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Title- Comparative Study Of Natural Superdisintegrants And Synthetic Superdisintegrants On Table Properties

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Abstract

This study aims to compare the disintegration properties of natural and synthetic superdisintegrants in mouth-dissolving tablet formulations. The main goal is to determine which superdisintegrant, natural or synthetic, shows better disintegration properties. The study used a mouth-dissolving tablet of rizatriptan benzoate, a novel anti-migraine medication, to create oral dosage forms (ODFs) for migraine treatment. The superdisintegrants used were hibiscus rosa sinensis mucilage, dehydrated banana powder, and crospovidone.

The extraction of hibiscus rosa sinensis mucilage and dehydrated banana powder was done by cleaning, grinding, and boiling the leaves. Dehydrated banana powder was extracted by crushing whole bananas into a paste with citric acid and drying them at 50°C. The tablets were then formulated using 2%, 4%, and 6% of these superdisintegrants, along with acacia as a binder, lactose monohydrate as a diluent, magnesium stearate as a flow property enhancer, and saccharin as a sweetening agent.

The disintegration time of the tablets decreased with an increase in superdisintegrant concentration. The formulations prepared using natural superdisintegrants showed faster disintegration than synthetic superdisintegrants. The F3 formulation, which contained dehydrated banana powder at a 6% concentration, showed a 45-second disintegration time, less than other formulations.

The drug content of all formulations was determined by UV-visible spectroscopy, and the drug content of rizatriptan benzoate was within the Indian Pharmacopeia limit. In an in vitro dissolution study, Formulation F3, which contained dehydrated banana powder at a 6% concentration, showed the best drug release.

Natural superdisintegrants Hibiscus rosa sinensis mucilage and dehydrated banana powder showed better disintegration properties than synthetic superdisintegrants like crospovidone. These natural agents are preferred over synthetic substances due to their cost, availability, non- irritating nature, and biodegradability.

Keywords: Dehydrated banana powder, *Hibiscus rosa sinensis* mucilage, Natural Superdisintegrants, Synthetic Superdisintegrants, Mouth dissolving tablet, Rizatriptan benzoate.

Introduction

In tablet formulations, disintegrating agents are substances that help the compacted mass dissolve into the active ingredients. They enhance binder efficiency by resisting compressional forces. To enhance the disintegration processes, "superdisintegrants" have been developed recently. Rather than absorbing large amounts of water, these super-absorbing materials swell quickly, weakening the structural integrity of disintegrable solid dosage forms (Gupta, Mittal and Jha, 2011).

A mouth dissolving tablet is one that can be taken without chewing or water because it dissolves rapidly in saliva in a matter of seconds. In the oral cavity, a mouth dissolving tablet typically dissolves in 15 to 3 minutes. A few super disintegrates and taste masking agents are included in the majority of MDTs (Patil, Gujarathi and Rane, 2014) (Konapure *et al.*, 2011) Tablets designed for fast dissolving have to dissolve or disintegrate in less than a minute (Garg and Gupta, 2013). Compared to conventional tablets, mouth-dispensing tablets exhibit superior bioavailability, efficacy, and biopharmaceutical properties, as well as improved patient compliance and acceptance (Joshi, Garud and Washim, 2020).

Mechanism of Superdisintegrants:

1) **Swelling**: Disintegrant particles swell and a swelling force form when they come into contact with the right liquid, breaking up the matrix.
2) **Wicking**: Tablet porosity makes gaps that allow liquid to seep in. When the tablet is submerged in the right aqueous medium, the medium seeps into the tablet and replaces the air adsorbed on the particles, causing the tablet to break into fine particles and weakening the intermolecular bond (Konapure *et al.*, 2011).
3) **Deformation Recovery:** The disintegrant particles undergo shape distortion during compression and return to their original form when wet, according to the deformation recovery theory. This causes the distorted particles to enlarge, which ultimately causes the tablet to disintegrate.

Enzymatic reaction: Enzymes in the body serve as disintegrants as well. By preventing the binder from binding, these enzymes facilitate disintegration (Gupta, Mittal and Jha, 2011).

Types of Superdisintegrants:

1. Natural Superdisintegrants:

The use of natural gums and mucilage's as gelling agents, granulating agents, suspending agents, disintegrants, and stabilizers in the pharmaceutical industry is growing because to its accessibility, affordability, soothing properties, and environmental friendliness. They are able to undergo chemical transformations (Rashid *et al.,* 2008). Plant-based goods are more affordable, environmentally friendly, biocompatible, and renewable than synthetic ones. The two primary topics of study for natural polymers with disintegrant action are proteins and polysaccharides (Pahwa and Gupta, 2011).

Hibiscus rosa-sinensis Linn. Mucilage:

Hibiscus rosa sinensis is a superdisintegrants plant belonging to the Malvaceae family. It is also referred to as the shoe-flower plant. β-rosasterol, malvate, methyl sterculate are all present in its mucilage. Calcium, fibres, protein, fat, carbohydrates, and carotene are all present in the leaves. D-galactouronic acid, and L-rhamnose are all present in the mucilage. It is anticipated that the mucilage yield will be 17%. Studies on toxicology and preformulation are being carried out to ascertain its suitability and safety as a disintegrating agent (Sharma, Arora and Ray, 2020).

Dehydrated Banana Powder (DBP):

Bananas, grown in 120 countries, are a common fruit in Southeast Asia. India is the world's top producer, accounting for most of the output in 2012-2013. Banana powder can be made using various drying methods, such as tray drying, oven drying, and multifunctional tray drying. High-quality banana powder is created by soaking it in a 1:1 lemon solution, reducing moisture content, drying time, and energy consumption. Nutrients, colour, flavour, and texture are considered for optimal consistency (Nagar *et al.*, 2011).

Synthetic superdisintegrants-

A group of super disintegrants including cross carmellose sodium starch glycolate most of these alleviate most of these problems. Use of the super disintegrates in fast dispersible tablets is possible as tablet shows optimum Physical properties (Kumar *et al.,* 2009).

Crospovidone:

Unlike other superdisintegrants that primarily rely on swelling, crospovidone disintegrates by a combination of wicking and swelling. For crospovidone a high crosslink density results in rapid swelling in water without gelling. It has been observed that the granular and highly porous

nature of crospovidone particles promotes fast disintegration of the particles and helps liquids wick into the tablet. Greater sizes of particles cause them to break down faster than smaller ones. Crospovidone disintegrants are very compressible materials due to their unique particle shape. There are two particle sizes available for the product: Polyplasdone-10 and XL versions of the drug (Chauhan and Jethva, 2016).

Migraine:

One of the ten most incapacitating conditions in the world, migraines are still underdiagnosed and undertreated despite recent advancements in treatment. It is estimated that American employers lose $US 13 billion annually to disability resulting from migraine headaches and their accompanying symptoms, owing to missed work days and decreased productivity. According to epidemiological studies, more than 90% of migraine patients report having felt queasy during a migraine attack.

In a similar vein, the majority (nearly70%) have puked at some point during an attack in order to avoid consuming too much liquid. Additionally, patients with migraines have a significant decline in their functional abilities, so receiving immediate assistance would be beneficial for them (Alam, Parvej and Sharma, 2012).

