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Formulation and Evaluation of Fast Dissolving Tablets of Cemetidine using Hibiscus Rosa Sinesis Mucilage as Super Disintegrating Agent

Mranal Geed[1], Komal Tikariya[2], Umesh K. Atneriya[1,] Dr. Dharmendra Solanki[2]

[1]Department of Pharmaceutics, Shri Bherulal Pharmacy Institute, Indore (M.P) India.

[2]Department of Pharmaceutics, BM College of Pharmaceutical Education & Research, Indore (M.P) India.

ABSTRACT

The present study was carried out in order to develop fast dissolving drug delivery system of Cimetidine using hibiscus rosa Sinesis mucilage as a natural superdisintegrants. The Hibiscus rosa Sinesis mucilage was extracted and evaluated for the physicochemical characterization of Hibiscus rosa Sinesis mucilage. The different formulation of Cimetidine FDTs were prepared by direct compression method using Hibiscus rosa Sinesis mucilage as a natural super disintegrants, Cimetidine were compared with various standard synthetic super disintegrants like SSG, Croscarmellose Sodium. The tablets were prepared. The drug content was found to be 98 to 99%. Water absorption ratio was found to be 61 to 70%. Disintegration rate was found to be 27 sec to 47 sec. The wetting time was found to be 22 sec to 46 sec. The percentage drug release from formulations F1 to F9 was found to be more than 95% drug within 25 minutes and drug release of marketed formulation was found to be 70.8% within 25 minutes. It can be concluded that solid dispersion of Cimetidine with Hibiscus rosa Sinesis as a natural super disintegrants shows promising result of solubility and in vitro drug release of FDT of Cimetidine.

Keywords:- Cimetidine, natural superdisintegrants, hibiscus rosa Sinesis, Fast dissolving Tablets, In vitro drug release.

INTRODUCTION

The main objective of the work is to carry out preparation of Cimetidine fast disintegrating tablets by selecting natural and synthetic super disintegrating agents with different concentration in order to ensure rapid onset of action at the administered site i.e. Mouth Cimetidine is a gastric acid reducer used in the short-term treatment of duodenal and gastric ulcers. Therefore, the drug effectively manages gastric hyper secretion and is used to manage reflux esophagitis disease and prevent stress-related gastric ulcers. Cimetidine is the API of choice as it is effective against ulcers of the stomach and intestine and prevents them from coming back after they have healed. Cimetidine is considered to

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bea cost-effective drug because of its low cost, good activity against GERD, and minor adverse effects. When administered as a dispersible solution form or as an immediate release dosage form, its bioavailability increases[1].

The goal of present study was to formulate fast dissolving tablet of Cimetidine using Hibiscus Rosa Sinesis mucillage as a natural superdisintegrant. Taste masking and taste assessment are the two main factors taken into consideration while formulating ODTs as they disintegrate and/ or dissolves in oral cavity. Taste masking in addition is related to patient compliance. Patient compliance is particularly important in pediatrics, geriatric and long drug therapy patients FDT is easy to administration for paediatric and geriatric patients and improves patient compliance. As the absorption site is mouth, so it is also reduces the gastric irritation[2].

MATERIALS AND METHOD

1. MATERIALS

Cimetidine was received as a gift sample from Yarrow chem Pvt. Ltd. (pithampur). Sodium Starch Glycolate, Croscarmellose Sodium, Microcrystalline cellulose, Glyceryl monostearate , Talc, Mannitol was procured from Lobachem Pvt. Ltd. Hibiscus Rosa Sinesis from Local market. All other solvent and reagent are used was of analytical grade.

2. EXPERIEMENTALS

2.1 Identification of Drug:

Authentication of drug sample by U.V. Spectrophotometer:

50mg of drug was weighed and was dissolved in 50ml of methanol (1mg/ml). 10ml of this solution was withdrawn and volume was made up to 100ml. Appropriate dilutions were made with methanol to give concentration of 10 µg/ml, scanned in UV range from 200-400nm and spectrum was recorded[3].

Authentication of drug sample by FTIR:

Fourier Transform Infrared spectroscopy (FTIR) Spectrum was recorded of pure sample were analysed by KBr pellet method using FTIR spectroscopy. About 10 mg of Cimetidine mixed with potassium bromide of equal weight .The spectra were scanned over a frequency range 4000 -400 cm^{-1} [4].

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Differential Scanning Calorimetry:

The DSC of Cimetidine is the thermogram of pure Cimetidine obtained by using DSC (mettle star 8.10) at heating rate 10^0C/minutes over a temperature range of 35- 300^0C. Accurately weight 2.0 mg of sample was hermetically sealed in an aluminum pan. Nitrogen gas was purged rate 10 ml / minutes for maintaining inert atmosphere[4].

