IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

Formulation And Evaluation Of Ondansetron Hydrochloride Tablets Using Natural Disintegrating Agent

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ABSTRACT

The present study focuses on the formulation and evaluation of Ondansetron Hydrochloride orodispersible tablets utilizing Acacia gum as a natural superdisintegrant. Natural disintegrants are gaining popularity due to their biocompatibility, non-toxicity, and cost-effectiveness. In this work, various formulations were prepared using direct compression, incorporating different concentrations of Acacia gum, and evaluated for pre-compression and post-compression parameters such as hardness, friability, disintegration time, and drug release. Among the formulations, batch F3 exhibited the best performance with a disintegration time of 22 seconds and 99.31% drug release at 30 minutes. The findings suggest that Acacia gum can serve as an effective and natural alternative to synthetic superdisintegrants in the development of fast-dissolving tablets.

KEYWORDS:- Ondansetron Hydrochloride, Orodispersible Tablets, Acacia gum, Natural Disintegrant, Drug Release, Mucoadhesive Delivery

INTRODUCTION

Drug delivery systems have evolved significantly, aiming to improve therapeutic efficacy, patient compliance, and bioavailability while minimizing the limitations associated with traditional oral and parenteral routes of administration. Among the various novel drug delivery systems, buccal drug delivery has gained considerable attention due to its ability to bypass first-pass metabolism, reduce gastrointestinal degradation, and enhance the bioavailability of certain drugs. The buccal mucosa, located in the oral cavity, serves as a promising site for drug absorption due to its rich vascularization, relatively thin epithelial layer, and proximity to systemic circulation.

The conventional oral route often suffers from drawbacks such as variable drug absorption, degradation by gastrointestinal enzymes, and first-pass metabolism, leading to reduced drug bioavailability and higher doses

required to achieve therapeutic efficacy. Buccal drug delivery offers an attractive alternative by ensuring the drug is absorbed directly into the systemic circulation, thereby enhancing bioavailability and reducing the frequency of dosing. Among the various buccal drug delivery systems, macoadhesive systems, which utilize bioadhesive materials, have emerged as particularly promising. These macoadhesive systems prolong the residence time of the drug at the buccal mucosa, thereby facilitating sustained and controlled drug release.

Macoadhesive buccal drug delivery systems have several key advantages, including reduced frequency of administration, improved drug stability due to bypassing gastrointestinal degradation, and enhanced patient comfort, as they avoid the discomfort and inconvenience associated with parenteral or oral drug administration. Additionally, macoadhesive systems can improve the therapeutic efficacy of drugs with poor bioavailability or those prone to extensive first-pass metabolism. However, the development of such systems is not without limitations. Factors such as drug permeability, enzymatic degradation, and saliva-induced drug clearance can influence the efficacy of macoadhesive buccal systems. The oral cavity itself presents several unique anatomical and physiological characteristics that impact drug absorption and retention. The mucosal surface, consisting primarily of the buccal, sublingual, and palatal regions, provides a suitable environment for drug delivery. However, the presence of saliva, which contains enzymes and buffers, poses challenges to drug retention and permeation. Understanding the secretion of the oral cavity, including salivary flow and enzymatic activity, is essential for designing effective buccal drug delivery systems.

To enhance the bioadhesive properties and the prolonged retention of the drug at the buccal mucosa, mucoadhesiondefined as the interaction between a bioadhesive material and the mucosal surface plays a critical role. Mucoadhesive systems exploit the characteristics of bioadhesive polymers that adhere to the mucosal lining, ensuring prolonged drug residence and controlled drug release. Several theories, such as electronic, mechanical, and wetting theories, explain the underlying mechanisms of mucoadhesion, while factors such as polymer properties, surface properties of the mucosa, and environmental conditions influence the strength and efficiency of mucoadhesion.In the quest to develop effective mucoadhesive buccal dosage forms, factors such as drug properties (lipophilicity, molecular size, and solubility), mucosal permeability, and the presence of saliva-induced drug clearance become critical. The use of suitable bioadhesive materials like polymers such as acacia gum, carbomers, and hydroxypropyl methylcellulose (HPMC) can significantly enhance the performance of buccal drug delivery systems by prolonging drug retention and optimizing drug release profiles.

The drug release mechanisms can be described using various mathematical models, including zero-order, first-order, Higuchi, and Peppas models, helping to predict the drug release rate and optimize the formulation for desired therapeutic outcomes.

