International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1004-1017 www.ijprajournal.com ISSN: 2249-7781

Formulation and Evaluation of Oral Disintegrating Tablets Containing Loratadine Using Natural Super Disintegrants (Ispaghula Mucilage Powder)

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Submitted: 12-01-2023 Accepted: 24-01-2023

ABSTRACT
The present study aimed at developing oral disintegrating tablets of loratadine containing natural superdisintegrants by a direct compression process such as ispaghula mucilage powder. Total four formulations [FI1-FI4] were prepared using 10%, 15%, 20%, 25% of superdisintegrants. These tablets were graded for appearances, thickness [mm], hardness [kg/cm^2], friability [%], weight variation, drug content, wetting time, disintegration time and dissolution time.Best formulationsFI8 with ispaghula mucilage powder 25% showed 100.1%.Drug release of the formulation FI3 of oral disintegrating tablet of loratadine containing natural super disintegrants was greater than that of the tablets synthetic super disintegrants and marketed product.From the results, it is evident the oral disintegrating tablets prepared with natural superdisintegrants are superior which disintegrate in less time when compared oral disintegrating tablets with synthetic super disintegrants in terms of invitro drug release.
KEY WORDS :loratadine, banana powder, crospovidone.

I. INTRODUCTION

ORAL DISINTEGRATING TABLETS

Despite new innovations, oral drug administration remains the preferred route of therapeutic agent administration. More familiar oral dosage forms, tablets, and capsules sometimes create problems for some geriatric and most pediatric patients. Drinking water plays a fundamental role in the taking of capsules and tablets. Children find it difficult to consume tablets and capsules because of their underdeveloped muscles in GIT. And when there is a need to travel it is difficult to find water and this may restrict the convenience of orally administered formulations.

Tablets that breakdown in saliva in a few seconds and dissolve quickly without having to drink or chew.Oral disintegrating tablets usually diffuse within 15sec to 3min in the oral cavity. Oral disintegrating tablets are also known as mouth dissolving tablets, orodispersible tablets, fast dissolving tablets, melt-in-mouth tablets, rapimelts, porous tablets, quick-dissolving tablets, or rapid melt tablets.

SUPERDISINTEGRANTS

Disintegrants are substances routinely included in tablet formulations to help break the compacted mass into primary particles disassemble facilitate the dissolution or release of the active ingredients when they are placed in a liquid environment.

Mechanisms of superdisintegrants
The mechanisms by which tablets break down into small particles are described below.

- Swelling action
- Wicking [porosity and capillary]
- Heat of wetting
- Chemical reaction
- Deformation
- Particle repulsive force
- Enzymatic reactions

Swelling

It is the mechanism exhibited by explosives. When the disintegrants come into contact with the medium, it begins to swell and break the tablets. A low porosity leads to a adequate swelling forces being exerted.

Wicking

some disintegrants produce their effects through porosity and capillary action. When the tablet is exposed to the medium, the aqueous medium penetrates the tablet and replaces the air adsorbed on the particles.this weakens the intermolecular bonds

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Volume 8, Issue 1 Jan-Feb 2023, pp: 1004-1017 www.ijprajournal.com ISSN: 2249-7781

present in the tablet and breaks the dosage from into particules.

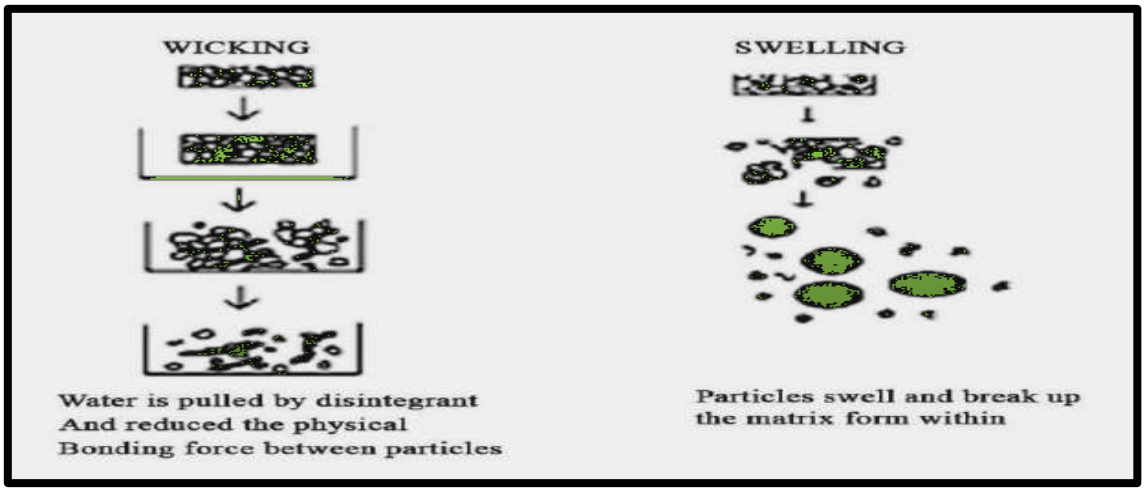

Figure 1.1 : Super disintegrant mechanism - Swelling and Wicking.

Heat of wetting

Explosives with exothermic properties trigger an explosive effect when wetted, sinces local stresses arise due to capillary air expansion. The mechanisms is shown in some explosive devices.

Chemical reaction

The decay effect is due to the release of CO_2 gas. It happens when tartaric acid and citric acids[acid] react with alkali metal bicarbonates or carbonates[base] in the presences of water. Therefore, these reactions are also referred to as acid-base reactions. Pressure builds up inside the tablet, causing the tablet to disintegrate.

Deformation

During compression, the shape of the explosive particles is distorted and the particles then return to their pre-compression shape in the wetting process. This leads to enlargement of the deformed particles and breakage of the tablet.