Treatment of Migraine:

Rizatriptan Benzoate:

Rizatriptan benzoate is a potent, selective 5-hydroxytryptamine1B/1D receptor agonist that is considered more effective than traditional triptans for treating acute migraine attacks. Its bioavailability is about 45%, superior to 14-17% of sumatriptan. Its fast onset of action within one hour provides immediate relief from migraines, benefiting migraine sufferers who have reduced functional ability. Rizatriptan benzoate is more effective than traditional triptans due to its potency and selective nature. (Keny, Desouza and Lourenco, 2010) (Bhupinder and Sarita, 2012).

MATERIALS AND METHODS

Materials:

Rizatriptan Benzoate received as a gift sample from Glenmark Pharmaceuticals, Mumbai. Crospovidone, Lactose Monohydrate were purchased from Vishal chem Pvt Ltd., Hibiscus Rosa sinensis Leaves and Banana collected foam Malegaon Nursery. All other chemicals used were of analytical grade and were used without further purification.

Methods

Isolation and Characterization of Mucilage form *Hibiscus rosa-sinensis*

To get rid of any dirt or debris, the freshly harvested hibiscus rosa-sinensis Linn leaves were cleaned with water. In order to allow the mucilage to fully release into the water, the leaves were ground into powder, soaked in water for five to six hours, boiled for thirty minutes, and then allowed to stand for an hour. A multilayer cloth bag made of muslin was used to extract the mucilage and marc from the mixture. The mucilage was precipitated by adding three times the volume of the filtrate to acetone. After the mucilage was separated, it was dried in an oven at a temperature below fifty degrees Celsius. After that, it was gathered, ground, and kept in desiccators at room temperature until it was required once more. Particle size, swelling index, angle of repose, percentage yield, and other physicochemical properties of dried powdered mucilage were reported.

Isolation and Characterization of Dehydrated Banana Powder

We gathered fresh, whole bananas, gave them a thorough cleaning, and then measured. In five minutes, the bananas with peeled skins were dipped in ethanol. Following the weighing and mashing of the bananas into a paste, 2-3% of citric acid was added to the paste in order to remove any sticky consistency. Processing and centrifugation were then used to separate the water. A hot air oven was used to dry the compressed material at 50°C. The dried materials were ground and sieved (#60) to produce a fine powder. With the prepared banana powder, various physical, phytochemical, and physicochemical tests can be carried out.

Preformulation studies

I. Determination of organoleptic properties

- Colour: A tiny amount of powdered Rizatriptan Benzoate and Paracetamol were taken in butter paper and examined in an area with good lighting.
- Taste and odour: Rizatriptan Benzoate and Paracetamol were used in very small amounts to help with tongue-based taste perception and olfactory detection.

II. U.V. spectroscopic method

Determination λ_{max} of Rizatriptan Benzoate in Water:

Dissolve 10 mg Rizatriptan Benzoate API in 100 ml water (100 ppm stock solution) 1ml of above solution was taken and make up volume up to 10 ml using water (10ppm), then absorbance of above solutions was taken using U V visible spectrophotometer. The solutions were scanned in the range of 200-400 nm.

III. Determination of stranded calibration curve

- **Preparation of stranded calibration curve of Rizatriptan Benzoate in water**

Dissolve 10 mg Rizatriptan Benzoate API in 100 ml water (100 ppm stock solution) to obtain a series of dilutions containing 2, 4, 6, 8, 10 ppm respectively. In the next step, the absorbance of the above dilutions was taken using a double-beam UV visible spectrophotometer by water as a blank. Then graph was plotted by taking concentration on the X-axis and absorbance on the Y-axis which gives straight line linearity of the standard curve, the curve was assessed from the square root of the correlation coefficient.

IV. Differential scanning colorimetry

Thermal properties of pure drug were analyzed by Differential scanning colorimeter.

V. Determination of melting point

The melting point of a pure drug can be determined using a Thiele tube filled with liquid paraffin. The tube is attached to a lattice or ring stand, filled with a small amount of sample, and sealed. The capillary is then attached to a thermometer and secured using a rubber band. The tube is submerged in the thermometer, gradually heated, and the temperature at which the material starts to melt is monitored.

VI. Compatibility studies:

FTIR spectroscopy

FTIR spectroscopy was carried out to check the drug purity and compatibility between the drug and the excipient. Infrared spectroscopy was conducted using Jasco FTIR- 4600 and the spectrum was recorded in the region 400–4000 cm− 1.

The sample pure drugs, excipients, drug and excipient mixture was prepared and analyzed using Jasco FTIR- 4600 and the spectrum was recorded in the region 400–4000 cm− 1.

Formulation design

Formulation of Mouth Dissolving tablets

Table No.1: Formulation Table of Mouth Dissolving tablets using Natural and synthetic Superdisintegrants

Ingredients	**Role**	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**
Rizatriptan Benzoate	API	10	10	10	10	10	10	10	10	10
Dehydrated Banana Powder	Superdisintegrant	2%	4%	6%						
Hibiscus Rosa Sinensis	Superdisintegrant				2%	4%	6%			
Crospovidone	Superdisintegrants							2%	4%	6%
Acacia	Binder	3	3	3	3	3	3	3	3	3
Saccharin	Sweetening Agent	3	3	3	3	3	3	3	3	3
Magnesium	Lubricant	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Lactose Mono Hydrate	Diluent	129.5	129.5	123.5	129.5	126.5	123.5	129.5	126.5	123.5
Average Wt. (mg)		150	150	150	150	150	150	150	150	150

Preparation of Mouth Dissolving:

By using the direct compression method, the MDTs for rizatriptan benzoate were created. All ingredients, with the exception of magnesium stearate, were precisely measured and homogeneously mixed using geometric dilution after being passed through mesh #40. Finally, magnesium stearate was added and thoroughly mixed with the lubricant. An apparatus for punching tablets with a punch and die set compressed the combined material directly.

Same Procedure as follow as for *Hibiscus Rosa-sinensis* Mucilage, Dehydrated Banana Powder and Risperidone use as superdisintegrants.

Precompression studies of the Blend

1. **Bulk Density** (Lieberman, Rieger and Banker, 2019) (Szumilo *et al.*, 2017) (Kore, Namade and Gaikwad, 2018)

Weight quantity of Rizatriptan Benzoate and other ingredients and was transferred into 50 ml measuring cylinder, volume occupied by blend without tapping was measured.

$Db = M / V0$

Where, Db= Bulk density

M= Mass of Blend

V0= Untapped volume

2. **Tapped density:** (Lieberman, Rieger and Banker, 2019) (Szumilo *et al.*, 2017) (Kore, Namade and Gaikwad, 2018)

Weight quantity of blend and was transferred into 50 ml measuring cylinder, volume occupied by granules after tapping was measured. Follow same procedure to determine bulk density of blend.

$Dt = M/V_1$

Where, Dt= Tapped density

M= Mass of blend

V_1= Tapped volume

3. **Compressibility index:** (Lieberman, Rieger and Banker, 2019) (Szumilo *et al.*, 2017) (Kore, Namade and Gaikwad, 2018)

The compressibility index of blend was determined by Carr's Compressibility index.

