



Development of Tropisetron Hydrochloride Orodispersible Tablet using Natural Superdisintegrants

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Authors' contributions

This work was carried out in collaboration among all authors. Authors RJ, GK, AG and RPA performed experimental design of the study, lab work, data analysis, wrote the protocol and first draft of the manuscript. Author VU wrote and reviewed the manuscript. Author RJ did overall experimental planning and execution of Data Analysis and Interpretation. All authors read and approved the final manuscript.

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ABSTRACT

The foremost objective of this research was to compare and evaluate natural super disintegrants with synthetic super disintegrants for the preparation of the orodispersible tablet. Tropisetron hydrochloride is widely used as an antiemetic drug, which is a potential drug candidate for developing an orodispersible tablet for quick onset of action. Various formulations were prepared using different concentrations (5%, 7.5%, and 10%) by direct compression method of natural super disintegrants (Banana powder and Cassia tora powder) and synthetic super disintegrants (Croscarmellose sodium, Crospovidone, and Sodium starch glycolate). The compatibility studies between the drug and excipients were carried out using FTIR spectroscopy before tablet formulation. The pre-compression parameters were evaluated for additive properties.

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Standardization of banana powder was done by various parameters like extractive value, ash value, loss on drying, TLC identification test, etc. Post-compression parameters like hardness, weight variation, friability, thickness, the time required for disintegration, wetting time, the release of drug *in-vitro*, and *in-vitro* dispersion time of the tablets were evaluated. The disintegration time and *in-vitro* drug release of optimized formulation (F2) were found to be 4.66 ± 1.15 secs and $99.25 \pm 0.15\%$. The optimized formulation (F2) was subjected to stability studies (40 C & 75 % RH) for one month. The results were shown that natural super disintegrants require less disintegration time as compared to synthetic super disintegrants. Hence present study reveals that the orodispersible tablets prepared using Banana powder and Cassia tora powder is super disintegrants that shown better appearance and rapid disintegration time.

Keywords: *Orodispersible tablets; natural super disintegrants; synthetic super disintegrants; banana powder; cassia tora powder and disintegration time.*

1. INTRODUCTION

To overcome these medical problems, various pharmaceutical technologists have introduced an oral dosage form known as Orodispersible Tablets (ODTs) which disintegrate rapidly in saliva, usually within seconds (15 seconds to 2 min), without the need to take it water. In ODTs drug dissolution and drug absorption as well as the onset of drug and drug bioavailability is greater than the conventional dosage forms [1].

Due to local accessibility, environment-friendly nature, and lower prices compared to imported synthetic products, plant products serve as an alternative to synthetic products. The majority of research in drug delivery systems on natural excipients is based on polysaccharides and proteins. Several natural, synthetic, and semi-synthetic materials are used in the various drug delivery systems [2]. The recent trend towards the use of vegetable and non-toxic products demands their placement of synthetic additives with natural ones. Natural materials like gums, mucilages have been extensively used in the field of drug delivery due to their easy availability and no side effects.

The objective of the present study was to formulate the orodispersible tablet of Tropisetron HCl and to compare the effect of natural superdisintegrants over commonly used synthetic superdisintegrants[3]. Tropisetron HCl is used as an antiemetic drug, which is a potential drug candidate for developing into an orodispersible tablet for quick onset of action. Orodispersible tablet of Tropisetron HCl avoids hepatic metabolism due to pregastric absorption of the drug, which reduces the dose and increases bioavailability. Orodispersible tablet of Tropisetron HCl results in quick dissolution and rapid absorption which provide a rapid onset of action.

In this study, natural substances like, Cassia tora powder and Banana powder were used as natural super-disintegrants in the formulation of orodispersible tablets. In this study orodispersible tablets were prepared with natural and synthetic superdisintegrants. Improvement of oral bioavailability. Rapid onset of action and is a major concern in the treatment of emesis. Rapid disintegration in saliva without the need for water gives the greater dissolution rate. Natural super disintegrants serve as an alternative to synthetic super-disintegrants because of local accessibility, biocompatibility, and lower prices compared to imported synthetic products. Some natural super-disintegrants demonstrated stronger disintegrating properties than the synthetic super-disintegrants most commonly used [2,4].

2. MATERIALS AND METHODS

Tropisetron hydrochloride was purchased from Beijing pharma, Beijing, China. Whereas, the banana powder was extracted in the laboratory. Also, reagents like Cassia tora powder was ordered from Agro gums, Ahmedabad. The rest of the ingredients like Croscarmellose sodium, Crospovidone, Sodium starch glycolate, Microcrystalline cellulose, Aspartame, Vanillin was received from Chemdyes Corporation, Vadodara.

2.1 Tropisetron Hydrochloride

Tropisetron HCl was initially characterized by preliminary studies such as organoleptic properties, melting point, solubility, UV Spectroscopy, and FTIR studies. The results indicate that it complies with pharmacopoeial specifications. FTIR spectroscopy was performed for studying drug excipient compatibility and confirmed the undisturbed structure of Tropisetron HCl which indicates no

drug excipients interaction. For estimation of the drug, a UV spectrophotometric analytical method was selected using 284nm (λ_{max}) of Tropisetron HCl in Phosphate buffer pH 6.8. The method was found to be linear [5].

2.2 Banana Powder

The banana powder was extracted at lab scale and standardization of Banana powder was performed. Extractive value, Ash value, and TLC identification of Banana powder were performed. Banana powder showed an R_f value of 0.9 which is similar to standard. The swelling Study of all the superdisintegrants has been carried out as per British Pharmacopoeia specification and Cassia tora powder showed the highest swelling index than other superdisintegrants [6].

The key element in the formulation of the orodispersible tablet is to minimize the disintegration time while maintaining a good mechanical strength of the tablet. Orodispersible tablets of Tropisetron HCl were formulated by using various super disintegrants in which natural superdisintegrants such as Banana powder and Cassia tora powder and synthetic superdisintegrants for example Croscarmellose sodium, Crospovidone, and Sodium Starch glycolate. Values of compressibility index, Hausner ratio, angle of repose, bulk density, tapped density, size and shape, surface area, indicate excellent flow properties and the blends were suitable for direct compression. For various criteria, tablets have been evaluated including weight variation, hardness, thickness, friability, wetting time, the ratio of water absorption, disintegration time, dispersion time, drug content, and *in-vitro* drug release [7].

The disintegration time for all formulation was considered to be within the acceptable limit. It is observed that when Cassia tora powder was used as super disintegrant the tablet disintegrated rapidly within a short time at lower concentration due to pronounced hydration and rapid swelling ability of Cassia tora powder when compared with other tablets prepared using croscarmellose sodium, Crospovidone, Banana powder, and Sodium starch glycolate. The disintegration time of formulation F2 was found to 4.66 ± 1.15 seconds. Batch F2 gives rapid disintegration time and Drug content was found to be 99.50 ± 0.87 . Results of *in-vitro* dissolution data of batch F2 showed drug

release up to 99.25 ± 0.15 % in 14 min. Hence batch F2 was subjected to stability studies. Optimum formulation F2 is stable at 40°C and 75% RH under selected stability conditions. As per the data obtained from stability studies, it was found that formulation F2 was stable and maintain its integrity throughout the storage period. From the above evaluation data, it was concluded that the development of Orodispersible tablet of tropisetron HCl containing Cassia tora powder is super disintegrant, was most promising and optimum formulation.

3. PREFORMULATION STUDIES OF PURE DRUG

3.1 Identification of Drug

3.1.1 Color

The color and physical state of the drug were characterized visually and noted.

3.1.2 Solubility analysis

Tropisetron HCl solubility was determined in distilled water, phosphate buffer 0.1N HCl and methanol of pH 6.8. The accurately weighed drug was dissolved in 10 ml of solvent up to saturation. The solution was sonicated for 15 minutes, filtered, and then diluted if required. The amount of drug dissolved was measured using a U.V spectrophotometer at 284 nm [8].

3.1.3 Melting Point

The melting point was determined using the capillary method which is an essential parameter for the identification of the drug. It is a temperature at which the physical state of a substance converts from solid to liquid. A small amount of drug sample was taken in a capillary tube which was closed at one end. Then it was put in melting point apparatus and raise in temperature till gradually drug melt. The temperature was noted at the time of drug melt [9].

