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PREPARATION AND IN VITRO EVALUATION OF ORAL DISINTEGRATING TABLETS OF CISAPRIDE MONOHYDRATE

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ABSTRACT

The development of Cisapride Monohydrate Verbal Weakening Tablets served as the foundation for this audit. Super disintegrants comprised Bug Bean Gum, Tulsion 339, and Plantago Cheer Seed Powder. Polaxomer is employed to enhance solubility. The aggregation of all the details depicted significant attributes of the stream, including mass thickness, tapped thickness, and the quality of rest. The tablets that were prepared demonstrated remarkable post-pressure thresholds and effectively exceeded all quality control evaluation limits. Among all the varieties, F5 exhibited the highest medication release rate at 99.25 percent, occurring rapidly—thus establishing a standard reference point.

KEYWORDS: Cisapride monohydrate, Grasshopper bean gum, Tulsion 339, Plantago applaud seed powder, and oral crumbling tablets are among the ingredients in this product.

1. INTRODUCTION

The verbal process of union is commonly regarded as the most comprehensive form due to its simplicity of self-connection, minuteness, and primary assembly. Regardless of the circumstances, the primary concern with commonly employed accelerated assessment methods—such as pills and capsules—is that they are difficult for patients to ingest, potentially resulting in obstructions, especially among younger and older patients. In any event, this is too authentic for individuals who are not approaching water, as well as for those

who are well-rested, energetic, committed, or traveling.

Therefore, many individuals are contemplating the development of tablets with rapid disintegration or splitting characteristics for use in the Rapid Pit. Dispersible tablets are recommended for both conventional individuals and those who experience difficulty swallowing.

Orally disintegrating tablets (ODTs) exhibit consistent composition and rapidly disintegrate— within approximately one moment—when placed on the dry tongue. After being severely dragged downward or expelled forcibly, the course of action is ultimately swallowed and retained by the gastrointestinal tract.

The US Food and Drug Administration (FDA) described ODT tablets as "a solid, structurally stable form designed to disintegrate rapidly—generally within seconds—when placed on the tongue." Recently, the term "Sensible dispersible tablet" has been adopted by the European Pharmacopoeia to describe a tablet that is placed in the mouth and rapidly disintegrates shortly after ingestion.

Numerous terms have been used to describe rapid-disintegrating tablets, including viable dissolving tablets, disintegrating pills, fast-dissolving tablets, accelerated dispersible tablets, quick-dissolving tablets, and conventional dissolving tablets.

With the progress made in 2008 Clearly for Industry: Verbal Genuine Tablets, the U.S. Food and Drug Administration paid particular attention to this study (Rosie et al., 2009). The activity of the final bearing is significantly diminished due to three primary issues

- An ODT's in vitro duration should be under 30 seconds, as exceeding this threshold is detrimental.

The overall influence of the tablet's weight, estimation, and disintegration properties collectively contribute to the suitability of an ODT for both patients and administrators; in any event, the weight of the tablet should not exceed 500 mg globally.

- Although the bearing appears to be the most distant focus of the ODT approach, it neither alters nor dismisses the exceptionally satisfactory definition that was referenced. Considering all factors, the primary goal of an ODT remains to conceal oneself within a

matter of seconds.

1.1 Assistance Needed with ODT

With patients' limited authorization and alignment with existing vehicle frameworks, coupled with the projected increase in sedation-related affiliations and employment arrangements, and the significant costs associated with disease, there is an urgent need for a non-invasive delivery system, such as rapidly dissolving tablets.

Information Patients Should Be Informed Of:

Rapidly adapting assessment designs are highly beneficial for patients seeking one or more clarifications. Address the prudence of consuming medication with an 8-ounce glass of water.

This strengthened the approach following

- Patients of all ages experiencing difficulty swallowing or digesting, assessed through comprehensive evaluation protocols.

Patients who are confused or uncertain about their ability to ascend staircases due to a lack of confidence in their capacity

- Inactive patients who are unable to consume a standard hamburger.
- An adaptable eight-year-old who necessitates a more assertive approach than gentle pharmaceutical medication should be administered.
- A modestly constructed woman undergoing radiation therapy for chest cancer may be too exhausted to effectively take her H2-blocker.

For example, a quiet individual with schizophrenia residing in an institution may attempt to avoid taking their prescribed antipsychotic medication by concealing a standard tablet beneath their tongue.

- An individual who is unfamiliar with the illness or has limited control over the situation may exhibit persistent symptoms and frequent vomiting. The patient's more rapid progression is a notable aspect of these classifications.

Pregastric support from clear plans is caused by drool accumulation in the accessible area during situations where the course of activity disperses swiftly. Assistance areas for precise arrangements include the buccal, pharyngeal, and gastric regions.

• Medications that undergo extensive hepatic metabolism may benefit substantially from any pregastric administration, as it bypasses first-pass metabolism.

- Furthermore, solutions with high maintenance requirements in the Fast Pity and Pregastric districts of GIT, as well as those that produce substantial levels of undesirable metabolites through first-pass liver metabolism and gastric administration, may exhibit superior efficacy profiles.

Parts for Assembling and Operating

1.1 MECHANISM OF ACTION OF ODT IN FAST MUCOSA

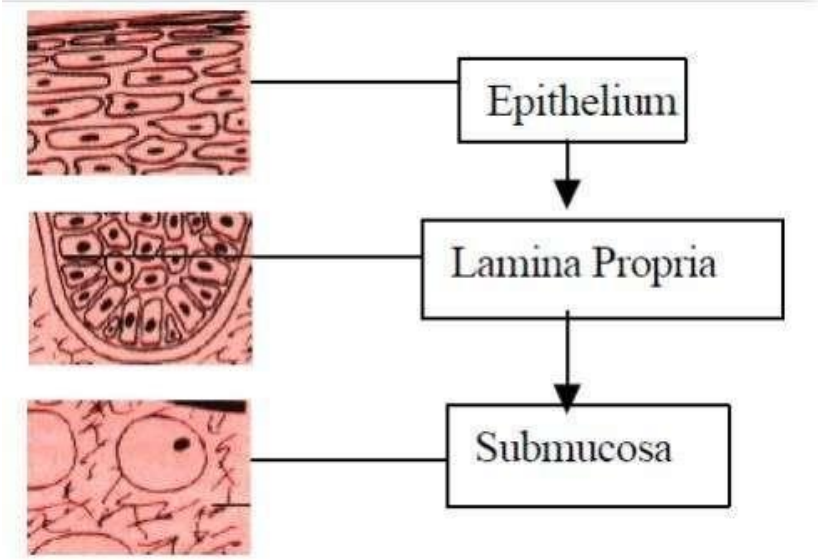


Fig: 1.1 Different layers of Fast mucosa.

MECHANISAM OF ACTION: The ODT is applied to the patient's tongue or another robust mucosal tissue. The hydrophilic polymer and other additives facilitate rapid wetting when saliva is present. To facilitate rapid mucosal absorption, the tablet dissolves and isolates at the optimal moment.

1.2. Advantages of ODTS

ODTs enjoy several advantages in the process of ingesting.

- An appropriate course of action for more experienced, more sprightly, more knowledgeable individuals, as well as courageous hospitalized patients facing difficulties in swallowing the medication.
- Under no circumstances do ODTs agree that water should be consumed in place of standard evaluation procedures. Patients who are confused or in urgent need of water

should pay close attention to this, as it may lead to a deficiency of precise information.

When all other options are comparable, they remain the most favored choice for patients due to their ability to deliver accurate dosages, ensure coordinated relief, and maintain exceptional physical and chemical stability. There is also space allocated within the room for unit structures.

- The regulation of outline bioavailability is a distinctive outcome of the pharynx, esophagus, and expedient. Pregastric sponsorship offers additional advantages, including increased bioavailability and, to a lesser extent, enhanced clinical implementation with fewer adverse effects. Rapid convalescence 1.3 Verbal inscriptions that diminish in certain locations.