Particle repulsive force

This mechanism is evident in tablets with non-swelling disintegrants. When the tablet is exposed to the medium, the medium penetrates through the hydrophilic pores and a starch network is formed. Hydrogen bonds are broken. Repelling electrical forces between the particles lead to the disintegration process.

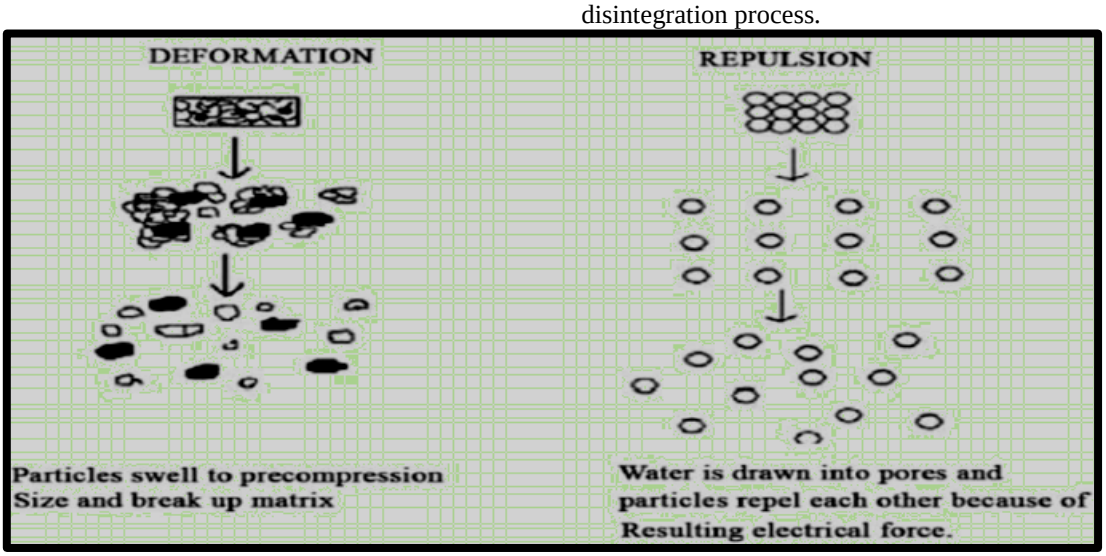

Figure1.2: Super disintegrant mechanism - Deformation and Replusion.

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Volume 8, Issue 1 Jan-Feb 2023, pp: 1004-1017 www.ijprajournal.com ISSN: 2249-7781

Enzymatic reactions

Enzymes already present in the body can also act as disintegrants. This leads to a lack of binding effect of the binders in the tablets and consequently to disintegration.

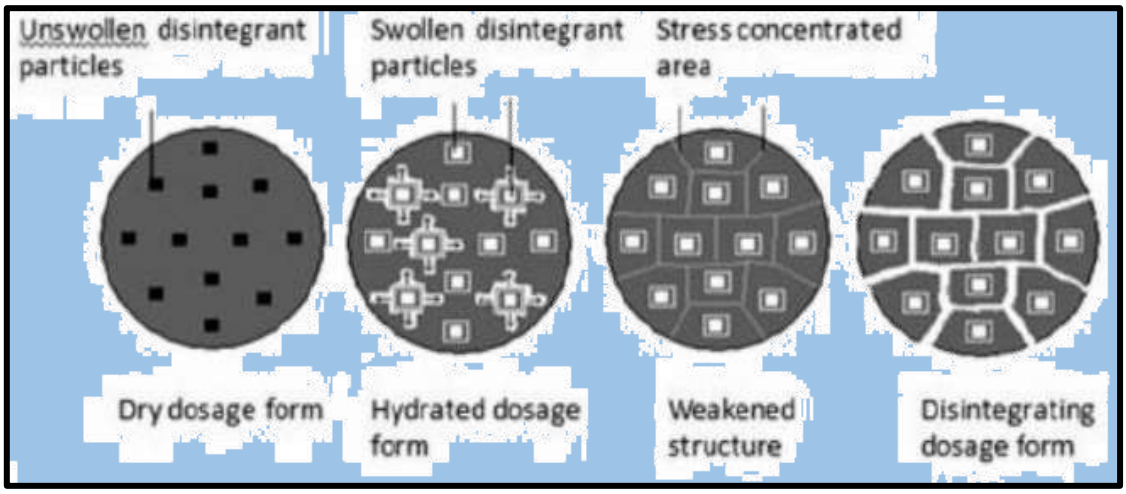

Figure 1.3 : Super disintegrant mechanism - Enzymatic reactions.

NATURAL SUPERDISINTEGRANTS

Natural superdisintegrants

These superdisintegrants occur naturally and are preferred over synthetic substances because they are comparatively cheaper, widely available, and inherently non-irritating and non-toxic. Natural materials such as gums and mucilages have been widely used in the field of drug delivery due to their ready availability, cost-effectiveness, environmental friendliness, emollient and non-irritating nature, non-toxicity, and ability to undergo a variety of chemical modifications, while being degradable and compatible with due to its natural origin. They are several gums and mucilages are obtainable which as super-disintegrating activity.

Some examples of natural superdisintegrants

Lepidium sativum mucilage

Lepidium sativum [family - cruciferae] is proclaimed as asaliyo and is extensively used as an herbal medicine in India. It is readily available in the market and has a very low price. The parts utilized are leaves, roots, oil, seeds, etc. The seeds accommodate a higher amount of mucilage, dimeric imidazole lepidine alkaloids B, C, D, E, and F and two new monomeric imidazole semilepidinoside alkaloids A and B. the slime of Lepidium sativum has various properties such as gelation, binding, disintegration.

Gum karaya

Gum karaya is a gloomy colloid and a complex, high molecular weight polysaccharide. The hydrolysis produces galactose, rhamnose and galacturonic acid. Gum karaya occurs as a partly acetylated derivative. It is a dried exudate of the Sterculia Uren tree [Sterculiaceae family]. Its synonyms are karaya, sterculia, Indian Astragalus, Bassora Astragalus, Kadaya, Kadira, Katila. Gum karaya is compatible with other herb hydrocolloids, as well as with proteins and carbohydrates.

