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Formulation and Evaluation of Mouth Dissolving Loratadine Tablet Using Super Disintigrants

Mrs. S. Sangeetha[1], Dr. S. Chandra[2], Dr. N. Senthil Kumar[3], S. Kavya[4]

[1,2,3,4]Department of Pharmaceutics, J.K.K.Munirajah Medical Research Foundation, Annai J.K.K.Sampoorani Ammal College of Pharmacy Komarapalayam, Namakkal Dt- 638183, Tamilnadu, India

Abstract

The objective of the work was design to improve palatability in orally administered products has prompted the development of formulation with improved performance and acceptability. Mouth-dispersing tablets dissolve or break down in saliva and are ingested without the use of water. Antihistamine loratadine is primarily used to treat hay fever, allergies, itchy eyes, and hives symptoms. It functions by obstructing histamine, which the body releases after an allergic reaction. The objective of the current study was to use the physical mixing approach to increase the solubility and dissolving rate using Croscarmellose sodium. From FIIR identification of drug is done and followed by physicochemical parameters. Determination of drug polymer incompatibility is by FTIR method. Loratadine MDT were prepared by using different superdisintegrants as Croscarmellose sodium, Orange peel pectine and Hibiscus mucilage by direct compression method. Only the physiochemical characterization, formulation, and in-vitro assessment of Loratadine mouthwash pills were carried out in this study. In addition to in-vitro research, in-vivo drug studies are crucial . Future in-vivo research is vital to establish the in-vitro in-vivo correlation that is required for the development of successful formulations and also long term stability studies.

Keywords: Loratadine, Super disintegrants, Croscarmellose sodium, Mouth soluble tablet, In-vitro drug release.

I.INTRODUCTION

When one wants to obtain a quick onset of action or increased bioavailability for medications with high first-pass metabolism, drug administration via the oral mucosa is a potential method. The development of alternate dosage forms, such as orally fast disintegrating tablets, which enable a rapidly dissolving medicine to diffuse directly into the systemic circulation through the oral mucosa, is therefore gaining interest. Among the several methods of administration, the oral route remains the most favoured due to numerous advantages such as ease of consumption, avoidance of pain, variety, and, most significantly, patient compliance. Some of the obstacles in developing mouth dissolving tablets include achieving rapid tablet disintegration, avoiding tablet size increases, protecting against moisture, and not being influenced by pharmacological qualities. The current needs of the industry are improved solubility/stability, biological half-life and bioavailability enhancement of poorly absorbed drugs. Another cause for the increase in accessible fast-dissolving/disintegrating products is pharmaceutical marketing. It is typical for pharmaceutical producers to create a particular pharmacological molecule in a

new and enhanced dosage form as its patent life approaches its end.

The administration of pediatric, geriatric, and psychiatric patients who refuse to swallow a tablet is one of the features of a mouth dissolving drug delivery method. When opposed to liquids, it is easier to administer and provides more exact dosing. There is no need for water to consume the dosage form, which is a very helpful aspect for depressed patients. Rapid medication breakdown and absorption, which may result in a rapid commencement of action. Capability to deliver liquid medicine advantages in the form of solid dispersion.

Methodology employed for mouth dissolving formulation are melt granulation, phase transition process, sublimation, mass extrusion, spray drying, floss blend, floss processing, floss chopping and conditioning, blending and compression, direct compression and super disintegrants. A recently developed Nano melt method comprises milling the medicine using a patented wet-milling technique to reduce the particle size of the drug to nanosize. The force-equivalent idea (the combined assessment of swelling forced development and amount of water absorption) underpins disintegration efficiency.Force equivalency describes a disintegrant's ability to convert ingested water into swelling (or disintegrating)force. Molding process is of two type's i.e. solvent method and heat method. Solvent method involves moistening the powder blend with a hydro alcoholic solvent followedby compression at low pressures in molded plates to form a wetted mass.

In this study, an attempt was made to develop a mouth dissolving Loratadine tablet using super disintegrants like Croscarmellose sodium, Hibiscus mucilage, Orange peel pectin and ingredients with three different ratios in order to improve bioavailability of the drug. Hence the main objective of the present study was to carry out the Formulation and Evaluation of mouth dissolving tablet using super disintegrant.

1. MATERIALS AND METHODS

Loratadine, Orange peel pectin, Hibiscus mucilage, Croscarmellose sodium was received from Sun pharma; Magnesium state, Mannitol, Microcrystalline cellulose was obtained from MADRAS pharmaceuticals, Chennai; Aspartame was received from Orchid pharmaceuticals, Chennai. All other materials used were of pharmaceutical grade.

FT-IR spectroscopy:

The compatibility study of the drug with the excipients was determined by FTIR Spectroscopy using Shimadzu spectrometer. The sample was mixed with equal quantity of KBr ratio is 1:1,and placed in sample cell to record its IR spectra. The spectra of pure drugs, physical mixtures of drugs, and polymers were recorded. The spectra were captured over the 4000-400 cm^{-1} wave number range.

