analytical devices. In a combination of water and methanol, the medication solution was derivatized using taurine and sodium periodate. A distinct λmax in methanol was observed at 282nm for the molecule. A linear relationship was seen between 10-80 µg/ml, with a r2 value of 0.997. The quantity of the medicine that was supposedly included in the pill was quite similar to what was stated on the label. In addition to recovery experiments, the approach was statistically validated. For voglibose determination in bulk and tablet dose forms, the proposed methods are accurate and economical.

3-AIMANDOBJECTIVE

Aim:

This project aims to create controlled release tablets of Voglibose using the wet granulation process and polymers such HPMC , CVP, and PVP . Then, we will test the edication's release in a lab setting.

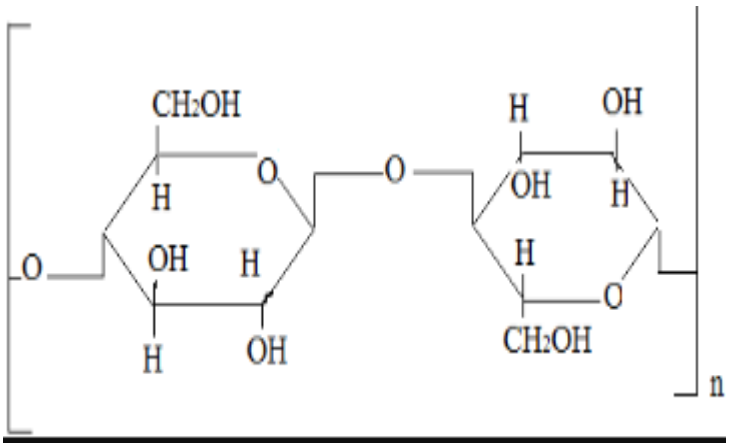
Objectives:

- Develop controlled-release tablets exhibiting robust physical integrity.
- Administration of the medicine will be required once day, ensuring that The therapeutic range is maintained by the medication concentration.
- Enhance patient adherence. ¬ Assess prepared tablets for the subsequent evaluations.
- Resistance to deformation
- Material depth
- Variation in mass
- Friability
- Laboratory dissolution
- Separation process

4-EXCIPIENTPROFILE

HydroxyPropylMethylCellulose:

Structure:



1. **Non-proprietaryNames**:
   BP: Hypromellose, JP: Hypromellose, PhEur:Hypromellose, USP: Hypromellose
2. Synonyms:
   Hydroxypropylmethylcellulose, HPMC, Hypromellsum, Methocel,Methylcellulosepropyleneglycolether, Methyl hydroxy propyl cellulose, Metolose.
3. **ChemicalName**:
   Cellulosehydroxylpropylmethylether
   Emulsion stabilizer, Extended-releaseagent, Film forming agent, Foaming agent, Granulation aid, Modified-releaseagent, Muco-adhesive, Releasemodifyingagent, Solubilizing agent, Stabilizing agent, Suspending agent, Sustained release agent, Tablet binder, Thickening agent, Viscosity-increasingagent.
4. Applicationsin PharmaceuticalFormulation or Technology:
   The most common uses for hypromellose in the oral products industry are film coating, extended-release tablet matrix, and tablet binder. At concentrations of 10-80% w/w in tablets and capsules, high-viscosity grades may be used to hinder the release of pharmaceuticals from a matrix.
5. **Description:**Powdered hypromellose may have a fibrous or granular consistency and looks white or creamy-white. It has no taste and is flavorless.
6. **Common Characteristics.**
   For a 2%w/w water solution, the acidity/alkalinity pH ranges from 5.0 to 8.0.

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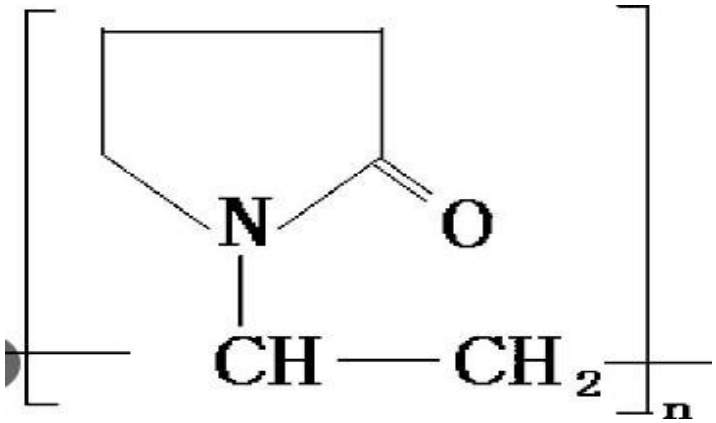
Ash ≤1.5%

Density(bulk)0.341g/ml

PolyvinylPyrrolidone(PVP) Structure:

Synonym:
Polyvinylpyrrolidone Povidone



PVP
ChemicalName:1-Ethenyl-2pyrrolidonehomo polymerMolecular Formula:(C6H9NO)n
Category:
Binder for tablets, aid in dissolving, agent to suspend, and disintegrant.