Fenugreek seeds mucilage

Trigonella Foenum- graceum, recognized as fenugreek, is a herbaceous plant of the legume family. It has found wide applications as a food, food additive, and as a traditional medicine. The leaves and the ripe and immature seeds of Trigonella Foenum graceuma are used as a vegetable. Fenugreek has been used to treat colic, flatulence, dysentery, diarrhea, dyspepsia with loss of appetite, chronic cough, dropsy, enlarged liver and spleen, rickets, gout, and diabetes. It is also used as a gastric protector, antiurolithic, diuretics, antidandruff, anti-inflammatory and antioxidant.

Cassia fistula gum

Cassia fistula gum seeds obtained from the Cassia fistula tree. From the seeds of the Cassia fistula comprises β-[1→4]-linked d-mannopyranose units with a random distribution of α[1→6]-linked d-galactopyranose units as side chain. Carboxymethylation and carbamoylethylation of cassia gum are reported to improve cold water solubility, improve viscosity and increase microbial resistance compared to native gum. Therefore,

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attempts were made to incorporate calcium or sodium salts of carboxymethylated or carbamoyethylated Cassia fistula gum as superdisintegrants into the development of the TDF formulation.

Guar gum

Guar gum is a galactomannan that is commonly used in cosmetics, foods, and pharmaceutical formulations. Guar gum consists, mainly of high molecular weight polysaccharides [about 50,000-8,000,000] composed of galactomannans and is obtained from the endosperm of the seed of the guar plant cyamopsis tetragonaloba [L]
Taub. It is used as a thickener, stabilizer and emulsifier and is approved in most regions of the world [e.g. EU, USA, Japan, and Australia.

Hibiscus rosa-sinensis Linn

Hibiscus rosa-sinensis Linn from the Malvaceae family is well known as shoe flower plant, chinese rose and chinese hibiscus. The plant accessible in large quantities in India and its slime has proven to be a super explosive. The plant obtains cyclopropanoids, methyl esterculate, methyl 2-hydroxyesterculate, 2-hydroxyesterculate malvate and β - rosasterol.

Pectin from mango peel

Pectin, a hydrophilic colloid formed from a group of heteropolysaccharides. Although pectin cannot be used to anticipate super-disintegrating behavior, its high swelling index and solubility in biological fluids means it is used to make orodispersible tablets.

Agar

It looks yellowish or gray or colorless and tastes like slime. It comes in the form of dry gelatinous material derived from various species such as Gelidiumamansii, Gracilaria and aslo Pterocladia [red algae]. Agar consists of polysaccharides such as agarose and agaropectin. The first is the reason for the strength of the gel, and the high strength of the gel makes it a suitable disintegrant for the formulation of orally disintegrating tablets.

Chitin and Chitosan

Chitin is found in the shells of carbs and shrimp. Unlike chitosan, it contains an amino group covalently bonded to the acetyl group. Chitosan is made by deacetylating chitin, a structural component of the exoskeletons of crustaceans [crabs and shrimp] and the cell walls of fungi. Chitosan appears to be superior to corn strach as a disintegrant and is suitable for use as a super disintegrant in tablets.

Soy polysaccharide

It is also one of the naturally occurring super explosives. It is established from soy beans. It involves a high molecular weight carbohydrate polymers such as xylose, galactose, mannose and arabinose. Acts as a superdisintegrant when compressing tablets directly.

Dehydrated banana powder

The powder derived from various types of bananas known as ethane and ethrane. It belongs to the Musaceae family. Due to the large amount of carbohydrates, as it is a good source of energy.

Locust bean gum (carob gum)

It is the gum obtained from the extraction of Ceratonia siliqua seeds. It exploit as a gelling agent, thickening agent and also as a bioadhesive agent. It resemble as yellowish white and odorless powder.

Advantages of natural superdisintegrants

- **Environmental-friendly**

The explosives are inherently biodegradable as they are derived from natural resources.

- **Low cost**

Production costs are lower than synthetic materials.

- **Increased accessibility**

Areas where there is a large variety of plants will have high production of pharmaceutical excipients such as gum and slime.

- **Bio compatible in nature**

These substances are repeating sugar polysaccharides.

- **Good acceptance by public**

Less likely to experiences side effect.

The model drug used in this study was loratadine, which is a piperidine - histamine H_1 receptor antagonist with anti-allergic properties and no sedative effect.

PRE - FORMULATION STUDIES :

EXTRACTION OF ISAPGHULA MUCILAGE POWDER

Preparation of isapghula mucilage powder:

a. Seeds of Plantago ovata were soaked in distilled water for 48 hours and boiled for a few minutes.
b. Collected material was pressed through a muslin cloth to separate them.
c. An equal volume of acetone was then added to the filtrate to precipitate mucus.

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d. The separated slime was dried at 40℃ in a tray-dryer.
e. The dried slime was pulverized and sieved through the No.80# sieve.
f. The resulting powder was stored in a desiccator and used for the present study.

Characterization of banana powder and isapghula mucilage powder :

A. **Solubility test :**

1 gm of isapghula mucilage powder was dissolve in 10ml of cold water was determined and the results are recorded.

B. Angle of repose :

The angle of repose was calculated by using the subsequent formula :

Tan θ = h / r
Where, h = height
r = circular heap of radius

Table 3.3 : Flow property and corresponding angle in accordance with I.P.