Physiochemical parameter:

Organoleptic properties:

For a tablet to be accepted by consumers, its overall appearance, visual identity, and "elegance" are crucial. Included are the sizes, shapes, colors, odors, tastes, surface textures, physical faults, consistency, and legibility of any identifying markings that were visually noticed on the tablet.

Solubility profile:

Solubility is a valuable metric, especially for weakly soluble medicines. When a drug's solubility is less than 10mg/ml over the pH range 1-8, bioavailability issues are common. The drug's solubility

was measured using various descriptive methods.

Analytical Method:

Determination of absorption maximum in Solvents

10 mg of Loratadine was weighed and transferred to three separate 100 ml standard flasks, where it was diluted with methanol, 0.1N HCL, and Phosphate Buffer pH 6.4. To obtain a concentration of 10 g/ ml of each solution, take 1 ml of each solution and combine it with a 10 ml standard flask. Each blank was maintained separate and scanned in the 200-400 nm range to identify the drug absorption maxima in three solvents. 0.1N HCl 247.5 nm, Methanol 275.0 nm, Phosphate buffer 6.8.bb 274.0 nm

Preparation of standard calibration curve of Loratadine in solvents

A stock solution of Loratadine from the above solution and to get the concentration of 5 to 30 µg/ ml in three solvents and it's obey the beer's law.

Determination of percentage purity of drug

A precisely weighed 100 mg of loratadine was dissolved in 0.1 N HCl and the volume was increased to 100 ml with the same to make a standard solution with a concentration of 1000 g/ml. Aliquots of 3 ml of the aforementioned solution were transferred to 10 ml volumetric flasks, and the final volume was adjusted to 10 ml with 0.1N HCl. The absorbance of these solutions was measured at 275 nm against a blank (0.1N HCl) using a Shimadzu-1700 Pharmaspec UV-Visible spectrophotometer. The calibration graph approach (least square method) was used to calculate the % purity of the medication.

Determination of drug-polymer compatibility:

By Fourier Transforms Infra-Red (FTIR) Spectroscopy

The approach of matching infrared spectra was utilized to detect any probable chemical reaction between the medication and the superdisintegrants. A physical mixture of medication and superdisintegrants (1:1) was made and combined with the appropriate amount of potassium bromideA hydraulic press at 10 tons pressure was used to compress 100mg of this combination into a clear pellet. In a Parkin elmer-Pharmaspec-1 FTIR Spectrophotometer, it was scanned from 4000 to 400 cm-1. The IR spectra of the physical mixture was compared to that of the pure medication, and matching was performed to detect any peak appearance or disappearance.

Formulation and Characterization of the powder blend:

Method

The medicine and all ingredients were weighed precisely according to the formula , and the powder,with the exception of aerosil and magnesium sterate, was homogeneously blended with mortor and pestel for 15 minutes. The prepared powder blend was filtered using sieve #60. Finally, aerosil and magnesium sterate that had been passed through sieve No. 30 were added and combined for 10 minutes. Angle of repose, bulk density, Tapped density, Compressibility Index, and Hausner ratio were all calculated for the powder blend.

1. Angle of Repose:

The Angle of repose was calculated using the cylinder method.

The mixture was poured through a funnel that could be raised vertically until a maximum cone height.

$\theta = \tan^{-1}(h/r)$ Where, θ= angle of repose; h=height of pile; r= radius

2. Bulk Density:

Apparent bulk density was determined by pouring the blend into a graduated cylinder. The bulk volume and weight of powder was determined The bulk density was calculated using the formula. $D_b = M/V_0$ Where, D_b= Bulk density; M= mass of powder (g); V_0=bulk volume of powder (cc)

3. Tapped Density:

The measuring cylinder containing a known mass of blend was tapped for a fixed number of taps. The minimum volume occupiedin the cylinder and the weight of the blend was measured. The tapped density was calculated using the following formula:

Tapped density = mass of powder (g) / tapped volume of powder (cc)

4. Hausner's Ratio:

Hausner's ratio is an index of ease of powder flow; it is calculated by following the formula

$$\text{Hausner's ratio} = \frac{\text{Tapped Density of the powder}}{\text{Bulk density of the powder}}$$

5. Carr's Index

The simplest way of measuring of free flow property of powder is compressibility, an indication of the case with which a materialcan be induced to flow is given by compressibility index(I) which is calculated as follow

$$\text{Carr's Index} = \frac{\text{Tapped density} - \text{bulk density}}{\text{Tapped density}} \times 100$$

Formulation of Mouth Dissolving Tablet of Loratadine

Table 1: Formulated Composition of different Batches of Mouth Dissolving Loratadine Tablets

