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FORMULATION AND EVALUATION OF DOLASETRON ORAL DISPERSIBLE TABLETS BY DIRECT COMPRESSION

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ABSTRACT

This work aims to create Dolasetron orally disintegrating tablets using direct compression and evaluate their properties. This dosage type is more suitable for pediatric and geriatric individuals. This technique is suitable for oral dispersion due to its convenience. Compared to all other excipient medicines, cross povidone exhibits high activity. Dolasetron along. Cross povidone resulted in over 95.34% drug release, outperforming SSG and cross carmellose. Cross povidone has a faster disintegration time than others. This study suggests that dolasetron may have significant anti-emetic properties.

KEYWORDS: dolasetron, cross carmellose sodium, cross providone, sodium starch glyacolate, oral dispersible tablet, direct compression.

INTRODUCTION

The majority of oral medicinal dose forms, such as standard tablets and capsules, are designed to be ingested or chewed. These dose forms can be difficult for the elderly and toddlers to swallow. Bedridden patients face a more significant challenge. This issue also applies to persons who are actively working or travelling and do not have easy access to water. Recent breakthroughs in innovative drug delivery systems aim to provide rational medication therapy by improving drug molecule safety and efficacy through the development of a convenient dosage form for administration, as well as improving patient compliance. Oro Dispersible Tablets (ODTs) is one such technique. An ODT is a solid dose form that disintegrates and dissolves in the mouth (on or beneath the tongue, or in the buccal cavity) without the need of water in 60 seconds or less. The demand for ODTs has skyrocketed over the last decade, especially among geriatric and pediatric patients who have trouble swallowing conventional pills and capsules. ODTs of various drug categories, such as ibuprofen, lansoprazole, hydrochlorthiazide, cefixime trihydrate, furosemide, nimesulide, and atenolol, have been developed by researchers for use in therapy when a rapid peak plasma concentration is required to achieve the desired pharmacological response.

ODTs are prepared using a variety of processes, including freeze drying, tablet molding, direct compression, spray drying, and sublimation. Direct compression is a simple and cost-effective tablet manufacturing technology. The advantages of this technology include the use of normal equipment, readily available excipients, and a reduced number of processing stages. The disintegration and solubilization of a directly compressed tablet is determined by the action of disintegrants, water-soluble excipients, and effervescent agents, either individually or in combination. Croscarmellose sodium (crosslinked carboxymethylcellulose), crospovidone (crosslinked povidone), and sodium starch glycolate are some of the most regularly used superdisintegrants. In many orally disintegrating tablet technologies based on direct compression, the inclusion of superdisintegrants primarily influences the rate of disintegration and thus dissolution. Disintegration is accelerated by the addition of additional formulation ingredients such effervescent agents and water-soluble excipients.

Dolasetron is an antinauseant and antiemetic drug used to prevent nausea and vomiting caused by moderately emetogenic cancer chemotherapy, as well as postoperative nausea and vomiting. Dolasetron is an extremely precise and selective serotonin 5-HT3 receptor antagonist. This medication has not been found to activate other known serotonin receptors and has a poor affinity for dopamine receptors.

To prevent nausea and vomiting caused by emetogenic cancer chemotherapy, including both initial and repeat

rounds. Also used to prevent post-operative nausea and vomiting. This medicine can be administered intravenously to treat postoperative nausea and vomiting.

Dolasetron is a highly specific and selective serotonin 5-HT3 receptor antagonist that has not been found to act on other known serotonin receptors and has a low affinity for dopamine receptors. It is physically and pharmacologically similar to other 5-HT3 receptor agonists. The serontonin 5-HT3 receptors are found on the vagus nerve terminals in the periphery and centrally in the chemoreceptor trigger zone of the postrema. Chemotherapeutic drugs are thought to release serotonin from the enterochromaffin cells of the small intestine by inducing degenerative changes in the GI tract. The serotonin then stimulates the vagal and splanchnic nerve receptors that project to the medullary vomiting center, as well as the 5-HT3 receptors in the postrema region, triggering the vomiting reflex and causing nausea and vomiting.

Dolasetron inhibits and inactivates 5-HT3 receptors on the nerve terminals of the vagus nerve in the periphery and centrally in the chemoreceptor trigger zone of the area postrema, thereby blocking the activity of serotonin released from the small intestine's enterochromaffin cells.

