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DEVELOPMENT AND CHARACTERSATION OF FASTDISSOLVING TABLETS OF LAFUTIDINE BY USING NATURAL SUPER DISINTIGRANT

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ABSTRACT

The Fast dissolving tablets of Lafutidine have been organized via way of means of direct compression approach. The drug solubility become better by means of solid dispersion strategies like Melt evaporation approach and solvent evaporation approach. The characterization of the organized strong dispersions become finished. The mucilage extracted from the dehydrated Banana powder and *Plantago ovata* seeds become used as natural super disintegrant. The physicochemical parameters like pre-compression and post compression assessment have been accomplished as in step with pharmacopoeia requirements and compatibility. The FTIR spectral evaluation confirmed that there has been no drug interplay with formulations components of the tablet as there may be no variation and shift in bands, it could be justified there may be no interplay among drug and polymer. The Solid dispersion with 1:3 ratio suggests higher aqueous solubility and is the reason higher dissolution price of the drug. Pre compression parameters confirmed top glide properties. And Post compression parameters like thickness, hardness, weight-version, friability, wetting-time, water absorption ratio, disintegration time, drug content, in-vitro drug release take a look at proven top consequences. Formulation F2 confirmed desirable outcomes throught the take a look at. From the consequences, it become concluded that the FDTs of Lafutidine containing Dehydrated banana powder with the Solid dispersion Cross caramallose sodium are confirmed much less disintegration time and in-vitro drug release take a look at is quicker than the Solid dispersion of drug with the PEG 4000.

KEYWORDS: Fast dissolving tablets (FDTs), Lafutidine, Dehydtrated banana powder (DBP)and *Plantago ovata* mucilage (POM).

INTRODUCTION

The concept of the rapidly dissolving drug delivery system arose from a desire to provide patients with a convenient means of taking their medication. Due to the associated physiological changes, older people and children in particular can hardly swallow (dysphagia). Recent technological developments have prompted scientists to develop FDT with better compliance and patient comfort. When placed in the mouth, these tablets will dissolve or disintegrate in the mouth in the absence of additional water to facilitate administration of the active pharmaceutical ingredients).^[1]

United States Food and drug administration (FDA) defined fast dissolving tablet (FDT) as "a solid dosage form containing medicinal substance or active ingredient which disintegrate rapidly usually within a matter of seconds when placed upon the tongue.^[2]

Solid dispersions are generally used to improve the dissolution of poorly water-soluble drugs. The term solid dispersion encompasses a large number of systems. Solid

dispersions can increase dissolution rate through the following mechanisms; eutectic formation, increased drug surface area due to precipitation in the carrier, formation of a true solid solution, improved wettability due to intimate contact with a hydrophilic carrier, precipitation as a metastable crystalline form, or reduced crystallinity of Substance Both the vehicle and drug combination and the Manufacturing processes have a major impact on the type of solid dispersion formed."^[3]

In recent years, some newer substances known as super disintegrants have been developed. Natural super disintegrants are derived from natural origins and have a number of benefits such as Inexpensive, non-toxic, biodegradable, environmentally friendly, without side effects, renewable and are also a dietary supplement. Several studies have shown that natural polymers are more effective and safer than synthetic polymer.

MATERIALS AND METHODS Materials

Lafutidine was received as gift sample by Dr. Reddy

Laborotiers., *Planatago ovata* mucilage and Dehydrated banana powder was extracted in pharmaceutical lab, cross caramallose Na, PEG 4000, Lactose, Gelatin, Magnesium sterate, Talc are used for the formulation of tablets. All reagents and chemicals used were of laboratory grade.

METHODS

Preparation of Lafutidine solid dispersions

The solid dispersions of Lafutidine- cross caramallose sodium and Lafutidine – PEG 4000, were prepared by solvent evaporation method and Melt evapouration method respectively.