S.No.	Ingredients(mg/tab)	Formulation code								
		F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Loratadine	10	10	10	10	10	10	10	10	10
2	Hibiscus mucilage	4	6	8	-	-	-	-	-	-
3	Orange Peel Pectin	-	-	-	4	6	8	-	-	-
4	Croscarmellose sodium(Ac-di-sol)	-	-	-	-	-	-	4	6	8
5	Microcrystalline cellulose	74	72	70	74	72	70	74	72	70
6	Mannitol	100	100	100	100	100	100	100	100	100
7	Aerosil	4	4	4	4	4	4	4	4	4
8	Aspartame	6	6	6	6	6	6	6	6	6
9	Magnesium stearate	2	2	2	2	2	2	2	2	2
10	Vanilla flavor	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s
11	Total	200	200	200	200	200	200	200	200	200

2. EVALUATION OF LORATADINE TABLETS:

1. Weight variation Method:

Twenty tablets were chosen at random from each batch and weighed individually. The standard deviation and average weight of 20 pills were computed. If no more than two individual tablet weights depart from the average weight, the batch passes the weight variation test.

2. Hardness:

Monsanto Hardness Tester was used to evaluate hardness or tablet crushing strength (Fo), which is the force necessary to break a tablet in a diametric compression.

The hardness of 6 tablets was evaluated for each formulation using the Monsanto hardness tester. The tablet was held between the tester's two jaws along its axis. The value should be 0 kg/cm2 at this stage.

The knob was then rotated to apply constant force until the tablet shattered. At this stage, the value was indicated as kg/cm2.

3. Friability:

Friability of the tablets was determined using Roche Friabilator. This gadget exposes the tablets to abrasions and stress in a plastic chamber rotating at 25 rpm and roping the tablets at a height of 6 inches in each revolution. A pre weighed sample of tablets was inserted in the Friabilator and rotated 100 times. The tablets were dedusted using a soft muslin cloth and reweighed; the formula gives the friability (F). A pre weighed sample of tablets was inserted in the Friabilator and rotated 100 times. The tablets were dedusted using a softmuslin cloth and reweighed; the formula gives the friability(F).

%F= (Initialwt.-Finalwt./ Initialwt.)x 100.

1. Drug content uniformity:

20 finely powdered tablets were dissolved in 100ml of methanol, and the drug concentration was determined using a UV-Visible spectrophotometer set to 275.00nm.

2. Disintegration time:

The disintegration time of the tablets was determined using a monograph from the Indian harmacopoeia. The USP disintegrate test instrument (Veego scientific VTD-DV) was used for the experiment. It consisted of a device in which six tablets were placed in each of six cylindrical tubes, the lower end of which was covered by a 0.025 in wire mesh.

The tubes were then raised and lowered through a distance of 5.3 to 5.7 cm in a disintegrating media of phosphate buffer pH 6.8 and 0.1N HCl pH 1.2 maintained at 370 20 C, and the time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds.

3. In-vitro Dissolution studies:

The Loratadine tablet dissolution profiles were established using the USP Type II Dissolution test apparatus (Veego scientific VDA-8DR) with a paddle speed of 100 rpm. Dissolution was carried out in 900 ml of 0.1N HCl kept at 370 0.50C.

A 5 ml aliquot of dissolving medium was extracted at 3, 6, 9, and up to 12 minutes intervals and filtered using Whatmann filter paper. A UV-Visible spectrophotometer was used to quantify the amount of medication dissolved. by measuring the sample's absorbance at 247.5 nm. After each sampling, an equivalent volume of new medium prewarmed at 37oC was added to the dissolution medium to maintain the consistent volume throughout the test. Three experiments were conducted for each batch, and the average % drug release was calculated using the PCP disso V3 software.

4. Stability studies:

The time from the date of manufacture of the formulation until its chemical or biological activity is not less than a set level of labeled potency and its physical properties have not changed considerably or negatively. A pharmaceutical product's formulation and development are not complete unless it undergoes rigorous stability analysis to determine its physical and chemical stability as well as its safety.