Many methods have been devised to produce ODTS. These include vacuum drying, lyophilization, molding and compressing wet powder to create a highly porous structure, the crystalline transition method, and the direct compression method.9-11) Direct compression is an inexpensive and convenient approach for making tablets with adequate mechanical integrity. Researchers are looking for immediately compressible agents that can improve the mechanical integrity of ODTs and breakdown the tablets in a few seconds in the oral cavity. Superdisintegrants such as croscarmellose sodium, crospovidone, and sodium starch glycolate can swiftly disintegrate tablets with a crushing strength of less than 4 kg. 12) The addition of microcrystalline cellulose (Avicel-PH101 or PH102) or dicalcium phosphate to ODT formulations to improve disintegration results in an unpleasant grittiness in the mouth.

In view of these observations, the current study attempted to develop an dolasetron ODTS via direct compression. ODTS previously prepared using typical superdisintegrants such as crospovidone or croscarmellose sodium. To investigate the mechanism of disintegration, the influence of starch and glycine concentrations on disintegration time (DT), wetting time (WT), and water absorption ratio (WAR) was determined.

Tablets are solid preparations that contain a single dose of one or more active compounds and are typically made by compressing consistent quantities of particles. Tablets are designed for oral administration. Some are ingested whole, some after chewing, some dissolved or dispersed in water before administration, and some are held in the mouth, where the active ingredient is released.

Several types of tablets for oral usage can be distinguished

- Uncoated tablets
- Coated tablets
- Effervescent tablets
- Soluble tablet
- Dispersible tablets
- Orodispersible tablets
- Gastro-resistant tablets
- Modified-release tablets
- Controlled release
- Sugar coated
- Enteric coated tablet

Oral methods of medication administration are widely accepted, accounting for 50-60% of all dose forms. Solid dosage forms are popular due to their ease of administration, accuracy in dosing, self-medication, pain avoidance, and, most importantly, patient compliance. One of the major disadvantages of these dose forms for some people is the difficulty in swallowing. Drinking water helps you swallow oral dose forms better. When water is not available, people frequently find it difficult to swallow conventional dosage forms such as tablets, as well as during motion sickness and abrupt episodes of coughing during the common cold, allergic condition, or bronchitis. As a result, pills that can quickly dissolve or disintegrate in the oral cavity have received a lot of attention. Orodispersible pills are suitable not just for persons who have difficulty swallowing, but also for those who are physically active.

SETTINGS FOR QUICKLY DISMANTLING DRUG DELIVERY SYSTEMS

The tablets should not be

• It should dissolve or disintegrate in the mouth in a matter of seconds rather than requiring water to swallow.
• Be combine with taste masking.
• Be transportable and unaffected by fragility.
• Feel good in the mouth.
• Oral administration leaves little to no residue in the mouth.
• Show little sensitivity to external conditions including temperature and humidity.
• Utilize low-cost conventional processing and packaging equipment for tablet manufacturing.

The salient characteristics of the ORODISPLAY drug delivery system

• Easy administration and precise dosage in comparison to liquids.
• Simultaneous administration to patients, including pediatric, geriatric, and psychiatric patients, who refuse to take a tablet.

• Patients who are traveling and do not have instant access to water will find this feature incredibly useful as it eliminates the need for water to consume the medication.
• When ODDS is taken correctly, it can help shift people's perceptions of medications as "bitter pills," especially in the case of younger patients.
• Some drugs are absorbed from the mouth pharynx and oesophagus as the saliva passes down intothe stomach, in such cases bioavailability of drugs is increased.
• Quick medication absorption and dissolution, which could result in a quick start of action.
• Better bioavailability and, due to lower dosages and fewer side effects, enhanced clinical performance can be obtained from pregastric absorption.

ADVANTAGES OF ORODISPERSIBLE TABLETS
• No water required.
• No chewing required.
• Improved flavor.
• Improved stability.
• Perfect for controlled/sustained release actives.
• Allows for heavy drug loading.
• Offers the benefits of liquid medication in a solid composition.
• Cost-effective.
• Prompt pharmacological therapy intervention.
• High drug loading is conceivable.
• Experience a lovely mouthfeel and good taste.
• Leave minimal residue.