S.no	Flow property	Angle of repose [θ]
1.	Excellent	25-30
2.	Good	31-35
3.	Fair	36-40
4.	Passable	41-45
5.	poor	46-55
6.	Very poor	56-65
7.	Very very poor	>66

C. **Bulk Density :**

Bulk Density [BD] = M / V
Where, M = Mass
V = Volume

D. Tapped Density :

Tapped Density [TD] = M / V
Where, M = Mass
V = Volume

E. Carr's Index :

Carr's index [%] was determined by using the subsequent equation
Carr's index = [TD [Tapped density] - BD[Bulk density] / TD[tapped density] x 100

Table 3.4 : Scales of flowability

S.no	Flowability	Carr's index	Hauser's ratio
1.	Excellent	5-11	1.00-1.11
2.	Good	12-16	1.12-1.18
3.	Fair	18-21	1.19-1.25
4.	Passable	23-25	1.26-1.34
5.	Very poor	33-38	1.46-1.59
6.	Very very poor	>40	>1.60

F. **Hausner's ratio :**

Hausner's ratio was determined by using the subsequent equation

HR = TB [tapped density] / BD [bulk density]

G. Swelling capacity :

Tapped volume occupied by 10g each of isapghula mucilage powder [Vd] in a 100 ml graduated cylinder was recorded. The powder was then diffuse in 85 ml distilled water and the volume make up to 100 ml with more water. After standing for 18 hours, the volume of the sediment [Vw] was evaluated and the swelling capacity was calculated as

Swelling capacity = Vw - Vd

H. Microbial test :

The pour plate method was used to culture 1 ml of isapghula mucilage powder with distilled water on Hilton-Muller agar medium for enumeration of bacteria and flavoured dextrose agar medium for fungi. The plate was incubated at 37℃ for 24 hours for bacteria. While the fungal plates were incubated at 27℃ for 72 hours. The bacterial and fungal colonies formed were counted at the end of the incubation period.

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3.5.3 CHARACTERIZATION OF LORATADINE :

Absorption maximum of loratadine :

Weigh approximately 2.38 gm of di- sodium hydrogen phosphate; 0.19 gm of potassium dihydrogen phosphate; and 8 gm of sodium chloride and ortho-phosphoric acid up to 2 ml was added up to pH to 6.75 and the volume make up to the 1000 ml with water.Weighed accurately 10 mg of loratadine was transferred to a 10 ml of volumetric flask, then add 2-3 ml of methanol and dissolve the drug. The volume was standardize to 10ml salivary simulated fluid to acquire 1000 µg/ml solution. 1 ml of aliquot of above solution was diluted to 10 ml with the SSF to give the 100µ/ml solution . considerably 1 ml of aliquot was taken from above solution and diluted to 10 ml with buffer to give 10 µg/ ml solution.

This 10 µg/ml standard solution of loratadine in stimulated salivary fluid was scanned on a double beam UV spectrophotometer from wave length of 200-400 nm. From UV spectrum λ_{max} of loratadine was acquired.

3.5.4DRUG - EXCIPIENTS COMPATABILITY STUDY BY FTIR :

An infrared spectral matching approach was used to detect possible chemical reactions between the drug and the natural superdisindegrants. A physical mixture [1:1] of drug and natural superdisintegrants was prepared and mixed with appropriate amount of potassium bromide and analysed by shimaduz FTIR in the frequency range between 4000-400cm^{-1}.

3.5.5 ESTABLISHMENT OF STANDARD PLOT FOR UV VISIBLE SPECTROPHOTOMETERIC ANALYSIS OF LORATADINE :

Stock solution preparation for loratadine with pH simulated salivary fluid :

Weighed accurately 10 mg of loratadine was transferred to a 10 ml of volumetric flask, then add 2-3 ml of methanol and dissolve the drug. The volume was standardize to 10ml salivary simulated fluid to acquire 1000 µg/ml solution.

From the above stock solution, 2.5 ml of taken in the volumeteric flask and make up to 25 ml with simulated salivary fluid to obtain 100 µg/ml solution of loratadine. From this solution aliquots of 0.5, 1.0, 1.5, 2.0, 2.5, and 3.0 ml were taken in separate flasks and adjust the volume to 10 ml to get 5, 10, 15, 20, 25, and 30 µg/ml solutions of loratadine in SSF. The absorbance of solutions was determined at 247 nm against SSF as blank. The experiment was accomplished in triplet and a standard graph showing the mean absorbance vs different concentrations was plotted and correlation [R^2]was calculated

Formulation of oral disintegrating tablet :

Table 3.6 : Composition for formulation from totally different batches of loratadine oral disintegrating tablets

Ingredients [mg/tab]	FI1	FI2	FI3	FI4
Loratadine [model drug]	10	10	10	10
Banana powder	-	-	-	-
Isaphgula mucilage powder	10	15	20	25
MCC	76	71	66	61
Mannitol	90	90	90	90
Aerosil	2	2	2	2
Sodium saccharin[sweetner]	6	6	6	6
MagnesiumStearate [lubricant]	2	2	2	2
Talc [hydrous magnesium silicate] [glidant]	2	2	2	2
Flavour[Vanilla]	2	2	2	2
Total	200	200	200	200

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Formulation of oral disintegrating tablets of Loratadine:

The orally disintegrating tablets were made by the direct compression method using two different natural super disintegrants, namely banana powder and isapghula mucilage powder in 10, 15, 20, 25 concentrations.

Microcrystalline cellulose, mannitol as a diluent and a mixture of aerosil and magnesium stearate were used as lubricants. The composition of the oral disintegrating tablet formulation is shown in table.

The accurately amount of drug and all the ingredients were weighed according to the formula shown in table and the powder except aerosil, talc and magnesium stearate were homogeneously mixed in a motor for 15 minute. The powder blend prepared passed through a #sixty sieve.

Finally, the aerosil, talc and magnesium stearate passed through a #thirty was added and mixed again for 10 minutes.

An accurately weighed 200 mg homogeneous powder blend was manually fed and pressed with constant compression force and hardness into a 16 station Cadmach tablet press machine with 9mm lead flat punches. A complete of eight formulations were prepared.

3.7 EVALUATION PARAMETER :

i. Physical appearance :

Tablets had been inspected for smoothness, absences of chips, cracks and other undesirable features.

ii. Hardness :

Tablet hardness or breaking strength [F_0] , the force required to break a tablet under diametrical compression was measured with the Monsanto hardness tester.