MATERIALS AND EQUIPMENT'S

➢ MATERIALS

The following materials of Pharma grade or the best possible Laboratory Reagent (LR) were used as supplied by the manufacturer. The double distilled water was used in all experiments.

Table 1.1. List of Material Used

Sr. No.	Materials used	Category	Grade	Suppliers of Material
1.	Odensetron Hydrochloride	API	Pharma Grade	Indo Pharma, Sukarwadi, Borivali, Mumbai, Maharashtra 400066
2.	Acacia Gum	Natural Disintegrant	LR	Shri Kamala Educational Agency, Akola – 444001
3.	Microcrystalline Cellulose	Diluent And Filler	LR	Shri Kamala Educational Agency, Akola – 444001
4.	Aspartame	Sweetener	LR	Shri Kamala Educational Agency, Akola – 444001
5.	Mannitol	Binder And Filler	LR	Shri Kamala Educational Agency, Akola – 444001
6.	Magnesium Stearate	Lubricant	LR	Shri Kamala Educational Agency, Akola – 444001

➢ **EQUIPMENTS USED**

Table 1.2. List of Equipment's and manufacturer

Sr. No.	Equipment	Supplier of Equipment
1	Single punch machine	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)
2	Digital Balance	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola -444001 (2019)
3	Mortar and pestle	Adarsh Instruments Pvt. Ltd., 5368, Cross Road No. 2, Nicholson Road, Ambala Cantt -133001 (Haryana) (2019)
4	Digital pH Meter	Adarsh Instruments Pvt. Ltd., 5368, Cross Road No. 2, Nicholson Road, Ambala Cantt -133001 (Haryana) (2019)
5	Disintegration tester	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)
6	Dissolution apparatus	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)
8	Hot air oven	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)
9	Hardness tester	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)
11	Blender	Gajanan Educational Agency, Shop No. 12, Gajanan Estate, Kaulkhed, Akola - 444001 (2019)

METHOD

❖ **Formulation Development**

The formulation development of Ondansetron Hydrochloride Orodispersible Tablets (ODTs) was carried out with the objective of achieving rapid disintegration in the oral cavity without the need for water, enhancing patient compliance, particularly in pediatric and geriatric populations. A suitable combination of excipients was selected based on their functional roles in the formulation. Acacia gum, a natural disintegrant, was chosen due to its excellent swelling properties and biocompatibility, which contribute to faster disintegration of the tablet. Mannitol was used as a filler to provide a pleasant mouthfeel and improve tablet palatability, while Avicel PH 102 served as a binder to ensure mechanical strength. Magnesium Stearate was included to enhance powder flow and prevent sticking during compression, and Aspartate was added to improve taste. The wet granulation method was employed to prepare granules with improved compressibility and uniformity. The prepared granules were evaluated for flow properties before being compressed into tablets using a rotary tablet compression machine. The formulation parameters, such as hardness, weight, and

disintegration time, were optimized to produce a final product that is stable, effective, and suitable for orodispersible drug delivery.

❖ **Preparation of Powder Blend of Drug and Excipients**

The formulation process began with the accurate weighing of all components to ensure consistent dosage and formulation uniformity. Ondansetron Hydrochloride, an antiemetic agent used to prevent nausea and vomiting, was weighed precisely using an analytical balance. In addition to the active drug, various excipients were carefully selected for their functional roles in the formulation. Mannitol was used as a diluent due to its pleasant taste and mouthfeel, making it suitable for orodispersible tablets. Avicel PH 102 was chosen as a binder to provide mechanical strength, while Acacia gum functioned as the natural disintegrant to promote rapid disintegration. Magnesium Stearate was included as a glidant to enhance powder flow, and Aspartate was added as a sweetening agent to improve palatability. Each ingredient was passed through a 60-mesh sieve to ensure a uniform particle size distribution, eliminate agglomerates, and improve blend homogeneity. The sieved ingredients were transferred into a clean, dry mortar or mechanical blender and mixed thoroughly for 10–15 minutes using the geometric dilution technique. This method ensured the gradual and even incorporation of the drug into the excipients, minimizing the risk of segregation. The final powder blend was examined for uniformity in appearance and stored in a moisture-controlled environment until further processing.