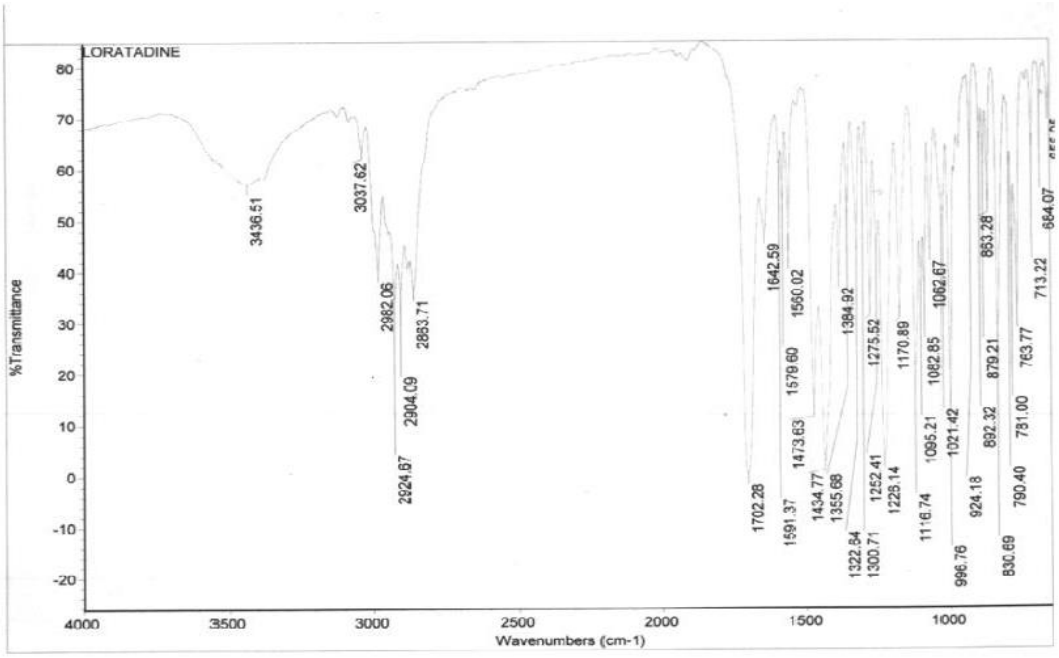
3. RESULTS AND DISCUSSION

Compatibility study (Fourier transform infrared spectroscopic studies)

Major functional groups present in Loratadine show characteristic peaks in IR spectrum. Table No.8.11 shows peaks observed at different wave numbers and the functional group associated with these

peaks.The major peaks are identical to functional group of Loratadine. Hence, the sample was confirmed as Loratadine.

Figure 1 FTIR spectrum of Loratadine



Physicochemical parameters of drug:

Organoleptic properties

Colour: White

Nature: Fine powder

Odour: Odourless

Solubility study of the drug:

Table 2: The solubility of Loratadine in different solvents

S.No.	Solvent	Parts of solvent required Per part of solute	Inference
1	Distilledwater	1000	Practicallly Insoluble
2	Acetone	2	FreelySoluble
3	Methanol	2	FreelySoluble
4	Chloroform	2	FreelySoluble
5	Toluene	2	FreelySoluble
6	0.1NHCl	2	FreelySoluble

Analytical Methods:

Determination of λmax. and Preparation of Calibration Curve of Loratadine by using 0.1 N HCl.

Loratadine's UV absorption spectra in 0.1 N HCl shows a maximum at 247.5 nm. Table 8.3 shows absorbance for various doses of Loratadine in 0.1 N HCl.In the concentration range of 10g/ml, the

graph of absorbance vs. concentration for Loratadine was found to be linear. In the 10/ml range, the medication follows Beer- Lambert's law.

Table 3: Data of Concentration and Absorbance

S.No.	Concentration(µg/ml)	Absorbanceat247.5nm
1	5	0.186
2	10	0.339
3	15	0.527
4	20	0.663
5	25	0.879
6	30	1.050

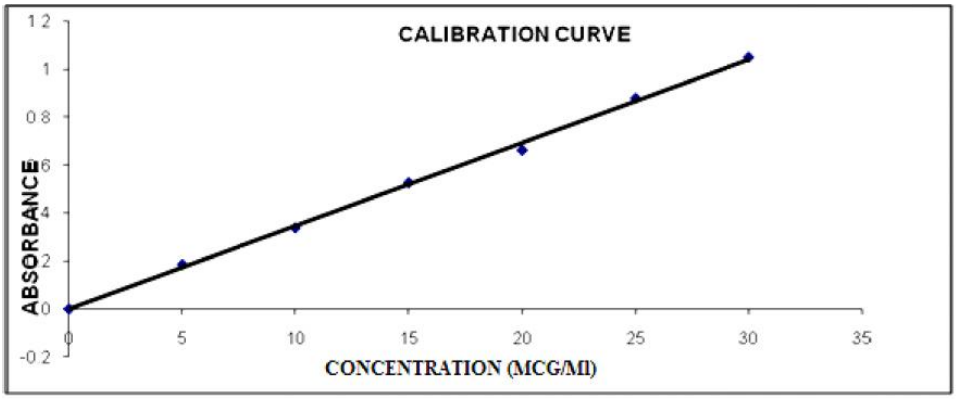


Figure 2: Calibration curve for Loratadinein0.1N HCL

Table 4:Data for Calibration Curve Parameters

S.No.	Parameters	Values
1	Slope(m)	0.03472
2	Intercept(c)	0.00014
3	Correlation coefficient(R)	0.99915

Determination of λ max and Preparation of Calibration Curve of Loratadine by using Methanol

Loratadine's UV absorption spectra in Methanol shows a maximum at 275 nm. Table 8.6 shows the absorbance measured for various concentrations of Loratadine in Methanol. In the concentration range of 10g/ml, the graph of absorbance vs. concentration for Loratadine was found to be linear. In the 10 g/ml range, the medication follows Beer Lambert's law.