DISADVANTAGES OF ORODISPERSIBLE TABLETS
• bad flavor /unpleasant taste.
• an expensive manufacturing procedure.
• Absence of physical barrier in typical blister packs.
• restricted capacity to add active drug concentrations that are higher.

Litrature Review
• The article by Brahmeshwar Mishra et al. (2009) discusses advancements in manufacturing quantity dissolving tablets using available technologies. Apart from the usual way of construction, this review includes a full understanding of certain unique patented technologies such as zydis, Lyco, quicksolvs, orasolv, Durasolv, flash tab, oraquick, wow tab, and zip, as well as its advantages and drawbacks.
• According to Galal El-Mahrouk et al. (2009), meloxicam, a non-steroidal anti-inflammatory medication, has low water solubility and dissolution, resulting in variable bioavailability. This study aims to improve meloxicam availability by developing an orally dispersible capsule comprising a soluble drug combination with beta-cyclodextrin. Complexes were synthesized for diffraction, infrared spectroscopy, and dissolution efficiency experiments. Orodispersible capsule shells were made by freeze-drying typical hard gelatin capsule shells and tested for moisture content using image analysis microscopy.
• Swamy et al. (2010) created an orally dispersible tablet containing diethylcarbamazine citrate (anthelmintic) using an effervescent technique using sodium bicarbonate, tartaric acid, and treated agar as the disintegrant. The current study clearly shows that an orodispersible tablet of diethylcarbamazine citrate may be successfully manufactured by direct compression in a cost-effective manner using treated agar. The addition of effevescent mixture significantly enhances flavor masking.
• Metker Vishal et al. (2011) developed mouth-dissolving lornoxicam tablets with KYRON T-314 (polacrillin) as a new superdisintigrate. Lornoxicam and menthol pills that dissolve in the mouth act as a subliming agent. The current investigation indicated the potential for quick absorption, increased bioavailability, effective therapy, and patient compliance.
• The International Journal of Pharmacy and Pharmaceutical Sciences, edited. At (2017)—formulation and evaluation of an orodispersible tablet of a model antihypertensive medication, the rationale for the current work was to formulate and analyze an orodispersible tablet using direct compression techniques with the goal of improving patient compliance and accelerating the beginning of addition.
• Formulation and Evaluation of Dolasetron Orally Disintegrating Tablets S. Jecintha Jebamalar1, Dr. L. Karpagavalli2.
•Prajapati R.H et.al(2010)—the purpose of this research was to mask the intensively bitter taste of dolasetron by complexing with indion 204 resinby the solvent evaporation and formulate the mouth dissolving tablet of a taste-masked drug. Tablet where formulated by direct compression method using different superdisintigrate like polyplasdone XL-10 & sodium starch glycolate (SSG) in different concentration, diluents like mannitol, microcrystalline cellulose (MCC 112), sweeting agent aspartame, flavouring agents like peppermint and vanilla, lubricant magnesium stearate & glidant aerosil. All formulation where evaluated for disintegration time wetting time percentage friability. Content uniformity and in vitro dissolution rate. Formulation with 7% polyplasdone XL-10 showed the disintegration time 14 seconds and wetting time 25second in vitro drug release study of taste masked tablet show complete drug release within 10 minutes and successful masking of taste and rapid disintegration of the formulated tablet in a oral cavity.

AIM
The project's goal is to develop and test dolasetron orodispersible tablets via direct compression.

OBJECTIVES
- To investigate the impact of drug-to-polymer ratio on in vitro drug release.
- To optimize medication release patterns.
- Improve therapeutic efficacy.

Plan of Work

- Choose drugs and polymers for the oral disintegrating system.
- Formulate the dosage form and evaluate the tablet.
- Weight variation.
- Hardness.
- in vitro dissolution test.
- UV spectroscopy.
- drug content are all factors to consider.

Material and Equipment

Drug

Sr. no	Drug	Suppliers/ manufacture
1	dolasetron	Mayer healthcare pharmaceuticals, Bangalore

Polymers

Table 1: List of chemicals/Reagents used.