Determination of Melting Point:

Melting point of drug sample was determined by using melting point apparatus. The drug sample was taken and placed in a thin walled capillary tube; the tube was approximately 10-12 cm in length with 1mm in diameter and closed at one end. The capillary was placed in melting point apparatus and heated and when drug sample was melted the melting point of sample powder was recorded[5].

Preparation of calibration curve of Cimetidine :

The calibration curves of Cimetidine were prepared in distilled water and phosphate buffer pH 6.8 by using Shimadzu 1800 UV visible spectrophotometer. Accurately weighed 50 mg of Cimetidine was transferred into a 50 ml volumetric flask and the volume was made up with distilled water to obtain a 1000µg/ml stock solution of Cimetidine. From the stock solution 1 ml was taken and transferred into a 10 ml volumetric flask and rest of the volume was made up with solvent to obtain a 100µg/ml of solution from which further dilutions were prepared. Same procedure was followed for phosphate buffer pH 6.8 to prepare calibration curve[6].

Determination of solubility:

Determination of solubility of Cimetidine in various medium:

The solubility of Cimetidine in various medium was determined by equilibrium solubility method. In this method 5 ml of each solvent was taken into a separate vial and excess amount of Cimetidine was added in to vials containing distilled water and phosphate buffer pH 6.8. The vials put on mechanical stirrer at 37 ± 2^0C for 12 hrs. The solutions were allowed to equilibrate for next 24 h. The solution was transferred into eppendroff tubes and centrifuged for 5 min. at 2000 rpm. The supernatants of each vial were filter through 0.45 micron membrane filter, make appropriate dilutions and analyzed by UV visible

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spectrophotometer (UV-1800 Shimadzu ,japan) at 237 nm, the studies was performed in triplicate[7].

Drug-excipient interaction study:

The compatibility of the drug was assessed by drug-excipient interaction study. The drug was mixed with various excipients in a 1:1 ratio in glass vials which were properly sealed and kept undisturbed at 40°C temperature for 14 days. After 14 days incompatibility (if any) was confirmed by TLC.[8]

2.2 Preparation of Cimetidine Fast dissolving tablets by Direct Compression Method.

- Weighed all Ingredients as per the quantities defined in below given Table No. 6.3.
- Pass all the ingredients through sieve #80 and collected individuals in polybags.
- Mixed measured quantity of Hibiscus Rosa Sinesis Mucilage, sodium starch glycolate, croscarmellose sodium, microcrystalline cellulose and mannitol.
- Magnesium stearate and talc was added to it and blend for 5 min in pestle mortar. Compress final blend using D-Tooling, multiple rotatory compression machine using 10 mm round shaped punches and corresponding dies.

Table No. 1: Composition of Cimetidine Fast Dissolving Tablets.

S.No	Ingredients	Formulation Code (quantity in mg)								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	Cimetidine	200	200	200	200	200	200	200	200	200
2.	Hibiscus Rosa Sinesis Linn	7.5	10	12.5	-	-	-	-	-	-
3.	Sodium Starch Glycolate	-	-	-	7.5	10	12.5	-	-	-
4.	Croscarmellose Sodium	-	-	-	-	-	-	7.5	10	12.5
5.	Microcrystalline cellulose	86.5	84	81.5	86.5	84	81.5	86.5	84	81.5
6.	Mannitol	50	50	50	50	50	50	50	50	50
7	Glyceryl monostearate	50	50	50	50	50	50	50	50	50
7.	Magnesium stearate	3	3	3	3	3	3	3	3	3
8.	Talc	3	3	3	3	3	3	3	3	3
Total Weight (in mg)		**400**	**400**	**400**	**400**	**400**	**400**	**400**	**400**	**400**

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3. Evaluation of parameteres

3.1. Bulk characterisation.

Bulk characterisations of liquisolid system were estimated by Bulk density, Tapped density, Carr's index, and Hausner'sratio. The flow property was determined by Angle of repose. These properties were determined by using the following equations:[9]

Bulk Density = Mass (g)/ bulk volume

Tapped density= Mass (g)/tapped volume

Carr's index= Tapped density- bulk density/ tapped density X 100

Hausner's ratio= tapped density/ bulk density

Angle of repose= Tan0=h/r.

The bulk characterisation and flow properties of liquisolid compacts were recorded in table 6.

3.2. Evaluation of Post compression Parameter of Fast Dissolving Tablet:

Thickness: Twenty tablets were randomly selected from formulation and thickness was measured individually by screw gauge. The result was expressed in millimeters[10].