Table 5: Data of concentration and absorbance

S.No.	Concentration(µg/ml)	Absorbanceat275nm
1	5	0.1623
2	10	0.3256
3	15	0.4894
4	20	0.6543
5	25	0.8143
6	30	0.9768

Figure 3: Calibration curve for Loratadine in Methanol

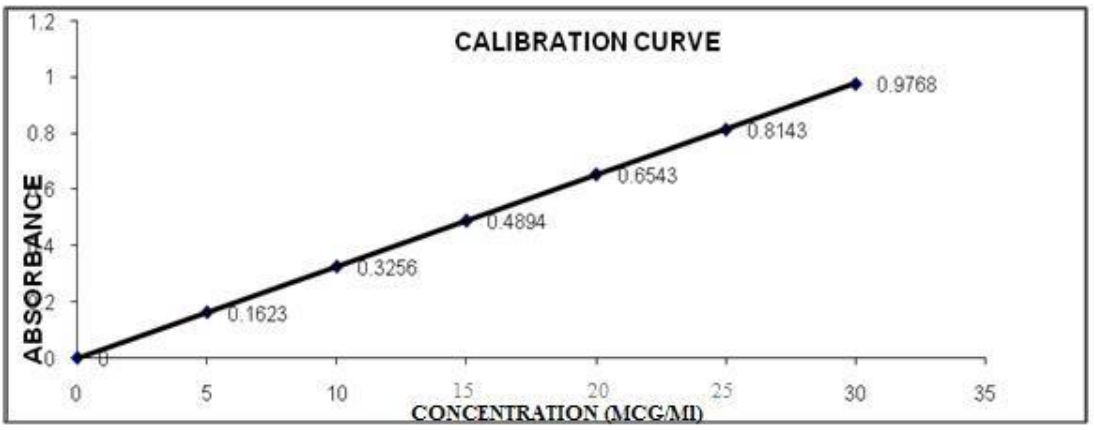


Table 6:Data for calibration curve parameters

S.No.	Parameters	Values
1	Slope(m)	0.032594
2	Intercept(c)	0.0000536
3	Correlation coefficient(R)	0.9999

Determination of λmax and preparation of calibration curve of Loratadine by using phosphate buffer pH 6.8

Loratadine's UV absorption spectra in phosphate buffer pH 6.8 shows a maximum at 274 nm. Table 8.8 shows the absorbance for various doses of Loratadine in phosphate bufferpH 6.8. Loratadine's absorbance Vs concentration graph was found to be linear in the concentration range of 10g/ml. Beer-Lambert'slaw in the range of 10 g/ml is the medication of choice.

Table 7: Data of concentration and absorbance.

S.No.	Concentration(µg/ml)	Absorbanceat274nm
1	5	0.2438

2	10	0.4891
3	15	0.7338
4	20	0.9945
5	25	1.2396
6	30	1.4921

Figure 4: Calibration curve for Loratadine in Phosphate buffer pH6.8

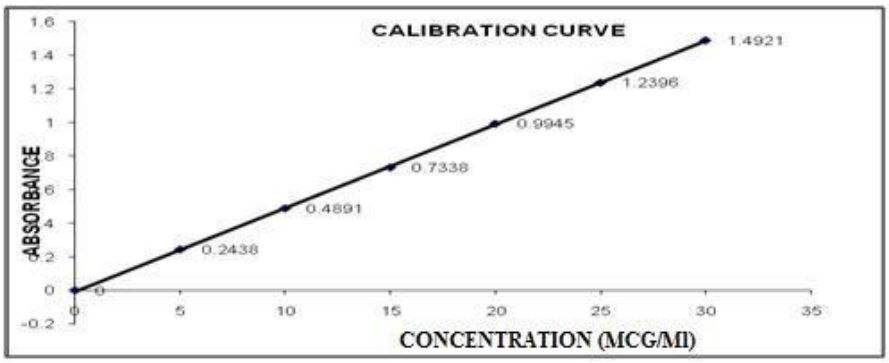


Table 8: Data for calibration curve parameters

S.No.	Parameters	Values
1	Slope(m)	0.049809
2	Intercept(c)	0.0053
3	Correlation coefficient(R)	0.999963

Percentage purity of pure drug

The percentage purity of drug was calculated by using calibration graph method (least square method).

Table 9: Percentage purity of pure drug

S.No.	**Percentage purity(%)**	**Avg. percentage purity(%)**
1	100.98	100.10 ± 0.64
2	99.64	
3	99.58	

All values are expressed as mean ± SE ,n=3.

Evaluation Of Powder Blends Of Loratadine

Table 10: Evaluation of Powder Blends of Loratadine

Formulation Code	Bulk density(g/ml)	Tapped density(g/ml)	Angle of repose(Θ)	Carr's index(%)	Hausner's ratio
F1	0.45±0.0125	0.50±0.0231	31.78±1.8815	11.19	0.8880
F2	0.43±0.0165	0.49±0.0099	30.67±0.9514	11.45	0.8854