For every formulation, the hardness of six tablets decided the use of the Monsanto Hardness Tester. The tablet was held between the two jaws of the tester along its longitudinal axis. At this the reading ought to be zero kg/cm^2. then constant force was applied by turning the knob until the tablet broke. At this point the value was noted in kg/cm^2.

iii. Thickness:

Tablets of three from each batch are randomly selected and the therefore thickness was measured with veriner calipers.

iv. Weight variation :

Twenty tablets from each batch were randomly selected and weighed individually weighed. The mean weight and standard deviation of twenty tablets were calculated. The batch passes the weight variation test if no more than two individual tablets vary from the average weight.

v. Friability :

The friability of the tablets was determined with Roche Friabilator. The device subjects tablets to the combined effects of abrasion and impact in a plastic chamber that rotates at 25 rpm and rolls the tablets 6inches in height with each revolution. A pre-weighed sample of tablets was placed within the friabilator and subjected to hundred revolutions. The tablets were dusted with a soft muslin cloth and weighed back, the friability[F] is given by the formula:

% friability = [a-b]/b x 100
Where, a = initial weight of the tablets
b = final weight of the tablets

vi. Drug content :

20 tablets which was equivalent to 10 mg of loratadine had been transferred in to volumetric flask. 2 ml of distilled water was added to this and made volume up to 25 ml with ethanol.then sonicated for 15 mins and filterate was filter through Whatman filter paper. 1ml of aliquot was taken and diluted up to 10ml with simulated salivary fluid. The absorbance was measured by using the UV Visible spectrophtometeric using simulated salivary fluid as buffer at 274nm. Drug concentration was estimated from the standard plot and the drug amount in the tablets were calculated.

vii. Weighting time and disintegration time :

A 10cm long piece of tissue paper folded twice was placed in a small 10cm diameter in petri dish which containing 6ml of water. A tablet was placed on the paper and the time it took for the water to reach the top surface of the tablet was noted in seconds. Following this tablet were allowed to disintegrate and the time for the tablet tablet to completely disintegration which was measured in seconds and reported as the disintegration time.

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viii. In vitro Dissolution study:

In vitro dissolution study was execute using the USP dissolution test apparatus, type II [paddle]. In the dissolution flask ,a petri dish was placed and on the petri dish place a 500ml of beaker in the basket. For maintaining the temperature of the medium within the inner beaker, water was taken in the basket. SSF [200ml] was used as the dissolution medium maintained at 37 ± 0.5℃. To the medium one tablet was added and stirred at 50rpm. After exactly one minute , sufficient quantity of the dissolution medium was with drawn and the sample was anaylzed using UV vivible spectrophotometeric at a 274nm.

STABILITY STUDIES :

The time from the date of manufacture of a formulation until its chemical or biological activity is not less than a predetermined level of labelled potency and its physical characteristics have not changed is referred to as its stability.Changed significantly or negatively.

ACCELERATED STABILITY STUDIES :

In general, observing the rate at which the product degrades at normal room temperature takes a long time. The principles of accelerated stability studies are used to avoid the undesirable delay by accelerating the parameters such as temperature, humidity, and light. The ICH specifies the duration of the study as well as the storage conditions.

Long -term testing :25±2°C/60% ±5% RH for 12 months.

Accelerated testing: 40±2° C/75%±5% RH for 6 months.

Procedure :

Stability tests were performed on an optimised formulation at 25 ±2°C/60±5% RH and 40± 2°C/75%± 5% RH for (FB4 & FI8) for 1months. The physical appearance, average weight, thickness, hardness, friability, disintegration test, in vitro dispersion time, assay, and in vitro drug release of the selected clear ALU-ALU packed formulations were evaluated.

II. RESULTS AND DISCUSSION

PRE FORMULATIOM STUDIES:

Characterization of isapghula mucilage powder

S.no	Property	Results [isapghula powder]
1.	Solubility	Form a gel
2.	Bulk density [gm/ml]	0.638gm/ml
3.	Tapped density [gm/ml]	0.75gm/ml
4.	Carr's index [%]	14.93%
5.	Hausner's ratio	1.17
6.	Angle of repose [θ]	29.68^{o}
7.	Swelling capacity	15ml
8.	Microbial test	Within the limit

Characterization of absorption maximum of loratadine :

Determination of absorption maximum of loratadine :

UV spectrum of a ten µg/ml solution of loratadine in SSF showed a characteristic absorption maximum at 274nm [figure].

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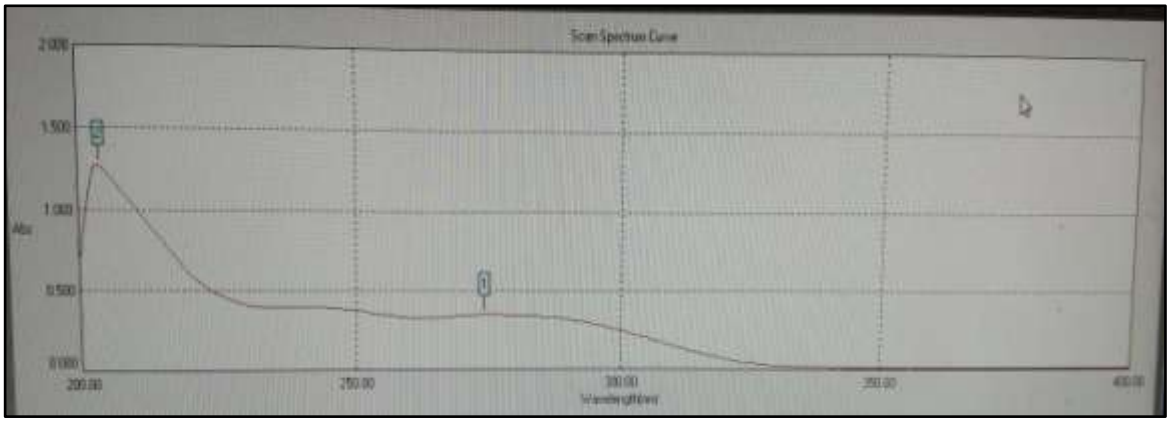

Figure 4.1 : UV absorption spectrum of a 10µg/ml solution of loratadine in simulated salivary fluid.