Hardness:

Hardness of the tablet indicates the ability of tablet to withstand mechanical shocks while packaging, handling and transportation. The hardness of the tablet was determined by Monsanto hardness tester. Placed the tablet on the lower plunger and zero reading was taken from Monsanto tester scale. The range of Monsanto hardness tester is "0 to 20" kg. The screw knob was moved forward until the tablet breaks and the force required breaking the tablet was noted. There are three tablets of each formulation batch were tested randomly and the averagereading was recorded. It is expressed in kg/cm^2 [11]

Weight variation

Twenty tablets were randomly taken from each batch and the weight of their average weight was determined. Then individual weight was compared with average weight. The weight was measured using weighing balance[12].

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Table No.2: Criteria for percent deviation from average weight:

Dosage form	Average Weight	% Deviation
Fast dissolving tablets or uncoated tablets	80 mg or less	10 %
	More than 80 but less than 250 mg	7.5 %
	250 mg or more	5 %

Friability:

Friability test was performed by using Roche friabilator. Ten tablets were weighed and place in the friabilator, which was then operated for 25 revolutions per minute. After four minute (100 revolutions) the tablet were dusted and reweighed. The percentage friability was determining using this formula[12].

Percentage friability = Initial weight - Final weight / Initial weight ×100

Wetting time:

The tablet was placed at the center of two layers of tissue adsorbent paper fitted into a petridish. After the paper was thoroughly wetted with distilled water, excess water was completely drained out of the dish. The time required for the water to diffuse from the wetted absorbent paper throughout the entire tablet was then recorded using a stopwatch[13].

Water absorption ratio:

The piece of tissue adsorbent paper was folded twice was placed in a small petri dish containing 6 ml of water. A tablet was put on the tissue paper and allowed to completely wetting. The wetted tablet was the again weighed. Water absorption ratio, R was determined using following equation

$$R = 100 \times (W_a - W_b)/W_a$$

Where,

W_a = Weight of tablet after water absorption

W_b = Weight of wetted tablet before water absorption [14]

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Drug contents:

Twenty tablets were taken and amount of drug present in each formulation was determined. The tablet was crushed in a mortar and the powder equivalents to 100 mg drug were transferred to 100 ml standard flask. The powder was dissolve in 5 ml of methanol and made up to volume with phosphate buffer pH 6.8 .The sample was mixed thoroughly the filtered through 0.45 micron membrane filter paper. The filter solution was diluted suitably and analyzed for drug content by U.V. Spectrophotometer at 237.80 nm[15].

In vitro Disintegration Test:

The USP disintegration test apparatus was used to determine disintegration time. Six tablets from each formulation were tested in 900 ml of water at 37^0C. The study was done in triplicate. [16]

In vitro Drug release study:

The in vitro dissolution study of formulated fast dissolving tablets F1-F9 was carried out using USP dissolution apparatus type II (Electro Lab Dissolution Tester USP II) (50 rpm, 37±0.5 ^{0}C ,and 900 ml of medium). A temperature of 37±0.5 ^{0} C was maintained throughout the study. The dissolution medium was phosphate buffer (900 ml pH 6.8) for the experiment. Five milliliter of the sample was withdrawn at specified time intervals and analyzed by UV spectrophotometer (Shimadzu 1800, japan) at 237.80 nm. The amount of drug released at each time point was calculated and summed to give cumulative amount of drug. In order to the study the effect of drug release in fast dissolving tablet were carried out in USP paddle type dissolution apparatus at 50 rpm sample were predetermined interval and analyzed by UV spectrophotometer (Shimadzu 1800, japan) at 273.80 nm. [17]

Stability studies:

The stability studies were carried out for a period of 1 month in the stability chamber. The tablets were stored under the following conditions as prescribed by the ICH guidelines (40°C±2°C and 75±5% RH, **Q1C**). The tablets were withdrawn periodically with an interval of 30 days and analyzed for Hardness, Disintegration, Dissolution, Wetting time, drug content etc.[17]

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4. Result and Discussion

Identification and Drug Characterization

Determination of Maximum wavelength using UV spectrophotometer :

The maximum wavelength of Cimetidine was found to be 237.80.nm which matches the reported wavelength[18].