Carr's index (%) = Tapped density- Bulk density / Tapped density × 10

4. **Determination of Hausner's ratio:** (Lieberman, Rieger and Banker, 2019) (Szumilo *et al.*, 2017) (Kore, Namade and Gaikwad, 2018)
   It was determined by the ratio of tapped density and bulk density.
   Hausner's ratio = V0/V1
   Where, Vo = Tapped density
   V1= Bulk density
5. **Angle of repose:** (Lieberman, Rieger and Banker, 2019) (Szumilo *et al.*, 2017) (Kore, Namade and Gaikwad, 2018)
   Using the funnel method, the blend angle of repose was determined. Until a pile formed, blend was fed through the funnel. On a burette stand, the funnel was fixed at a height of 2.5 cm. When the pile came into contact with the funnel tip, it stopped and a circle was drawn across it. An equation was used to determine the average value after the process was carried out three times.
   Tan θ= h/r or θ= tan-1h/r
   Where h and r are the height and radius of cone respectively.

Evaluation of Mouth Dissolving Tablets

a) Physical appearance

In physical appearance tablet was visually evaluated for color, shape and appearance.

b) Hardness

The degree of hardness that tablets possess dictates their ability to withstand breakage or damage during handling, storage, and transportation before being utilized. To calculate the hardness, kg/cm2 was utilized. Five randomly chosen tablets were inspected for hardness. The findings were recorded after averaging five tablet determinations (Lachman, Lieberman and Kanig, 1985) (Lieberman, Rieger and Banker, 2019) (Makwana *et al.*, 2015) (Kushwaha *et al.*, 2022).

c) Tablet thickness

For tablets to be the same size throughout, the thickness of the tablet matters. Vernier Calipers were used to measure thickness. Ten tablets of each formulation were checked for thickness in order to determine it. Metric and imperial scales are found on a vernier caliper. Prior to reading the "hundredths of mm" of the imperial scale, read the main metric scale. As soon as the lines match the primary metric scale, count the number of divisions. An additional 0.02 is added to

the number on the imperial scale. Once the number from the imperial scale is added to the primary metric scale, the final measurement is obtained (Lachman, Lieberman and Kanig, 1985) (Lieberman, Rieger and Banker, 2019) (Makwana *et al.*, 2015) (Kushwaha *et al.*, 2022).

d) Weight variation test

To investigate variations in weight Each batch of 20 tablets had its average weight determined by electronically balancing the tablets. Nobody's weight differs more than twice from the table's average weight, and nobody's weight differs more than twice that percentage (Lachman, Lieberman and Kanig, 1985) (Lieberman, Rieger and Banker, 2019) (Makwana *et al.*, 2015) (Kushwaha *et al.*, 2022) (*Indian Pharmacopeia*. 9th edn, 2022).

e) Friability test

Friability is the term used to describe the weight loss of tablets as a result of surface fines being removed, which suggests a lack of cohesiveness among the ingredients. A total of ten tablets were weighed, put inside a Roche friability, taken out, the fines removed, and then weighed once more. Utilizing a formula, the percentage friability was determined. For tablets, IP states that a maximum weight loss of 1.0% is acceptable. % Friability = Initial weight - Final weight/Initial weight × 100 is the formula (Lachman, Lieberman and Kanig, 1985) (Lieberman, Rieger and Banker, 2019) (Makwana *et al.*, 2015) (Kushwaha *et al.*, 2022) (*Indian Pharmacopeia*. 9th edn, 2022).

f) Content uniformity test (Assay):

For assay the drug content in each formulation was determined by triturating 20 tablets and powder equivalent to 10 mg was added in 5-7 ml of 0.1N Sodium Hydroxide followed by sonication for 30 minutes. The solution was filtered through Whatman filter paper, the filtrate diluted suitably and the absorbance of resultant solution was measured by using Shimadzu1700 Pharma spec UV-VISIBLE spectrophotometer at 227 nm using 0.1N as Sodium Hydroxide blank. For content uniformity 5 tablets were individually weighed and powdered. The powder equivalent to 10 mg was weighed and amount of Rizatriptan Benzoate in each formulation was determined by procedure said in assay.

g) Disintegration test

The disintegration test was conducted using a disintegration test apparatus and IP procedure. One tablet or capsule was introduced into each tube, and a disc was added if directed in the

general monograph. The assembly was suspended in a liquid beaker, and the apparatus was operated for a specified time. The tablets or capsules passed the test if all disintegrated. If one or two failed, the test was repeated on 12 additional tablets or capsules. If the tablets or capsules adhered to the disc and the preparation failed to comply, the test was repeated omitting the disc. The preparation complied with the test if all tablets or capsules in the repeat test disintegrated.

h) Dissolution test (Lachman, Lieberman and Kanig, 1985) (Lieberman, Rieger and Banker, 2019) (Makwana *et al.*, 2015) (Kushwaha *et al.*, 2022) (*Indian Pharmacopeia*. 9th edn, 2022).:

Dissolution test was performed using dissolution test apparatus II.

Dissolution of Mouth dissolving tablet was performed in buffer stage.

After filling the vessel with 900 ml of water, put the apparatus together. The dissolving medium should be warmed to 36.5 to 37.5 degrees. Put one dosage unit inside the device and run it at 100 revolutions per minute. Withdraw the 10 ml sample after 5 minutes for 30 minutes and filter the sample using Whatman filter paper. after the withdrawal of the sample add 10 ml fresh water to the dissolution medium to maintain the sink. perform analysis of samples using U-V visible spectroscopy.

RESULTS AND DISCUSSIONS

Phytochemical Characterization of Rizatriptan Benzoate:

Table No.2: Organoleptic Properties Rizatriptan Benzoate

Sr. No.	Properties	Observation
1.	Colour	White
2.	Odour	Odourless
3.	Taste	Very Bitter
4.	Appearance	Amorphous

Phytochemical Characterization of Dehydrated Banana Powder:

The test indicated presence of carbohydrate, proteins, saponin glycoside, alkaloids and tannins

Characterization of Dehydrated banana powder

Table No. 3: Organoleptic Properties Rizatriptan Benzoate

Sr. No.	Properties	Observation
1.	Colour	White Yellowish
2.	Odour	Sweet
3.	Taste	Irregular
4.	Appearance	Yellowish Powder
5.	Solubility	Slightly soluble in water, sodium hydroxide solution Completely soluble in ethanol
6.	pH	7.1

Characterization of Mucilage form Hibiscus rosa-sinensis

Table No.4: Organoleptic Properties of *Hibiscus rosa-sinensis* mucilage

Sr. No.	Properties	Observation
1.	Colour	Green
2.	Odour	Characteristics
3.	Taste	Mucilaginous
4.	Appearance	Greenish Powder
5.	Solubility	Slowly soluble in water to produce viscous solution
6.	Density of liquid	1.058±0.018
7.	pH	7.1±0.111

Preformulation Study

Identification Test:

Melting Point:

The MP of Rizatriptan Benzoate was found to be 182-184 °C.

Determination λ_{max} of Rizatriptan Benzoate (in water):

λ_{max} of Rizatriptan Benzoate was determine using double beam UV spectrophotometer. The λ_{max} of Rizatriptan Benzoate in water was found to be 224.6 nm and having actual value 225 nm.