4.1.3 DRUG EXCIPIENT COMPATIBILITY STUDIES BY FTIR:

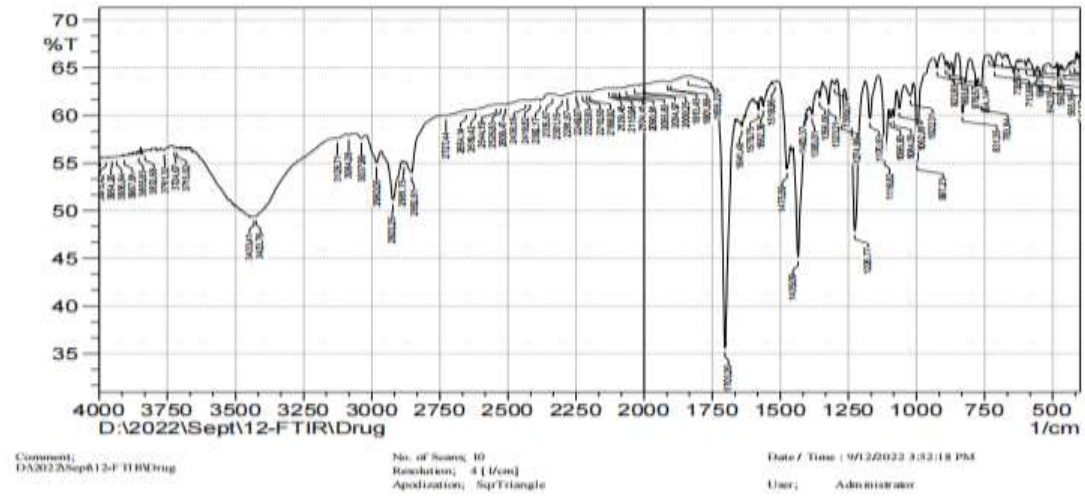

Figure 4.2: FTIR of loratadine pure drug

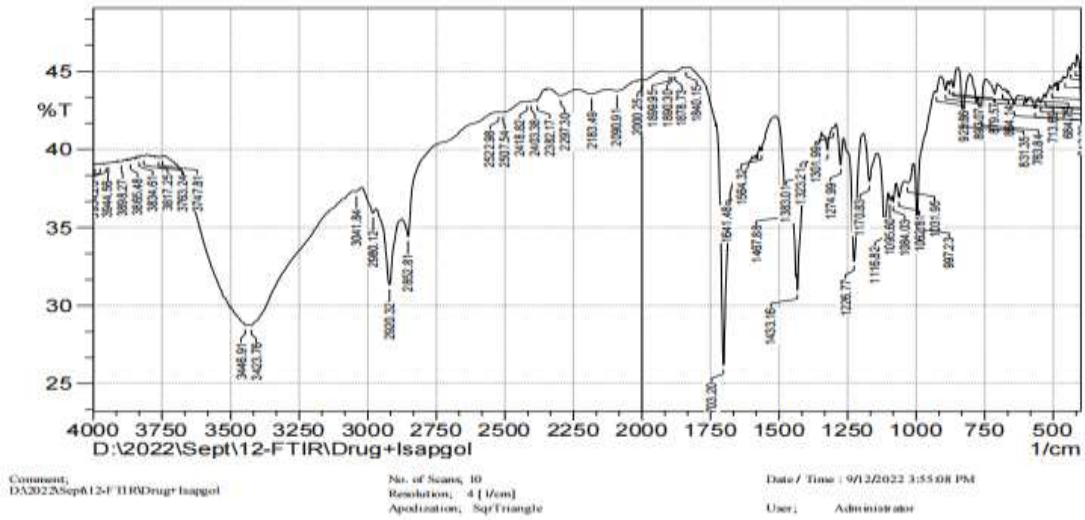

Figure 4.4 : FTIR of Loratadine + Isapghula mucilage powder

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EVALUATION PARAMETER :

1. Thickness :

Tablets were graded with vernier calipers.The thickness of the tablets ranged from 2.1mm - 2.4mm.

2. Hardness :

The tablets were tested using the Monsanto hardness tester. The hardness of the tablets ranged from 3.1-3.5 [kg/cm^2]. The hardness range obtained showed good mechanical resistances with the ability to withstand conditions of physical and mechanical stress.

3. Friability :

The tablets were graded using the Roche Friabilitor and the tablet friability was found to be within the acceptable range 0.7-0.9[%].

4. Weight variation :

The tablets were made use of technique is the direct compression. Since the material was free-flowing, tablet of uniform weight were obtained due to the uniform filling of the matrix.

5. Drug content :

The tablets were assessed using the assay method. The drug content was acquired in the acceptable limit. The drug content was found in the range of 95-101%w/w. the originated range was with in the specified limit in accordance Indian pharmacopoeia 2007.