ODTs, such as the antibacterial ciprofloxacin tablets with an approximate dosage of 500 mg, are being developed using formulations that primarily consist of larger excipient components.

Patients undergoing long-term anticholinergic therapy are likely unsuitable candidates for ODTS.

1.4 Desired Attributes and Actions to Provide Prompt Assistance with Dispersible Tablets.

Welcoming and hospitable The most fundamental advantage of ODT is its rapid degradation and minimal need for speculation, as will be demonstrated in the following explanation. It is not appropriately planned by an expert in system organization to choose a comprehensive decomposition that evaluates the optimal solution.

Comfort: Given that some courses of action may have irritating tendencies or be detrimental, it is advisable to consider administering Rapid Dispersible tablets, as they dissolve or disintegrate swiftly and minimize discomfort. Therefore, the flavor masking of Expedient dispersible tablets functions as an evaluation and represents the premier brand for ensuring rapid onset and consistent calmness.

Mechanical Consistency: The drive dispersible tablet's control system must rapidly limit it under conditions of control insufficiency, which is ideally at level 1.6. Recent Innovations in the Classification of ODT.

Enhancements that have not been obtained or permitted are among the developments

employed by various professionals to construct structures that quickly disintegrate into fragments.

Protected Headways: 1.7

Advancement within ZYDIS

Scherer has been monitoring Zydis' progress. The most consistently available breakthrough tablet was Zydis, the most widely used fast-dissolving/disintegrating tablet. The capsule dislodges from the Expedient as promptly as it reaches the level of mental coordination on the tongue.

Zydic tablets are produced through lyophilization or freeze-drying of the pharmaceutical in a cross-sectional form, which is often constituted of gelatin. Due to its exceptionally light weight and delicacy, it should be distributed within a large sensation pack.

Patients should be advised to stay away from the film when administering the medications, as it may interfere with their proper delivery. The Zydis formulation is expected to dissolve swiftly on the tongue. Furthermore, it captures essential progress.

WOWTAB Initiative

The Wowtab quick-dissolving and isolating tablet arrangement has been available in Japan for a considerable period. Yamanouchi Medicine Co. safeguards the integrity of Wowtab enhancement. It seems that the tablet should be operated "without water" in the wowtab. To disclose everything, it has been introduced into the United States.

This advanced formulation utilizes sugars and excipients that exhibit all the characteristics of sugar, such as mannitol, for example. A combination of tall, skillfully structured saccharides (a key limiting factor) and highly flexible saccharides (which retract quickly) are employed in this cycle.

The two rapid-release types of saccharides are combined to produce a tablet that exhibits optimal hardness and dissolution rate. Due to its superior durability, Wowtab's composition is significantly more resilient to environmental factors than that of Zydis or OraSolv.

The Frosta Methodology

- This improvement has been endorsed by Akina. It involves coordinating plastic particles and compacting them under moderate stress zones to ensure quality for rapid vehicle

production. Water entrance enhancer, cover, and plastic granules are transported using pFastus and plastic.

- The acquired tablets are significantly difficult to break and are rapidly isolated within 15 to 30 seconds, depending on their size.

ORASOLV TECHNOLOGY

- Of all the Cima component changes, OraSlov stands out the most due to how rapidly it reduces. Instep of dispersing in the oral cavity as Zydis does, Orasolv advances efficiently through the aid of commonly employed effervescence.
- In what manner The most effective method of administering the Orasolv product is in tablet form, which can be contained within a few seconds. The tablet will subsequently detach after a significant accumulation has formed. Two surges constitute a segment of the flavor concealment within the Orasolv narrative.
- Oraslov utilizes this enhancement as frequently as possible to promote non-specific formulations; sweeteners and flavors do not mask the unsettling nature of a settlement; and both coating the pharmaceutical powder and foam serve as methods for flavor concealment. Components of the cranium constituting this assembly. Due to its high compessibility, Oraslv offers a significant advantage with the DURASOLV Headway:
- Due to the use of expanded compaction during tableting, Durasolv possesses a more robust mechanical integrity than its predecessor, aligning with Cima's second-generation rapid dissolving/disintegrating tablet definition. Similar to Orasolv's bundling, it is open. Due to its solidity, it is typically packaged in vials or standard stun containers. Utilizing a friability of less than 2%, this tablet exhibits complete uniformity and is assembled using standard tablet compression procedures. Subsequently, the item is transported more rapidly and, remarkably, at a reduced cost.

Despite Oraslov's subtle influence, extensive arrangement evaluations may undermine the overall unaffected nature of any flavor concealment. The reality that it doesn't function with other pivotal parts of energetic progresses is one disadvantage of this progression. The compaction process may compromise the coating of the pharmaceutical powder, revealing the underlying formulation to the patient's taste receptors. As a result, subtle elements such as moment interest compound evaluations are where the DuraSolv revamp demonstrates its true excellence.

Transporting using FLASHDOSE

There are three rapidly degradable associated systems utilized for pharmaceutical transportation in Fuisz developments. The two most critical periods to chew fast-dissolving pills are fragile goody and EZ eat. These were finalized for Fuisz's most recent contemporary expansion, the Streak area.

In arrange to make a persuading course of action that appears like cotton sweet floss, the Flicker Piece update makes utilize of a partitioned turning component. The effective medication can subsequently be combined with this glass-like sugar prior to being formulated into a tablet. Fuis has established this system, known as the shear structure.

The outcome is highly susceptible to impairment. As soon as it is positioned on the tongue, it disintegrates and becomes restricted. Inquisitively, modulating the temperature and other circumstances amid generation can have a colossal impact on the properties of what is being created.

Advance on FLAASHAB

Inquire about that centers on graphemes has kept up with Flastab's advance. This amendment consolidates the restriction on the prompt isolation of tablets containing viable microcrystals.

To produce medicinal microgranules, one may employ conventional techniques such as coacervation, spheronization, microencapsulation, and film coating. Prior to being incorporated into tablets, the essentially inert microcrystalline grains of the fixing agent are integrated into the moist or dried granulated mixture of excipients.

The conventional tablet manufacturing procedure employed across all industries necessitates that the transported tablets possess mechanical integrity and a retention duration of less than one second.

ORAQUICK Progress

The Oraquick quick dissolving/withdrawing tablet definition headway is seen as more restricted than anticipated, in spite of the fact that the rapid feel is fundamentally way better than the flavor choice. The dispersal of solvents allows for more rapid and precise production without compromising flavor.

Furthermore, due to its delayed production rate relative to other rapid methods or diminished

enhancements, OraQuick remains an excellent option for heat-sensitive prescriptions.

To enhance adaptability, KV Sedate unequivocally affirms that the innovation of obtaining and encapsulating the treatment material within microencapsulated particles is paramount. As a result, it is possible to obtain high mechanical quality with minimal impact on flavor during tablet compression.

Fast Enhancement in DIS

- To fulfill the fundamental requirements of the exhibit, Lavipharm Labs Inc. (Lavipharm) has developed the most effective intrafast dissolving sedative delivery system.
- The film may be facilitated on either the floor or finest of the tongue.
- Motivation Dis, Lavpharm's initial lesson in safeguarding change, is an unstable, adaptable, and rapidly responsive film characterized by an innovative intrafast arrangement transport structure. It enters the deployment zone and immediately dispatches precisely targeted areas to the location. \u2022 The Quick Dis medication change structure is available in a variety of comprehensive designs, ranging from unit-specific sections to other components of complex arrangements.

Progress Tabs/Ziplets

Passano from Italy reviews this enhancement alongside Barnago. In order to transmit ODT with an impossible part person time and to address mechanical quality under negligible strain control, it utilizes water-insoluble overhauls coexisting with comparable thick areas.

- To ensure uniformity and, ultimately, sedimentation during freeze-drying, a slow-dissolving substance is employed. This has the brassy objective of avoiding nonhomogeneity. Tablets are less likely to attack with extended filler data, which speeds up degrading.