3.2 Fourier Transform Infrared Spectroscopic Studies (FTIR)

FTIR of the pure drug was taken for identification of pure drug.

Drug sample pellets were prepared with approximately 10-15% of dry KBr (IR grade). The

powder was triturated in a small size mortar and pestle until the powder mixture was fine and uniform. Pure KBr powder was used as a background, for baseline correction. The Pellet sample was placed in the sample holder. Afterward, the sample was transferred to the sample compartment. Pellet sample was scanned in the region of 4000-500 cm^{-1} using broker alpha spectrophotometer [10].

3.3 Drug-excipient Compatibility study

Compatibility with Drug-excipients was studied by FTIR (Fourier transform infrared spectroscopy). The drug powder was combined with other excipients homogenously which is used in the formulation in a ratio of 1:1. This homogeneous mixture was pressed to form pellets using a KBr press. The prepared pellet was located in the holder of the sample and IR peaks were observed and noted.

3.4 Flow Properties of Pure Drug

3.4.1 Bulk density

The sample of powder was tested by passing through sieve no. 18. In a 50 ml graduated cylinder, the 5 g equivalent sample was precisely weighed and filled. The powder was leveled and, V_0 was observed by the unsettled amount [11].

The bulk density unit is g/cm^3 and calculated by the formula,

$$\text{Bulk density } (\rho_0) = M/V_0$$

Where M = mass of powder taken
 V_0 = apparent unstirred volume

3.4.2 Tapped density

The sample of powder was tested by passing through sieve no. 18. In a 50 ml graduated cylinder the weight of the sample was equal to 5 g was filled. The mechanical tapping of the cylinder was done by means of a tapped density tester for 100 times at a constant rate. The volume was regarded as a tapped volume V_f .

The unit of tapped density is g/cm^3 and calculated by the formula,

$$\text{Tapped Density } (\rho_t) = M/V_f$$

Where M = weight of sample powder taken
 V_f = tapped volume

3.4.3 Hausner's ratio

Hausner's ratio was measured by the following formula:

$$\text{HR} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

3.4.4 Angle of repose

The height cone method was used to determine the angle of repose of the powder. At the desired height funnel was fixed and the powder was filled in it. The powder was allowed to stream down from the fixed horizontal surface below that a graph paper is placed and the given below formula is then used to calculate the angle of repose:

$$\tan \theta = h/r \text{ or } [\theta = \tan^{-1} (h/r)]$$

Where "h" is the height of the cone, "r" is the radius of the cone, θ is the angle of repose.

3.5 Determination of Analytical Wavelength of Tropisetron HCl

Preparation of stock solution: 10 mg Tropisetron HCl was weighed accurately and transferred to a 100ml volumetric flask. The final volume was made up to 100ml with distilled water to prepare the 100 $\mu\text{g/ml}$ stock solution.

Scanning: From the stock solution 10 $\mu\text{g/ml}$ solution of Tropisetron hydrochloride was prepared in phosphate buffer pH 6.8 and scanned between 200-400nm. The absorption maxima of 284 were found and used for further studies.

3.6 Standard Calibration Curve of Tropisetron HCl in Phosphate Buffer pH 6.8

From the above stock solution, aliquots of 0.4, 0.8, 1.2, 1.6, 2.0, 2.4 ml were taken and diluted upto 10 ml with phosphate buffer pH 6.8 to get 4, 8, 12, 16, 20, 24 ppm for Tropisetron hydrochloride respectively.

The absorbance was measured in the UV-spectrophotometer at 284 nm using phosphate buffer pH 6.8 as a blank and a graph of concentration versus absorbance was plotted. Standard plot data of Tropisetron hydrochloride in phosphate buffer pH 6.8 was reported in Table 7 and shown in Fig. 5.

4. EVALUATION OF BANANA POWDER AND CASSIA TORA GUM POWDER

4.1 Solubility Test

It is a part that representing some milliliters of solvents in which 1 g of solid is soluble. The solubility of powders was determined in solvents like water and alcohol.

4.2 Loss on Drying

In a Petri dish, 1 g of the sample was transferred and then dried in an oven at 105°C until a constant weight was obtained. The moisture content was then measured as a percentage the ratio of the weight of the loss of moisture to the weight of the sample expressed as a percentage. The data was obtained for triplicate determinations [12].

$\% \text{LOD} = \frac{\text{Weight of water in sample}}{\text{Weight of dry sample}} \times 100$

4.3 pH

The pH of 1%w/v solution of polymer was measured by using a digital pH meter.

4.4 Swelling Index

The swelling index (SI) is the volume occupied in ml by 1gram of the medication, including any adhering mucilage after swelling for 4hours in an aqueous medium. The swelling index was determined according to the BP method. 1g of Cassia tora gum powder and the banana powder was filled in a 25ml ground stoppered cylinder graduated over a height of 120 to 130 mm in 0.5 divisions. To that mixture, 2 ml of water was added and it was shaken vigorously for every 10min for 1h and then allowed to settle down for 24 h. The volume occupied by the mucilage together with adhering mucilage was measured. The swelling index was calculated from the mean of determinations.

$$SI = \frac{V_2}{V_1}$$

Where V_2 = Mucilage occupied volume before hydration

V_1 = Mucilage occupied volume after hydration

4.5 Test for Carbohydrates (Molisch's test)

Two drops of Molisch's reagent (5% 1-naphthol in alcohol) was added to about 2ml of the test

solution and mixed well. The tube was inclined and added about 1ml of concentrated Sulphuric acid along the sides of the tube. The color was observed at the junction of the two liquids [13].

4.6 Test for Proteins (Xanthoproteic test)

1ml of concentrated nitric acid was added to the 5ml of the test solution and boiled. Then 40% sodium hydroxide solution was added.

4.7 Test for Tannins (Ferric chloride test)

The extract was treated with ferric chloride solution and then the result was obtained.

4.8 Test for Starch (amylum)

To the aqueous extract, a weak aqueous iodine solution was added and the result was observed.

4.9 Microbial Test

The specified amount (10g) of the sample was dissolved in a suitable medium to have no antibacterial activity under conditions of test and the volume was adjusted to 7 ml. For examination of bacteria and fungi to a petri dish of 10cm diameter, 20 ml of nutrient agar solution was added at a temperature, not more than 45°C. The sample solution was spread on the surface of the solidified medium [14]. The Petri dishes of the required number were prepared and incubated at 37°C for 24 h. For the examination of fungi, sabouraud dextrose agar medium is used and the plate was incubated at 28°C for 48 h. The number of colonies formed was counted.

5. STANDARDIZATION OF BANANA POWDER

5.1 Determination of Ash Value

5.1.1 Total ash value

2 g of the ground air-dried material was taken and accurately weighed, in a previously ignite and tarred crucible (silica). The material was placed in an even layer and ignited by gradually increasing the heat to 500-600° C until it appeared completely white, indicating the absence of carbon. The material called ash was cooled in desiccators for 30 min and then weighed. The content of total ash was determined concerning air-dried plant material [15].

5.1.2 Acid-insoluble ash value

25 ml of HCL (~70g/l) was added to the crucible containing the total ash, covered with a watch glass, and boiled gently for 5 minutes. The watch glass was rinsed with 5 ml of hot water and washing was added to the crucible. Insoluble matter was collected on an ashless filter paper and washing of this filter paper was carried out with hot water until the filtrate was remaining neutral. The filter paper was moved to the original crucible containing the insoluble matter, which is then dried on a hot plate and ignited to a constant degree of weight. The residue was allowed to cool for 30 minutes in a suitable desiccator and then weighed without delay. The content of acid-insoluble ash was calculated concerning the weight of air-dried powdered plant material.

5.1.3 Water-soluble ash value

25 ml of water was added to the crucible containing total ash and boiled for 5 minutes. On an ashless filter pad, insoluble matter was collected. At a temperature not exceeding 450° C the residue was washed with hot water and burned in a crucible for 15 minutes. The weight of the residue was subtracted from the weight of total ash [16]. The content of water-soluble ash was determined concerning the weight of the air-dried powdered plant material.