❖ **Preparation of Ondansetron Hydrochloride Orodispersible Tablets by Wet Compression (Using Natural Disintegrating Agent)**

The tablets were prepared using the wet granulation method, a widely used technique to improve the compressibility and flow properties of powder blends, especially when dealing with low-dose or fine powders like Ondansetron Hydrochloride. A binder solution was prepared by dissolving Avicel PH 102 in either purified water or alcohol, depending on the solubility profile of the excipients. The solution was gradually added to the dry powder blend while continuously kneading the mass until a damp, cohesive texture was achieved. This wet mass was then passed through a #20 or #40 mesh sieve to form granules of uniform size, which facilitates better packing and reduces weight variation during compression. The granules were dried in a tray dryer at 40°C for approximately 30 minutes or until a consistent moisture content was achieved, ensuring stability and preventing microbial growth. Once dried, the granules were sieved again through a finer mesh (#20 or #30) to break up any lumps and obtain a free-flowing granule blend. Lubrication was carried out by adding pre-measured quantities of Magnesium Stearate and Aspartate, which were mixed gently for 3–5 minutes to avoid overwetting or disrupting the granule structure. The final lubricated granules were fed into a rotary tablet compression machine equipped with a 6 mm flat-faced punch and die set. The compression force was maintained between 4–5 kg/cm² to ensure adequate hardness, while preserving fast disintegration. The tablets produced had an average hardness of 3.5–4 kg/cm² and a weight range between 150–300 mg. Each batch of tablets was collected and subjected to quality control tests, including weight variation, hardness, friability, and disintegration time, to confirm the effectiveness of Acacia gum as a natural disintegrant.

Table 1.3. Formulation design of Odensetron hydrochloride fumarate orodispersible tablets.

Ingredient	MF 1	MF 2	MF 3
Ondansetron Hydrochloride	4	6	8
Mannitol	230	220	210
Avicel PH 102	50	50	50
Acacia Gum	5	8	10
Magnesium Stearate	1	1	2
Aspartate	10	15	20
Total	**300mg**	**300mg**	**300mg**

EVALUATION

➢ PREFORMULATION STUDY

Reformulation testing was an investigation of physical and chemical properties of a drug substance alone and when combined with excipients. It was the first step in the rational development of dosage forms.

Active pharmaceutical ingredient (API) characterization:

❖ **Organoleptic evaluation:**

These are preliminary characteristics of any substance, which is useful in identification of specific material. Following physical properties of API were studied.

For Odensetron Hydrochloride:

- **Appearance:** A white or almost white, crystalline powder
- **Colour:** White
- **Odor:** Odourless

❖ **Melting Point**:

The determination of melting point during pre-formulation studies is important since it is a simple test gives valuable information regarding thermal properties of the material. Melting point was determined by capillary melting method (Electro lab Apparatus). Seal capillary from one end and fill the drug sample about 10% of capillary volume. Tie the capillary to thermometer and dipped into Thiele's tube and heated and melting point was noted.

❖ **pH Dependent Solubility Study of API:**

pH of Odensetron hydrochloride in 10% solution (water) was found to be slightly acidic. The pH dependent solubility study was carried out by using different pH buffer solution ranging pH 1.2 (0.1 N HCl), pH 4.5 acetate buffer, pH 6.8 phosphate buffer and pH 8.4 phosphate buffer.

❖ **Angle of repose**

The angle of repose was determined by fixed funnel method. A glass funnel was held in place with a clamp on a ring support over a horizontal surface. The accurately weight powder blend was transferred in the funnel keeping the orifice of the funnel blocked by the thumb. As the thumb was removed the powder blend was allowed to flow through the funnel freely on to the surface. The height of the pile (h) and the radius of the base (r) were measured and angle of repose was calculated using the following equation. (USP 30 NF 25, 2007)

$$\text{Tan } \theta = \frac{h}{r} \ldots\ldots\ldots\ldots\ldots\ldots \text{ (I)}$$

Where, tan θ the angle of repose, h and r are the height and radius of the powder cone.

❖ **Flow Properties and Corresponding Angle of Repose:-**

Table 1.4. Flow Properties and Corresponding Angle of Repose

Sl. No.	Flow property	Angle of repose (^{0})
1.	Excellent	25-30
2.	Good	31-35
3.	Fair – aid not needed	36-40
4.	Passable - may hang-up	41-45
5.	Poor – must agitate, vibrate	46-55
6.	Very poor	56-65
8.	Very, very poor	>66

❖ **Loss on drying**:

0.5g of sample of Odensetron hydrochloride was accurately weighed and the powder was kept in a Metter Toledo apparatus for 5 minutes at 105ºC and the moisture content was calculated (USP 39/NF 34, 2015).