Advancements in PHARMABURST

This statement is endorsed by SPI Pharma, an esteemed and innovative organization. Within 30 to 40 seconds, the co-oversaw the isolation of excipients, enabling the progression of the ODT. This definition integrates the flavor and emollient properties of the treatment within a dried mixture prior to compression into tablets.

The tablets are in a suitable condition for administration to patients.

Conveyance of Nanocrystals

The German soul musician is renowned for this. As part of the process for advancing nanocrystals, colloidal particles are subjected to lyophilization.

- Filling the stuffing cure and water-soluble additive compartments with respective items;

This strategy is ultimately unsuitable for highly hazardous conditions, as it does not incorporate the combination cycle, which is included in processes such as granulation, blending, and tableting.

Promptly Address

- Janssen Pharmaceuticals continues to advance this progress. It retains within the mind two rapidly separating solvents for positioning a cross piece. To isolate framework components in water, a method known as "dissolvable extraction" employs excess amounts of alcohol.
- The formulated protest exhibits adequate directional precision and maintains a consistent velocity.

1.8 Non-Licensed Technologies

There are two strategies that consolidate the various routine activities employed in ODT's social initiatives, contemplating their approaches.

I. Types of progression employing the warming cycle

Utilize Control Prepare for Advancements II. Lyophilization, also known as freeze-drying Dissolvable substances can be separated from a solidified formulation or a mixture containing excipients that represent structures through the freeze-drying process, also known as lyophilization. The subsequent tablets are often notably soft and typically possess porous structures that facilitate rapid dissolution or degradation. The freeze-dried unit quickly disintegrates upon contact with the tongue, releasing the combined pharmaceutical. In order to prevent any potential adverse effects of heat on the stability of the coarse material during production, the solidification and dehydrating process is carried out at temperatures below evaporation.

Due to minor moisture within the pores, the lyophilized tablets became isolated in less than five seconds when placed in the control orifice. In accordance with Manoj et al. (2010), lyophilization plays a crucial role in the preservation of heat-sensitive forms, including thermolabile compounds.

This section refers to a standard method for collecting ODT using this framework. The definitive course of action is either dispersed or restricted as a fluid depiction of a polymer carrier.

The wells of the sharp packets are filled with the mixture, which is measured by weight.

In order to solidify the treatment method or facilitate dissemination, the plate containing the distress packets is transferred through a liquid nitrogen solidification chamber. The next stage involves placing the solidified aggravation loads into cold cabinets to facilitate the commencement of the freeze-drying process. The aluminum thwart backing is actually subjected to a testing and fastening apparatus following the processes of freeze-drying. Finally, the headline pieces have been secured and conveyed.

Regarding bioavailability, the freeze-drying process has proven to be unparalleled. The lyophilization process has several significant disadvantages, including a high cost, extended processing time, the fact that the items are too sensitive to be packaged in a conventional manner, and the presence of potentially hazardous compounds throughout the process (Guptha et al., 2010). Drying of Sprinkles.

During the biochemical and curing phases, the application of spray drying techniques is occasionally employed. One effective strategy for producing exceptionally fine particles while simultaneously eliminating solvents is through shower drying. You may employ shower drying to rapidly isolate tablets.

To produce an exceptionally fine and rapid-dispersing powder, this method necessitates a particulate carrier that effectively facilitates the arrangement, which is created by spray-drying a liquid formulation containing a supporting structure and various components. Moving forward, it is approached with vigorous plans and discussed on a tablet. Using a sprinkle dehydrating system, Allen et al. prepared fast-dissolving tablets (Kuldeep et al., 2010). This update ensures that the tablets will disintegrate in less than twenty seconds.

Creating an outline

The flavor and overall speed of tablet division are both enhanced through the incorporation of water-soluble carbohydrates in the dispersal process. Weight Trim (Dissolvable Strategy) is among the limited ineffective methods that can be employed to organize swiftly dissolving tablets.

- The most effective method for regulating the production of indistinguishable tablets involves maintaining the powder mixture in a soluble state, such as ethanol or water, and subsequently shaping it into tablets under a pressure lower than that used for standard tablets (Yourong et al., 2014).

- The next stage is to allow the dissolvable to dry completely. Layout tablets often provide a more prominent appearance, facilitating easier handling and oversight due to their reduced compressive strain compared to standard compacted tablets.

For rapid tablet deterioration from a fluid structure with dispersed or isolated attachments, trim- by-force is a fundamental approach. The control layout cycle is capable of dividing the drug- containing fluid fabric into a tablet form. When a control depiction procedure is employed with an agar technique, it may be advisable to establish robust regions for effective detection.

Complimentary Graduation

The various granulation methods are processes that a tablet coating utilizes to effectively agglomerate settled particles. Unlike standard granulation, this preparation does not necessitate the use of water or conventional solvents.

The process is more efficient and energy-conserving than moist granulation, as it eliminates the need for a drying step. Additionally, it facilitates the rapid disintegration of medications that are not highly water-soluble.

A case illustrating how griseofulvin ODT was formulated involves combining a hydrophilic viscous film (super polystate) with Stake - 6 sterate. The waxy compound Superpolystate exhibits a hydrophilic and lipophilic whiteness of 14, with a melting point ranging from 33 to 37 degrees Celsius.

Apart from its limitations as a portfolio and its efforts in the authentic evaluation of tablets, it essentially functions in conjunction with their analysis since.

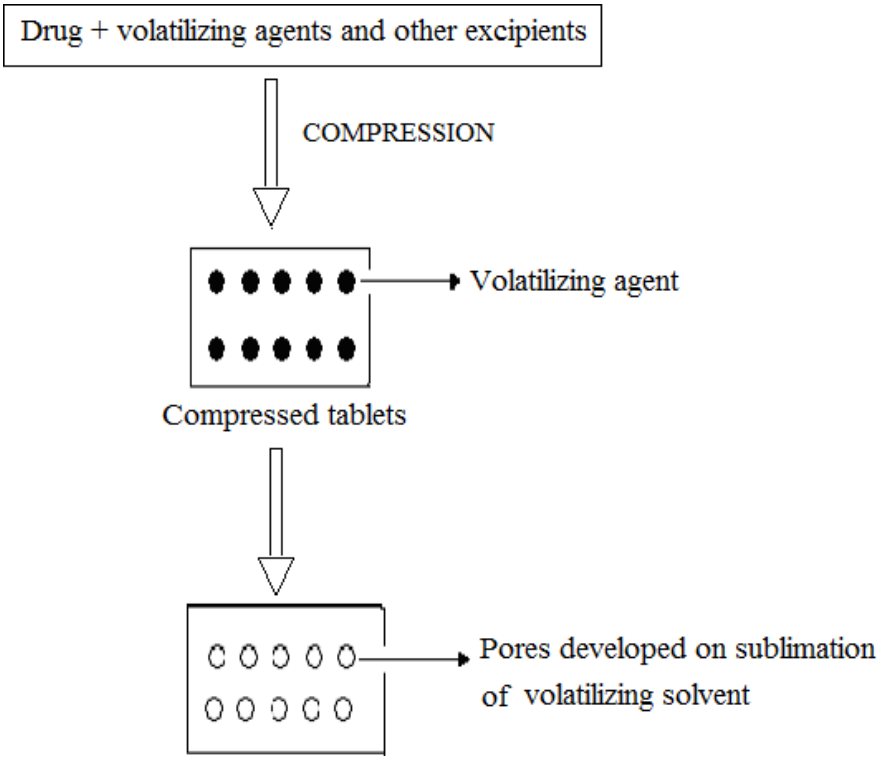


Figure 1.2 Steps involved in Sublimation.