5.2 Determination of Extractives

5.2.1 Alcohol soluble extractive

Accurately weighed 4gm of coarsely powdered air-dried material was taken in a glass-stoppered conical flask. The content was macerated with 100 ml of ethanol for 6 hours with frequent shaking and then allowed to stand for 18 hours. In order to ensure that no solvent was lost the material was filtered. In a tarred flat-bottomed dish 25 ml of filtrate was transferred and evaporated to dryness in a water-bath and dried for 6 hours at 105° C, cooled in desiccators for 30 min, and weighed without delay. Percent of alcohol soluble extractive value was calculated concerning the original weight of the air-dried material.

5.2.2 Water soluble extractive

Accurately weighed 4gm of coarsely powdered air-dried material was taken in a glass-stoppered

conical flask. The content was macerated with 100 ml of distilled water for 6 hours with frequent shaking and then allowed to stand for 18 hours. In order to ensure that no solvent was lost the material was filtered. In a tarred flat-bottomed dish 25 ml of filtrate was transferred and evaporated to dryness in a water-bath and dried for 6 hours at 105° C, cooled in desiccators for 30 min, and weighed without delay¹⁶. Percent of water-soluble extractive value was calculated concerning the original weight of the air-dried material.

5.2.3 TLC identification test

TLC identity of all the three raw materials was carried out to detect the presence of active markers in the samples. TLC study was carried out on pre-coated Aluminum-backed silica gel 60 F254 plates.

Preparation of Mobile phase: Mobile phase was prepared by using hexane and ethanol in a ratio of 6:4. The TLC plates were then put into the chamber for 30 min for saturation. The solvents were allowed to rise till 1.5 to 2 cm near to the top then the R_f value was calculated [16].

6. METHOD OF PREPARATION OF ORODISPERSIBLE TABLET OF TROPISETRON HCL BY DIRECT COMPRESSION METHOD

Each tablet containing 5mg of tropisetron hydrochloride was prepared by the direct compression method. The drug and excipients were passed through a sieve (No.60). The final blend was mixed in a polybag with proper mixing. The blend was compressed into 100 mg tablets by direct compression method using 10 stations rotary punching machine (punch: 5 mm, round shape) [11].

7. PRELIMINARY TRIAL BATCHES FOR OPTIMIZATION OF SUPER DIS-INTEGRANT

Preliminary trial batches of tropisetron orodispersible tablet were prepared using various synthetic super-disintegrants likewise sodium starch glycolate (5%, 7.5%, and 10%), crospovidone (5%, 7.5%, and 10%), croscarmellose sodium (5%, 7.5%, and 10%) were used in different amounts as shown in Table 1.

Table 1. Trial batches for optimization of super disintegrants

| Ingredients | Quantity per tablet (mg) | | | | | | | | |
|----------------------------|--------------------------|-----|------|------|-----|------|------|-----|------|
| | K1 | K2 | K3 | K4 | K5 | K6 | K7 | K8 | K9 |
| Tropisetron hydrochloride | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Sodium starch glycolate | 5 | 7.5 | 10 | - | - | - | - | - | - |
| Croscarmellose sodium | - | - | - | 5 | 7.5 | 10 | - | - | - |
| Crospovidone | - | - | - | - | - | - | 5 | 7.5 | 10 |
| Microcrystalline cellulose | 88.5 | 86 | 83.5 | 88.5 | 86 | 83.5 | 88.5 | 86 | 83.5 |
| Vanilla | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Aspartame | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Magnesium Stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |

8. OPTIMIZATION OF FINAL BATCHED OF TROPISETRON HYDROCHLORIDE ORODISPERSIBLE TABLETS USING NATURAL SUPER-DISINTEGRANTS AND SYNTHETIC SUPER-DISINTEGRANT

Formulation of the orodispersible tablet of tropisetron hydrochloride prepared by direct compression using synthetic super-disintegrants like crospovidone (5%, 7.5%, and 10%) and natural super-disintegrants such as Cassia tora powder (5%, 7.5%, and 10%) and Banana powder(5%, 7.5%, and 10%) as shown in Table 2.

9. EVALUATION PARAMETERS

9.1 Pre-compression Parameters

Before going for the compression the lubricated blend was evaluated for different parameters such as bulk density, tapped density, angle of repose, Carr’s index, Hausner’s ratio to determine the flow behavior.

9.2 Post-compression Evaluation of Prepared Tablets

9.2.1 Thickness and diameter

Vernier caliper was used to determine the thickness of the tablets. Randomly 10 tablets were selected for determination of thickness (mm). The procedure was performed in triplicate.

9.2.2 Weight variation

Twenty tablets were weighed individually and all together. As shown in Table 3 the average weight was determined from the total weight of

all the tablets. The individual weights were compared with the average weight. Under acceptable limits ($\pm 7.5\%$) the percentage difference in the weight variation should be carried. Using the following formula, the percent variance was calculated.

$$\% \text{ deviation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

Either under medication or over medication any difference in the weight of tablets (for any reason) results. So every tablet should have a uniform weight for each test [17]. As the tablet weighs 100 mg deviation is permitted within the BP permissible limit of 7.5 percent. Corrections have been made to achieve uniform weight during the compression of tablets.

9.2.3 Hardness

Hardness (diametric crushing strength) is a force sufficient to crack it through the diameter of the tablet. An indicator of strength is the hardness of the tablet. The tablet should be stable against mechanical stress during manipulation and transport. The degree of hardness varies with various types of tablets from different manufacturers. The hardness was tested using a Monsanto tester. Hardness was determined and recorded. The force was measured in kilograms per centimeter square [17].

9.2.4 Friability

The 10 tablets were weighed and placed in the Roche Friabilator test apparatus and the tablets were tested. Exposed to rolling and repeated shocks, resulting from free falls within the apparatus. The tablets were de-dusted after 100 rotations and weighted again. The friability of the tablets was calculated as the percentage loss in weight. Then the % friability was determined by using the formula:

Table 2. Formulation of tropisetron hydrochloride orodispersible tablet using natural and synthetic super disintegrant

| Ingredients | Quantity per tablet (mg) | | | | | | | | |
|----------------------------|--------------------------|-----|------|------|-----|------|------|-----|------|
| | B1 | B2 | B3 | B4 | B5 | B6 | B7 | B8 | B9 |
| Tropisetron Hydrochloride | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Cassia tora gum powder | 5 | 7.5 | 10 | - | - | - | - | - | - |
| Banana powder | - | - | - | 5 | 7.5 | 10 | - | - | - |
| Crospovidone | - | - | - | - | - | - | 5 | 7.5 | 10 |
| Microcrystalline cellulose | 81.5 | 79 | 76.5 | 81.5 | 79 | 76.5 | 81.5 | 79 | 76.5 |
| Vanilla | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Magnesium stearate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Aspartame | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |

Table 3. BP standards for percentage Weight variation

| The average weight of tablet(mg) | ± % deviation |
|--------------------------------------|---------------|
| 80 mg or less | 10 |
| Less than 250 mg and more than 80 mg | 7.5 |
| 250 or more | 5.0 |

To ensure uniformity in the weight of tablets in a batch the weight variation test was done

$$\% \text{ friability} = \frac{\text{Initial weight} - \text{final weight}}{\text{Initial weight}} \times 10$$

entire tablet to disintegrate completely was recorded. Determinations were made in triplicate [18].

9.2.5 Drug content estimation

Three tablets were selected randomly and the average weight was calculated. Tablets were crushed into a fine powder in a mortar, and a quantity of powder which was equivalent to 5 mg of tropisetron was introduced into a 100 ml volumetric flask and phosphate buffer diluted at pH 6.8. The solution was shaken periodically and kept for one hour to dissolve the drug completely. The solution was filtered, and the appropriate dilutions were made. The tropisetron content was determined by measuring the absorbance at 284 nm using a UV-Visible spectrophotometer. Using the standard calibration curve, the drug content was identified. The mean drug content percentage was determined as an average of 3 determinations.

9.2.7 Wetting time

The wetting time of the formulation is correlated with the angle of contact. The wetting period of the orodispersible tablet is another important parameter to be evaluated to provide insight into the disintegration properties of the tablets; a lower wetting time means a faster disintegration of the tablet. It is possible to calculate the wetting time of the tablet using a simple method [18].

A piece of tissue paper was folded twice, placed in a small Petri dish containing 10ml of water, placed on the paper with a tablet, and measured the time for full wetting. Three trials for each batch were performed.