6. Wetting time :

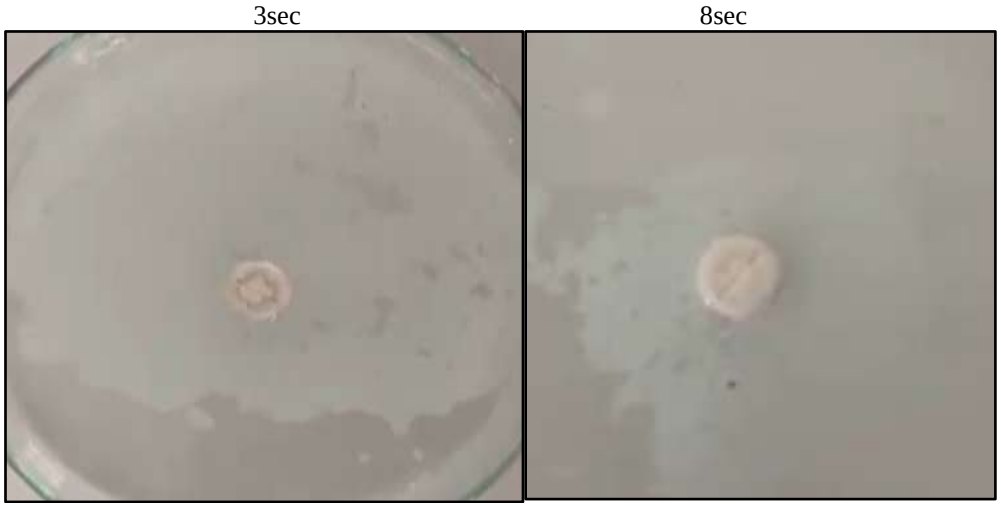
The wetting time for the eight formulation was run in duplicate. Wetting time was rapid with banana powder and isapghula mucilage powder. It was also observed that as the concentration of the natural superdisintegrant increased , the wetting time was shortened.

7. Disintegration time :

The tablet were subjected to invitro disintegration time on the USP disintegration tester. The invitro disintegration time for the four formulation ranged from 15-30 seconds. More rapid disintegration was observed in formulation FI1 and FI4.An isapghula powder , when in contact with water, speedily absorb the water into the tablet by capillary action to create an internal pressure that dissolves the tablet.

This is due to the rapid absorption of water from the medium, the effect of swelling and explosion. Its show that the formulations with a higher concentration of banana powder and isapghula mucilage powder showed a significantly faster disintegration.

Figure5.4 : B8 disintegration time.



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11sec 15sec

Table 4.6 : Post compression parameters of optimized formula

Formula	Thickness [mm]	Hardness [kg/cm^2]	Friability [% loss in weight]	Weight variation	Drug content	Wetting Time [sec]	Dissolution Time [sec]
FI1	2.3	3.2	0.8	0.21	97.9	9.8	25
FI2	2.4	3.2	0.85	0.24	98.4	8	23
FI3	2.1	3.2	0.9	0.24	99.8	7	18
FI4	**2.1**	**3.5**	**0.9**	**0.22**	**100**	**6**	**15**

8. Invitro dissolution studies :

Table 4.7 : % drug release of all formulations

Time	FI1	FI2	FI3	FI4
1min	85.08	88.97	90.85	91.78
2min	87.78	91.6	92.68	93.6
3min	90.3	93.56	94.8	95.78
4min	92.95	96.95	97.85	98.66
5min	94.98	97.99	99.97	100.1

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1004-1017 www.ijprajournal.com ISSN: 2249-7781

Formulation of FI1 with isapghula mucilage powder 0.01gm showed 94.98% and FI2 isapghula mucilage powder 0.015gm showed 97.99%, FI3 with isapghula mucilage powder 0.02gm showed 99.97% and FI4 with isapghula mucilage powder 0.025gm showed 100.1%.The resulting formulation of FI3 and FI4 showed the best release of 99.97% and 100.1%. FI3 formulation was chosen, which gives good results with a high percentage.As the concentration of natural super disintegrant increases, there is fast and higher drug release.FI4 formulations were optimised based on all the evaluation tests.

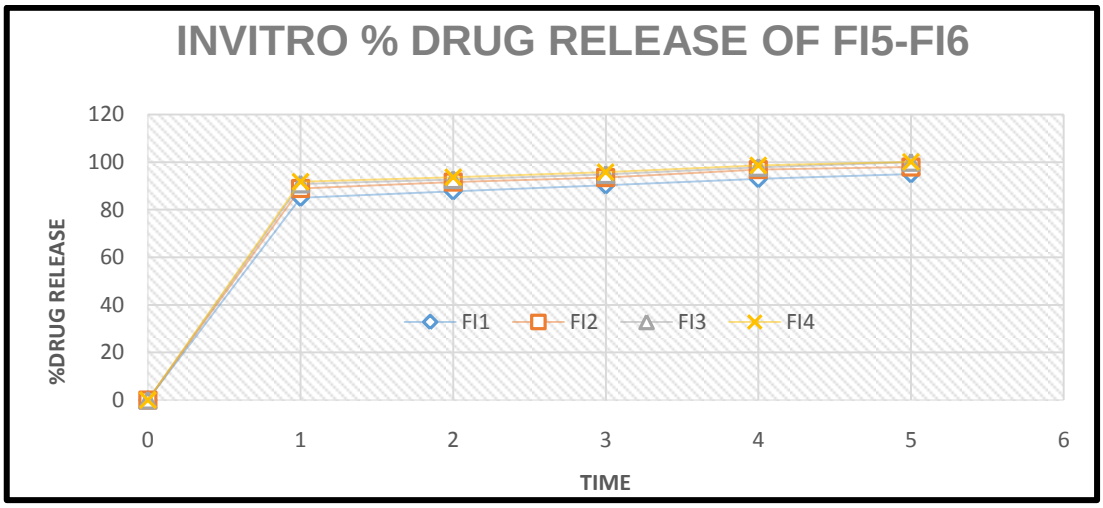

Figure 5.6 : % drug release of formulation FI1-FI4.

9. Comparative studies :

The oral disintegrating tablets prepared using synthetic superdisintegrant i.e crospovidone , which was taken in 20% by direct compression method.Formulation FI3 is compared with synthetic super disintegrant such as crospovidone and also compare with marketed formulation.

Table 4.8: Disintegration time and wetting time of synthetic super disintegrants.

Formulation	Wetting time (sec)	Disintegration time(sec)
Crospovidone	38	56

Table 4.9 : % drug release compared with the synthetic natural super disintegrants and marketed formulation.