LITERATURE REVIEW

Vangala mohan (2014)58 et al., Meclizine hydrochloride sublimated oral disintegrating tablets should be promoted to regularly review their segregation rate through frequent inspections conducted by various sublimation specialists. These pre-press oral disintegrating tablets were characterized for their hardness, weight uniformity, friability, moisten time, water absorption capacity, and binding time. The definition F3 with camphor (10% w/w) as the sublimating pro demonstrated a rapid confinement of approximately 98.61% within 30 minutes and a rotation time of 43 seconds when isolated from other sublimating organized substances, as evaluated through in vitro separation methods. The initial sequestration rate for plan F3 was 3.29% per minute, and the drug discharge percentage at 30 minutes (Q30) was 98.61% ± 0.25%. Proclaimed tablets exhibited significantly higher levels (65.43 ± 0.57%, 2.18%/min). With F3 FDT pills that differed from the ones disclosed, the isolation threshold was extended by 1.4 units beyond the permissible limit of 63.37. There was no possibility of forming a hypothesis, as evidenced by multiple analyses employing calorimetry and Fourier transform infrared spectroscopy. Ultimately, a viable framework to enhance the dissolution rate involves the formulation of oral dissolving tablets containing meclizine hydrochloride through the sublimation process.

Appapurapu ashok kumar(2014) et al.,62 To enhance the understanding of how to incorporate superdisintegrants such as crosscarmellose sodium, cross povidone, and sodium starch glycolate into the formulation of orodispersible fluoxetine hydrochloride tablets, an evaluation was conducted. When addressing mental health concerns such as depression, fluoxetine hydrochloride may be beneficial due to its role as a selective serotonin reuptake inhibitor. The moist granulation and sublimation process was employed to evaluate the efficacy of three super disintegrants, each incorporated at different proportions of 1.5%, 3%, and 4.5%. The preformulation concentrates exhibited no evidence of interaction between the polymers and pharmaceuticals as determined by FTIR analysis. The configuration details of the pre-pressure settings were presented, and the quality remained within the established parameters while demonstrating outstanding free streaming capabilities. The tablets prepared using a moist granulation and sublimation technique were evaluated for limitations, wetting time, disintegration time, content uniformity, and in vitro sequestration. They were regarded as immaculate and within the limits of what was previously deemed achievable. Since the sublimation of camphor enhances the porosity of the tablet, the associated sublimation technique exhibited exceptional outcomes concerning disintegration time, hydration time, and in vitro drug release studies. Based on their exemplary certified limits, the shortest hydration time (10 seconds), and the overall higher medication release rate (99.5 percent) at 15 minutes, the sublimation-structured tablets containing crospovidone at a concentration of 4.5 percent (FS-6) were regarded as the optimal formulation. In conclusion, the transportation philosophy was finalized through the integration of data into multiple motor models and the implementation of the staggering system, which initially referenced energy.

Gracious tack-Oon (2013) et al., 63 The present study aims to identify drifting gastroretentive tablets containing Metformin that utilize a sublimation agent. In this evaluation, the emergence of the medication from a framework tablet was observed, potentially attributable to the properties of the medication and the polymer. The influence of PEO on the expansion and disintegration of the incompletely settled material. The water uptake and disintegration behavior of the gastroretentive (GR) capsules were significantly influenced by the extent of PEO content. The water uptake increased in conjunction with the expanding PEO focus within the tablet lattice. The decrease in weight resulting from tablet use diminished as the extent of PEO increased.Camphor was employed as the sublimation agent to produce low-density, easily floatable GR tablets. Camphor was converted into cavities within the tablet during the sublimation process. SEM revealed that the GR tablet

possesses a highly permeable morphology. The drifting characteristics of tablets and their thickness were affected by the sublimation of camphor. Arranged drifting gastroretentive tablets maintained continuous drift for each 24-hour period without any lag time in drifting. Nonetheless, as the concentration of camphor in the tablet network increased, the destructive potency of the tablet decreased after sublimation. Discharge profiles of the medication from the GR tablets remained unaffected by variations in tablet thickness or porosity. In pharmacokinetic investigations, the average plasma concentration of the GR tablets following oral administration was more pronounced than the centralization observed with Glucophase XR. Similarly, the average AUC0-∞ values for the GR tablets were notably higher than the plasma concentrations observed with glucophase XR.

Rathod C.P. (2013) et al., 64 This study seeks to develop orodispersible tablets of sumatriptan succinate with an enhanced disintegration rate, potentially leading to increased bioavailability. Utilizing sublimation technology, the present study formulated an orodispersible tablet incorporating sumatriptan succinate. The intended tablets were evaluated for several limitations. Sumtriptan succinate tablets were also fabricated using a sublimation process, with camphor acting as the subliming agent and superdisintegrants such as croscarmellose sodium (ac-Di-Sol), sodium starch glycolate (Explotab), and crospovidone (Polyplasdone XL). In a brief period or less, croscarmellose sodium accounted for 97% of the fundamental in vitro drug appearance. Research employing DSC, NMR, 13C NMR, and IR spectroscopy has demonstrated a comparable scope for the consumption of the unadulterated prescription brand name during social events and the nuances of support bundles. Sumatriptan succinate is a pharmaceutical agent used to mitigate the symptoms of migraines.

AIM AND OBJECTIVES

AIM

The objective of the current review is to evaluate Cisapride Monohydrate Oral disintegrating tablets through the application of super disintegrants.

OBJECTIVES

Oral administration is the most widely recognized method compared to other measurement systems due to its ease of ingestion, avoidance of discomfort, flexibility, and, above all, compliance with understanding. However, a significant drawback of the solid dosage form is the difficulty in swallowing (dysphagia) or chewing, particularly among pediatric and

geriatric patients.

Patient compliance and consistency are crucial in the design of the original medication delivery system; one such system is oral disintegrating tablets (ODTs), which have gained recognition and popularity in recent times.

The key factor contributing to the business success of oral disintegrating tablets is their significant impact on consistent performance across all age groups. These measurement structures are designed to deteriorate or disintegrate rapidly upon contact with saliva in patients, within seconds, without the need for water, thereby facilitating a speedier initiation of activity. The primary aim of this study is to enhance the solubility of Cisapride Monohydrate through the use of super disintegrants.

4. Work Plan

1. An overview of pertinent scholarly research

2. Medication Choice

3. Advancements in the logical methodology

a. Calibration curve with twist (standard graph)

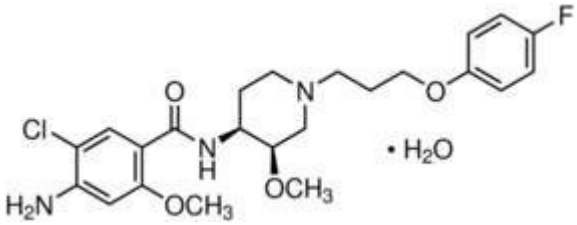
4. Strategies for the administration of swiftly dissolving Cisapride Monohydrate tablets.

5. Micrometric features precisely described.

- Respite signal
- Mass thickness
- Thickness with a probe Indes manufactured by Carr
- The endorsement of Hausner

6. Tabular depiction of the following limitations

- Arrangement of weight



3. Density • Difficulty

Dependability • Employee retention The consistency of the content

8. Drug-Excipient Correspondences 7. In vitro degradation evaluations Infrared spectroscopy

DRUG PROFILE

Drug: Cisapride Monohydrate

Synonyms: Cisapridum, Prepulsid, Propulsid

Drug Category: Aminobenzoates, Anti-Ulcer Agents, Benzamides

Organization: Chemical designation / IUPAC nomenclature: (±)- cis 4-amino-5-chloro-N-(1-[3-(4- fluorophenoxy)propyl])- 3-Methoxy-4-piperidyl-2-Methoxybenzamide

Molecular Formula: C22H29N3O4CLF·H2O

Molecular Weight : 483.96 g/mol Physicochemical Properties

Physical State: Solid

Solubility: Dissolves in acetone. Very minimally soluble in methanol; insoluble in chilly water and hot water.