Solvent evaporation method

Weighed amount of Drug and carrier taken in ratio of 1:1, 1:2 and 1:3 (SD1, SD2, SD3). The polymer was dissolved in an adequate amount of methanol and Dichlromethane (1;1) ratio withconstant vigorous stirring until get a clear solution. The solvent was then rapidly evaporated in hot air oven (up to about 40 °C) with 50 RPM to form a uniform solid mass. The co-precipitate was crushed and stored in desiccators until further use.

Melt evapouration method

Weighed amount of Drug and carrier taken in ratio of 1:1, 1:2 and 1:3 (SD1, SD2, SD3). The complexation was done by heating the drug and carrier mixture at 55 TO 60 C. above the meltingpoint of the drug (94 C). The molten mass was cooled upto 40 to 45C. The methanolic solution of drug was added into molten mass in small portions with constant stirring. The methanol was evaporated in vaccum evaporator. The co-precipitate was crushed and stored in a desiccators until further use.

Isolation of plantago ovata Mucilage

Isapghula consists of dried seeds of the plant plantago ovata and it contains mucilage which is present in the epidermis of the seeds. The seeds of *Plantago ovata* were soaked in distilled water for 48 hrs. Then boiled for few minutes for complete release of mucilage into water. The material was squeezed through muslin cloth for filtering and separating out the marc. Then, an equal volume of acetone was added to the filtrate so as to precipitate the mucilage. The separated mucilage was dried in oven at temperature less than 60°C.^[5]

Isolation of Dehydrated banana powder

Bananas were purchased from local market of Bagalkot. Peels were removed and fruits were sliced. Sliced pulp was washed with distilled water to remove water soluble contents. 0.2% w/w methyl paraben was added as preservative. Sliced pulp was ground in domestic mixer and driedin oven at 45°C for 24 hour.^[6]

CHARACTERIZATION OF SOLID DISPERSIONS Phase Solubility studies

The solubility of both Lafutidine drug: Cross caramallose sodium and PEG 4000 solid dispersions was determined in the water. Solubility study was conducted as per the method reported by Higuchi and Connors.^[15] Excess quantity (50 mg) of the drug was taken for study. The solubility of Lafutidine and physical mixture was determined in different media (0.1N HCL and distilled water). Drug and carrier as per the specified drug: Carrier ratio was weighed accurately and added to 10 ml of water in screw-capped bottles. All the bottles were shaken in anincubator shaker at 37°C and 24°C for 24 h. Then, the solutions were filtered, and concentration of drug was determined by ultraviolet (UV) spectrophotometer.^[7]

Product Yield

The production of yield of solid dispersions was calculated using the final product after drying with respect to the initial total weight of the drug and carrier used for the preparation of solid dispersion. Percent production yield were calculated as per the formula mentioned below,

 $Py = Wo/Wt \times 100Where,$

Py= Product yield,

Wo= Practical mass (solid dispersion) Wt= Theoretical mass (carrier + drug)

Drug content

About 100 mg drug equivalent of SD was weighed accurately and transferred to 100 ml volumetric flask. From this stock solution (100 μ g/ml), 1 ml was withdrawn and further diluted up to 10 ml with 1.2 pH. This solution was used for the assay for drug content by UV spectrophotometer at 236nm. Concentration of drug in stock solution was calculated by using calibration curve and from which percent drug content was calculated.

% Drug content = Absorbance \times D.F/100 \times 1000Where, D.F= Dilution factor.

Dissolution study of solid dispersion with pure drug

In-vitro dissolution study of optimized SDs was carried out using Lab India Dissolution Apparatus (LABINDIADS 8000, India), Samples equivalent to 10 mg of Lafutidine was hold inmuslin cloth and then added 900ml phosphate buffer pH 1.2, maintained at 37±1 for at 50 rpm. 5ml of sample was withdrawn after specified time dissolution medium. Collected samples were analysed spectro photometrically at measured wavelength of 236nm, and cumulative percent drug release was calculated. Drug release profile was studied using percentage drug releaseversus time (hr) plot.