F3	0.45±0.0042	0.50±0.0063	34.53±1.7870	9.56	0.9043
F4	0.41±0.0105	0.47±0.0124	28.42±1.2725	12.26	0.8773
F5	0.45±0.0090	0.52±0.0213	33.78±1.4577	13.79	0.8620
F6	0.47±0.0120	0.54±0.0217	29.04±1.1461	12.69	0.8730
F7	0.46±0.0103	0.50±0.0107	33.65±0.5445	9.65	0.9034
F8	0.48±0.0134	0.56±0.0216	28.66±1.673	14.18	0.858
F9	0.43±0.0171	0.48±0.0263	26.59±0.4705	10.31	0.8968

Evaluation of filled Loratadine tablets

Table 11 : Evaluation of Loratadine tablets.

mulationCode	Dimension		Hardness(kg/cm^2)	ability(%)	Drug content (%w/w)	Weightvariation
	Thickness (mm)	Diameter (mm)				
F1	2.90±0.10	7.86±0.20	3.26±0.05	0.8±0.05	98.50±0.11	204.6± 1.18
F2	2.9±0.17	7.73±0.32	3.36±0.11	0.8±0.15	98.75±0.01	205.15 ± 1.59
F3	2.76±0.25	7.83±0.24	3.26±0.15	0.9±0.1	98.25±0.15	206.15 ± 1.63
F4	2.80±0.10	7.96±0.20	3.36±0.15	0.9±0.13	95.25±0.13	207.15 ± 1,53
F5	2.70±0.17	7.76±0.32	3.33±0.25	0.8±0.07	98.50±0.06	207.10 ± 1.61
F6	3.0±0.10	7.80±0.45	3.4±0.10	0.8±0.09	97.70±0.23	205.10 ± 1.48
F7	2.86±0.11	7.93±0.35	3.4±0.10	0.8±0.06	97.75±0.14	206.40 ± 1.66
F8	2.96±0.05	7.76±0.30	3.4±0.10	0.9±0.10	98.75±0.17	207.15 ± 1.53
F9	2.8±0.10	7.83±0.20	3.0±0.10	0.9±0.11	98.75±0.01	201.55 ± 1.63

Weight variation

The direct compression technique was used to create the tablets. Because the material was free flowing, uniform die fill produced tablets of uniform weight. Tablets were obtained with permitted weight variations of less than 7.5 as per Pharmacopoeia standards.

Hardness

The Monsanto Hardness tester was used to analyze the tablets. The tablets' hardness ranged from 3.0 0.1 to 3.4 0.1 kg/cm2. Because of the identical compression force, uniform hardness was obtained. The hardness range measured demonstrated strong mechanicajl strength and the capacity to withstand physical and mechanical stress conditions.

Friability

The friability of tablets was determined using the Roche Friabilator, and it was found to be within an acceptable range. 0.8 0.090 - 0.9 0.117 (less than one percent) This suggested that the manufactured oral dissolving pills have a high mechanical resistance.

Drug content of Loratadine

The assay method was used to analyze the tablets. The drug content was within the permissible range. The drug content was found to be between 95.25 0.13 and 98.75 0.01 %w/w (i.e. 99-101% w/w). According to the Indian Pharmacopoeia 2007, the discovered range was within the specified limit.

Disintegration time

In the USP Disintegrate test device, tablets were tested for in-vitro disintegration time.VTD-DV (Veego Scientific) The in-vitro disintegration time ranged from 12 1.8973 to 30 1.8973 seconds for all nine formulations. Orange peel pectin and Croscarmellose sodium formulations exhibited quick disintegration. This is owing to the medium's quick intake of water, swelling, and burst effect. It was also shown that when the content of Croscarmellose sodium, Hibiscus Mucilage, and Orange Peel Pectin increased, the time required for the disintegrate decreased.

***In –Vitro* Dissolution Studies**

The Loratadine tablet dissolution profiles were established using the USP Type II Dissolution test apparatus (Veego scientific VDA-8DR) with a paddle speed of 100 rpm. Dissolution was carried out in 900 ml of 0.1N HCl kept at 370 0.50C. A 5 ml aliquot of dissolving medium was extracted at 3, 6, 9, and up to 12 minutes intervals and filtered using Whatmann filter paper. A UV-Visible spectrophotometer was used to quantify the amount of medication dissolved. by measuring the sample's absorbance at 247.5 nm. After each sampling, an equivalent volume of new medium prewarmed at 37oC was added to the dissolution medium to maintain the consistent volume throughout the test. Three experiments were conducted for each batch, and the average % drug release was calculated using the PCP disso V3 software.

