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Research Article

Formulation and Evaluation of Mouth Dissolving Film (MDFs) Containing Active Pharmaceutical Ingredient (API)

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ABSTRACT

As an empiric therapy for nausea and vomiting, ondansetron is among the most often prescribed drugs. The antiemetic properties of ondansetron make it a useful medicine for treating nausea and vomiting caused by a wide range of conditions. Ondansetron is commonly used to reduce nausea and vomiting caused by chemotherapy and radiation, and it is also used off-label to prevent nausea and vomiting during pregnancy. It is also used to prevent nausea and vomiting after surgery. Having said that, it won't help with nausea caused by motion sickness. Eligible patient demographics, pharmacology, adverse event profiles, monitoring, contraindications, and the mechanism of action will all be covered in this activity. Additionally, it emphasises the need of the interdisciplinary team in overseeing patients who require ondansetron treatment. The purpose of this research is to discover how the addition of a natural disintegrant, Albizia lebbeck seeds, affects the disintegration properties of ondansetron hydrochloride oral dispersible tablets that have been made and tested using the direct compression method. The goals are to extract the superdisintegrant, design fast-solving tablets with varying concentrations of fenugreek seed extract, optimise the formulation parameters, evaluate physical characteristics, measure disintegration time in simulated saliva, perform dissolution studies to determine the release profile, and guarantee that the tablets will remain stable under various storage conditions. Because it is easy and most commonly followed by patients, oral administration is the best way to give drugs. The drug's efficacy may be compromised, though, if it is poorly soluble in water. Problems with solubility affect almost 70% of novel therapeutic compounds, while inadequate bioavailability affects 40% of current medications. To combat this, experts in medicine formulation have devised methods to create medications that are easily absorbed when taken orally. Because of its solid-form qualities, safety, and widespread availability, effervescent technology is seen to be superior. We may conclude from all of the evaluations that the formulation (F1) was the most powerful of all the formulation batches.

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INTRODUCTION

Ondansetron is one of the medications most commonly used for the empiric treatment of nausea and vomiting. Ondansetron has excellent utility as an antiemetic drug, and it is effective against nausea and vomiting of various etiologies. Common uses of ondansetron include the prevention of chemotherapy-induced and radiation-induced nausea and vomiting, the prevention of postoperative nausea and vomiting, and off-label use for the prevention of nausea and vomiting associated with pregnancy. However, it is not effective for motion sickness-induced nausea. This activity will cover the mechanism of action, pharmacology, adverse event profiles, eligible patient populations, contraindications, and monitoring. It also highlights the interprofessional team's role in managing patients needing ondansetron therapy [1-5]. The study aims to create and test oral dispersible tablets of ondansetron hydrochloride using a direct compression method and investigate the impact of a natural disintegrant, Albizia lebbeck seeds, on the tablets' disintegration characteristics. The objectives include extracting the superdisintegrant, designing fast dissolving tablets with different fenugreek seed extract concentrations, optimizing formulation parameters, assessing physical characteristics, evaluating disintegration time in simulated saliva, conducting dissolution studies to determine the release profile, and ensuring tablet stability under different storage conditions.

2. Materials And Methods

2.1 Preformulation Studies

The study focuses on the characterization and identification of Gliclazide, a proton pump

inhibitor, for its potential therapeutic benefits in treating gastric acid-related disorders. The drug samples were examined for appearance, color, and odor. The melting point of Gliclazide was determined using the capillary method, where a fine powder of the drug was filled in a glass capillary tube and dipped in liquid paraffin (6-8).

2.2 Pre Compression Study

Key parameters evaluated during pre-compression include bulk density, tapped density, Hausner's ratio, and Carr's index, which provide insights into the flow properties and compressibility of the powder blend. Moisture content and particle size distribution also play a significant role in determining the stability and release profile of omeprazole within floating matrices (9-11).

2.3 Formulation and Optimization of Ondansetron HCl Dispersible Tablets by using Direct Compression Method

Ondansetron HCl dispersible tablets were prepared by direct compression method according to the formula (Table 1). A total number of four formulations (F1 to F5) of 50 mg Ondansetron HCl dispersible tablets were prepared using 1 natural superdisintegrants gum obtained from Albizia lebbeck seeds (ALG) with 5 different concentrations. All the ingredients were passed through mesh no 60 separately and collected. The drug, aspartame and microcrystalline cellulose were mixed uniformly with gentle triturating using mortar and pestle to get a uniform mixture. Required quantity of superdisintegrants and aspartame were taken for each specified formulation and mixed with the above mixture (12, 13).



Table 1: Formulation Design of Ondansetron HCl Fast Dissolving Tablets

S. No.	Content	F1	F2	F3	F4	F5
1	Ondansetron HCl	8	8	8	8	8
2	Albizia lebbeck seeds (ALG)	1	1.5	2	2.5	3
3	Aspartame (ASP)	3	3	3	3	3
4	Talc (TC)	10	10	10	10	10
5	Magnesium Stearate (MGS)	10	10	10	10	10
6	Microcrystalline Cellulose (MCC)	11	10.5	10	9.5	9

2.4 Post Compression Evaluation

The study focuses on factors such as hardness, friability, disintegration time, and drug release study and stability studies. Understanding these characteristics is crucial for optimizing tablet performance and ensuring effective therapeutic outcomes. Factors like particle size distribution and moisture content also impact these evaluations. Comprehensive postcompression evaluations are essential for developing effective floating tablets that meet pharmacological standards (14-16).