Formulation of Fast Dissolving Tablets of Lafutidine

Fast dissolving tablets of Lafutidine were prepared by direct compression method, in this powder blends of active ingredient and suitable excipient, which flow uniformly in the die cavityand forms a firm compact was prepared as per the composition shown in the below table. Solid dispersion of drug was mixed with Mucilage of Dehydrated Banana powder and *Plantago Ovata* as a super disintegrants in 2.5%, 5%, Lactose used as diluent, to enhance compressibility, Carboxy methyl cellulose

and , talc used as a glidant, magnesium stearate as a lubricant. All the powders were mixed well and compressed in Multi station tablet punching machine using 8 mm round shaped, flat punches to obtain the tablets. Each tablet weighed 200mg.

INGREDIENTS(mg)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Lafutidine									10
Lafutidine SD (solvent evaporation method)	80	80	80	80					
Lafutidine SD (Melt evapouration)					80	80	80	80	
DBP	10	30			10	30			
РОМ			05	10			05	10	
Lactose	95	75	100	95	95	75	100	95	165
CMC	10	10	10	10	10	10	10	10	10
Gelatin	2	2	2	2	2	2	2	2	2
Mg. sterate	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Talc	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5

EVALUATION OF TABLETS

Preformulation studies

Pre-compression studies were carried out by standard methods. The flow property were characterized in terms of angle of repose, bulk density, tapped density, carr's index, hausner'sratio.^[8]

Post compression parameters

Compressed tablets were then evaluated for thickness, hardness, weight variations and friability. Diameter and thickness were measured by using digital vernier caliper. Hardness was measured by Monsanto type hardness tester. Weight variation is carried out in single pan balance. Friability testing was done by using Roche friabilator.^[9]

Wetting Time

The method was applied to measure tablet wetting time. A piece of tissue paper folded twice wasplaced in a small petridish (i.d. = 6.5cm) containing 10ml water, a tablet was placed on the paper, and the time for complete wetting was measured. Three trials for each batch were performed and standard deviation was also determined.^[10]

Water absorption ratio

A piece of tissue paper folded twice was placed in a small petridish containing 6ml of water. Atablet was put on the paper and time required for complete wetting was measured. The wetted tablet was then weighed. Water absorption ratio, R was determined using following equation. Three tablets from each formulation were performed and standard deviation was also determined.^[11]

R = 100(Wa - Wb)/Wb

Where,

Wb – weight of tablet before absorption, Wa – weight of tablet after absorption

In-vitro disintegration time

The process of breakdown of a tablet in to a smaller particles is called as disintegration. The *in-vitro*

disintegration time of a tablet was determined using disintegration apparatus as per I.P specifications.

I.P specifications: Place one tablet in each of 6 tubes of the basket. Add a disc to each tube andrun the apparatus using pH 1.2 maintained at $37^{\circ}\pm 2^{\circ}$ C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the pH 1.2 maintained at $37^{\circ} \pm 2^{\circ}$ C. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

Drug content

Six tablets weighed and crushed in a mortar then weighed powder contain equivalent to 100mg of drug transferred in 100ml of Methanol. Subsequently, the solution in volumetric flask was filtered, suitable dilutions will be carried out. And final solution were analysed at 236nm using UV-visible spectrophotometer Shimadzu UV-2450, Japan.^[12]

In-vitro release study

In-vitro drug release was studied using Lab India Dissolution Apparatus (LABINDIADS 8000, India), in 900ml phosphate buffer pH 1.2, maintained at 37 ± 1 for 60 minutes, at 50 rpm. 5ml of sample was withdrawn after specified time dissolution medium. Collected samples were analysed spectrophotometrically at measured wavelength of 236nm, and cumulative percent drug release was calculated. Drug release profile was studied using percentage drug release versus time (hr) plot.