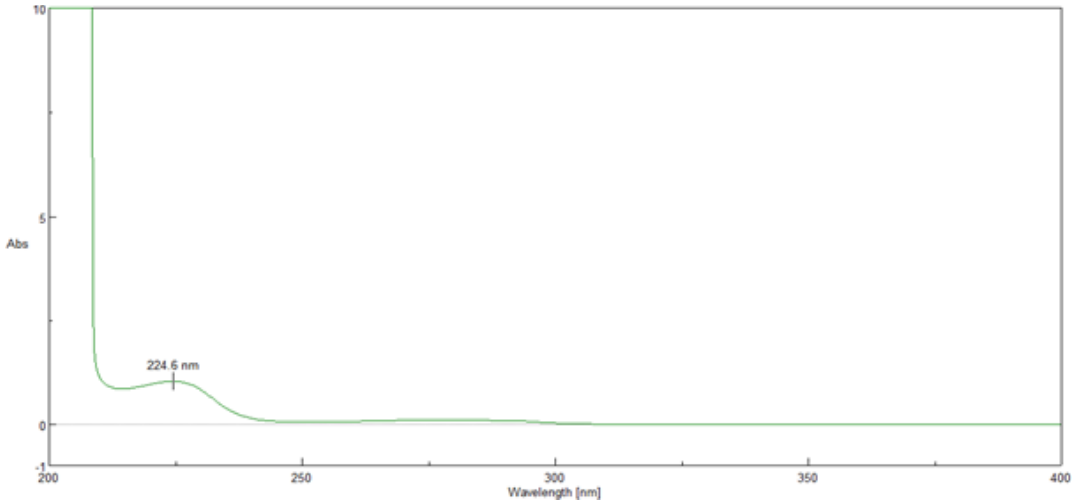

Figure No.1: λ_{max} of Rizatriptan Benzoate (in water)

Determination Calibration Curve of RB (in water):

Calibration Curve of RB was determine using double beam UV spectrophotometer.

Table No.5: Calibration Curve of Rizatriptan Benzoate (in water)

Concentration	**Absorbance**
2	0.308
4	0.652
6	1.055
8	1.382
10	1.825

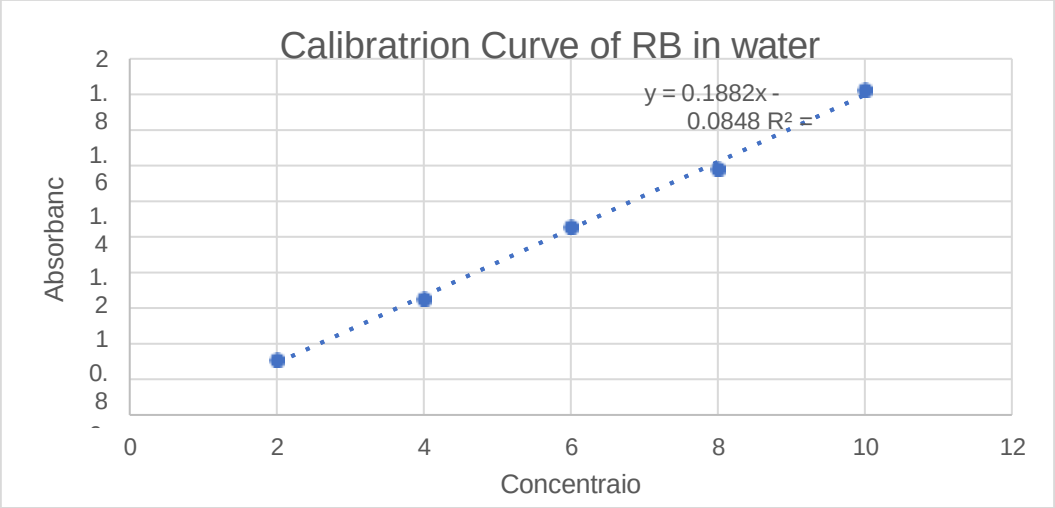

Figure No.2: Calibration Curve of RB (in water)