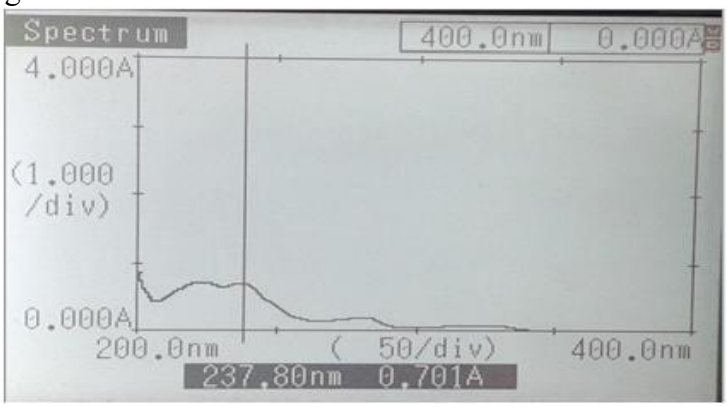

Figure 3: UV Spectrum of Cimetidine in ethanol

Authentication of drug sample by I.R. Spectroscopy:

FTIR: (Fourier Transform Infrared Spectroscopy) The prominent IR absorption peak of Cimetidine at 3144.37 and 2350.48 that thease broad peaks may be due to OH hydrogen bonding. 2177.24 and 1590.99 carbonyl group vibration. 1303.32 indicate the presence of C=C ring stretching and 1236.19 N-H bending presence in the FTIR of Cimetidine[18]

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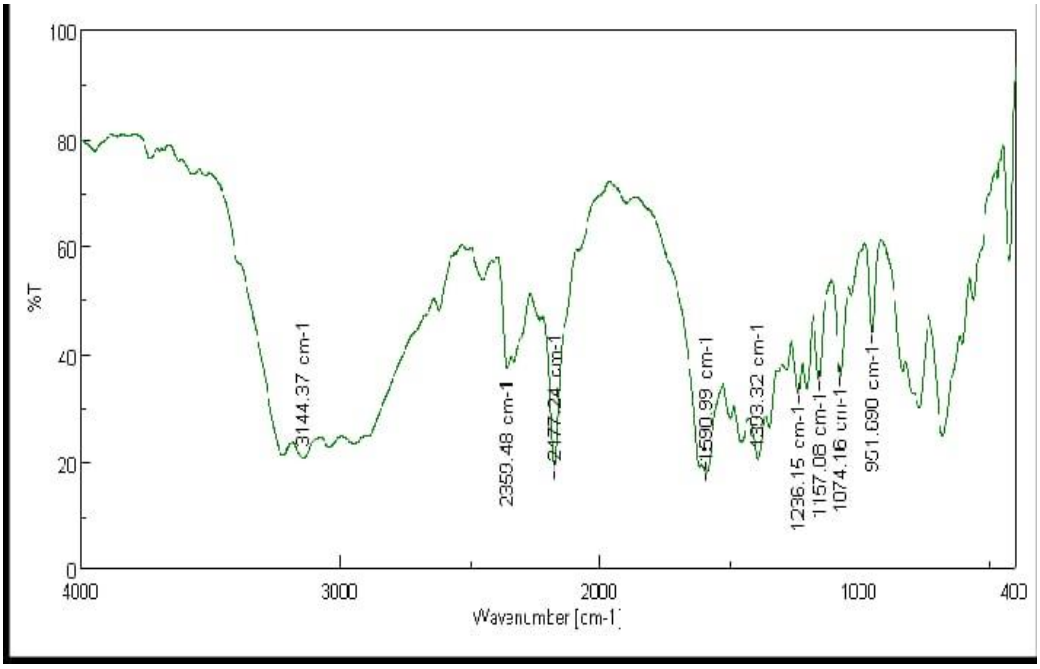
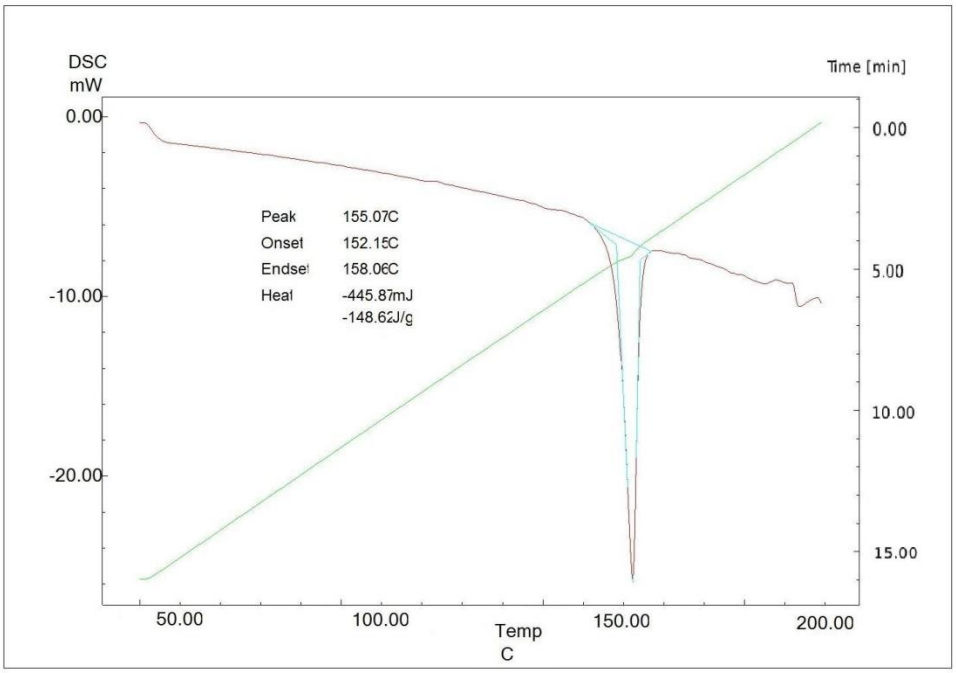