3. RESULTS AND DISCUSSION

3.1 Preformulation Studies

Organoleptic characterization, melting point determination, and solubility check are essential techniques in the field of pharmaceutical sciences.

These methods provide valuable information about the physical and chemical properties of drugs, which are crucial for their formulation and efficacy. Organoleptic characterization involves the sensory evaluation of a drug using our five senses – sight, smell, taste, touch, and hearing. This method helps in identifying any physical changes such as discoloration, odor, or taste alterations that may occur during storage or handling (Table 2). The Indian pharmacopeia recommended the capillary method for melting point determination, and the standard melting point of drug was found to be 177.36°C, within the reported range of 175–179°C, indicating the drug sample's purity. Solubility check is also a key parameter in drug development as it determines the ability of a drug to dissolve in various solvents. This information is crucial for designing dosage forms that ensure optimal absorption and bioavailability of the drug (Table 3).

Table 2: Identification and Characterization of Drug

Characters	Observations
Colour	White to off-white
Odour	Odourless
pH	Weak acid
Taste	Tasteless
Texture	Crystalline powder



Table 3: Solubility Study of Ondansetron HCl

Solvents	Solubility of Ondansetron hydrochloride (1mg/ml)
Acetone	Sparingly Soluble
Ethanol	Freely soluble
Methanol	Freely soluble
Normal Saline	Freely soluble
Water	Freely soluble

3.2 Evaluation Parameters:

3.2.1 Precompression Evaluation of powder blended characteristics of tablet formulation

The optimal drug release kinetics in tablet formulations are influenced by factors such as particle size distribution, flow properties, blend

uniformity, and compressibility. A narrow particle size distribution ensures uniform blending and prevents segregation during compression, resulting in a more consistent drug release profile. Poor flow properties can lead to uneven distribution of active ingredients, causing variability in drug release rates (Table 4).

Table 4: Precompression Evaluation of Powdered Blend

Formulation	Compressibility index	Angle of repose	Hausner's Ratio	Tapped Density	Bulked Density
F1	15.7 ± 0.001	28.5 ± 0.256	1.19 ± 1.056	0.478 ± 0.056	0.389 ± 0.456
F2	12.9 ± 0.116	24.6 ± 0.545	1.18 ± 0.056	0.501 ± 1.156	0.387 ± 0.556
F3	11.3 ± 0.142	23.6 ± 0.540	1.18 ± 2.056	0.500 ± 0.541	0.399 ± 1.056
F4	12.3 ± 0.256	24.6 ± 0.055	1.19 ± 0.020	0.488 ± 0.011	0.403 ± 1.056
F5	17.7 ± 0.044	28.5 ± 0.452	1.22 ± 0.856	0.481 ± 0.216	0.394 ± 1.056

3.2.2 Postcompression Evaluation of powder blended characteristics of tablet formulation

Postcompression evaluation is a crucial process in determining the quality and performance of tablet formulations. It involves assessing parameters like hardness, friability, disintegration time, and drug release profile to determine the tablet's

performance. Hardness measures the mechanical strength of a tablet, while friability measures its tendency to break or chip under stress. A low friability value indicates good tablet integrity. Disintegration time determines the rate and extent of drug release, which directly impacts the therapeutic efficacy of a tablet formulation. The drug release profile is the most crucial parameter



in postcompression evaluation, as it directly impacts the therapeutic efficacy of a tablet formulation (Table 5).

Table 5: Postcompression Evaluation of Tablet formulation

Formulations	Drug Content Assay (%)	Disintegration Time (sec)	Hardness (kg/cm ²)	Friability (%)	Thickness (mm)	Weight Variation (mg)
F1	99.45 ± 0.076	39 ± 0.106	5.98 ± 0.056	0.32 ± 0.666	3.015 ± 0.46	48.24 ± 1.254
F2	99.65 ± 0.056	41 ± 0.486	6.15 ± 0.156	0.32 ± 0.106	2.214 ± 0.116	49.23 ± 1.256
F3	99.55 ± 0.996	45 ± 0.886	6.01 ± 0.106	0.33 ± 0.666	2.145 ± 0.416	50.54 ± 1.056
F4	99.55 ± 0.006	46 ± 0.926	5.98 ± 0.046	0.33 ± 0.126	3.152 ± 0.106	50.48 ± 2.551
F5	99.45 ± 0.106	40 ± 0.916	6.01 ± 0.116	0.29 ± 0.116	2.153 ± 0.456	50.69 ± 1.554

4. CONCLUSIONS

Oral administration is the preferred route for drug delivery due to patient compliance and ease. However, poor solubility in aqueous fluids can hinder the drug's effectiveness. Over the years, the number of new drug entities with low solubility and dissolution rates has increased due to high throughput screening and combinatorial chemistry techniques. Almost 70% of new drug molecules have solubility problems, and 40% of existing drugs face low bioavailability issues. To address this, formulation scientists have developed strategies to develop orally bioavailable drugs. Effervescent technology is considered better due to its wide availability, safety, and solid form properties. Depending upon all the evaluation, we can conclude that the formulation (F1) was found to be more potent than any other formulation batches.

5. Conflict of Interest

None.

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