Sr. no	Polymer	Suppliers
1	Sodium Bicarbonate	Yarrow chem.
2	Citric acid	Yarrow chem.
3	Cross Carmellose Sodium	Shreeji chemicals, Mumbai
4	Cross Povidone	SD fine chemicals, Mumbai
5	Sodium Sacchrin	Yarrow chem.
6	Dicalcium Phosphate	Yarrow chem.
7	Magnesium Stearate	Yarrow chem.

List of Instruments Used

Table 2: List of Instruments used.

Sr.no	Name of Equipment
1	Tablet compression machine
2	Dissolution test apparatus
3	Tablet hardness Tester
4	UV-Visible spectrophtometer

EXPERIMENTAL WORK

PREFORMULATION STUDIES

Preformulation testing is the initial step in developing dosage forms for a pharmacological ingredient. It involves studying physical and chemical properties.

The qualities of a drug substance, both alone and in combination with excipients. It provides detailed information for achieving high-quality results and determining the right dosage. Preformulation studies on the medication (API) included melting point, solubility, and compatibility testing.10 The following preformulation studies were conducted for Dolasetron Hcl and polymers.

(A) Bulk Density (DB).

It is the ratio of powder's total mass to its bulk volume. It was measured by pouring weighed powder into a measuring cylinder and noting the initial weight. This initial volume was known as the bulk volume. From this, the bulk density was determined using the formula below. It is represented in grams per milliliter and given by

Bulk density (Db) = Mass (M)/Bulk volume (Vb)

where, M is the powder's mass, and Vb is its bulk volume.

(B) Tapped density (DT).

It is the ratio of the powder's total mass to it's tapped volume. Volume was determined by tapping the powder 750 times, and the tapped volume was recorded if the difference between the two volumes was less than 2%. If it is greater than 2%, tapping is repeated 1250 times, and the tapped volume is logged. Tapping was repeated until the difference between successive volumes was less than 2% (in a bulk density apparatus). Tapped density (Dt) = Mass (M) / Tapped volume (Vt), expressed in grams per milliliter. Where M is the powder's mass and Vt is its tapped volume.

(C) Angle of repose.

The powder's angle of repose was determined using the funnel method. The carefully weighed powder was placed in a funnel. The funnel's height was changed so that the tip only touches the apex of the powder heap. The powder was allowed to flow freely through the funnel and onto the surface. The diameter of the powder cone was measured, and the angle of repose was computed using the equation below. $\theta = \tan^{-1} h/r$. Where h and r are the height and radius of the powder cone, respectively.

Table 3: Flow properties and corresponding angle of repose.

ANGLE OF REPOSE	FLOW PROPERTY
25 – 30	Excellent
31 – 35	Good
36 – 40	Fair
41 – 45	Passable
46 – 55	Poor
56 – 65	Very poor
> 66	Extremely poor

a) Carr's Index (% compressibility)

It has an indirect relationship with particle size, cohesiveness, and relative flow rate. It is a simple,

common, and efficient method for forecasting powder flow properties. Based on the apparent bulk density and the tapped density, the % compressibility of the bulk medication was estimated by the following formula.
Compressibility index (%) = TD - BDTD ×100; Where, TD = Tapped density, BD = Bulk density.

Table 4: Flowability based on compressibility index.

Carr's index	Type of flow
5 – 15	Excellent
12 – 18	Good
18 – 23	Poor
35 – 38	Very poor
> 40	Extremely poor

b) Hausner's ratio.
The ratio of tapped density to bulk density is known as the hausner ratio. It is an indirect indicator of the ease of powder flow. It is calculated using the following formula.
Hausner ratio = Tapped density (Dt)/Bulk density (Db)
Lower hausner ratios (<1.25) suggest superior flow qualities compared to higher ones (>1.25)

Table 5: Scale of flowability based on Hausner's ratio.

HAUSNER'S RATIO	TYPE OF FLOW
Less than 1.25	Good flow
1.25 – 1.5	Moderate
More than 1.5	Poor flow

PREPARATION OF DOLASETRON HYDROCHLORIDE ORODISPERSIBLE TABLETS

Dolasetron orodispersible tablets were manufactured using the effervescent method described in the formula. All of the ingredients were filtered through # 60 mesh sieves separately. The medication and directly compressible excipient were mixed together by adding a small amount of each at a time and blending until a homogenous mixture was achieved, then set aside. To eliminate residual moisture, sodium bicarbonate and tartaric acid were pre-heated at 80ºC for 2 hours. They were then thoroughly combined in a mortar to make a homogenous powder and added to the mixture. The other materials were then blended in geometric order, with magnesium stearate and purified talc added last and mixed for an additional two minutes. The blend was compacted using 9 mm flat round punches to produce 100 mg tablets on a 10-station rotary tablet machine. A batch of ten tablets was made for each of the designed formulas.