Figure 4: FTIR Spectra of Cimetidine

Differential Scanning Calorimetry: The DSC thermogram of Cimetidine exhibited endothermic peak at 155.07 ^{0} C which corresponds to the melting point of Cimetidine[19].

Figure 5: DSC graph of Cimetidine.



Melting point determination:

The melting point of Cimetidine was found to be 150^{0}C which is same as reported in literature[19].

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Preparation of calibration curves:

The calibration curves of Cimetidine in various solvents e.g. Distilled water, 6.8 pH phosphate buffers were prepared and shown in Table No. 7.6

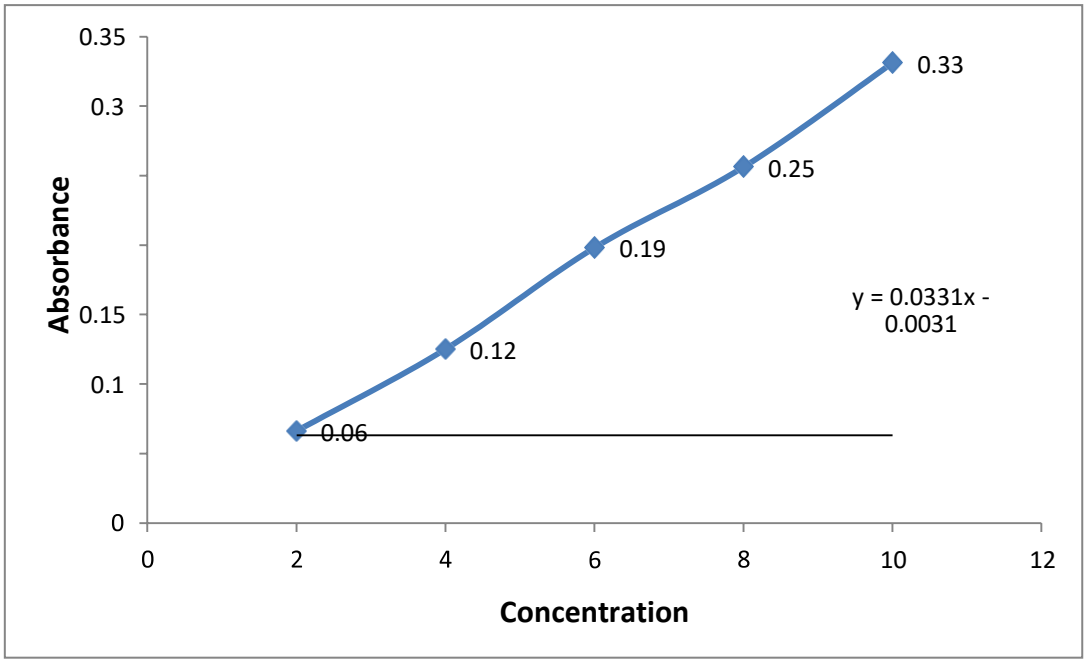

Figure 6: Calibration curve of Cimetidine in distilled water

Table No. 7: Absorbance data of Cimetidine in distilled water

S. No.	Concentration (µg/ml)	Absorbance (n=3)
1	2	0.066±0.1
2	4	0.125±0.6
3	6	0.198±0.3
4	8	0.256±0.1
5	10	0.331±0.2

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Table No. 8: **Absorbance data of Cimetidine in phosphate buffer pH 6.8 for preparation of calibration curve, at 237.80 nm.**