Stability: The product demonstrates consistent performance and reliability. Storage conditions: Store at temperatures ranging from 15°C to 30°C. Dosage: Tablet

Melting point: 109.8 °C pKa (strongest acidic): 14.58 Log P: 3.3 Pharmacokinetic Characteristics

Bioavailability: approximately 30-40%

Half-life: 10 hours

Absorption: Quickly assimilated following oral administration Volume of distribution: 180 liters

Protein binding: 97.5%

Metabolism: Hepatic CYP3A4 and intestinal CYP3A4 pathways Excretion: renal and biliary pathways

Adverse Effects

- Allergic reaction (including convulsions, hives, etc.)
- Diarrhea
- Abdominal discomfort

PHARMACODYNAMICS: As a parasympathomimetic agent, cisapride is likely to function as a 5- HT4 serotonin receptor agonist. In the context of gastrointestinal physiology, the activation of serotonin receptors facilitates the release of acetylcholine. Cisapride enhances upper gastrointestinal motility without inducing stimulation of the pancreatic, biliary, or gastric secretions. By relaxing the pyloric sphincter, the duodenal bulb, and the duodenum, cisapride extends the duration and enhances the intensity of gastric, particularly antral, motility effects. It also induces peristalsis in the duodenum and jejunum, leading to more rapid gastric and intestinal

transit. It enhances the baseline distensibility of the esophageal sphincter's diameter. It influences the motility of the gallbladder or colon.

Cisapride does not interfere with the enhancement of acetylcholinesterase activity nor does it accelerate the activation of muscarinic or nicotinic receptors.

Element of the activity: Cisapride exerts its effect by stimulating the serotonin 5-HT4 receptors, thereby enhancing acetylcholine release within the enteric sensory system, specifically the myenteric plexus. This results in increased tone and adequacy of gastric compressions, particularly in the antral region, relaxation of the pyloric sphincter and the duodenal bulb, along with enhanced peristalsis of the duodenum and jejunum, facilitating more efficient gastric emptying and digestion.

Restorative adequacy / Indicators: For the provisional management of adult patients experiencing nocturnal dyspepsia due to gastroesophageal reflux disease

Contraindications

Sensitivity to Cisapride Monohydrate is a contraindication. Furthermore, Cisapride Monohydrate should not be administered if you have the following conditions

- Excessively sensitive reactions
- Coronary disease
- Renal failure
- Gastric obstruction
- Severe pulmonary conditions.

- **INTERACTIONS**

Associations with pharmaceuticals

- The serum centralization of Cisapride Monohydrate can be enhanced when combined with Atazanavir.
- The absorption of Cisapride may be enhanced when combined with Carbamazepine.
- Metoclopramide may prolong the QTc interval, thereby extending the duration of Cisapride's effects.

Food Partnership Initiatives

- Grape organic juice should be avoided throughout treatment, as it can significantly elevate serum levels of this substance.

- Increases ingestion, requiring a 30-minute interval prior to supper.

DRUG FORMULATION

S.No	Drug name	Label Claim	Brand name	Company
1	Cisapride Monohydrate	20 mg	Propulsid	Janseen pharmaceuticals

EXCIPIENT PROFILE

TULSION 339

It is an ion exchange resin.

Chemical name : Polyacrylic co polymer

CAS registry number : [557-04-0]

Description : It is very fine, light white, precipitated or milled, Impalpable powder of flow bulk density, with faint Odour of stearic acid and acharacteristic taste. It is Greasy to the touch readily adheres to the skin.

Melting point : 126-130°c

Functional category : Super disintegrate

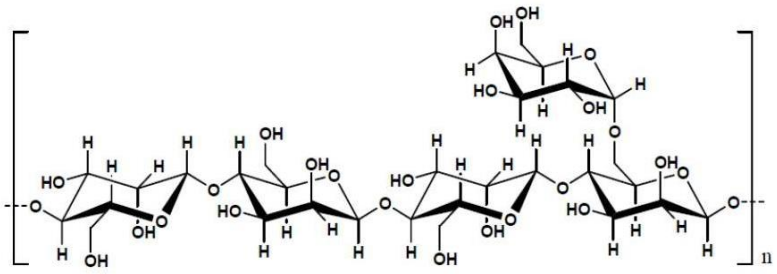
LOCUST BEAN GUM

Synonyms: algarroba: carob bean: carob flour; ceratonia gum; ceratonia siliqua; ceratonia siliqua gum; Cheshire gum; E410; gomme de caroube; locust bean gum; meyprofleur; St. John's bread.

Chemical name: Carob gum

Molecular formula: 310

Structural formula



Functional category: Controlled-release agent; stabilizing agent; suspending agent; tablet binder; viscosity-increasing agent.

Description: Ceratonia occurs as a yellow-green or white colored powder. Although odorless

and tastless in the dry powder form, ceratonia acquires a leguminous taste when boiled in water.

Physicohemical properties

A) Soloubility: Ceratonia is dispersible in hot water, forming a sol having a ph 5.4-7.0 that may be converted to a gel by the C Ceratonia addition of small amounts of sodium borate. In cold water, ceratonia hydrates very slowly and incompletely. Ceratonia is practically insoluble in ethanol.

B) Viscosity: 1200-2500 mps s (1200-2500 cp) for a 1% w/c aqueous dispersion at 258C. viscosity is unaffected by ph within the range ph 3-11. Viscosity is increased by heating: if heated to 958C then cooled, practically clear solutions may be obtained that are more viscous than prior to heating.

Stability and storage: The bulk materialsshould be stored in a well-closed container in a cool, dry place. Ceratonia loses not more than 15% of its weight on drying.

Safety: Ceratonia is generally regarded as an essentially noncarcinogenic nontoxic and nonirritant material. Therapeutically, it has been used in oral in formulations for the control of vomiting and diarrhea in adults and children; 20-40 g daily in adults has been used dispersed in liquid. As an excipient ceratonia is in oral controlled release formulations approved in Europe and the USA.

Incompatibilities: The viscosity of xanthan gum solution is increased in the presence of ceratonia. This interaction is used synergistically in controlled release drug delivery systems.

Applications: Ceratonia is a naturally occurring material generally used as a substitute for tragacanth or other similao gums. A ceratonia mucilage that is slightly more viscous than tragacanth mucilage may be prepared by boiling. 1.0-1.5% of powdered ceratonia with water. As a viscosity-increasing agent, ceratonia is said to be five times as effective as starch and twice as effective as tragacanth. Ceratonia has also been used as a tablet binder(1) and is used in oral controlled-release drug delivery systems approved in Erope and theUSA. Cerationia is widely used as abinder, thickening agent, and stabilizing agent in the cosmetics and food industry. In foods, 0.15-0.75% used. Therapeutically, ceratonia emits acrid smoke and irritating fumes.

Method for Manufacture: Ceratonia is a naturally occuring material obtained from the ground endosperms seperatyed from the seeds of locust been tree, Ceratonia siliqua (Leguminose). The tree is indigenous to soythern Europe and the Mediterranean region.

METHODOLOGY

Buffer preparation

Preparation of 0.2 M Potassium dihydrogen orthophosphate solution: Accurately weighed 27.128 gm of monobasic potassium dihydrogen orthophosphate was dissolved in 1000 ml of distilled water and mixed.

Preparation of 0.2 M sodium hydroxide solution: Accurately weighed 8 gm of sodium hydroxide pellets were dissolved in 1000 mL of distilled water and mixed.

Preparation of pH 6.8 phosphate buffer: Accurately measured 250 mL of v0.2 M potassium dihydrogen orthophosphate and 112.5 mL of 0.2 M NaOH was taken into the 1000 mL volumetric flask. Volume was made up to 1000 mL with distilled water.

Analytical method development for Cisapride Monohydrate

a) Determination of absorption maxima

A spectrum of the working standards was obtained by scanning from 200-400 nm against the reagent blank to fix absorption maxima. The Amax was found to be 276 nm. Hence all further investigations were carried out at the same wavelength.

b) Construction of standard graph

100 mg of Cisapride Monohydrate was dissolved in 100 mL of pH 6.8 phosphate buffer to give a concentration in 1mg/mL (1000µg/mL) 1 ml was taken and diluted to 100 ml with pH 6.8 phosphate buffer to give a concentration of 0.01 mg/ml (10µg/ml). From this stock solution aliquots of 0.2 ml, 0.4 ml, 0.6 ml, 0.8 ml, 1 ml, were pipette out in 10 ml volumetric flask and volume was made up to the mark with pH 6.8 phosphate buffer to produce concentration of 2,4,6,8 and 10µg/ml respectively. The absorbance of each concentration was measured at respective (max) i.e., 276 nm.