Fourier Transform Infra-red Spectroscopy

FTIR carried out by KBr disc method. KBr was dried in hot air oven at 60°C for 1hr. The samples were prepared by mixing it thoroughly with potassium bromide. This mixture was then placed in a scanning slot of Fourier Transform Infra-red (FTIR) spectrophotometer and scanned at range from 400 to 4000 cm-1 to obtain FTIR of API. The spectrum was then compared with the spectrum of reference standard.

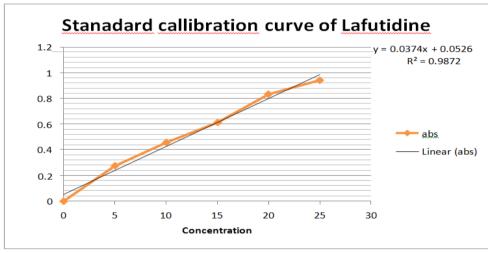
Stability Studies

Stability studies of pharmaceutical products were done as per ICH guidelines. In order to determine the change in *in-vitro* release profile on storage, stability study of formulation codeF3- F5 was carried out at 40°C in a humidity chamber having 75% RH. Samples werewithdrawn at regular intervals during the study of 60 days. Formulation is evaluated for change in hardness, friability, disintegration time, drug content and *in-vitro* drug release pattern.^[13]

RESULTS

1. Standard calibration curve. Table No. 2: Absorbance data for the standard calibration curve of Lafutidine.

SI. NO.	Concentration (µg/ml)	Absorbance
1	0	0
2	5	0.275
3	10	0.457
4	15	0.613
5	20	0.832
6	25	0.943



Characterization of solid dispersion Phase Solubility studies.

Phase solubility study

Table no 03: Results of Phase solubility study.

SI.NO	Drug	polymer	Ratio	Solubility (mg/ml)±S.D
1	Lafutidine			0.023
2	Lafutidine	Cross caramallose Na	1:1	0.048
3	Lafutidine	Cross caramallose Na	1:2	0.063
4	Lafutidine	Cross caramallose Na	1:3	0.092
5	Lafutidine	PEG 4000	1:1	0.032
6	Lafutidine	PEG 4000	1:2	0.053
7	Lafutidine	PEG 4000	1:3	0.097

Product yield

The production yield of solid dispersions of Cross caramallose Na and PEG 4000 prepared by solvent

evaporation method and Melt evaporation method was found to be 93% and 95%.

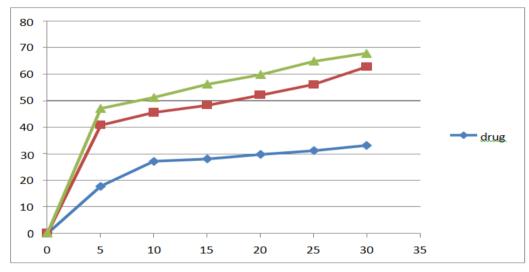
Drug content

Table no 4: Result of Drug content (%)

in or Drug	it of Drug content (76)								
SL.NO	Drug	Polymer	Ratio	Drug content(%)					
1	Lafutidine	Cross caramallose Na	1:1	91.2±21					
2	Lafutidine	Cross caramallose Na	1:2	97.8±43					
3	Lafutidine	Cross caramallose Na	1:3	99.3±54					
4	Lafutidine	PEG 4000	1:1	97.5±34					
5	Lafutidine	PEG 4000	1:2	95.2±13					
6	Lafutidine	PEG 4000	1:3	98.7±51					

		% Drug release						
SL. No.	Time(min)	Drug	Lafutidine +cross caramallose Na (1:3)	Lafutidine +PEG 4000 (1:3)				
1	10	10.8%	40.8%	47.1%				
2	20	15.6%	45.6%	51.2%				
3	30	18.2%	48.3%	56.2%				
4	40	22.2%	52.1%	59.8%				
5	50	24.2%	56.1%	64.8%				
6	60	27.1%	62.8%	67.9%				

Dissolution study of solid dispersions of Lafutidine and pure drug (Lafutidine). Tableno 5: Dissolution study of pure drug and Lafutidine solid dispersions.