S. No.	Concentration (µg/ml)	Absorbance (n=3)
1	2	0.145±0.6
2	4	0.296±0.2
3	6	0.443±0.7
4	8	0.641±0.2
5	10	0.765±0.1

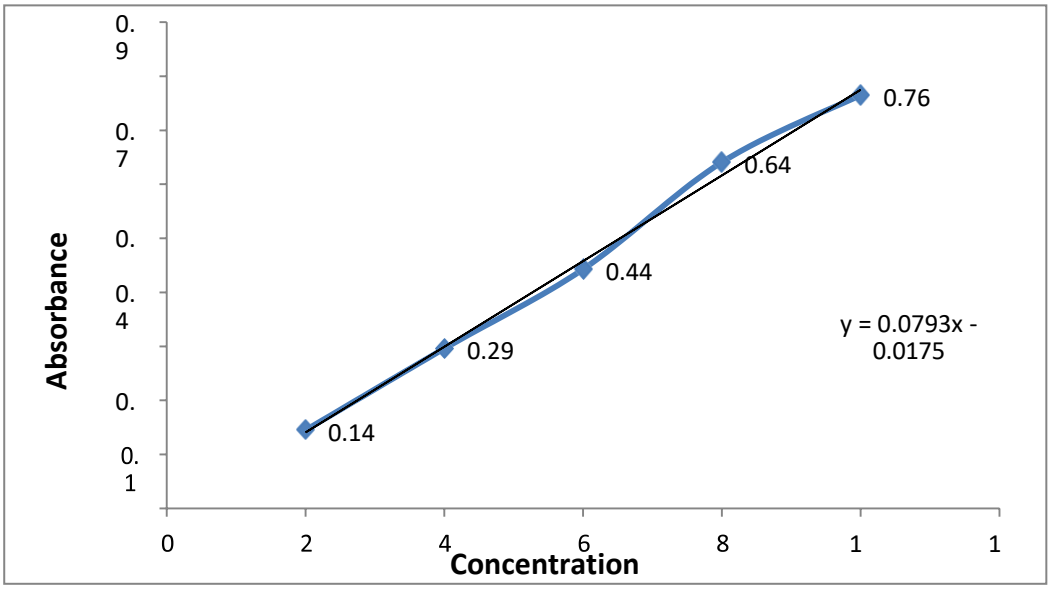

Figure 9: Calibration curve of Cimetidine in Phosphate Buffer pH 6.8

Determination of solubility of Cimetidine in various medium:

The solubility of Cimetidine in various mediums was studied and the results of study were shown in below table no.7.9

Table No. 10: Solubility study data of Cimetidine in different mediums:

S.No.	Solvent	Solubility of Cimetidine (µg/ml)
1	Distilled water	4.06±0.11µg/ml
2	Phosphate buffer (pH) 6.8	574.19±0.12µg/ml

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Drug-excipient interaction study:

The drug (Cimetidine) was found to be compatible with various excipients which were selected for formulation of Fast dissolving tablets. The compatibility was assessed by TLC and the retention factors of all ratios found similar[19].

Table No.11: Data of drug-excipient interaction study

S.No.	Drug/ drug+ Excipient Ratio (1:1)	Present Day (Rf)	Present 8 Days (Rf)	After 14 Days (Rf)
1	Drug (Cimetidine)	0.531±0.01	0.531±0.01	0.531±0.02
2	Drug + PVP-K 30	0.541±0.86	0.541±0.85	0.541±0.08
3	Drug + Hibiscus Rosa Sinesis mucillage	0.730±0.81	0.730±0.81	0.730±0.82
4	Drug+ Croscarmellose sodium	0.508±0.89	0.508±0.89	0.508±0.87
5	Drug + Sodium Starch Glycolate	0.510±0.81	0.510±0.80	0.510±0.81
6	Drug + Micro Crystalline Cellulose	0.566±0.86	0.566±0.86	0.566±0.89
7	Drug + Glyceryl monostearate	0.558±0.86	0.558±0.89	0.558±0.87
8	Drug + Mannitol	0.616±0.63	0.616±0.61	0.616±0.61
9	Drug + Magnesium Sterate	0.583±0.71	0.583±0.71	0.583±0.72
10	Drug + Talc	0.591±0.52	0.591±0.50	0.591±0.55

Determination of various flow properties:

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Bulk density, **Tapped density**, **Carr's index**,**Hausner's ratio**, **Angle of repose**

The bulk density, tapped density, Carr's index, Hausner's ratio and angle of repose of selected formulations were performed and shown in table no.-16. All the results show that the final formulations possess a good flow property[20].