Description:
Povidone is a hygroscopic powder that is fine, odorless, and white to creamy white in color. Spherical povidone with a K-value of 30 or below is created by spray drying. Values for Povidone K.90 and better K Plates of povidone are the end result of the drum drying process. The United States Pharmacopeia (USP) classifies Povidone as a man-made polymer with a range of molecular weights produced via polymerization of linear 1-vinyl-2-pyrrolidone units. Its viscosity is what makes it unique.

5-MATERIALS&METHODS

TableNo.2 Detailed Inventory of Formulation Materials and Their Uses

Sr. No	**ameofthe materials**	**Manufacturer/Supplier**	**UseinFormulation**
1.	Voglibose	Purchased	Active ingredient
2.	HPMCK4M	ResearchLabFineChem. Industries,Mumbai.	HydrophilicPolymer
3.	PVPK-30	Research–LabBombay.	HydrophilicPolymer
4.	CVP	Research–LabBombay	HydrophilicPolymer
5.	Lactose	Research–LabBombay	Filler
6.	SiO_2	-LabFineChem Industries.	Glidant

7.	Magnesiumstearate	S.KanthHealthCareLtd.	Lubricant
8.	IsoPropylAlcohol	Research–LabBombay	GranulatingAgent

Sr.No.	**Equipments**	**Source**
1.	DissolutionTestApparatus	ElectrolabMumbai.
2.	ElectronicBalance	CitizenMumbai
3.	UV-VisibleSpectrophotometer	Simadzu
4.	pHMeter	Equiptronics
5.	HotAiroven	ShitalScientificIndustries,Mumbai
6.	DistillationApparatus	Fill-Well
7.	VernierCaliper	ICIcheckinginstruments
8.	TabletCompressionMachine	Rimek
9.	RocheFriabilityTester	Labhosp
10.	MonsantoHardnessTester	DolphinMumbai.
11.	LaboratorySieves	Unique
12.	DisintegrationTestApparatus	Veego
13.	FTIR	ilentCary630ATRFTIR Spectrophotometer.

TableNo.3 Equipmentusedfor formulation

6-RESULTS AND DISCUSSION

CharacterizationofVoglibose

Characterization of organoleptic properties and measurement of melting point

Table:A review of Voglibose's physicochemical properties

Sr.No.	**Test**	**Observations**
1.	Color	WhiteAmorphousPowder

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2.	Odor	Odorless
3.	Taste	Metallic
4.	MeltingPoint	162-163°C
5.	pH	6.5

It was determined that the medication utilized in the formulation was pure according to I.P. specifications as its melting point and organoleptic character were found to be as per standard drug.

Solubilityanalysis:
Table: SolubilityprofileofVoglibose

Sr.No.	**Solvent**	**Solubility**
1.	Water	Freelysoluble
2.	chloroform	Soluble
3.	Methanol	slightlysoluble
4.	ethanol	soluble
5.	0.1NNaOH	soluble

In order to assess the solubility of the pure pharmaceutical, 10 mg of the medication was dissolved in 10 ml of water, methanol, and 0.1 N NaOH.