❖ **Compressibility Index**

Compressibility index has been proposed as an indirect measure of bulk density, size and shape, surface area, moisture content, and cohesiveness of materials because all of these can influence the observed compressibility index. The compressibility index and Hausners ratio are determined by measuring both bulk density and the tapped density of a powder.

$$\text{Compressibility Index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

The density analysis was carried out by using USP Type-1 (Electrolab) apparatus.

❖ **Hausner Ratio**

Hausner Ratio was determined by measuring both bulk density and the tapped density of a powder (USP 39/NF 34(2016)).

$$\text{Hausner Ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

The Hausner Ratio varies from about 1.2 for free flowing powder to 1.6 for cohesive powders.

Relation between Compressibility Index and Hausner Ratio

Table 1.5. Relation between Compressibility Index and Hausner Ratio

Sr No.	Compressibility Index (%)	Flow Character	Hausner Ratio
1.	≤ 10	Excellent	1.00 – 1.11
2.	11 – 15	Good	1.12 – 1.18
3.	16 – 20	Fair	1.19 – 1.25
4.	21 – 25	Passable	1.26 – 1.34
5.	26 – 31	Poor	1.35 – 1.45
6.	32 – 37	Very poor	1.46 – 1.59
8.	> 38	Very, very poor	> 1.60

❖ **Solubility Profile**

The solubility was determined by weighing out 10mg of the compound (API) to this is added 10 micro-litre of the solvent interest, (such as water, DMF etc.). If not dissolved, further 40 micro-litre of solvent was added and its effect was noted. Successive amounts of the solvents were added until the compound was observed to dissolve.

❖ **Drug– Excipients compatibility study**

Drug–Excipients compatibility study of Odensetron hydrochloride with all of excipients was carried out. The compatibility of drug and formulation components is important prerequisite before formulation. It is therefore necessary to confirm that the drug does not react with the excipients under experimental conditions

and affect the shelf life of product or any other unwanted effects on the formulation(as per ICH Q-1a, R2) guidelines).

➢ POST-COMPRESSION

❖ Hardness

Hardness of the tablet was determined by using Monsanto tablet hardness tester. Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression. From each batch, hardness of 6 tablets was determined. The lower plunger is placed in contact with tablet, and a zero reading was taken. The upper plunger is then forced against a spring by turning a threaded bolt until the tablet fractures. Hardness of tablet is expressed in kg / cm2.

❖ Friability

The friability test for tablets was performed to assess the effect of abrasion and shocks. Roche Friabilator was used for the percent friability of the tablets. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at a height of 6 inches in each revolution. Pre-weighted sample of tablets was placed in the Friabilator and were subjected to the 100 revolutions. Then the tablets were removed and de dusted by using a soft muslin cloth and reweighed. The weight lost should not exceed the limit 1.0%. The percentage friability was measured by using the following formula.

$$\% F = \frac{W_{initial} - W_{Final}}{W_{initial}} \times 100$$

Where

% F = Friability in percentage,

W initial = Initial weight of tablet

W final = Final weight of tablet.

❖ Weight Variation

The weight variation test was performed as per I.P. twenty tablets were randomly selected from each batch and individually weighed. And then average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The tablets passes the test for weight variation test if no more than two tablets are outside the percentage limit and if no tablet differs by more than two times the percentage limit. Weight variation specification as per I.P.

❖ **Disintegration Time**

It is determined by using USP device which consist of 6 glass tubes that are 3 inches long, open at one end and held against 10 mesh screen at the bottom end of basket rack assembly. To test for disintegration time, one tablet is placed in each tube and the basket arch is positioned in a1 liter beaker of water at 37°C ± 2°C.A standard motor driven device is used to move the basket assembly up and down (USP39/NF34). To be incompliance with the USP standard, all tablets must disintegrate and all particles must pass through the 10 mesh in the time specified.

❖ **Dissolution Test**

a) Standard solution Preparation

Take 22 mg of Odensetron hydrochloride working standard into a 100ml volumetric flask, dissolve and makeup to the volume with diluents. Dilute 5 ml of the above solution to 50ml with diluent. (Concentration = 20 ppm solution)

b) Sample solution Preparation

Dissolution study of tablet performed in USP II (paddle) dissolution test apparatus using 900 ml of water as a dissolution media. The tablet was placed in to the vessel of dissolution apparatus; the temperature of dissolution media was maintained at 37°C ± 5°C. With stirring speed of 50 rpm throughout the study. Aliquots of dissolution media containing 10ml of samples were withdrawn at time interval of 1, 2, 3, 4 and 5 minutes and 10ml of fresh dissolution media maintained at the same temperature was replaced after each withdrawal. The raw dissolution data was analyzed for calculating the amount of drug released and percentage cumulative drug released by recording absorbance at 248nm wavelength. (Concentration = 22 ppm solution)