9.2.6 In-vitro disintegration time

Disintegration is the process of breakdown of a tablet into smaller particles. The disintegration time of tablets from each formulation was determined by the USP tablet disintegration test apparatus. Six tablets were placed along with a disc individually in each tube of disintegration test apparatus containing 900 ml phosphate buffer pH 6.8 at a temperature of 37±2°C was maintained and time taken for the

9.2.8 In-vitro dispersion time

As disintegration without water is required, the period of disintegration for orodispersible tablets needs to be adjusted, so the test should mimic disintegration in salivary content [19]. A 9ml Petri dish (10cm in diameter) phosphate buffer solution pH 6.8 will be filled to provide salivary nature (which correlates the pH of saliva). The tablet will be carefully placed in the middle of the Petri dish and time has been noted for the tablet to disintegrate completely into fine particles.

9.2.9 *In-vitro* dissolution studies

The *In-vitro* dissolution studies were carried out using a Magnetic stirrer containing 30 ml of phosphate buffer pH 6.8 as dissolution medium at 50 rpm and maintained at 37±0.5° C. Aliquots of dissolution media was withdrawn at different intervals. 1ml samples were withdrawn at specific time intervals and the same volume was replaced to maintain sink conditions. The sample was analyzed using a UV spectrophotometer [19].

9.2.10 Stability studies

Stability is defined as the ability to stay within the physical, biological, therapeutic, and toxicological requirements of a given medication or dosage type in a specific container. During stabilization, drug decomposition or degradation occurs due to chemical modification of the active ingredients or due to product instability, decreasing the dosage-form concentration of the drug. The stability of pharmaceutical preparation should be evaluated at room temperature conditions and accelerated conditions. The optimized formulation of Tropisetron hydrochloride orodispersible tablet was selected for stability studies. The accelerated condition (40 ± 2° C and 75 ±5% RH) were selected for 1 month. The tablets were evaluated for the analysis of hardness, drug content, and dissolution and contrasted with tablets that were immediately evaluated after development.

10. RESULTS AND DISCUSSION

10.1 Preformulation Study

Identification of Drug

Colour: white

Solubility: Solubility was determined in Distilled water, 0.1N HCl, Phosphate buffer 6.8, Methanol.

The solubility of the drug was determined in four different mediums which are given above in Table 4, It was observed that the drug was freely soluble in distilled water, 0.1N HCl, Phosphate buffer pH 6.8, and methanol.

10.2 Fourier Transform Infrared Spectroscopic Studies (FTIR)

FTIR graph is obtained for the identification of the drug and stretching data was observed to identify functional groups. The drug shows characteristic peaks. From these peaks identification of various functional groups present in the drug was determined as shown in Table 5 and peaks obtained are shown in Figs. 1, 2, and 3.

The IR spectrum of the tropisetron HCl was having the same peaks as of pure drug spectra given in BP 10. The drug excipients compatibility study reflected that there was no change in peaks of tropisetron HCl with selected excipients. All excipients selected here were compatible with tropisetron HCl.

The IR spectrum of the tropisetron HCl was having the same peaks as of pure drug spectra given in BP 10. The drug excipients compatibility study reflected that there was no change in peaks of tropisetron HCl with selected excipients. All excipients selected here were compatible with tropisetron HCl.

Table 4. Solubility of Tropisetron HCl

| Media | Solubility(mg/ml)±SD |
|----------------------|----------------------|
| Distilled water | 12.785 ± 0.0020 |
| 0.1N HCl | 10.742 ± 0.0020 |
| Phosphate buffer 6.8 | 12.785 ± 0.0015 |
| Methanol | 4.954 ±0.0022 |

Table 5. IR data of tropisetron HCl

| Ingredients | Principle peaks(cm ⁻¹) | | | |
|-----------------|------------------------------------|---------|---------|---------|
| | -C=C | =CH | -C=O | -NH |
| Tropisetron HCl | 1584.48 | 2987.64 | 1692.18 | 2587.50 |

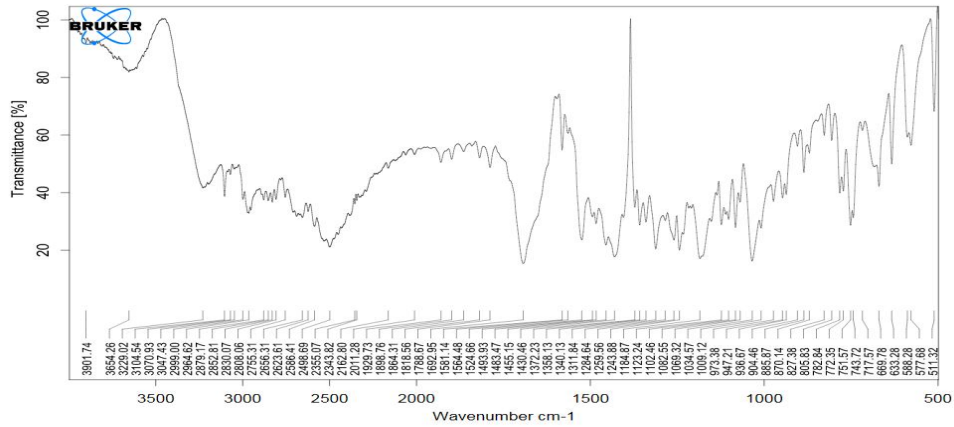


Fig. 1. IR Spectrum of Tropisetron HCl

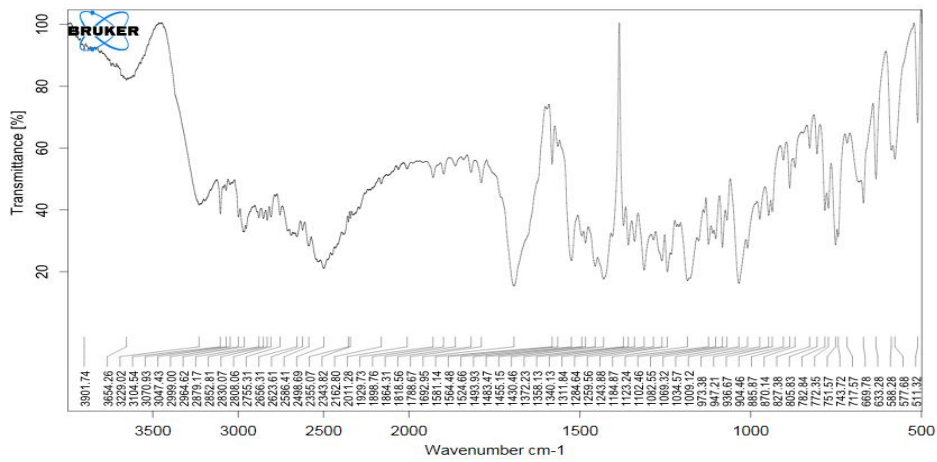


Fig. 2. IR spectrum of Tropisetron and crospovidone

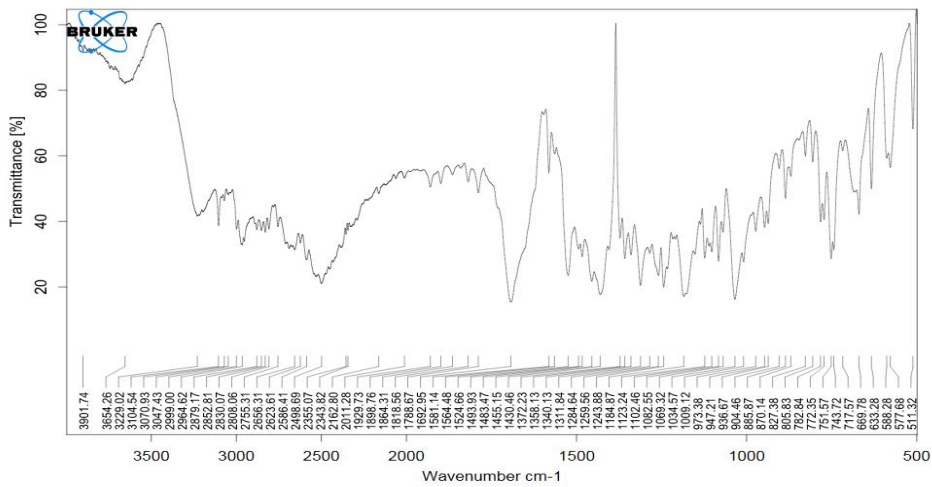


Fig. 3. IR spectrum of Tropisetron and Banana powder

10.3 Flow Property of Drug

Table 6. Flow property of tropisetron HCl

| Sr.No | Physical parameters of drug | | | | |
|-------|-----------------------------|-----------------------------------|----------------------------|------------------|------------------------|
| 1. | Bulk Density ±SD (gm/ml) | Tapped Density ±SD (gm/ml0) | The angle of repose ±SD | Carr's index ±SD | Hausner's Ratio ±SD |
| 2. | 0.55 ± 0.022 | 0.62 ± 0.020 | 25.46 ±0.033 | 12.09% ± 0.01 | 1.12 ±0.028 |

(n=3 mean± SD)

10.4 The Analytical Method for Estimation of Tropisetron Hydrochloride

blank and the same was used for further analysis.