Cumulative percentage drug release Vs Time of SD

Pre-Compression evaluations of Lafutidine formulations.	
Table No. 6: Physical Properties of Lafutidine formulations.	

Formulation.	Angle of repose(θ)	Bulk Density. (gm/ml)	Tap Density. (gm/ml)	CarrsIndex. (%)	Hausnersratio
F1	25.29	0.521	0.612	14.86	1.174
F2	28.56	0.483	0.531	9.039	1.099
F3	26.24	0.512	0.606	15.51	1.183
F4	27.38	0.621	0.652	4.829	1.042
F5	26.43	0.532	0.619	14.05	1.163
F6	25.26	0.582	0.623	6.581	1.070
F7	28.47	0.531	0.629	15.58	1.184
F8	27.38	0.593	0.641	7.488	1.080
F9	25.56	0.491	0.523	6.118	1.065

Post-compression evaluation of Lafutidine

Table No. 7: Evaluated for Thickness, Hardness, Uniformity of Weight variation, Friability.

Formulation	Thickness (mm) ± SD	Hardness(kg/cm ²) ± SD	Weight variation(mg) ±SD	Friability(%)±SD
	~ -			
F1	2.93±0.02	2.72±021	201.3±1.23	0.80 ± 0.04
F2	2.82±0.11	2.42±003	201.4±1.08	0.97±0.03
F3	2.28±0.51	2.91±020	200.1±1.32	0.10±0.12
F4	2.13±0.32	3.21±003	200.7±0.82	0.19±0.11
F5	2.06±018	2.03±012	200±0.13	0.15±0.08
F6	2.12±010	2.18±031	199.7±0.89	0.35±0.12
F7	2.96±001	3.12±018	199.6±0.15	0.20±0.13
F8	2.86±003	2.41±002	199.2±1.42	0.46±0.12
F9	3.03±033	3.05±0.23	199.5±1.23	0.35±0.11

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Formulation	Wetting time.(Sec) ± SD	Water absorption ratio(%)± SD	Disintegrationtime(sec) ± SD	Drug content(%)
F1	62±0.32	47.91±0.23	42.3±1.03	94.6
F2	48±0.43	48.71±0.54	33.6±1.21	98.1
F3	58±0.14	47.01±0.32	43.3±1.41	91.6
F4	62±0.53	50.24±0.14	41±1.03	95.4
F5	72±0.18	42.21±0.62	54.7±1.52	94.0
F6	68±0.17	56.7±0.14	54.6±1.02	97.04
F7	77±0.52	41.8±0.42	55.3±1.09	92.4
F8	62±0.17	39.6±0.71	48.6±1.13	97.2
F9	125±0.43	49.2±0.21	150±1.04	95.9

Table No. 8: Evaluated for Wetting-time, Water absorption Ratio, Disintegration time, Drug- Content.

Table No.9: In-vitro dissolution studies.

Time(Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	30.4	35.72	30.32	35.05	37.04	23.75	28.36	38.04	14.06
2	43.23	54.30	45.75	53.12	39.57	37.31	46.0	51.07	18.56
5	51.23	63.36	55.25	61.67	43.25	55.16	54.85	54.83	20.15
10	63.23	64.44	64.60	64.57	54.70	64.23	63.72	63.24	41.32
15	69.67	79.10	69.17	78.86	64.34	68.28	72.59	77.23	52.51
30	77.86	85.69	72.67	82.73	71.58	79.86	78.55	83.49	40.32

Solid Dispersion with Cross caramallose Na

- F1 : Dehydrated banana powder 2. 5%
- F2: Dehydrated banana powder 5%
- F3 : Plantago ovata mucilage 2.5%
- F4 : Plantago ovata mucilage 5%