Table No. 12: Various flow properties of formulation F1– F9:

Characterization	F1	F2	F3	F4	F5	F6	F7	F8	F9
Bulk density (g/ml)	1.35± 0.23	1.33± 0.14	1.31± 0.21	1.36± 0.40	1.37± 0.41	1.39± 0.28	1.37± 0.26	1.37± 0.44	1.36± 0.08
Tapped density (g/ml)	1.58± 0.14	1.60± 0.24	1.62± 0.23	1.58± 0.08	1.58± 0.19	1.58± 0.22	1.56± 0.16	1.58± 0.20	1.58± 0.26
Carr's index (%)	14.55	16.87	19.13	13.92	13.29	12.02	12.17	13.29	13.92
Hausner's ratio	1.17	1.20	1.23	1.16	1.15	1.13	1.13	1.15	1.16
Angle of Repose (^{0})	26 ^{0}	30 ^{0}	25 ^{0}	24 ^{0}	29 ^{0}	27 ^{0}	28 ^{0}	30 ^{0}	29 ^{0}

Data are represented as mean ±SD (n=3).

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FORMULATION AND DEVELOPMENT:

- **Formulation of FDTs:**

The different formulation of Cimetidine FDTs were prepared by direct compression method using fenugreek gum as a natural super disintegrants, Cimetidine were compared with various standard synthetic super disintegrants like SSG, Croscarmellose Sodium. The tablets were prepared.

- **Evaluation of Fast Dissolving Tablets:**

The various physicochemical properties were evaluated like thickness, hardness, weight variation, friability, drug content, disintegration time, wetting time and the results of the study were shown in below table:

Table No.13: Weight Uniformity, Thickness, Hardness, and Percentage Friability and of Batch F1-F9

Batch	Weight Variation Mean ± SD	Thickness Mean ± SD	Hardness Mean ± SD	Friability Mean ± SD
F1	400.0±0.81	3.99±0.2	4.3±0.1	0.845±0.01
F2	401.1±0.26	3.98±0.1	4.2±0.1	0.704±0.01
F3	400.1±0.39	3.99±0.2	4.0±0.15	0.561±0.02
F4	398.4±0.89	3.98±0.01	4.3±0.15	0.702±0.1
F5	398.6±0.93	3.98±0.02	4.6±0.1	0.571±0.02
F6	400.1±0.32	3.99±0.6	4.2±0.15	0.568±0.01
F7	400.1±0.29	3.98±0.2	4.3±0.1	0.842±0.02
F8	399.1±0.43	3.99±0.2	4.2±0.05	0.560±0.02
F9	399.6±0.28	3.98±0.2	4.5±0.05	0.835±0.01

Table No. 14: Wetting time, Drug Content Uniformity, Water Absorption Ratio, Disintegration Time and In-vitro dissolution of Batch F1-F9.

Batch	Wetting time (Sec)±SD	(%) Drug Content Uniformity ±SD	Water Absorption Ratio (%)	Disintegration time (sec)±SD
F1	33±1	99.23±0.53	66.10±0.25	41±3
F2	25±2	99.34±0.44	61.15±0.90	32±2

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F3	15±1	99.64±0.24	63.00±0.19	21±3
F4	46±2	99.56±0.14	69.70±0.20	51±2
F5	35±1	99.05±0.65	66.65±1.01	43±3
F6	23±1	98.62±0.61	62.30±0.90	31±1
F7	41±3	99.23±0.40	70.00±0.32	47±2
F8	30±2	99.11±0.56	66.10±0.20	36±3
F9	22±3	99.17±0.26	62.00±0.30	27±3

All value expressed in Standard deviation (n=3)

In-vitro drug release study for fast dissolving tablet:

The percentage drug release from formulations F1 to F9 was found to be more than 95% drug within 25 minutes and drug release of marketed formulation was found to be 70.8% within 25 minutes.

Table-No. 15: Percentage drug release data of F1 to F9 formulation of Fast dissolving tablets

S. No.	Time (in min)	% Drug Release data									
		M.F	F1	F2	F3	F4	F5	F6	F7	F8	F9
1.	0	0	0	0	0	0	0	0	0	0	0
2.	1	5.8	11.67	12.4	14.54	12.95	16.62	15.01	13.56	14.55	17.25
3.	2	12.3	22.25	24.55	27.01	24.65	20.08	27.86	22.45	26.42	27.91
4.	3	24.5	34.93	36.42	38.94	36.82	32.25	30.21	34.56	37.14	35.65
5.	5	36.7	45.55	47.14	50.57	47.91	44.56	42.54	47.95	49.95	50.15
6.	10	50.4	67.5	69.95	72.98	59.98	67.98	54.99	59.78	54.17	66.45
7.	15	57.8	72.45	74.17	82.52	71.54	79.78	76.98	66.66	73.02	81.26
8.	20	62.4	79.45	83.02	88.24	79.56	86.56	89.84	75.84	86.23	86.21
9.	25	70.8	81.21	90.23	98.05	85.23	90.34	93.29	86.01	91.01	94.54