FTIR spectra of Dehydrated Banana powder

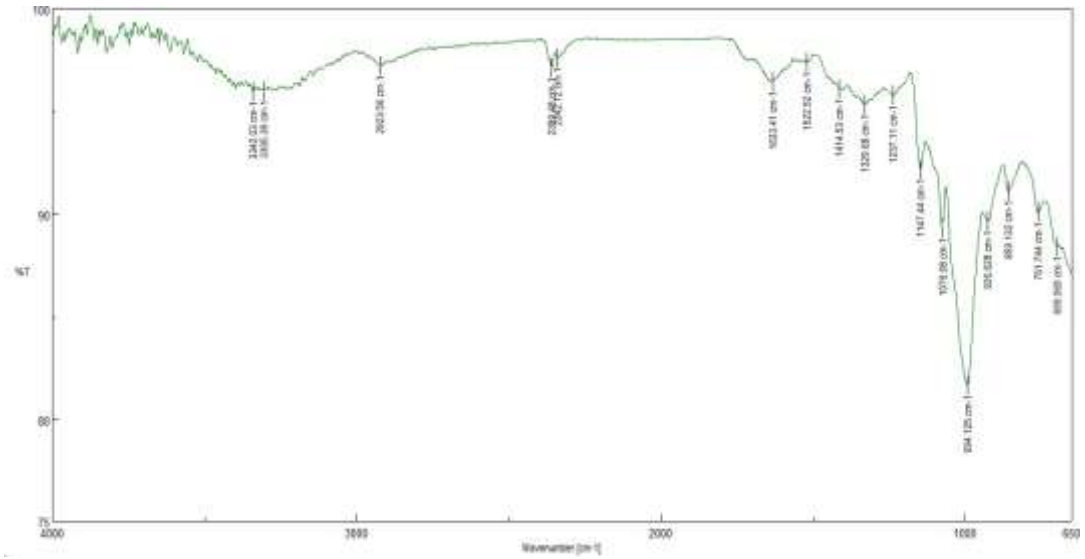

Figure No. 3: FTIR spectra of Dehydrated Banana powder

FTIR spectra of *Hibiscus rosa-sinensis mucilage*

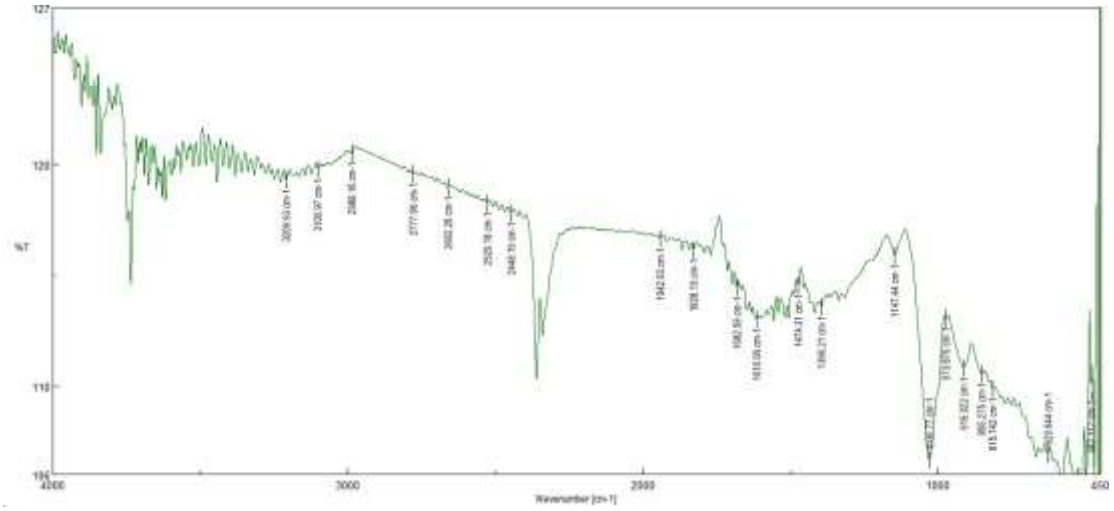

Figure No. 4: FTIR spectra of *Hibiscus rosa-sinensis* mucilage

Differential Scanning Calorimetry (DSC) Study

DSC Study of pure Drug

Figure No.5 shows DSC thermogram of Rizatriptan benzoate. It shows the melting Peak at 183.38^{0}C (nearby the melting point of Rizatriptan Benzoate), onset at 281.12^{0}C and end set at 286.83^{0}C. Further sharp peak indicates the crystalline nature of Rizatriptan benzoate.

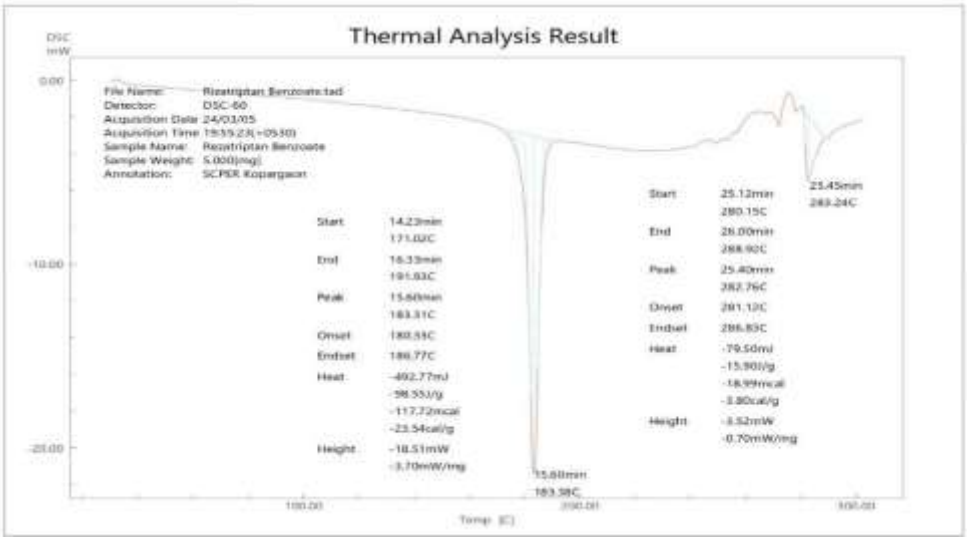

Figure No.5: DSC of Rizatriptan Benzoate

DSC can detect exothermic peaks associated with crystallization events, providing insights into the crystallization kinetics and behaviour of materials. The crystalline nature of a substance refers to how its molecules arrange themselves in a repeating pattern, forming a solid crystal lattice structure. This arrangement is influenced by various factors such as molecular shape, intermolecular forces, and environmental conditions like temperature and pressure.

Compatibility Study:

A. Rizatriptan Benzoate

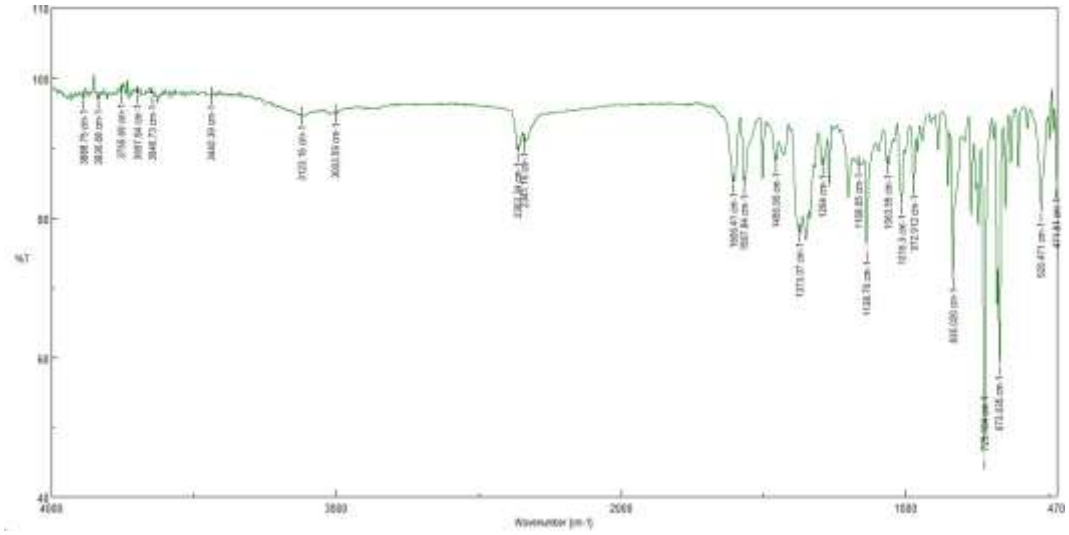

Figure No.6: FTIR spectra of Rizatriptan Benzoate

B. Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of Dehydrated banana powder and rizatriptan benzoate physical mixture.

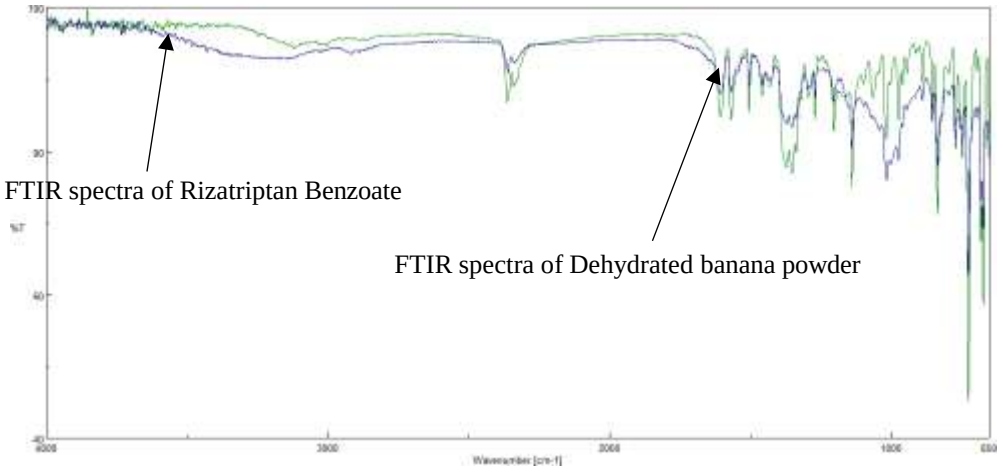

Figure No.7: Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of Dehydrated banana powder and rizatriptan benzoate physical mixture.