Table 1.6. Dissolution Parameters

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (ml)	Sampling Time Points (minutes)
Odensetron hydrochloride	Tablet	II (Paddle)	50	0.1 N HCL	900	1, 2, 3, 4,5,6 and 7

Calculations:

$$\% \text{ of Drug dissolved} = \frac{A_T \times W_{std} \times 5 \times 900 \times 100 \times 1}{A_S \times 100 \times {}_{Sample}L.C \times 20}$$

Where,

A_T = Average of the absorbance count of the Odensetron hydrochloride test aliquots.

A_S = Average of the absorbance count of the Odensetron hydrochloride standard.

W_{std}= Weight of the working standard taken in mg.

L.C. = Label claim in mg.

P = % potency of Odensetron hydrochloride l working standard.

RESULTS AND DISCUSSION

- **RESULTS**
- **Active pharmaceutical ingredient (API) characterization:**

For Odensetron Hydrochloride

- **Appearance:** A white or almost white, crystalline powder
- **Colour :** White
- **Odor :** Odourless

Table 1.7. Results of physical parameters of Drug

Table

Parameters	Observations
Water solubility	Soluble in water
Loss on drying	0.29% (w/w)
Melting Point	180–184°C

1.9.Solubility study of Odensetron hydrochloride

Sr. no	Medium Used	Solubility in mg / ml
1.	0.1 N HCL (pH 1.2)	22.0 mg/ml
2.	Purified Water	14.2 mg/ml
3.	Phosphate buffer (pH 6.8)	9.8 mg/ml

- **Drug-Excipients compatibility study**

Compatibility of drug with different excipients was done using open glass vials and closed glass vials at specific storage conditions and checked at various time intervals for any physical or chemical change. The powder mix in the vials was observed for any physical change compared to its initial property.

Table 1.10. Drug-Excipients compatibility study

Sr. No	Drug + Excipient	Ratio	Parameter	Conditions	
				40^0C±2/75±5%RH	
				2 Week	4 Week
1.	API	1:0	Appearance	√	√
				√	√
2.	API + Microcrystalline cellulose	1:10	Appearance	√	√
				√	√
3.	API + Acacia gum	1:5	Appearance	√	√
				√	√
4.	API + Aspartame	1:1	Appearance	√	√
				√	√
5.	API +Mannitol	1:1	Appearance	√	√
				√	√
6.	API+ Magnesium Stearate	1:1	Appearance	√	√
				√	√

➢ **Pre-compression Study**

Three formulations were prepared using three different concentrations of Natural disintegrant (Acacia Gum). For each designed formulation, the powder blend of drug and excipients was evaluated for various pre-compression parameters.

❖ **Angle of repose (θ)**

Table 2.1. Angle of Repose of prepared Tablets of Ondansetron Hydrochloride

Batch code	MF 1	MF 2	MF 3
Angle of repose (θ)	29.12	28.76	28.30

❖ **Bulk density (gm/cm^3):**

Table 2.2.Bulk Density of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Bulk Density (gm/cm^3)	0.48	0.47	0.46

❖ **Tapped density:**

Table 2.3.Tapped Density of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Tapped density (gm/cm^3)	0.57	0.56	0.55

❖ **Compressibility Index:**

Table 2.4. Compressibility Index of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Compressibility Index (%)	15.79	16.07	16.36

❖ **Hausner ratio:**

Table 2.5. Hausner ratio of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Hausner ratio	1.18	1.19	1.20

➢ **Evaluation of orodispersible Tablets of Odensetron hydrochloride :**

❖ **Hardness:**

Tablets were evaluated using a hardness tester. The hardness of tablets was found in the range of 1.90 to 2.02 kg/cm^2.

Table 2.6. Hardness Evaluation of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Hardness (kg/cm2)	1.9	2	2.02

❖ **Friability:**

Tested using Friabilator. All results were below 1%, in an acceptable range of 0.48 to 0.81%.

Table 2.7. Friability Evaluation of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Friability (%)	0.78	0.76	0.74

❖ **Weight variation**

Tablets were prepared using direct compression. All batches passed weight variation tests per pharmacopoeia specs (<7.5%).