Table 6: Table of Formulation of all batches.

ODT	F1	F2	F3	F4	F5	F6	F7	F8
Drug(mg)	4	4	4	4	4	4	4	4
Sodium Bicarbonate (mg)	18	18	18	18	18	-	-	18
Citric acid(mg)	18	18	18	18	18	-	-	18
Cross Carmellose Sodium(mg)	4	2	-	-	4	4	-	-
Sodium StarchGlycolate(mg)	-	2	4	2	4	4	4	4
Cross Povidone (mg)	-	-	-	2	-	-	4	4
Sodium Saccharin (mg)	4	4	4	4	4	4	4	4
Dicalcium Phosphate (mg)	50	50	50	50	46	82	82	46
MagnesiumStearate (mg)	2	2	2	2	2	2	2	2

DOLASETRON HYDROCHLORIDE STANDARD CURVE PREPARATION

PREPARATION OF 0.1N HCL SOLUTION

Take 8 milliliters of strong HCl solution, then add 1000 milliliters of purified water to it.

DOLASETRON HYDROCHLORIDE STANDARD CURVE PREPARATION

In a 100 ml volumetric flask, 100 mg of dolasetron hydrochloride was precisely weighed, dissolved in a tiny amount of 0.1N hcl solution, and the volume was increased to 100 ml with buffer. The main stock solution is this. Precisely 10 ml was taken out of the main stock solution and put into a 100 ml volumetric flask. The volume was then increased to 100 ml using buffer. Aliquots of 2–10 mcg (2 ml, 4 ml, 6 ml, 8 ml, and 10 ml) were pipetted out of the secondary stock solution into a series of 10 with buffer. The phosphate buffer pH 6.8 was used as a blank to measure the absorbance of the above-set solutions at 248 nm. Next, a calibration curve was drawn, with the absorbance on the Y-axis and the concentration on the X-axis.

Table 7: Concentration and drug absorbances at 248nm.

Concentration in (µg/ml)	Absorbance at 248 nm
0	0
0.2	0.058
0.4	0.126
0.6	0.193
0.8	0.258
1.0	0.320

DOLASETRON HYDROCHLORIDE STANDARD CURVE IN PHOSPHATE BUFFER, pH 6.8

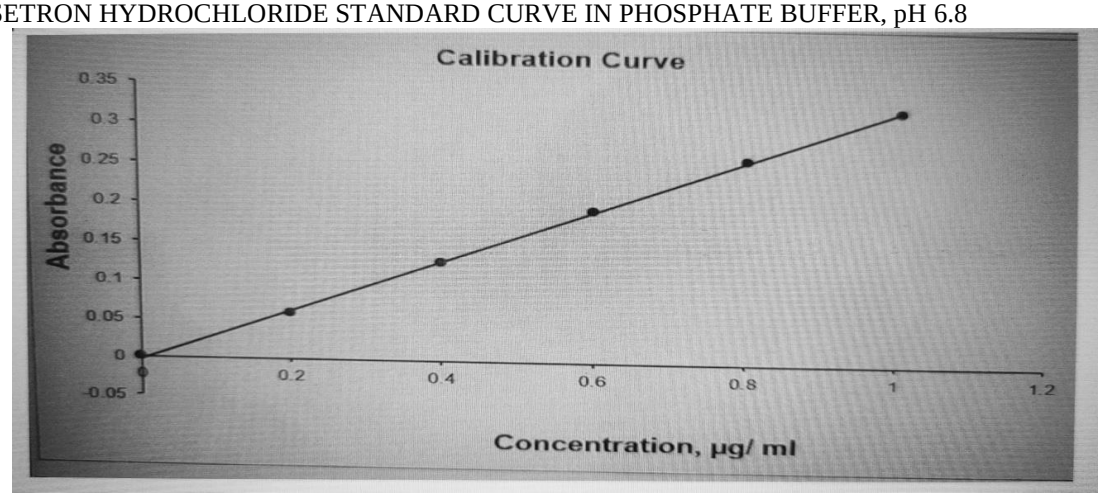

Fig: Standard curve of Ondansetron hydrochloride in phosphate buffer ph 6.8

PHYSICO CHEMICAL EVALUATION

A. Variation in weight

On a digital weighing balance, the weights of the ten tablets were recorded both individually and collectively. The total weight was used to calculate the average weight of a single tablet. The percentage variation of each tablet was computed by comparing the average weight with the individual weight.