Figure 5: Graphical representation of *invitro* dissolution profile of Loratadine tablet (F1-F9)

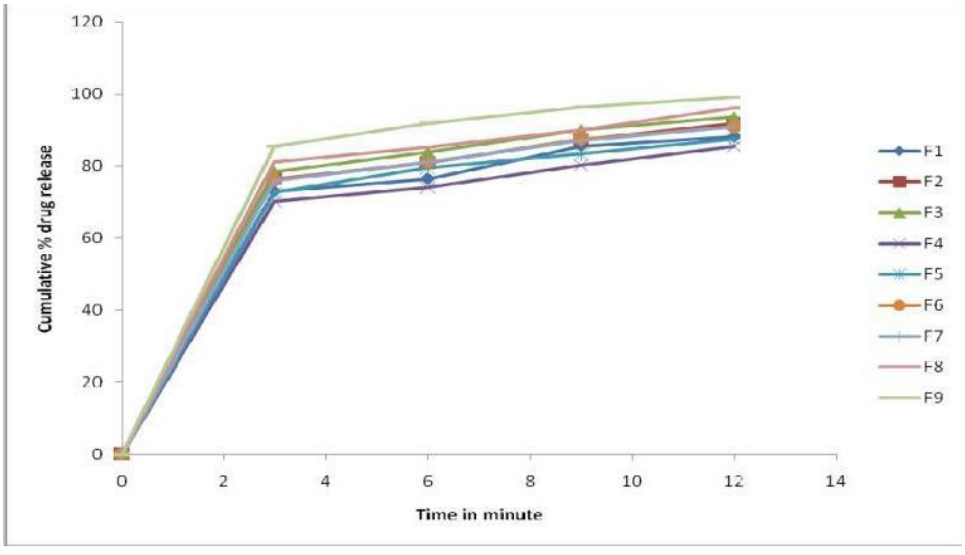


Table 12:*In-vitro* dissolution data of formulation F1

S.No.	Time (minutes)	Amount of drug released (mg)	%DE	MDT (minutes)	Cumulative %drug Release
1	0	0.00	0.00	0.00	0 ± 0.00
2	3	7.28	36.04	1.50	72.91±0.6266
3	6	7.64	55.24	1.69	76.42 ± 0.7985
4	9	8.54	63.84	2.26	85.5 ± 0.6221
5	12	8.81	69.60	2.57	88.14 ± 0.2214

Dissolution Profile for FormulationF3

Table 13: *In-vitro* dissolution data of Formulation F3

S.No.	Time(Minute)	Amount of drug released (mg)	%DE	MDT(Minute)	Cumulative % drug Release
1	0	0.00	0.00	0.00	0.00
2	3	23.48	39.00	1.33	78.31 ± 1.0102
3	6	25.14	41.21	1.42	83.81 ± 0.9072
4	9	8.99	44.06	1.53	90.01 ± 1.7596
5	12	9.35	45.61	1.58	93.54 ± 0.9073

Figure 6: Cumulative % drug release profile of formulation F1–F3

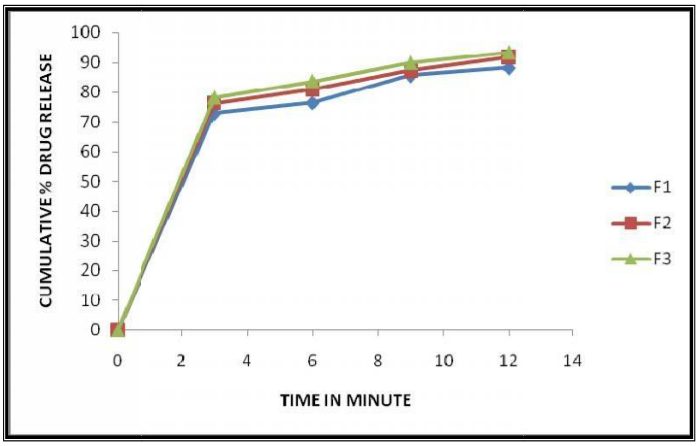


Table 14: *In-vitro* dissolution data of formulation F4

S.No.	Time(min)	Amount of drug released (mg)	%DE	MDT (Minute)	Cumulative% drug Release
1	0	0.00	0.00	0.00	0.000 ± 0.00
2	3	7.01	35.07	1.50	70.20± 1.9053

3	68.22	53.80	1.69	74.05± 0.5212
4	98.9	61.71	2.07	80.16 ± 1.0627
5	129.48	66.95	2.57	85.43 ± 0.5692