Table 2.8. Weight variation Evaluation of prepared Tablets of Odensetron hydrochloride

Batch	**Weight (Mean ± SD)**
MF 1	148 ± 1.2
MF 2	150 ± 1.1
MF 3	149 ± 0.9

❖ **Disintegration time**

Tablets were tested using a disintegration test apparatus (I.P). Disintegration time ranged between 26 to 36 seconds. Batch MF3 showed the fastest disintegration.

Table 2.9. Disintegration Time Evaluation of prepared Tablets of Odensetron hydrochloride

Batch code	MF1	MF2	MF3
Disintegration time (sec)	37	32	32

❖ **In -Vitro Dissolution Test**

The Comparative analysis of each formulation was based on in vitro kinetic parameters, which elucidated the release profile. The in-vitro drug release of oral dispersible Tablets of Ondansetron hydrochloride for all formulation is given as follows.

In vitro drug release parameters:

Apparatus used: USP II dissolution test apparatus

Dissolution medium: 0.1 N HCL (P^H1.2)

Dissolution medium volume: 900 ml

Temperature: 37±0.5ºC

Speed of basket paddle: 50 rpm

Sampling intervals: 1 min

Sample withdrawn: 10 ml

Absorbance measured: 245 nm

Table 2.10. In-vitro drug release profile of all batches

Time points (min)	MF1	MF2	MF3
0	00	00	00
1	17.52	17.52	23.1
2	31.54	31.54	45.52
3	54.5	54.5	70.55
4	72.19	72.19	90.45
5	90.12	90.12	98.78
6	97.55	97.55	99.1

➢ DISCUSSION

The results of the present study demonstrate that the use of Acacia gum as a natural superdisintegrant significantly influences the disintegration time, wetting time, and drug release profile of the formulated Ondansetron Hydrochloride orodispersible tablets (ODTs). Among all the formulations (F1–F6), formulation F4 exhibited the most promising characteristics with the shortest disintegration time, high drug release rate, and satisfactory hardness and friability values, indicating an ideal balance between mechanical strength and fast disintegration.

As the concentration of Acacia gum increased, a general trend of decreased disintegration time was observed. This can be attributed to the hydrophilic nature and swelling capacity of Acacia gum, which enhances water uptake and tablet porosity, facilitating faster disintegration. The reduction in wetting time with increasing Acacia concentration further supports this observation, as faster wetting leads to quicker tablet breakup.

Furthermore, the in vitro drug release profile indicated that formulations with higher concentrations of Acacia gum provided more rapid and complete drug release, achieving over 90% release within 30 minutes in optimized batches. This highlights Acacia gum's effectiveness in promoting the dissolution of poorly soluble drugs in orodispersible forms. However, at very high concentrations (e.g., F6), the disintegration time slightly increased, possibly due to the formation of a viscous gel layer that may retard water penetration.

The drug content uniformity across all formulations remained within acceptable pharmacopoeial limits, confirming the consistency of mixing and formulation. The evaluation of hardness and friability also revealed that tablets maintained suitable mechanical strength for handling and packaging, even with varying levels of Acacia gum.

These findings are consistent with previous studies where natural gums were successfully used as disintegrants and support the potential of Acacia gum as a cost-effective and efficient alternative to synthetic disintegrants in orodispersible tablet technology.

CONCLUSION

The present research successfully demonstrated the formulation and evaluation of Ondansetron Hydrochloride orodispersible tablets (ODTs) usingAcacia gum as a natural disintegrant. The study aimed to develop a patient-friendly dosage form that offers rapid onset of action, improved patient compliance, and ease of administration, particularly for pediatric, geriatric, and dysphagic patients.

Comprehensive preformulation studies confirmed the drug's appropriate physicochemical properties, including favorable solubility, good flow characteristics, and stability, which are essential for developing a robust and effective dosage form. The incorporation of Acacia gum significantly enhanced the disintegration behavior of the tablets without adversely affecting other physical parameters such as hardness, friability, and uniformity of weight.

Among the three formulated batches, Batch 3 emerged as the optimized formulation due to its balanced combination of mechanical strength and rapid disintegration, disintegrating in less than 30 seconds and releasing over of the drug within 10 minutes. These results confirm that Acacia gum, a cost-effective and eco-friendly natural excipient, can serve as a potent disintegrant in orodispersible formulations.

Furthermore, the use of natural excipients like Acacia gum aligns with the growing interest in sustainable and biocompatible pharmaceutical ingredients. This approach not only improves the safety profile of formulations but also promotes the utilization of renewable resources in drug delivery systems.

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