Table 8: Weight variation limit as per IP.

Average weight of Tablet	Percentage Deviation
80 mg or less	± 10%
More than 80 mg but less than 250 mg	± 7.5%
250 mg or more	± 5%

B.Thickness

The tablets' thickness was measured using an Electro lab type vernier caliper. Five tablets are chosen at random from each batch. It is presented in millimeters, and average values were derived.

C. Hardness

Hardness was assessed by collecting five pills from each formulation and measuring them with a Monsanto hardness tester. The hardness was measured in kilograms per cubic centimetre.

D. Friability

The friability of the tablet was determined using a Roche friabillator (Electro lab, India).Twenty reweighed tablets were revolved at 25 rpm for 4 rpm, with the tablets being dropped from a height of 6 inches at each revolution, for a total of 100 revolutions. The tablets were then dedusted with a delicate muslin cloth, weighed again, and the percentage of weight loss computed. The % friability of the tablets was determined using the following formula.

Percentage friability = (Initial weight - final weight/Initial weight) × 100.

E. In vitro dispersion period

The in vitro dispersion time was determined by dropping a tablet into a 900 mL chamber of a dissolution equipment. The experiment was set to run for 6 minutes, with samples collected using a pipette at 2 minutes, 4 minutes, and 6 minutes. The dissolution of orodispersible tablets was tested in vitro using a USP XXIII type-II dissolution test apparatus (Electro lab, model: TDT-06N) with a paddle stirrer at 50 rpm and 900 ml of 0.1 N HCL buffer at 37±0.5o C as the dissolving medium. Each test involved one pill. Aliquots of dissolving medium were extracted at predetermined intervals and evaluated for drug content by measuring absorbance at 248 nm. The volume extracted at each time interval was replaced with a new quantity of dissolving medium. The cumulative percentage of drugs released was computed and shown against time.

RESULT AND DISCUSSION

Table 9: Physicochemical Evaluation Parameter as per IP.

Formulation code	Weight variation(mg)	Thickness (mm)	Hardness (kg/cm2)	Friability (%)
F1	100.4±0.84	2.35±0.03	2.20±0.10	0.831±0.01
F2	100.2±1.35	2.34+0.01	2.13±0.20	0.781±0.03
F3	100.1±0.06	2.34±0.03	2.13±0.21	0.836+0.07
F4	100.3±0.94	2.32+0.01	2.30±0.17	0.747±0.08
F5	100.1±0.05	2.31±0.01	2.33±0.11	0.814±0.04
F6	100.3±0.94	2.34+0.01	2.40±0.26	10.832+0.01
F7	100.2±0.05	2.32+0.00	2.02+0.15	0.780±0.10
F8	99.9±1.10	2.33±0.01	2.16±0.11	0.907±0.08

WEIGHT VARIATION

The weight variation among all ten formulations ranged from 199.8±1.34 to 200.4±0.84 mg. Formulations met pharmacopeial standards, with free flow of the powder blend and exhibiting the effectiveness of particle compression into tablets.

HARDNESS

The pills disintegrate quickly, hence the hardness was kept between 2.02±0.15 and 2.40±0.26 kg/cm2. There was no difference in hardness, which clearly indicates that the mixture was properly blended for the manufacturing of orodispersible tablets. The produced tablets in all formulations have good mechanical strength and appropriate hardness.

THICKNESS

Tablet thickness ranged from 2.31±0.01 to 2.35±0.03 mm, indicating satisfactory consistency.

PERCENTAGE FRIABILITY

Percentage Friability is below 1% in all formulations with values ranging from 0.747±0.08 to 0.941±0.04%. It suggested that the tablets had strong mechanical resistance.