Discussion: The analytical wavelength of tropisetron was found at 284 nm in phosphate buffer pH 6.8 as shown in Fig. 4.

10.4.1 Determination of analytical wavelength of tropisetron HCl in phosphate buffer pH 6.8

Scanning of tropisetron HCl: The standard stock solution was prepared as per the method described in the materials and method section and scanned by UV-Visible spectrophotometer. The UV absorption spectrum of tropisetron HCl showed a peak at 284.0 nm against reagent

10.5 Calibration Curve of Tropisetron HCl in Phosphate Buffer pH 6.8

The calibration curve and the data obtained by the procedure described in the materials and method section were given in Table 7 and Fig. 5 respectively. The data had a correlation coefficient of 0.994.

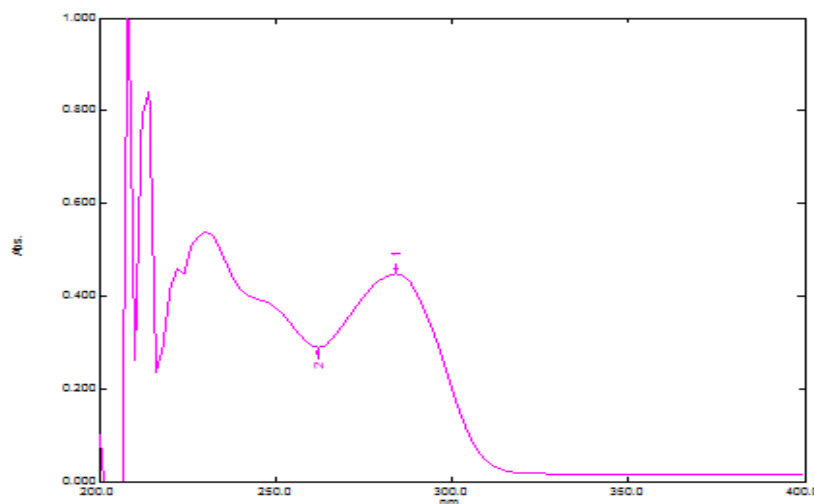


Fig. 4. Determination of analytical wavelength of tropisetron hydrochloride

Table 7. Calibration curve data for tropisetron HCl in phosphate buffer pH 6.8

| Sr.No | Concentration (µg/ml) | Absorbance at 284 nm ±SD |
|-------|-----------------------|--------------------------|
| 1 | 0 | 0 |
| 2 | 4 | 0.184 ± 0.0079 |
| 3 | 8 | 0.348 ± 0.0324 |
| 4 | 12 | 0.445 ± 0.0037 |
| 5 | 16 | 0.577 ± 0.0165 |
| 6 | 20 | 0.773 ± 0.0192 |
| 7 | 24 | 0.907 ± 0.0077 |

(n=3 mean ± SD)

Calibration Curve of tropisetron HCl in phosphate buffer pH 6.8.

10.6 Evaluation of Banana Powder and Cassia tora Gum Powder

Discussion: Results of evaluation parameters of banana powder and Cassia tora powder mentioned in Tables 8 and 10 all the results are obtained within the limit. The swelling index is

the main characteristic for disintegration and from the above results, Cassia tora powder and banana powder both show a good swelling property. Because Cassia tora powder and banana powder both having carbohydrate, protein. Along with this cassia tora powder having tannins into it and banana powder having starch into it. Therefore both showing very good swelling property.

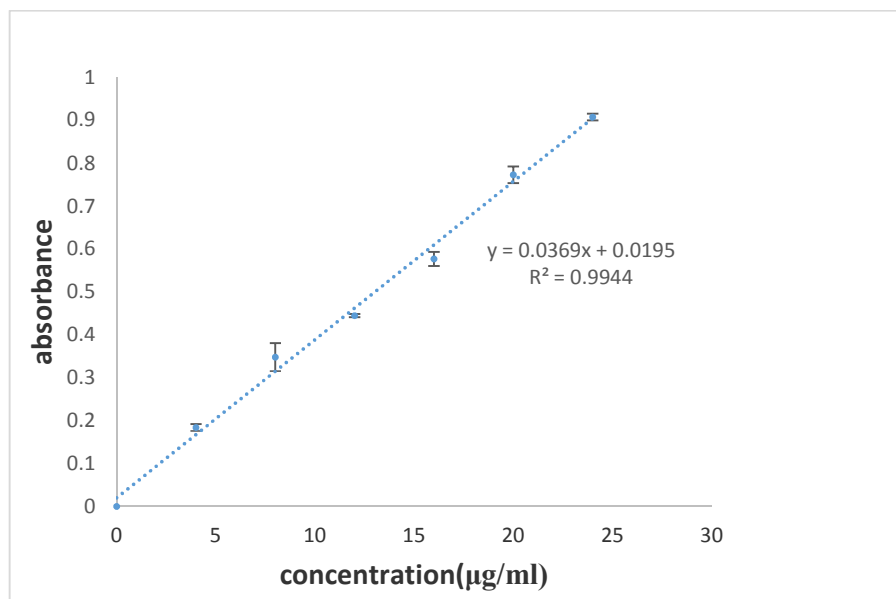


Fig. 5. Standard Plot of tropisetron HCl

Table 8. Evaluation parameters of Banana powder and Cassia tora gum powder

| Sr.No | Parameter | Cassia tora powder | Banana powder |
|-------|---|---|---|
| 1 | Colour | Pale yellow | Yellow to brown |
| 2 | Solubility | Sparingly soluble in cold water, quickly soluble in hot water, and soluble in organic solvents like ethanol, methanol, acetone, and ether | Easily soluble in cold water, quickly soluble in hot water, and insoluble in organic solvents like ethanol, methanol, acetone, and ether. |
| 3 | Loss on drying | 7.5% | 4.3% |
| 4 | pH | 7.3 ± 0.056 | 6.2 ± 0.775 |
| 5 | Swelling Index (%) | 12 ± 0.708 | 10 ± 1.03 |
| 6 | Test for carbohydrates (Molisch's test) | Positive | Positive |
| 7 | Test for Proteins (Xanthoproteic test) | Positive | Positive |
| 8 | Test for Tannins (Ferric chloride test) | Positive | Negative |
| 9 | Test for Starch (amylum) | Negative | Positive |
| 10 | Microbial test | Negative | Negative |
| 11 | Percentage yield | 34.67% | 48.79% |

(n=3 mean ± SD)

Standardization of Banana Powder
Determination of Ash value

Table 9. Determination of Ash value

| Sr. No | Parameter | Result |
|--------|--------------------|-------------------|
| 1 | Total Ash | 3.20 ± 0.7 % w/w |
| 2 | Water soluble Ash | 2.40 ± 0.12 % w/w |
| 3 | Acid insoluble Ash | 0.66 ± 0.05 % w/w |

(n=3 mean ± SD)

Discussion: Results of the experiment on the ash values of banana powder are given in Table 9. The results revealed that Banana powder has mainly water-soluble ash and a very low amount of acid-insoluble ash suggesting the acceptable range of undesired heavy metal impurities. Determination of Extractive values

Table 10. Determination of Extractive value

| Sr.No | Parameter | Result |
|-------|----------------------------|-----------------|
| 1 | Water soluble extractive | 30 ± 0.45 % w/w |
| 2 | Ethanol soluble extractive | 60 ± 1 % w/w |

(n=3 mean ± SD)

Discussion: The results of water and alcohol soluble extractives are mentioned in Table 10. High values of these indicate the presence of a good amount of water and alcohol soluble chemical constituents.