Figure No.7: Contains an overlay of Rizatriptan Benzoate FTIR spectra with the Rizatriptan benzoate and Dehydrated Banana Powder physical mixture, which shows that there is no change in bands and spectra, which indicates the absence of incompatibility between Rizatriptan benzoate and Dehydrated Banana Powder.

C. Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of *Hibiscus rosa-sinensis* mucilage and rizatriptan benzoate physical mixture.

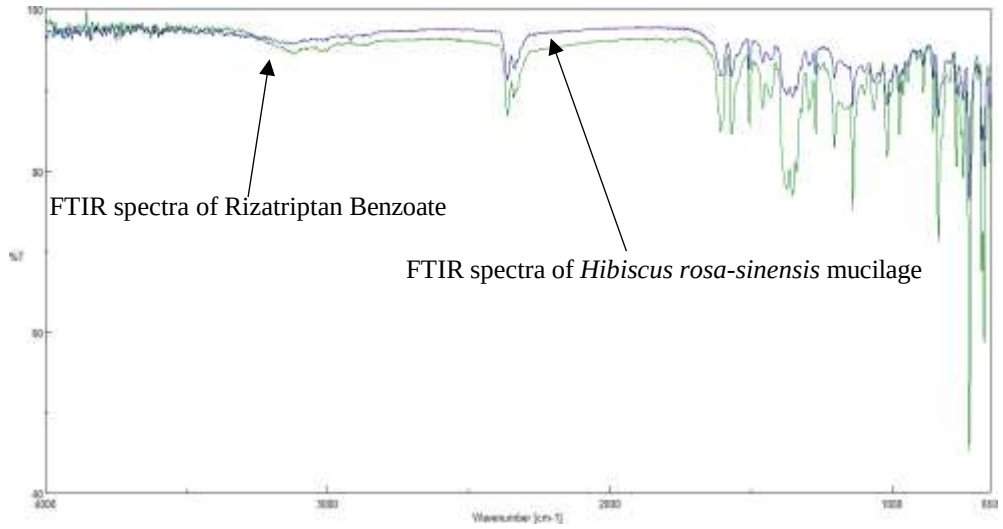

Figure No.8: Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of *Hibiscus rosa-sinensis* mucilage and rizatriptan benzoate physical mixture

Figure No.8 contains an overlay of Rizatriptan Benzoate FTIR spectra with the Rizatriptan benzoate and *Hibiscus rosa-sinensis* mucilage physical mixture, which shows that there is no change in bands and spectra, which indicates the absence of incompatibility between Rizatriptan benzoate and *Hibiscus rosa-sinensis* mucilage.

D. Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of crospovidone and rizatriptan benzoate physical mixture.

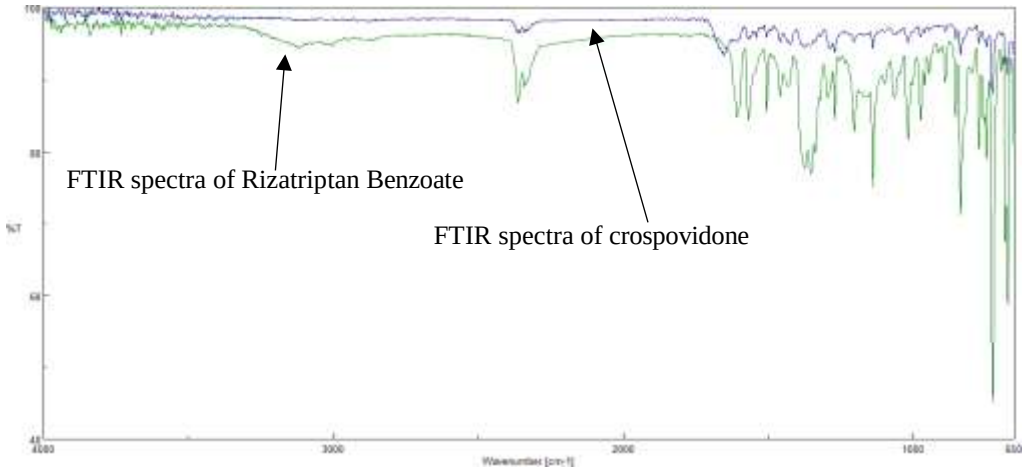

Figure No.9: Overlay of Rizatriptan Benzoate FTIR spectra with FTIR spectra of Crospovidone and rizatriptan benzoate physical mixture.

Figure No.9 contains an overlay of Rizatriptan Benzoate FTIR spectra with the Rizatriptan benzoate and crospovidone physical mixture, which shows that there is no change in bands and spectra, which indicates the absence of incompatibility between Rizatriptan benzoate and crospovidone.

Pre-Compression Parameters of Formulation batches

Table No.6: Results of precompression parameters of the formulation batches

Batch No.	**Pre-Compression Parameters**				
	Bulk Density (gm/ml) ± SD	**Tapped Density (gm/cc) ± SD**	**Angle of Repose ± SD**	**Compressibility Index (%) ± SD**	**Hausner's ratio ± SD**
F1	0.42 ± 0.0816	0.47 ± 0.0816	25.20 ± 1.2472	10.63 ± 0.8688	1.11 ± 1.2580
F2	0.43 ± 0.0124	0.47 ± 0.0816	28.79 ± 0.8164	8.51 ± 1.0230	1.09 ± 1.2559
F3	0.42 ± 0.0124	0.46 ± 0.0163	29.18 ± 0.8164	8.69 ± 0.8789	1.09 ± 1.2559
F4	0.42 ± 0.0124	0.48 ± 0.0816	27.45 ± 0.8164	12.5 ± 0.8498	1.14 ± 0.4421
F5	0.44 ± 0.0163	0.49 ± 0.0816	25.35 ± 0.8164	10.20 ± 0.8219	1.11 ± 1.2580
F6	0.40 ± 0.0124	0.45 ± 0.0816	31.50 ± 1.2472	11.11 ± 1.2384	1.25 ± 0.4249
F7	0.43 ± 0.0816	0.48 ± 0.0816	27.88 ± 1.2472	10.41 ± 1.6443	1.11 ± 0.4477
F8	0.46 ± 0.0816	0.49 ± 0.0816	28.41 ± 0.8164	6.52 ± 0.8525	1.06 ± 1.2528
F9	0.41 ± 0.0205	0.46 ± 0.0124	29.15 ± 0.8164	10.86 ± 0.8191	1.21 ± 1.2696

Mean ± SD (n = 3)

The study examined precompression properties of bulk powder, including bulk density, tapped density, angle of repose, compressibility index, and Hausner's ratio. Results showed good packing characteristics, a compressibility index below 15, excellent flow properties, and a range of 25° to 30° angle of repose. The Hausner's ratios ranged from 1.05-1.18, indicating excellent powder flow.