Figure 7: Cumulative % drug release profile of formulation F4 – F6

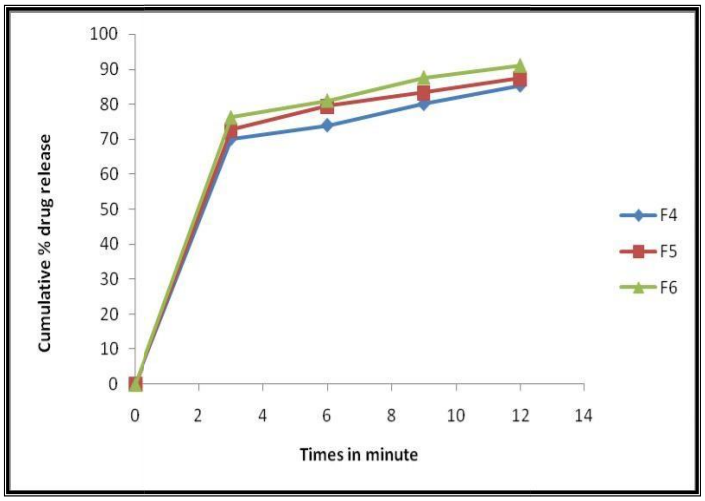
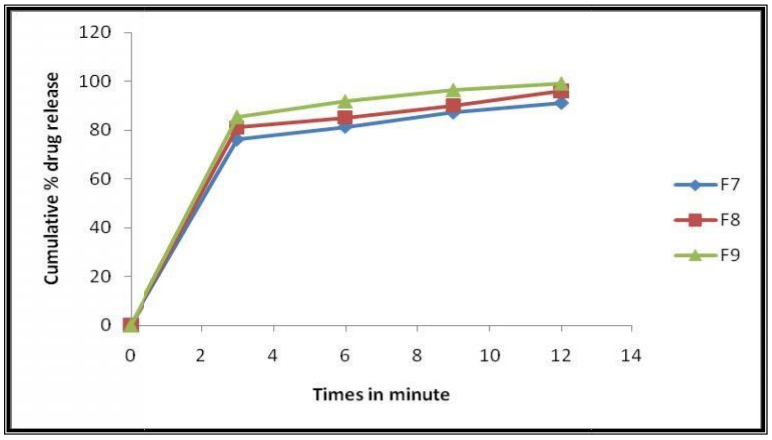


Figure 8: Cumulative % drug release profile of formulation F7–F9



STABILITY STUDIES:

Ageing studies for optimized formulation F9 of mouth dissolving Loratadine tablet at accelerated condition of

40oC ± 2oC/75% RH ± 5% (Initial)

Table 15: Comparative In-vitro dissolution data of formulation F9

Time in minute	**Cumulative% Release of Loratadine (Mean±S.D.,n=3)**			
	Initial	Firstmonth	Secondmonth	Thirdmonth
05	85.42 ± 1.673	85.10± 0.1	84.22± 0.230	83.99± 0.09
10	91.78 ± 0.905	90.68± 0.13	88.78± 0.1501	86.56± 0.103
15	96.40 ± 1.583	96.10± 0.1	94.56± 0.103	92.78± 0.04
30	99.10 ± 0.942	99.02± 0.011	98.52± 0.041	98.70± 0.264

Stability tests on formulation F9 were performed by exposing the samples to temperatures ranging from 40oC to 75% RH. According to the findings, there were no significant changes in the disintegration time, release characteristics, or physicochemical features of the tablets utilized in the release study. Based on the findings, the designed mouth dissolving pills were stable in accelerated stability conditions (40oC 2oC and 75% 5% RH) for three months. Even though its stability is guaranteed for three months, additional tests in accordance with ICH requirements are required to determine its shelf-life.

4. CONCLUSION:

The current study was conducted to develop and test an immediate release mouth dissolving tablet of Loratadine with the main goal of achieving a speedy start of action, followed by a pleasant mouth feel, and enhanced patient compliance.

Loratadine acts as an antihistaminic and is used as a potential drug to provide quick relief from sudden allergic reactions such as urticaria, angioedema, and in the treatment of perennial and seasonal allergic rhinitis. Considering this parameter, it is necessary to formulate the Loratadine as a fast disintegrating mouth dissolving tablet. Mouth dissolving pill bypasses hepatic metabolism unlike other typical oral dose forms, which are less accessible. This mouth dissolving tablet promotes medication absorption through the oral cavity, pharynx, and esophagus, resulting in a rapid beginning of action, enhanced bioavailability, and patient compliance.

As super disintegrants, orange peel pectin, hibiscus mucilage, and croscarmellose sodium were used. Microcrystalline cellulose is used as a diluent and, to a lesser extent, as a disintegrant. Similarly, Mannitol is utilized as a diluent and has the ability to provide a cooling sensation in the mouth. Aerosil was introduced at the same concentrations as a glident in all formulations. As a lubricant, magnesium sterate is used. Aspartame was invented.

Wetting time and swelling capacity of disintegrants are essential criteria for comparing disintegrate process efficiency. The maximum concentration of Orange peel pectin used in the F9 formulation demonstrated the greatest hydration and swelling capacity of 11 seconds and 125.80%, respectively. In just 10 seconds, orange peel pectin has 5 to 10 times the swelling capability. Orange peel pectin disintegrated faster than Croscarmellose sodium and Hibiscus Mucilage formulations.

The disintegrate time for all formulations ranged from 12 1.67 to 30 1.89 seconds. The disintegrate time for the F9 formulation, which has the highest concentration of Croscarmellose sodium, was found to be quite short.

This formulation met all of the tablet evaluation criteria for the Mouth Dissolving Drug Delivery System. As a result, it was determined that the F9 Formulation is the best formulation among F1 to F9.

Formulation Optimization F9 was evaluated for accelerated stability for three months according to ICH requirements and was determined to be stable at 40oC ± 2oC temperature and 75% 5% relative humidity.

Loratadine mouth dissolving tablet will undoubtedly provide a speedy start of action, quick relief, minimal side effects, a pleasant mouth feel, good stability, enhanced patient compliance, and increased popularity in the near future.

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