TLC Identification Test

Mobile Phase: Hexane: Acetone (6:4)

Test Sample: Banana powder dissolved in acetone

Detection: UV (366 nm)

Sample Identification: Vitamin A.

R_f value: 0.9

Discussion: vitamin A is the main constituent of banana powder and TLC was performed as shown in Fig. 6 and the R_f value obtained was 0.9 which is similar to the standard R_f value of Vitamin A.

Optimization of superdisintegrants

Trial batches of tropisetron orodispersible tablets were prepared using synthetic super disintegrants.

Discussion: Formulation having the lowest disintegration time is the most primary parameter for the preparation of ODTs. For the selection of superdisintegrants disintegration, the test was performed. The disintegration test of batches K1 to K9 is shown in Table 11. From this study, Crospovidone showed less disintegration time in concentrations of 5%, 7.5%, and 10% (batch K7-K9) than other superdisintegrants. Therefore, Crospovidone was selected as a synthetic super disintegrating agent.

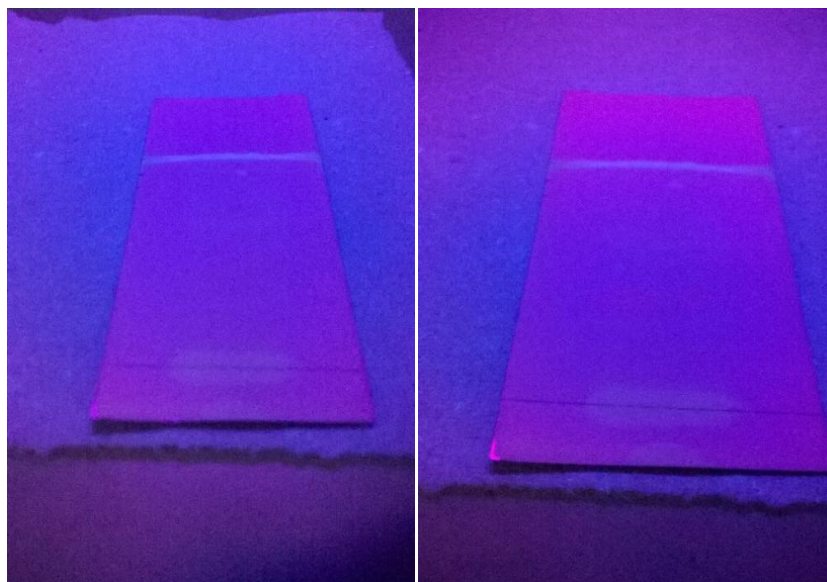


Fig. 6. TLC Identification of Banana powder

10.7 Evaluation Parameters

Post compression evaluation parameters

The orodispersible tablets were manufactured for the batches B1 to B9 using the ingredients shown in the previous section. After getting all the physical properties of the powder blend which was used for direct compression, tablets were prepared. The physical properties of powder blends are shown in Table 12.

Table 11. Disintegration time of batch K1 to K9

| Batch | Disintigration time* (sec) |
|-------|----------------------------|
| K1 | 51.667 ± 0.577 |
| K2 | 53.333 ± 1.527 |
| K3 | 43.333 ± 3.05 |
| K4 | 55.666 ± 1.527 |
| K5 | 60 ± 2.645 |
| K6 | 55.666 ± 0.577 |
| K7 | 42.333 ± 1.154 |
| K8 | 27.333 ± 1.527 |
| K9 | 28.666 ± 0.577 |

(*n=3 mean±SD)

Discussion: Several technologies are available to manufacture orodispersible tablets. The most common method of preparation is the direct compression technique. Flow properties of the powder, resistance to particle movement can be judged from the angle of repose. This measurement gives a qualitative and quantitative assessment of internal cohesive and frictional force under low levels of external loading as might be applied in mixing and tableting. Values of the angle of repose range from $25.13^{\circ} \pm 0.033$ to $26.88^{\circ} \pm 0.012$. Carr's index of the prepared blend falls in the range of $13.63\% \pm 0.19$ to $16.41\% \pm 0.12$ and this is also supported by Hausner's ratio which was in the range of 1.14 ± 0.004 to 1.19 ± 0.021 . Hence the prepared blend possessed good flow properties as shown in Table 6 and these can be used for tablet manufacture. All the tablets were prepared under similar conditions and all the formulations exhibited white color, odorless with a smooth surface.

Evaluation of prepared Tropisetron HCl orodispersible tablet

Tropisetron HCl orodispersible tablets have been prepared using the process of direct compression. The prepared tablets were defined by various post-compression parameters such as

hardness, friability, diameter, thickness, variance in weight, dispersion duration, drug quality, water absorption ratio for wetting time, which is summarized in Tables 13 and 14.

Discussion: The characteristic of prepared orodispersible tablets are mentioned in Tables 13 and 14. The average weight of the tablet prepared by direct compression method was 97 ± 2.5 to 102 ± 1.69 mg. The hardness and friability of all the formulations were within acceptable limits. Hardness of prepared tablets was 2.8 ± 0.024 to 3.30 ± 0.24 kg/cm². It was found that the friability of all the formulations was less than 1% and therefore the tablets with lower friability could not break during handling and shipping on machines. The average thickness of tablets was 2.7 ± 0.24 to 2.4 ± 0.028 mm and diameter was found in the range of 6.05 ± 0.004 to 6.00 ± 0.009 mm. wetting time is a very important parameter for the orodispersible tablet which is desired to be less than 40 seconds for orally disintegrating tablets. This helps to swallow and also plays an important role in drug absorption in the oral cavity and thereby facilitates bioavailability. The wetting time of the prepared tablet with natural superdisintegrants was in the range of 3.33 ± 0.34 to 20 ± 1.23 sec. The order was Crospovidone > Banana powder > Cassia tora powder. This is findings agree with results obtained from wetting time since Cassia tora powder swells with more gelling than Banana powder and Crospovidone, which extend disintegration time as a result. Wetting time is used as an indicator of the ease of the tablet disintegration in the oral cavity. After contact with water the tablets containing Cassia tora powder swelled immediately, the outer edge appeared gel-like. Tablets containing Casia tora powder wicks water and were hydrated, but were soft as compared to tablets prepared with banana powder and crospovidone. The drug content of prepared tablets was in the range of $97.69 \pm 0.75\%$ to $99.85 \pm 0.37\%$. Disintegration time is a very important parameter for an orodispersible tablet. Disintegration time of prepared tablets ranges from 4.66 ± 1.15 to 41.66 ± 1.52 sec. from the result it concluded that batch B2 containing cassia tora powder (5%) as a super disintegrant show less disintegration time.

In-vitro dissolution for batches B1 to B9

In-vitro, drug release studies were performed as per the procedure described in the methodology. Formulations having a lower disintegration time

were preferred for the best formulation of orodispersible tablets as shown in Fig. 7. The samples were withdrawn at specified time intervals and analyzed by the Method of UV. As shown in Figs. 8, 9, and 10, the percent cumulative drug release was determined based on the amount of Tropisetron HCl present in the respective formulations. *In-vitro* drug release

data (B1-B9) for formulation were shown in Tables 15 and 16, respectively. The percentage cumulative drug release of formulations of Tropisetron HCl was plotted against time to obtain drug release profiles as shown in Figs. 8, 9, and 10. The highest drug release in the lowest time (14 mins) was Shown in by B2 (99.25%).