Evaluation of mouth dissolving tablets

Table No.7: Results of mouth dissolving tablets

Batch No.	**Thickness (mm) ± SD**	**Hardness (Kg/cm^2) ± SD**	**Friability (%) ± SD**
F1	3.64 ± 1.2265	2.54 ± 0.4086	0.31 ± 0.0081
F2	3.65 ± 0.8195	2.07 ± 0.6182	0.31 ± 0.0081
F3	3.64 ± 0.4421	2.59 ± 0.617	0.32 ± 0.0081
F4	3.64 ± 0.8191	2.15 ± 0.6141	0.33 ± 0.0124
F5	3.67 ± 0.8754	2.13 ± 0.6149	0.32 ± 0.0163
F6	3.62 ± 0.6154	2.54 ± 0.6203	0.32 ± 0.0081
F7	3.62 ± 0.8359	2.17 ± 0.8204	0.33 ± 0.0081
F8	3.65 ± 0.6407	2.63 ± 0.8187	0.31 ± 0.0124
F9	3.58 ± 0.4099	2.53 ± 0.6210	0.32 ± 0.0124

Mean ± SD (n = 3)

The results of the thickness, weight variation, and friability of tablets are shown in Table No. 7, which shows that the average hardness of fast dissolution is between 2.14 and 2.63. The average thickness of tablets is between 3.58 and 3.67. The friability of all batches is not more than 1%, which passes. All batches passed the weight variation test.

Weight variation (mg)

Table No.8: Average weight and limit of weight variation test for tablets as per IP

Formulation code	**Average weight of tablets (mg) ± SD**	**7.5% of Average weight (mg)**	**Limit (mg)**
F1	141.8 ± 0.8164	10.57	131.2 – 152.3
F2	141.9 ± 0.8178	10.64	131.1 – 152.5
F3	141.8 ± 0.6976	10.57	131.2 – 152.3
F4	141.7 ± 0.2054	10.62	131.0 – 152.3
F5	142 ± 0.8164	10.65	131.3 – 152.6
F6	141.9 ± 0.4496	10.64	131.1 – 152.5
F7	142.1 ± 0.4496	10.65	131.3 – 152.6
F8	141.8 ± 0.4320	10.57	131.2 – 152.3
F9	141.9 ± 0.9021	10.64	131.1 – 152.5

Disintegration time of Mouth Dissolving Tablets

Table No. 15: Disintegration time of Mouth Dissolving Tablets

Batch No.	Disintegration Time (in second) ± SD
F1	58 ± 0.816497
F2	51 ± 0.816497
F3	45 ± 0.816497
F4	83 ± 0.816497
F5	80 ± 0.816497
F6	73 ± 0.816497
F7	74 ± 0.816497
F8	69 ± 0.816497
F9	65 ± 0.816497

Mean ± SD (n = 3)

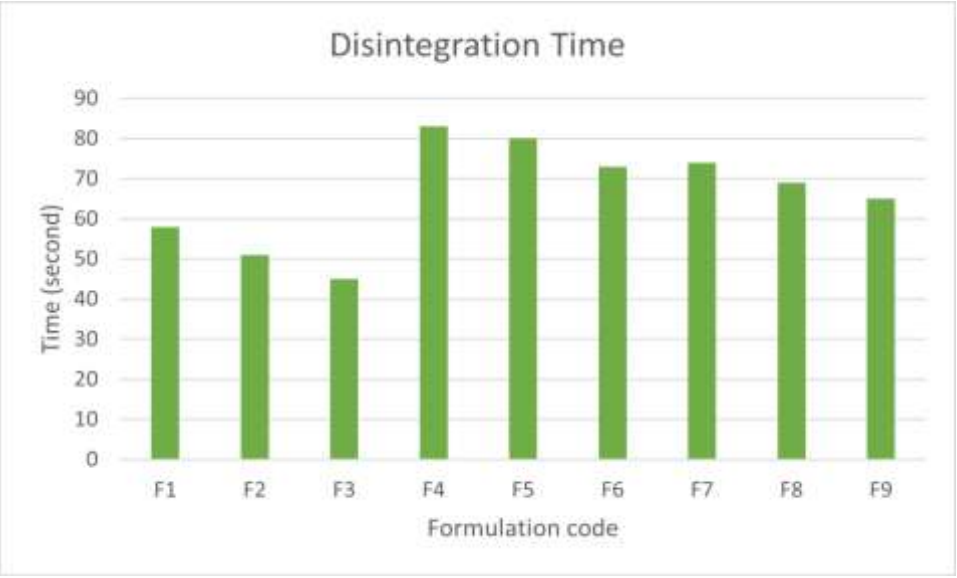

Figure No.10: Disintegration time of Mouth Dissolving Tablets

The formulation batches F1, F2, and F3 containing banana powder as a superdisintegrant show superdisintegration times of 58 seconds, 51 seconds, and 45 seconds, respectively. Also, the formulation batches F4, F5, and F6 containing *Hibiscus rosa-sinensis* mucilage show disintegration times of 83 seconds., 80 seconds., and 73 seconds., respectively. And also,

formulation batches F7, F8, and F9 containing Crospovidone show disintegration times of 74 seconds., 69 seconds., and 65 seconds., respectively. The above results show that the formulations F1, F2, and F3, which are formulated by using dehydrated banana powder as a superdisintegrant, show less disintegration time than the other formulations, which have *Hibiscus rosa-sinensis* mucilage and crospovidone superdisintegrants. Batch F3, which has a higher concentration of dehydrated banana powder than batch F1, and batch F2, show a 45-second disintegration time, which is less than the disintegration of F1 and F2. Hence, we conclude that the dehydrated banana powder has much greater disintegration properties than *Hibiscus rosa-sinensis* mucilage and crospovidone. Dehydrated banana powder is superior to *Hibiscus rosa-sinensis* mucilage and crospovidone.

Drug content of Mouth Dissolving tablet

Table No.9: Drug Content of Mouth Dissolving tablet

Formulation Code	**Drug content (%) ± SD**
F1	96.74 ± 0.4236
F2	98.22 ± 0.4290
F3	99.27 ± 0.4224
F4	98.37 ± 0.4128
F5	96.27 ± 0.4224
F6	98.87 ± 0.4224
F7	96.60 ± 0.4109
F8	96.74 ± 0.4236
F9	98.79 ± 0.4305

Mean ± SD (n = 3)

The content uniformity test of a mouth-dissolving tablet is conducted by using double-beam UV-visible spectroscopy. The percentage of drug content is shown in Table No.9. The drug content of Rizatriptan benzoate is NLT 95% and NMT 105%, as per the Indian Pharmacopeia. The above results show that the drug content of Rizatriptan benzoate in all batches is within the limit as per the Indian Pharmacopeia.