Formulation development

- Drug and different concentrations of super disintegrants (Plantago ovate seed powder, Tulsion 339, Locust bean gum) and required ingredients were accurately weighed and

passed through a 40-mesh screen to get uniform size particles and mixed in a glass motor for 15 min.

- The obtained blend was lubricated with magnesium stearate and glidant (Aerosil) was added and mixing was continued for further 5 min.
- The resultant mixture was directly compressed into tablets by using punch of rotary tablet compression machine. Compression force was kept constant for all formulations.

Table : Formulation table showing various compositions

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Cisapride Monohydrate	20	20	20	20	20	20	20	20	20
Plantago ovate seed powder	25	30	75	-	-	-	-	-	-
Tulsion 339	-	-	-	25	30	75	-	-	-
Locust bean gum	-	-	-	-	-	-	25	30	75
Spray dried Lactose	159.5	134.5	109.5	159.5	134.5	109.5	159.5	134.5	109.5
Aerosil	3	3	3	3	3	3	3	3	3
Magnesium stearate	3	3	3	3	3	3	3	3	3
Aspartame	2	2	2	2	2	2	2	2	2
Total weight	250	250	250	250	250	250	250	250	250

The tablets were prepared by using tablet compression machine. The hardness of the tablet was maintained as 2.0 to 3.5 kg/cm²

Evaluation of Tablets

Pre compression parameters

Measurement of Micromeritic properties of powders.

1. Angle of repose

The angle of repose of API powder is determined by the funnel method. The accurately weighed powder blend is taken in the funnel. The height of the funnel is adjusted in a way that the tip of the funnel just touched the apex of the powder blend. The powder blend is

allowed to flow through the funnel freely on o the surface. The diameter of the powder cone is measured and angle of repose is calculated using the following equation.

$$\tan \Theta = h/r \quad \ldots\ldots\ldots\ldots\ldots\ldots (1)$$

Where, h and r are the height and radius of the powder cone.

Table: Flow Properties and Corresponding Angle of Repose.

Flow Property	Angle of Repose (^{0})
Excellent	25-30
Good	31-35
Fair- aid not needed	36-40
Passable-may hang up	41-45
Poor-must agitate, Vibrate	46-55
Very Poor	56-65
Very, very Poor	>66

2. Bulk density

The powder sample under test is screened through sieve No.18 and the sample equivalent to 25 gm is weighed and filled in 100 ml graduated cylinder and the powder is leveled and the unsetled volume, V{0} is noted. The bulk density is calculated in g / c * m ^ 3 by the formula.

$$\text{Bulk density} = M / V_{0} \quad (2)$$

V_{0} = apparent unstirred volume

M = Powder mass

4. Tapped density

The powder sample under test is screened through sieve No. 18 and the weight of the sample equivalent to 25 gm filled in 100ml graduated cylinder. The mechanical tapping of cylinder is carried out using tapped density tester at a nominal rate for 500 times initially and the tapped volume V_{0} is noted. Tappings are proceeded further for an additional tapping 750 times and tapped volume, V_{b} is noted. The difference between two tapping volume is < 2%, V_{b} is considered as a tapped volume V_{f} . The tapped density is calculated in g / c * m ^ 3 by the formula.

$$\text{Tapped density} = M / V_{f} \quad (3)$$

M = of sample powder taken

V_{f} = Tapped volume

5. Compressibility index

The compressibility index of the powder blend is determined by Carr's index to know the flow character of a powder. This formula for Carr's index is as below:

$$\text{Carr's Index (\%)} = [\,(TD-BD)/TD\,] \times 100 \quad \ldots\ldots\ldots\ldots\ldots (4)$$

6. Hausner's ratio

The Hausner's ratio is a number that is correlated to the flowability of a powder or granular material. The ratio of tapped density to bulk density of the powders is called the Hausner's ratio. It is calculated by the following equation.

$$H = Pt / \rho B \quad \ldots\ldots\ldots\ldots\ldots\ldots\ldots\ldots (5)$$

Where rho*T = tapped density, rho*B = bulk density

Table: Scale of Flowability.

Compressibility index (%)	Flow character	Hausner Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Post compression parameters

a) Thickness

The thickness of the tablets was determined by using Digital micrometer. 10 individual tablets from each batch were used and the results averaged.

b) Weight variation

Twenty tablets were randomly selected from each batch and individually weighed. The

average weight and standard deviation 3 batches were calculated. It passes the test for weight variation test if not more than 2 of the individual tablet weights deviate from the average weight by more than the allowed percentage deviation and none deviate by more than twice the % shown. It was calculated on an electronic weighing balance.

c) Friability

The friability values of the tablets were determined using a Roche-friabilator. Accurately weighed six tablets were placed in The Roche friabilator and rotated at 25 RPM for 4 min. Percentage friability was calculated using the following equation. Friability ([Wo-W]/Wo) x 100 Where wo weight of tablet at time zero before revolution. w = weight of the tablet after 100 revolutions.

d) Drug content

The content of drug carried out by 5 randomly selected tablets of each formulation. The 5 rtablets were grinded to get powder, this powder was dissolved in pH 6.8 phosphate buffer by sonication for 30 min and filtered through filter paper. The drug content was analysed spectrophotometrically at 276 nm using UV spectrophotometer. Each measurement was carried out in triplicate and the average drug content was calculated.

e) Disintegration test

Six tablets were taken randomly from each batch and placed in USP disintegration apparatus baskets. Apparatus was run for 10 min. and the basket was lift from the fluid, observe whether all of the tablets have disintegrated.

f) Dissolution test of Cisapride Monohydrate

Drug release from Cisapride Monohydrate tablets was determined by using dissolution test USP 24 type II (paddle). The parameters used for performing the dissolution were pH 6.8 medium as the dissolution medium of quantity 900 ml. The whole study is being carried out at room temperature of 37° C and at a speed of 75 RPM.

5 ml aliquots of dissolution media were withdrawn each time intervals (5, 10,15, 20, 30, 45, 60 min) and appropriate dilution by UV spectrophotometer. The concentration was calculated using standard calibration curve.

Drug-Excipients compatibility studies

Drug excipients compatibility studies were carried out by mixing the drug with various

excipiennts in different proportions (in 1:1 ratio were to have maximum likelihood interaction between them) was placed in a vial, and closed with rubber stopper and sealed properly. Fourier Transform Infrared Spectroscopy (FTIR) studies were performed on drug, optimized formulation using Bruker FTIR. The samples were analyzed between wave numbers 4000 cm^{21} and 550 cm.[21]

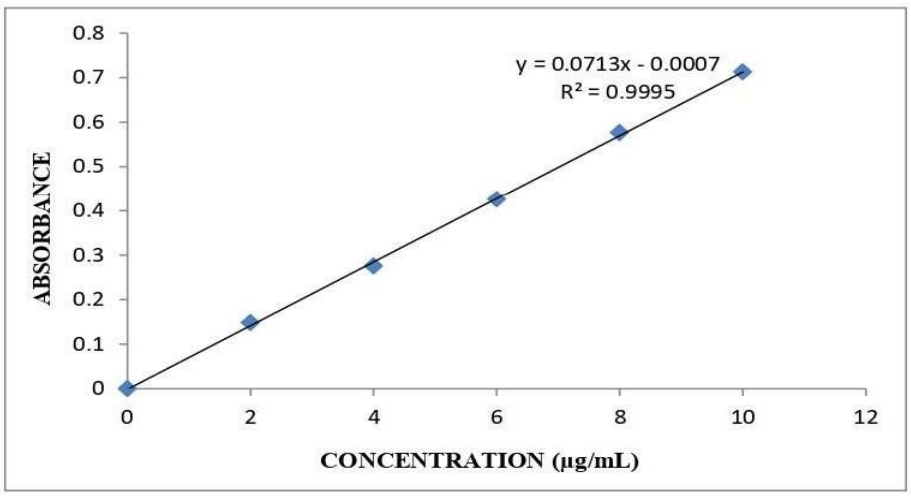
RESULTS AND DISCUSSION

Preparation of calibration curve of Cisapride Monohydrate:

The regression coefficient was found to be 0.999 which indicates a linearity with an equation of y=0.071 x-0.000. Hence Beer-Lmbert's law was obeyed.