Figure: FormulatedVoglibosegranules

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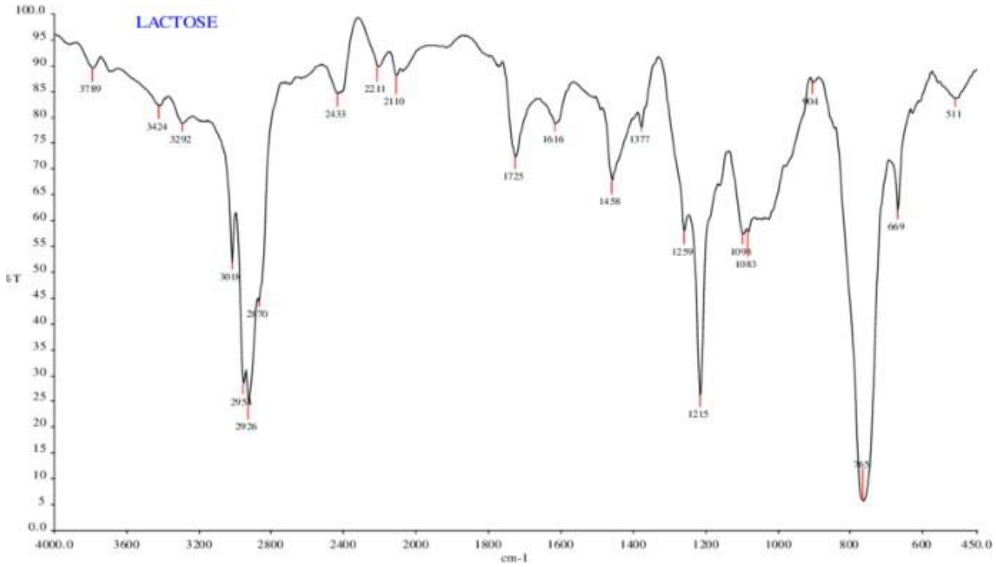

Figure :FTIR spectrumofLactose

Formulation&DevelopmentofVoglibose

Using a wet granulation method that included PVP, HPMC, and CVP polymers in different proportions, Voglibose controlled release tablets were manufactured.

Evaluationofpowderblends:

Three independent analyses were performed on each sample.

The Voglibose powder mix has excellent flow qualities, as shown by the findings of the angle of repose being less than 30. Reduced values for Carr's index provided more evidence of this. When the Carr's index is up to 20%, the flow qualities are good to exceptional. We observed satisfactory to outstanding flow characteristics for all of the excipients and drugs.

Charecterizionofpowderblend byFT-IR Spectroscopy

The IR spectra of the pure API (Voglibose) are analyzed using the Voglibose wave number to determine the various functional groups present. These spectra are then compared to the spectra of the formulation blend (API+Excipients) to determine if the prominent peaks of the API change when excipients are present. There seemed to be no discernible shifts in the drug's pronounced peak, according to the graph. hence, it is reasonable to assume that the excipients listed are highly compatible with the medicine.

Post-compressionparameteroftablets:

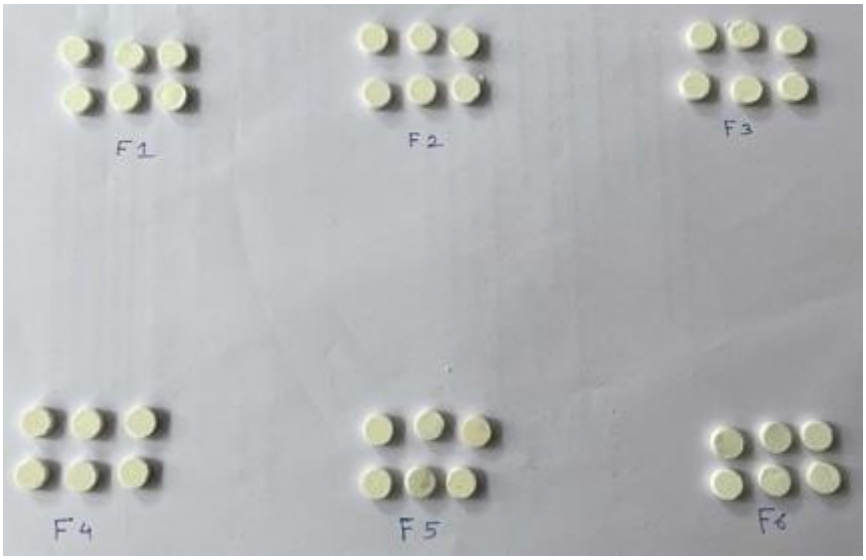

Figure: Formulated Tablets

7-CONCLUSION

To treat type 2 diabetes, the controlled-release tablet version of voglibose has been developed and is now available. Fillers such as lactose, polymers HPMC

K4M and PVP K30, and CVP extended the half-life of Voglibose by as much as 12 hours.
For pharmaceuticals and polymers, suitable pre-formulation research include bulk density, tapped density, carr's index, and Fourier transform infrared spectroscopy.
We can enhance formulation stability, fixed dosage, patient compliance, and medication bioavailability by formulating Voglibose.

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