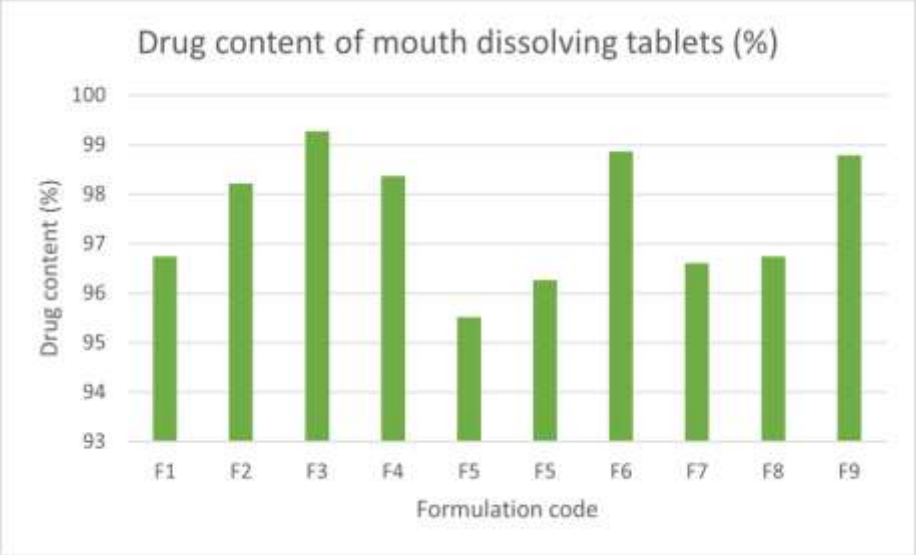

Figure No. 11: Drug Content of Mouth Dissolving tablet

In vitro dissolution test

Table No.10: In vitro drug release of Mouth dissolving tablets

	%CDR of Formulation batches								
Time	**F1±SD**	**F2± SD**	**F3± SD**	**F4± SD**	**F5± SD**	**F6± SD**	**F7± SD**	**F8± SD**	**F9± SD**
5	75.83± 0.4368	76.93± 0.4558	78.57± 0.4095	23.40± 0.4109	25.30± 0.4189	27.44± 0.4092	47.20± 0.4320	49.20± 0.4320	50.31± 0.4179
10	79.63± 0.4128	77.89± 0.4558	87.84± 0.4385	36.16± 0.4385	40± 0.8164	46.18± 0.4352	65.10± 0.4496	64.21± 0.4305	69.20± 0.4320
15	81.32± 0.4169	88.87± 0.4439	95.39± 0.4115	52.23± 0.4276	53.5± 0.4082	56.7± 0.4189	77.22± 0.4290	79.01± 0.4690	81.36± 0.4135
20	82.69± 0.4179	89.90± 0.4496	96.42± 0.4099	67.2± 0.4320	67.9± 0.4496	73.14± 0.4421	80.87± 0.4439	83.02± 0.4667	88.35± 0.4143
25	88.87± 0.4439	97.88± 0.4458	98.80± 0.4082	81.17± 0.4368	86.2± 0.4320	89.03± 0.4644	85.60± 0.4109	90.58± 0.4099	92.30± 0.4189
30	95.60± 0.4084	97.02± 0.4667	-	97.52± 0.4083	95.84± 0.4109	97.5± 0.4082	95.21± 0.4305	96.15± 0.4099	97.58± 0.4099

Mean ± SD (n = 3)

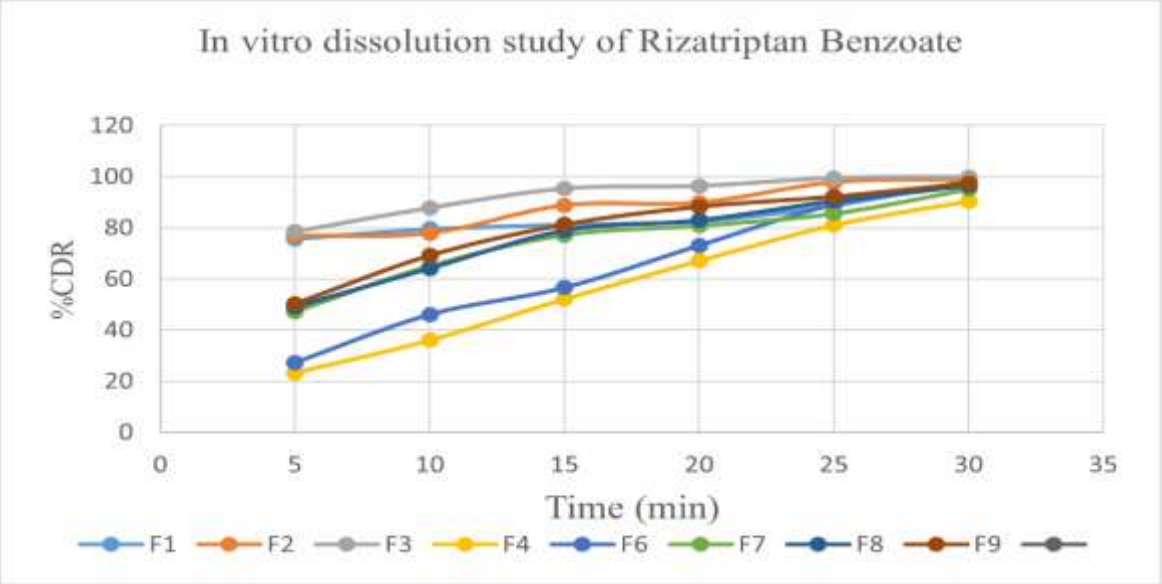

Figure No. 12: In vitro dissolution study Rizatriptan benzoate

The results of dissolution studies showed that as the concentration of superdisintegrant increases, drug release also increases. The formulations F1, F2, and F3 contain dehydrated banana powder and show 98.53% CDR, 99% CDR in 30 minutes, and 99.50% CDR in 25 minutes. F1, F2, and F3 show more than 80% drug release in 15 minutes. The formulation F3 batch, which contains a high concentration of dehydrated banana powder as a superdisintegrant, shows more than 80% drug release in 10 minutes. The formulations F4, F5, and F6 contain *Hibiscus rosa-sinensis* mucilage and show 90.52% CDR, 95.84% CDR, and 96.5% CDR in 30 minutes. The formulations F4, F5, and F6 show more than 80% drug release in 25 minutes. The formulations F7, F8, and F9 contain Crospovidone as a superdisintegrant and show 95.21% CDR, 96.58% CDR, and 97.58% CDR in 30 minutes. The formulations F7, F8, and F9 show more than 80% drug release in 20 minutes. From all the formulations, the F3 formulation, which contains dehydrated banana powder as a superdisintegrant, shows more effective drug release within 10 minutes; hence, we conclude that it shows the best disintegrating property and immediate drug release as compared to *Hibiscus rosa-sinensis* mucilage and crospovidone.

Conclusion

From the above comparative study conclude that the natural superdisintegrant used as a superdisintegrant in the preparation of mouth-dissolving tablets improves the tablet properties, such as disintegration time and dissolution rate, and improves patient compliance. The

formulation prepared using dehydrated banana powder as a superdisintegrant shows faster disintegration than synthetic superdisintegrant crospovidone. The F3 formulation, which contains dehydrated banana powder as a superdisintegrant at a concentration of 6%, shows a 45 ± 0.816497-second disintegration time, which is less than the disintegration time of other formulations. The in vitro dissolution study of the formulation done in water and was conducted for 30 minutes. Formulation F3, which contains dehydrated banana powder in 6% concentration, shows the best drug release. The F3 formulation shows more than 80% drug release in 10 minutes. This formulation is effectively producing their effect and dissolution characteristics, hence being chosen as the best formulation. The dehydrated banana powder shows better disintegration properties than *Hibiscus rosa sinensis* mucilage and crospovidone. These super-disintegrating agents are natural in origin and are preferred over synthetic substances because they are comparatively cheaper, abundantly available, non-irritating, nontoxic in nature, and biodegradable.

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