Table: Calibration curve data of Cisapride Monohydrate in pH 6.8 phosphate buffer.

Concentration	Absorbance
0	0
2	0.148
4	0.275
6	0.425
8	0.576
10	0.712



EVALUATION OF PRE-COMPRESION PARAMETERS OF POWDER BLEND

Table: Evaluation of pre-compression parameters of powder blend.

Formulation Code	Angle of Repose	Bulk Density (gm/mL)	Tapped density (gm/mL)	Carr's index(%)	Hausner's ratio
F1	25.01	0.59	0.57	14.03	1.16
F2	26.8	0.46	0.67	16.41	1.19
F3	27.7	0.32	0.54	18.75	1.23
F4	25.33	0.54	0.64	15.62	1.18
F5	25.24	0.52	0.65	18.46	1.22
F6	28.12	0.46	0.56	15.15	1.17
F7	27.08	0.58	0.69	15.94	1.18
F8	25.12	0.48	0.67	15.78	1.18
F9	26.45	0.54	0.65	16.92	1.25

- For each formulation blend of drug and excipients were prepared and evaluated for various pre compression parameters described earlier in methodology chapter.
- The bulk density of all formulations was found in the range of 0.32-0.59 and tapped densiy was in the range of 0.54-0.69
- The Carr's index and Hausner's ratio was calculated from tapped density and bulk density.

EVALUATIONS OF POST COMPRESSION PARAMETERS OF CISAPRIDE MONOHYDRATE ODTS

Table: Evaluation of post compression parameters of Cisapride Monohydrate Fast dissolving tablets.

Formulation codes	Average weight(mg)	Hardness (kg/cm^2)	Friability (%loss)	Thickness (mm)	Drug content (%)	In vitro disintegration Time(min)
F1	**252**	**3.2**	**0.52**	**3.8**	**99.76**	**4.3**
F2	251	3.1	0.54	**3.9**	99.45	4.4
F3	251.5	3.6	0.51	3.9	99.34	4.6
F4	249.4	3.4	0.55	3.9	99.87	4.8
F5	248.4	2.5	0.56	3.7	99.14	3.1
F6	247.3	2.7	0.45	3.6	98.56	3.3
F7	248.8	2.7	0.51	3.4	98.42	3.6
F8	249.7	2.8	0.49	3.7	99.65	3.7
F9	248.6	2.9	0.55	4.0	99.12	3.9

Weight variation and Thickness: All the formulations were evaluated for uniformity of weight using electronic weighing balance and the results are shown above. The average tablet weights of all the formulations were noted down.

Hardness and friability: All the ODT formulations were evaluated for their hardness using

Monsanto hardness tester and the results are shown above. The average hardness for all formulations was found to be between (2.5-3.6)kg/cm² which was found to be acceptable. Friability was determined to evaluate the ability of the tablets to withstand the abrasion during packing, handling and transpoting. All the ODT formulations were evaluated for their percentage friability using Roche friabilator and the results are shown above. The average percentage friability for all the formulations was between 0.45-0.56 which was found to be within the limit. Addition of Aerosil resulted in appreciable decrease in friability.

Drug content: All formulations were evaluated for drug content according to the procedure described in methodology section and the results were shown above. The assay values for all formulations were found to be in the range of (98.42-99.87). According to IP standards the tablets must contain not less than 95% and not more than 105% of the stated amount of the drug. Thus, all the ODT formulation comply with the standards given in IP.

In vitro disintegration time: In vitro disintegration studies showed from 3.1-4.8 minutes. The F5 formulation showed very less in vitro disintegration time i.e. 3.1 minutes.

IN VITRO DRUG RELEASE SYUDIES OF CISAPRIDE MONOHYDRATE

Table: Dissolution data of Cisapride Monohydrate.

Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
0	0	0	0	0	0	0	0	0	0
5	52.26	55.38	54.18	45.34	54.42	52.69	55.67	46.51	35.6
10	65.86	63.99	69.85	60.49	66.87	65.12	65.44	62.45	49.36
15	74.97	79.12	80.49	78.15	74.43	79.16	76.56	77.86	68.32
20	82.67	89.2	90.23	85.25	86.86	86.45	83.69	85.2	74.58
30	89.49	91.52	95.79	97.2	99.25	96.27	94.61	93.64	85.36

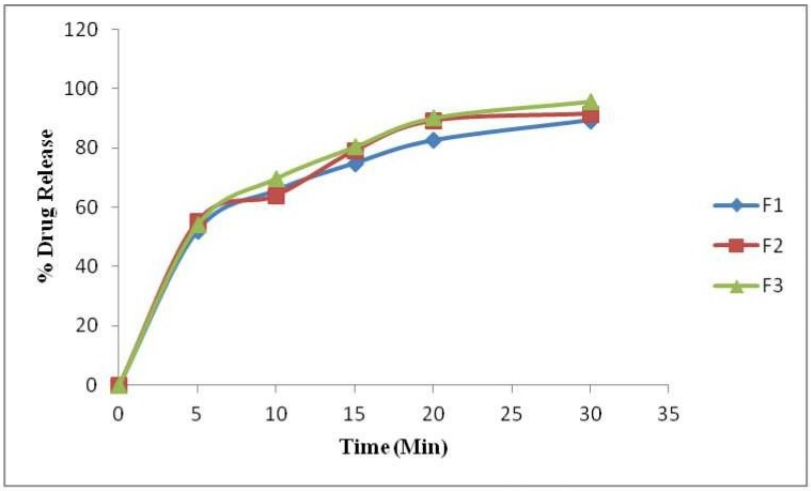


Fig. Dissolution profile of formulations F1,F2,F3.