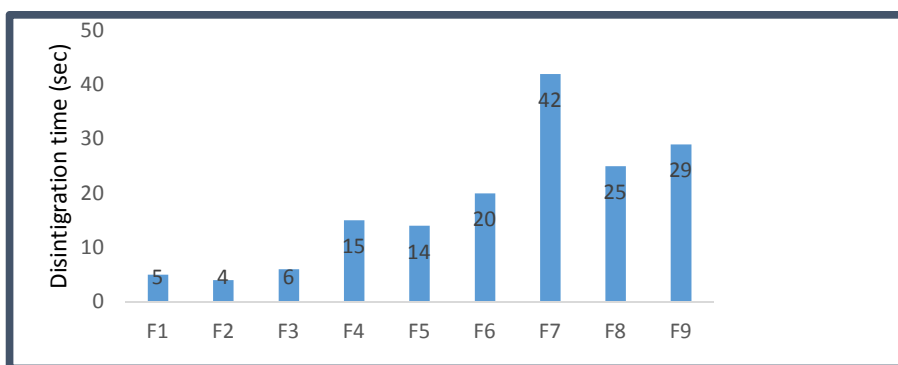


Fig. 7. Disintegration time for various batches B1-B9

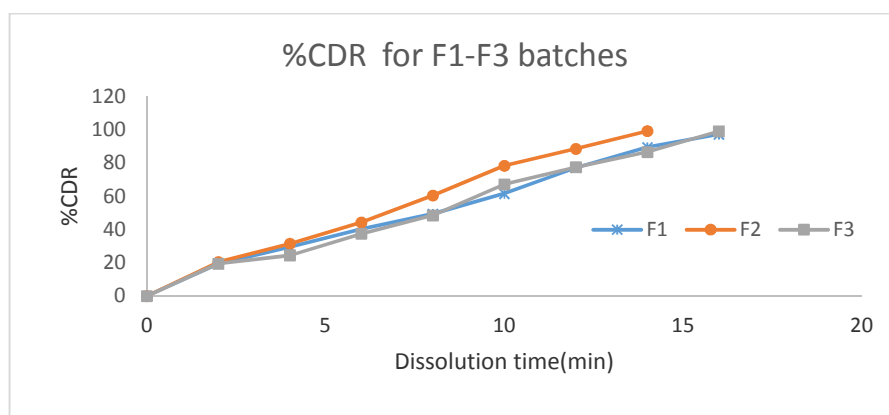


Fig. 8. % CDR of Batches B1-B3

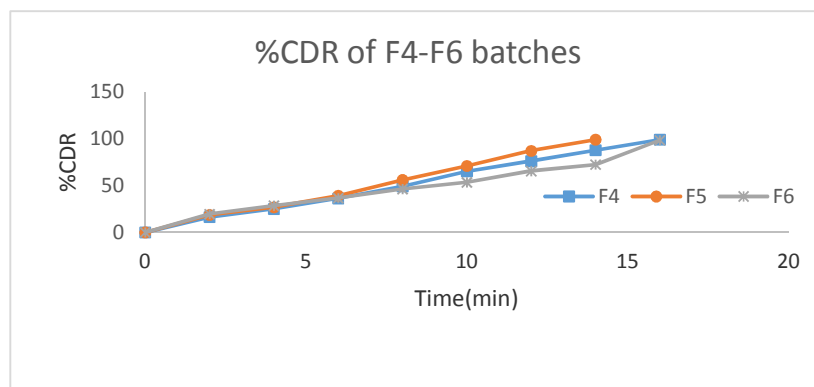


Fig. 9. %CDR of Batches B4-B6

Table 12. Physical properties of the powder blend

| Batch | Bulk density (gm/ml) ± SD | Tapped density (gm/ml) ± SD | The angle of repose θ (°)± SD | Compressibility index (%)± SD | Hausner's ratio ± SD |
|-------|---------------------------|-----------------------------|-------------------------------|-------------------------------|----------------------|
| B1 | 0.56 ± 0.012 | 0.65 ± 0.010 | 25.56 ± 0.033 | 13.84 ± 0.16 | 1.16 ± 0.008 |
| B2 | 0.56 ± 0.008 | 0.66 ± 0.008 | 25.13 ± 0.033 | 15.15 ± 0.11 | 1.17 ± 0.008 |
| B3 | 0.57 ± 0.021 | 0.67 ± 0.021 | 26.25 ± 0.032 | 14.92 ± 0.1 | 1.17 ± 0.008 |
| B4 | 0.55 ± 0.008 | 0.67 ± 0.021 | 26.88 ± 0.021 | 17.91 ± 0.15 | 1.21 ± 0.01 |
| B5 | 0.57 ± 0.016 | 0.67 ± 0.018 | 26.61 ± 0.028 | 14.92 ± 0.11 | 1.17 ± 0.018 |
| B6 | 0.57 ± 0.026 | 0.66± 0.008 | 26.70 ± 0.022 | 13.63 ± 0.19 | 1.15 ± 0.008 |
| B7 | 0.56 ± 0.024 | 0.65 ± 0.012 | 26.45 ± 0.021 | 13.84 ± 0.2 | 1.14 ± 0.004 |
| B8 | 0.55 ± 0.021 | 0.65 ± 0.008 | 26.61 ± 0.035 | 15.38 ± 0.9 | 1.18 ± 0.021 |
| B9 | 0.56 ± 0.020 | 0.67 ± 0.012 | 26.88 ± 0.012 | 16.41 ± 0.12 | 1.19 ± 0.021 |

(*n=3, mean ± SD)

Table 13. Post compression parameters of batches B1-B9

| Batch | Diameter (mm) ± SD | Thickness (mm) ± SD | Hardness (kg/cm ²) ± SD | Friability (%)± SD | Weight variation (mg) ± SD |
|-------|--------------------|---------------------|-------------------------------------|--------------------|----------------------------|
| B1 | 6.00 ± 0.009 | 2.5 ± 0.09 | 3.0 ± 0.08 | 0.79 ± 0.008 | 101 ± 1.4 |
| B2 | 6.00 ± 0.037 | 2.6 ± 0.04 | 3.05 ± 0.008 | 0.82 ± 0.008 | 100 ± 2.3 |
| B3 | 6.02 ± 0.075 | 2.5 ± 0.24 | 3.12 ± 0.09 | 0.76 ± 0.009 | 99 ± 1.3 |
| B4 | 6.03 ± 0.07 | 2.5 ± 0.04 | 3.00 ± 0.007 | 0.74 ± 0.004 | 98 ± 0.63 |
| B5 | 6.05 ± 0.004 | 2.6 ± 0.21 | 3.22 ± 0.008 | 0.77 ± 0.05 | 103 ± 3.4 |
| B6 | 6.02 ± 0.004 | 2.5 ± 0.26 | 3.0 ± 0.004 | 0.87 ± 0.024 | 97 ± 2.5 |
| B7 | 6.00 ± 0.009 | 2.7 ± 0.24 | 2.8 ± 0.024 | 0.72 ± 0.025 | 100 ± 3.7 |
| B8 | 6.00 ± 0.008 | 2.5 ± 0.02 | 2.5 ± 0.04 | 0.73 ± 0.225 | 101 ± 0.84 |
| B9 | 6.03 ± 0.026 | 2.4 ± 0.028 | 3.30 ± 0.24 | 0.82 ± 0.076 | 102 ± 1.69 |

(*n=3 mean ± SD)

Table 14. Post compression parameters of formulation batches B1-B9

| Batch | %Drug Content \pm SD | Disintegration time (sec) \pm SD | Wetting time (sec) \pm SD | Water absorption ratio \pm SD | <i>In-vitro</i> dispersion time (sec) \pm SD |
|-------|------------------------|------------------------------------|-----------------------------|---------------------------------|--|
| B1 | 99.85 \pm 0.37 | 6.33 \pm 1.5 | 4.2 \pm 1.5 | 59.66 \pm 2.51 | 6.52 \pm 0.37 |
| B2 | 99.50 \pm 0.87 | 4.66 \pm 1.15 | 3.33 \pm 0.34 | 64.66 \pm 2.081 | 4.56 \pm 0.87 |
| B3 | 99.77 \pm 2.75 | 7 \pm 1 | 6.66 \pm 1.57 | 67.66 \pm 1.52 | 8 \pm 2.75 |
| B4 | 98.71 \pm 1.50 | 17.33 \pm 2.08 | 15.55 \pm 2 | 71 \pm 1 | 16 \pm 1.50 |
| B5 | 99.32 \pm 2.49 | 15.66 \pm 1.52 | 16 \pm 0.989 | 73 \pm 1 | 15.30 \pm 2.49 |
| B6 | 99.58 \pm 1 | 22 \pm 2.64 | 20 \pm 1.23 | 73.66 \pm 2.081 | 21.58 \pm 1 |
| B7 | 99.40 \pm 0.97 | 41.66 \pm 1.52 | 40.33 \pm 2.56 | 79.66 \pm 1.52 | 41 \pm 1 |
| B8 | 98.03 \pm 0.79 | 25.66 \pm 2.08 | 22.33 \pm 1.57 | 78.66 \pm 2.081 | 26 \pm 2 |
| B9 | 97.69 \pm 0.75 | 27.33 \pm 1.5 | 25.88 \pm 2.04 | 72.33 \pm 2.51 | 28.10 \pm 2.8 |