FRIABILITY

The friability of the tablet was determined using a Roche friabillator (Electro lab, India).Twenty reweighed tablets were revolved at 25 rpm for 4 rpm, with the tablets being dropped from a height of 6 inches at each revolution, for a total of 100 revolutions. The following findings were obtained.

Percentage release of drug of all batches

Table 10: % release of drug of all batches.

Batch	2 min	4 min	6 min
F1	45.05%	46.50%	85.50%
F2	49.50%	63.00%	90.00%
F3	40.50%	45.00%	46.50%
F4	45.50%	63.00%	90.90%
F5	22.50%	45.00%	85.50%
F6	18.00%	22.50%	49.05%
F7	45.45%	90.45%	90.45%
F8	45.45%	46.80%	90.9%

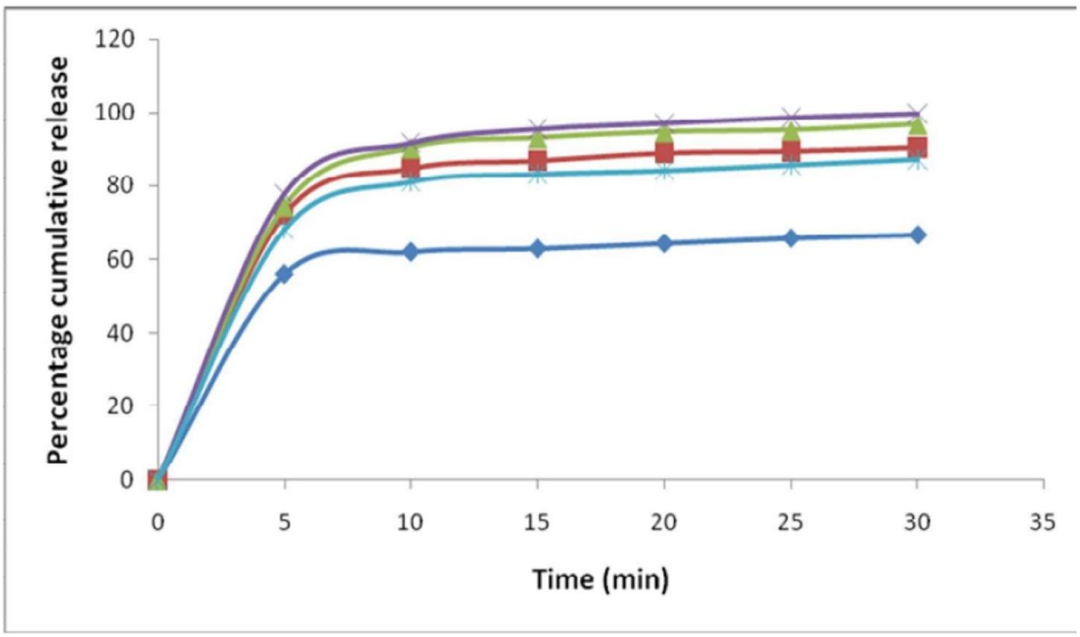

Fig: Percentage release of drug of batches F1, F2, F7, F8.

CONCLUSION

The current study was a successful attempt to develop an oral disintegrating drug delivery system for dolasetron, an orally administered anti-emitic medication, with the goal of enhancing its oral absorption.

The experimental results indicate that an oral disintegrating delivery system for dolasetron can be created through direct compression of various polymers, including citric acid, sodium bicarbonate, sodium starch glycolate, cross carmellose sodium, magnesium sterate, di calcium phosphate, cross povidone, and sodium sacchrin.

The tablets' weight ranged from 95mg to 105mg. So the manufactured tablets were inside the prescribed range.

The hardness of tablets ranges from 2.2-2.40 kg/cm2.

All of the prepared tablet formulations were determined to be acceptable without capping or chipping. All of the formulations contain a good amount of medication.

A suitable method of drug analysis using UV spectrophotometry was devised. In 0.1N hcl buffer, dolasetron absorption peaked at 248 nm. Citric acid, sodium bicarbonate, sodium starch glycolate, cross carmellose sodium, magnesium sterate, di calcium phosphate, cross povidone, and sodium saccharin were discovered to be promising polymers in controlling the rate and extent of drug release from the dosage form.

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