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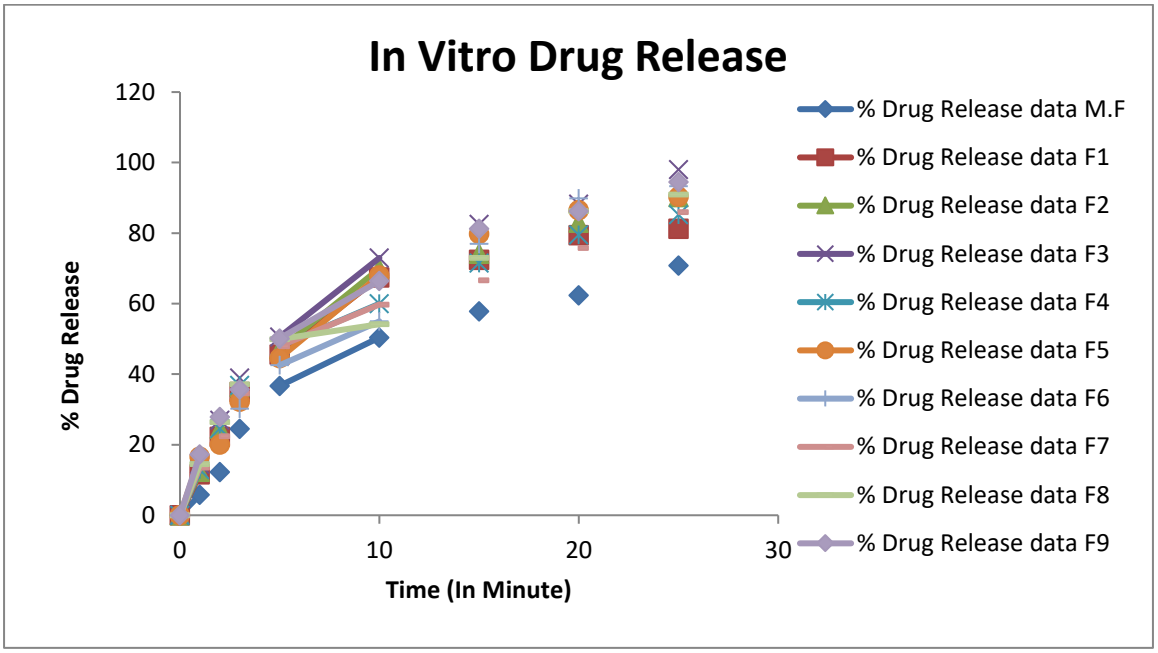

Figure 16: Percentage Drug Release from Fast dissolving tablets Formulation.

Stability studies: The stability studies F-3 Formulation were carried out for a period of 1 month in the stability chamber. The tablet were stored under the following condition as prescribed by the ICH guidelines (40^0C±2^0Cand 75±5%RH, Q1C).The tablet were withdrawn periodically with an interval of 30 days and analyzed for Weight variation, Hardness, Disintegration, Wetting time, Drug contents etc. Results are presented in table no. 17.

Table No. 17: Stability study for fast dissolving tablet of Formulation batch (F-3).

S.No.	Parameter	0 days	15 days	30 day	Result
1.	Weight Uniformity	400.1±0.32	400.1±0.39	400.1±0.41	No change
2.	Hardness	4.0±0.25	4.0±0.16	4.0±0.15	No change
3.	Drug content	99.64±0.34	99.64±0.24	99.62±0.22	Some change
4.	Wetting time	15±12	15±11	15±17	No change
5.	Disintegration	21±43	21±02	21±08	No change

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Conclusion

The present study was carried out in order to develop fast dissolving drug delivery system of Cimetidine using hibiscus rosa Sinesis mucilage as a natural superdisintegrants. Fast dissolving tablet are successfully developed for the delivery of drugs.

Oral is the most preferred route of drug administration, but is not suitable for the patients with dysphagia. To overcome this problem orodispersible tablets is one of the famous technological innovation in the contract manufacturing and pharmaceutical field. Taste masking and taste assessment are the two main factors taken into consideration while formulating ODTs as they disintegrate and/ or dissolves in oral cavity. Taste masking in addition is related to patient compliance. Patient compliance is particularly important in pediatrics, geriatric and long drug therapy patients.

The Hibiscus rosa Sinesis mucilage was extracted and evaluated for the physicochemical characterization of Hibiscus rosa Sinesis mucilage.

It can be concluded that Cimetidine with Hibiscus rosa Sinesis mucilage as a natural super disintegrants shows promising result of solubility and in vitro drug release of FDT of Cimetidine.

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