(*n=3 mean \pm SD)

Table 15. % Cumulative Drug release for batches B1-B5

| Time(min) | B1 | B2 | B3 | B4 | B5 |
|-----------|------------------|------------------|------------------|------------------|------------------|
| 0 | 0 | 0 | 0 | 0 | 0 |
| 2 | 19.45 \pm 0.37 | 20.49 \pm 0.36 | 19.49 \pm 0.37 | 16.45 \pm 0.20 | 18.72 \pm 0.41 |
| 4 | 29.51 \pm 0.32 | 31.51 \pm 0.37 | 24.52 \pm 0.41 | 25.03 \pm 0.90 | 26.83 \pm 1.36 |
| 6 | 40.47 \pm 0.28 | 44.29 \pm 0.26 | 37.51 \pm 0.43 | 36.21 \pm 0.21 | 39.14 \pm 0.38 |
| 8 | 49.48 \pm 0.27 | 60.5 \pm 0.34 | 48.47 \pm 0.34 | 49.13 \pm 0.83 | 56.40 \pm 0.35 |
| 10 | 61.52 \pm 0.30 | 78.37 \pm 0.09 | 67.21 \pm 0.22 | 65.36 \pm 0.54 | 71.02 \pm 0.64 |
| 12 | 77.26 \pm 0.26 | 88.53 \pm 0.40 | 77.52 \pm 0.35 | 76.08 \pm 0.14 | 87.07 \pm 0.73 |
| 14 | 89.45 \pm 0.31 | 99.25 \pm 0.15 | 86.56 \pm 0.29 | 87.89 \pm 0.65 | 99.10 \pm 0.09 |
| 16 | 97.27 \pm 0.25 | - | 99.13 \pm 0.11 | 99.06 \pm 0.28 | - |
| 18 | - | - | - | - | - |

(n=3 mean \pm SD)

Table 16. % Cumulative Drug release for batches B6-B9

| Time(min) | B6 | B7 | B8 | B9 |
|-----------|------------|------------|------------|------------|
| 0 | 0 | 0 | 0 | 0 |
| 2 | 19.5±0.42 | 15.47±0.38 | 16.35±0.45 | 20.50±0.38 |
| 4 | 28.55±0.30 | 21.50±0.35 | 27.66±0.39 | 30.6±0.49 |
| 6 | 36.51±0.43 | 29.28±0.31 | 36.91±0.29 | 38.41±0.37 |
| 8 | 46.31±0.29 | 39.57±0.38 | 46.25±0.28 | 47.55±0.39 |
| 10 | 53.45±0.33 | 50.53±0.32 | 53.43±0.38 | 55.38±0.48 |
| 12 | 65.48±0.36 | 62.48±0.31 | 64.59±0.36 | 66.51±0.38 |
| 14 | 72.48±0.38 | 78.49±0.44 | 75.57±0.34 | 78.58±0.36 |
| 16 | 98.50±0.39 | 89.31±0.28 | 86.46±0.31 | 89.48±.038 |
| 18 | - | 98.69±0.48 | 97.91±0.65 | 99.19±0.18 |

(n=3 mean ± SD)

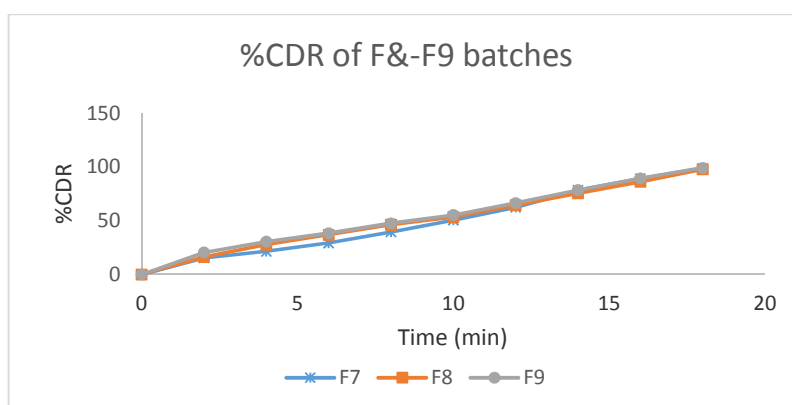


Fig. 10. %CDR of Batches B6-B9

Table 17. Stability study of selected batch B2 after one month

| Parameters | Room Temperature | | Accelerated Condition | |
|--------------------------------|------------------|--------------|-----------------------|--------------|
| | 0 days | 30 days | 0 days | 30 days |
| Hardness (kg/cm ²) | 3.0±0.008 | 3.0 ± 0.02 | 3.0±0.008 | 3.0 ± 0.5 |
| Thickness (mm) | 2.6±0.04 | 2.6 ± 0.08 | 2.6±0.04 | 2.5 ± 0.77 |
| Disintegration time (second) | 4.66±1.15 | 4.66 ± 1.01 | 4.66±1.15 | 4.50 ± 1 |
| Wetting time (second) | 3.33±0.34 | 3.33 ± 0.8 | 3.33±0.34 | 3 ± 0.06 |
| Dispersion time (second) | 4.56±0.87 | 4.55 ± 0.07 | 4.56±0.87 | 4.48 ± 0.53 |
| Drug content (%) | 99.50±0.87 | 99.47 ± 0.91 | 99.50±0.87 | 99.35 ± 0.54 |
| % CDR | 99.25±0.15 | 99.20 ± 0.7 | 99.25±0.15 | 98.5 ± 0.99 |

(n=3 mean±SD)

Discussion: Dissolution is an important parameter for the solubility of the drug. Dissolution is carried out using phosphate buffer pH 6.8 as a dissolution medium. The result revealed that the drug release is almost 100% (99.25%) in 14 min in the B2 batch which contains 5% of cassia tora powder as a super disintegrant. Cassia tora powder showed good disintegration time as well as good wetting time and also good swelling property so that Cassia tora provided rapid drug release.

10.8 Stability Study

Formulation B2 as shown in Table 17 which contains 5% cassia tora powder was exposed to various temperature and humidity conditions for one month to assess its stability. At the end of one-month samples were evaluated for physicochemical parameters, weight variation hardness, drug content, disintegration time, and dissolution profiles. There were no

significant changes observed in the physicochemical parameters.

Discussion: The result of the stability study demonstrated that the batches stored at accelerated conditions show a slight change in drug content, drug release, disintegration time. No significant change was found at room temperature conditions. So we may conclude that the prepared optimized formulation was stable at room temperature and % relative humidity condition up to one month.

11. CONCLUSION

Orodispersible tablets of Tropisetron HCl were formulated by using various super disintegrants in which natural superdisintegrants such as Banana powder and Cassia tora powder and synthetic superdisintegrants like Croscarmellose sodium, Crospovidone, and Sodium Starch glycolate.

The disintegration time for all formulation was considered to be within the acceptable limit. It is observed that when Cassia tora powder was used as super disintegrant the tablet disintegrated rapidly within a short time at lower concentration due to pronounced hydration and rapid swelling ability of Cassia tora powder when compared with other tablets prepared using croscarmellose sodium, Crospovidone, Banana powder, and Sodium starch glycolate. The disintegration time of formulation B2 was found to 4.66 ± 1.15 seconds. Batch B2 gives rapid disintegration time and Drug content was found to be 99.50 ± 0.87 .

Results of *in-vitro* dissolution data of batch B2 showed drug release up to 99.25 ± 0.15 % in 14 min. Hence batch B2 was subjected to stability studies. Optimum formulation B2 is stable at 40°C and 75% RH under selected stability conditions. As per the data obtained from stability studies, it was found that formulation B2 was stable and maintain its integrity throughout the storage period. From the above evaluation data, it was concluded that the development of Orodispersible tablet of tropisetron HCl containing Cassia tora powder is super disintegrant, was most promising and optimum formulation.

DISCLAIMER

The products used for this research are commonly and predominantly use products in our

area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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