Time	FI3	crospovidone	Marketed formulation
1min	90.85	70.43	65.89
2min	92.68	74.20	69.93
3min	94.8	80.56	72.71
4min	97.85	85.05	76.98
5min	99.97	89.99	80.21

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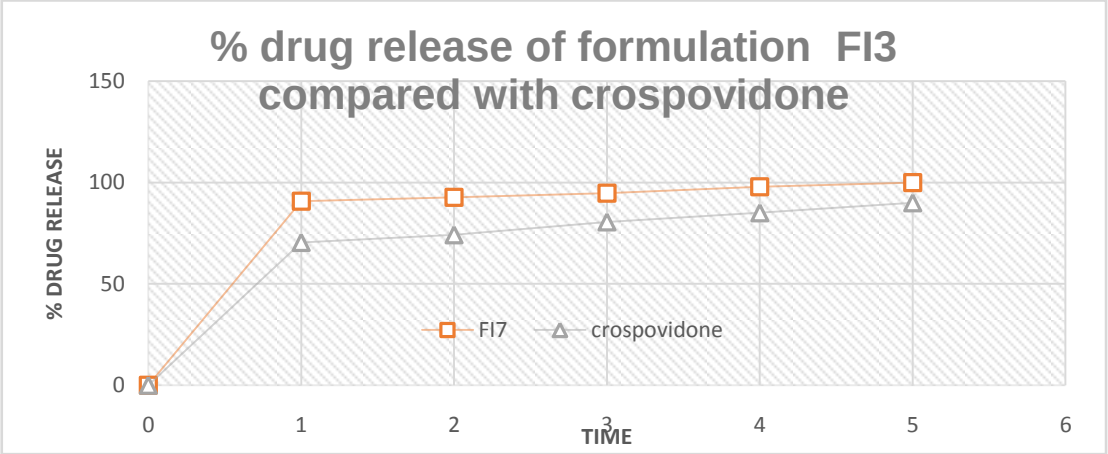

Figure 6.1: % drug release of formulation B3 and B7 compared with crospovidone.

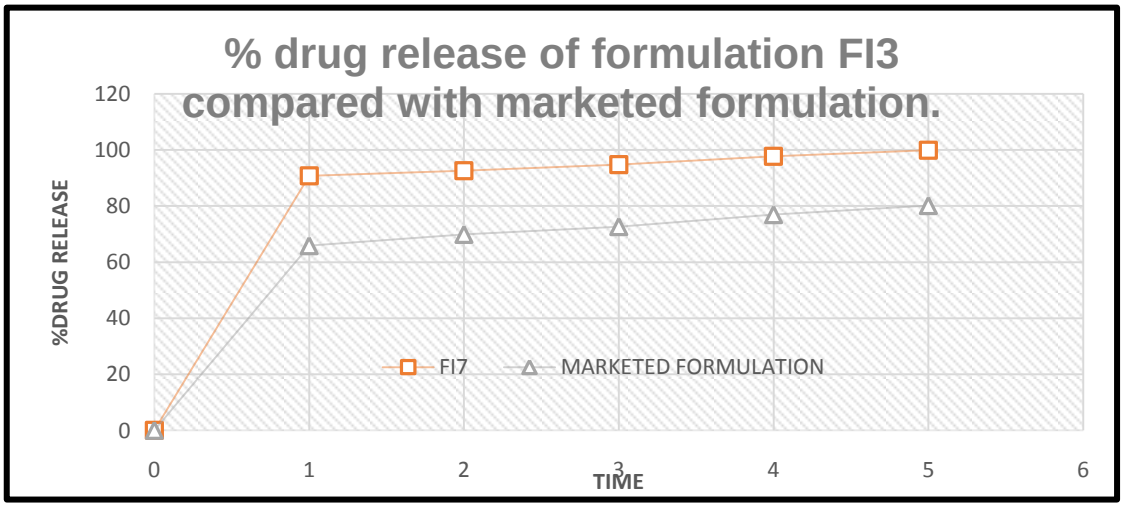

Figure 6.2 : % drug release of formulationB3 and B7 compared with marketed formulation.

Stability studies :

The optimised formulation (FI8) was chosen for the stability study and stored at 25 degrees Celsius.For one months, the temperatures were 25±2°C/60% ±5% RH and 40± 2°C/75%±5%The tablets were evaluated for physical appearance, average weight, thickness, hardness, friability, disintegration, in vitro dispersion, fineness of dispersion, dissolution, and assay.

Sno	**StorageConditions: 25±2°C/60%±5% RH**
	FI8
Physical appearance	Complies
Thickness (mm)	2.1mm
Hardness (kg/cm2)	3.5
Friability (%)	0.9
weight variation	0.22

International Journal of Pharmaceutical Research and Applications
Volume 8, Issue 1 Jan-Feb 2023, pp: 1004-1017 www.ijprajournal.com ISSN: 2249-7781

Wetting time	6sec
Disintegration test (sec)	15sec
Drug content	100
In vitro drug release (%)	100.1

Table5.0 : Stability Data of loratadine ODTS Stored at 25±2°C/60%± 5% RH (FI8).

III. CONCLUSION :

The present study aimed at developing oral disintegrating tablets of loratadine containing two natural super disintegrants by a direct compression process such as ispaghula mucilage powder.Total four formulations [FI1-FI4] were prepared using 10%, 15%, 20%, 25% of superdisintegrants. The appearances, thickness [mm], hardness [kg/cm2], friability [%], weight variation, drug content, wetting time, disintegration time, and dissolution time of these tablets were all graded. The best formulations FI4 with ispaghula mucilage powder 25% showed 100.1%.

From the results, it is evident the oral disintegrating tablets prepared with natural super disintegrants are superior when compared with synthetic super disintegrants in terms of disintegration and invitro drug release.

Acknowledgment

The author is thankful to I. Bala Tripura Sundari M.Pharm, (Ph.D.) for her support and valuable suggestions in completing this article.

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