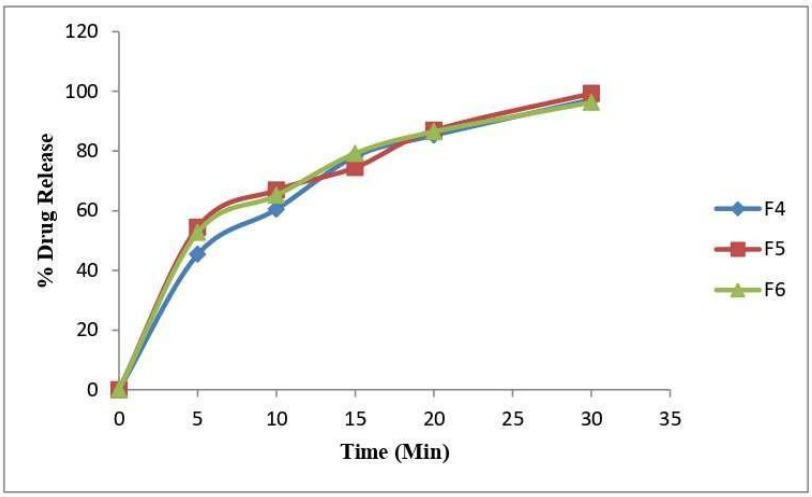


Fig: Dissolution profile of formulations F4,F5,F6

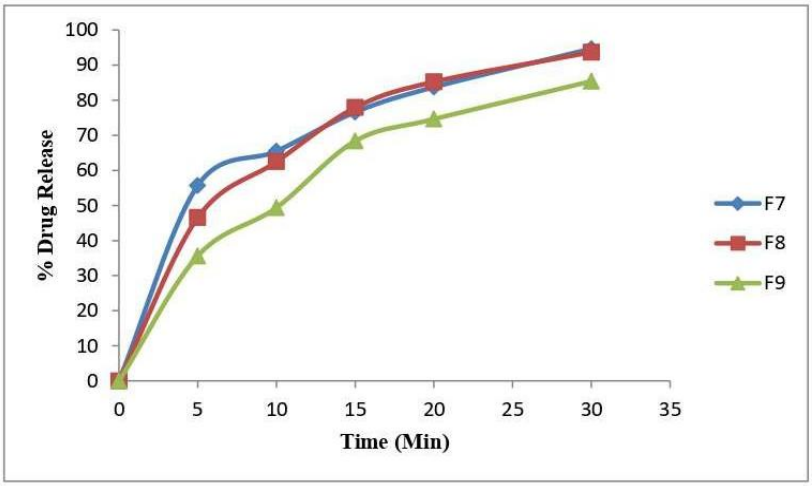


Fig: Dissolution profile of formulations F7,F8,F9

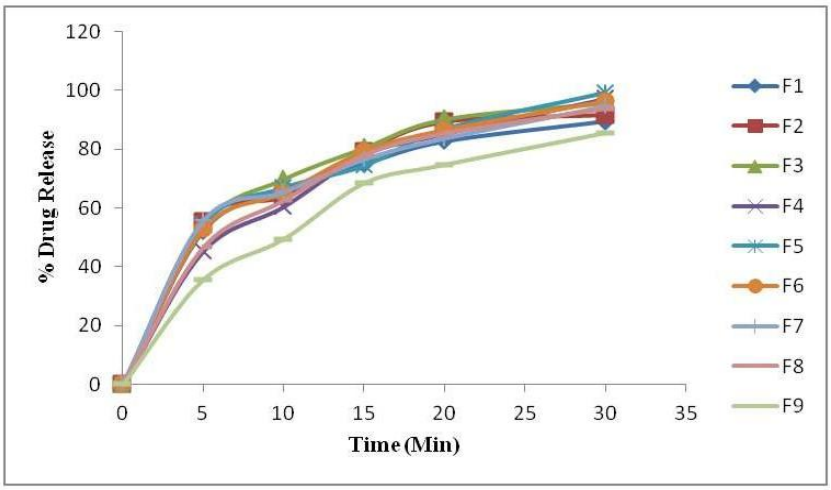


Fig: Dissolution profile of all formulations F1-F9.

From the table it was evident that the formulation prepared with Plantago ovate seed powder were showed good drug release i.e., F3 formulation (95.79%) in higher concentration of nlend i.e 75 mg. Formulations prepared with Tulsion 339 showed good drug release i.e., 99.25% (F5 formulation) in 50 mg concentration. When increase in the concentration of Tulsion 339 drug release retarded. Formulations prepared with Locust bean gum showed maximum drug release i.e., 94.61% (F7 formulation) at 30 min in 25 mg of blend. Among all formulations F5 considered as optrimised formulation which showed maximum drug release at 30 min i.e., 99.25%. Tulsion 339 showed good release when compared to Locust bean gum, Plantago ovate seed powder. Finally concluded that F5 formulation contains Tulsion 339 was optimized formulation.

FTIR RESULTS

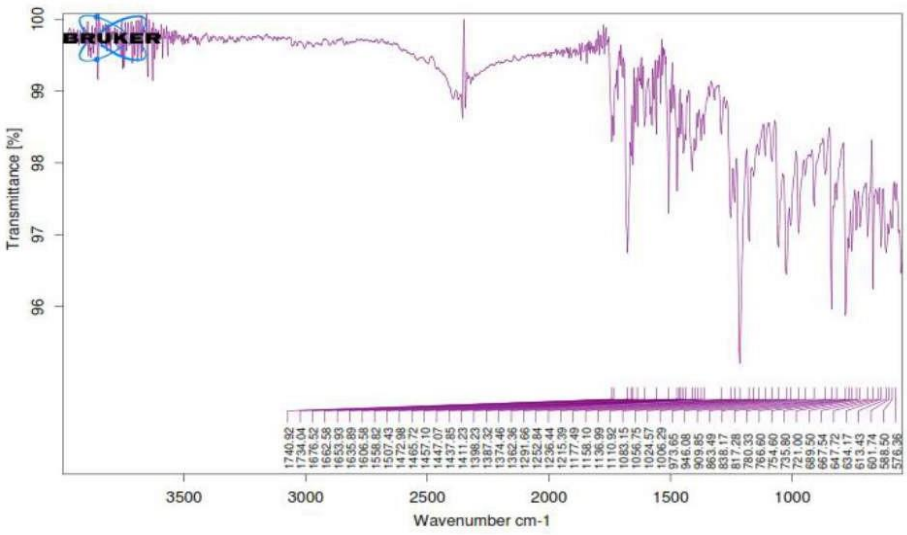


Fig : FTIR of Cisapride Monohydrate Pure Drug

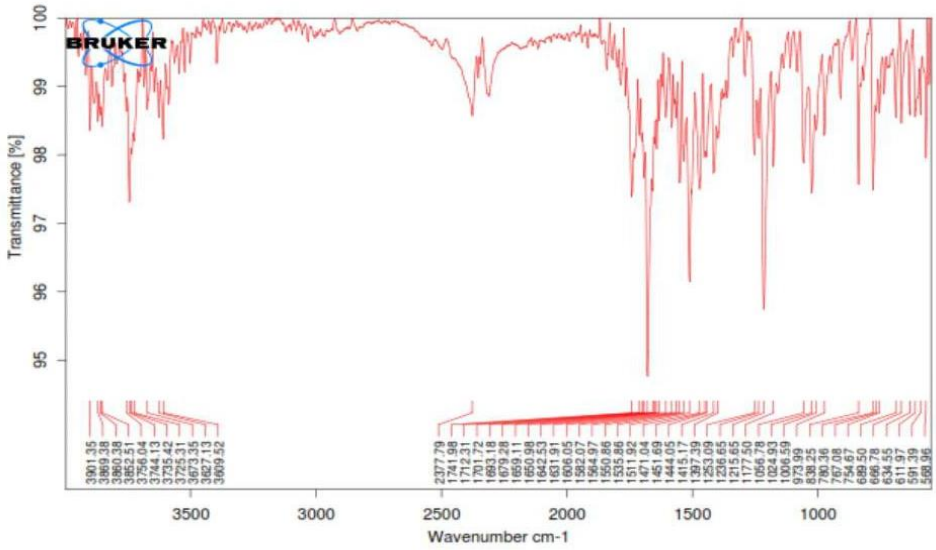


Fig: FTIR of Cisapride Monohydrate optimized formulation.

Cisapride Monohydrate was mixed with proportions of excipients showed no colour change providing no drug-excipient interactions

CONCLUSION

In the present work, an attempt has been made to develop Oral disintegrating tablets of Cisapride Monohydrate Locust bean gum, Tulsoin 339, Plantago ovate seed powder were used to super diintegrants. The blend of all formulations showed good flow properties su8ch as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits.

From the Dissolution data it was evident that the formulations prepared with Plantago ovata seed powder were showed good drug release i.e., 95.79% (F3) in higher concentration of blend i.e., 75 mg. Formulations prepared with Tulsion 339 showed good drug release i.e., 99.25% (F5) in 50mg concentration, when increase in concentration of Tulsion 339 drug release retarded. Formulations prepared with Locust bean gum showed maximum drug release i.e., 94.61%9F7) at 30 min in 25 mg of blend. Among all formulations F5 formulation was considered as optimized formulation which showed maximum drug release at 30 min i.e., 99.25%. Tulsion 339 was showed good release when compared to Locust bean gum, Plantago ovate seed powder. Finally concluded that F5 Formulation (containing Tulsion 339) was optimized better formulation.

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