Solid dispersion with PEG 4000

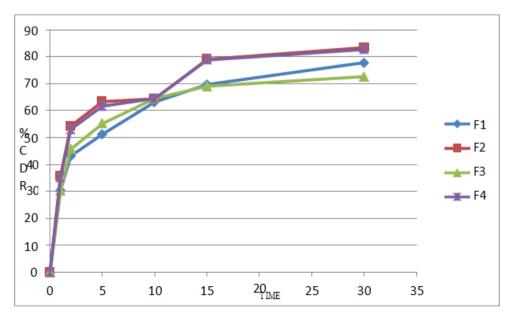
F5 : Dehydrated banana powder 2.5%

F6 : Dehydrated banana powder 5%

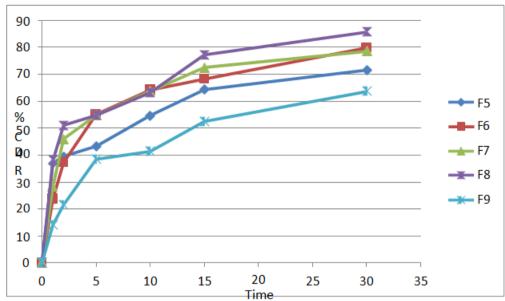
F7: Plantago ovata mucilage 2.5%

F8: Plantago ovata mucilage 5%

F9:- Without Solid dispersion and Disintegrating agents.



F1: Lafutidine SD (Cross caramallose Na) and Dehydrated banana powder 2.5% F2: Lafutidine SD (Cross caramallose Na) and Dehydrated banana powder 5% F3: Lafutidine SD (Cross caramallose Na) and *Plantago ovata* mucilage 2.5% F4: Lafutidine SD (Cross caramallose Na) and *Plantago ovata* mucilage 5%



F5 : Lafutidine SD (PEG 4000) and Dehydrated banana powder 2.5%

F6: Lafutidine SD (PEG 4000) and Dehydrated banana powder 5%

F7 : Lafutidine SD (PEG 4000) and *Plantago ovata* mucilage 2.5%F8 : Lafutidine SD (PEG 4000) and *Plantago ovata* mucilage 5%

F9:- Without any Disintegrating agents.

Stability studies for optimized formulations

Parameter.	0-Days.	15-Days.	30-Days.	60-Days.
Hardness(kg/cm ²)	2.42±0.03	2.42±0.03	2.39±0.03	2.23±0.03
Friability (%)	0.97±0.03	0.97±0.03	0.95 ± 0.03	0.91±0.03
Disintegration time (Sec)	33.6±1.21	33.6±1.21	33.2±1.21	32.6±1.21
Drug-Content (%)	98.1%	98.1%	97.9%	96.1%
In-vitro drug release (%)	85.69%	85.69%	84.69%	82.69%

DISCUSSION

In the prevailing look at nine formulations with variable concentration of polymer have been organized and evaluated for physiochemical parameters. The formulated batch compositions have been proven in The organized SD's have been subjected for solubility look at to assess the impact of carrier at the aqueous solubility of Lafutidine and end result of Phase solubility evaluation are proven in shape the end result of phase solubility evaluation it is able to be simply set up that the carrier like cross caramallose Na and PEG 4000 are having superb solubility improving property. The aqueous solubility of drug elevated appreciably with growing attention of the carriers. On the premise of the Phase improving property. the aqueous solubility of drug elevated appreciably with growing attention of the carriers. On the premise of the phase solubility determination, the solubility of the 1:3 ratio become observed to be 0.092mg/ml and 0.098mg/ml. The 1:3 ratio of solid dispersion become used for the in formulation and evaluated The in-vitro dissolution profiles of the drug and solid dispersion are proven in table 05. Drug exhibited a slow dissolution, in which as solid dispersion confirmed a marked enhancement in dissolution rate. Thus, dissolution as much as 62.8% and 67.9% become recorded with solid dispersion in 30 min.

The compatibility have a look at become accomplished via way of means of IR Spectroscopy. The FTIR spectral evaluation confirmed that there has been no drug interplay with formulations components of the tablets.

Angle of repose become achieved with the aid of using funnel method. All the formulations have been observed with inside the variety of 22.29° to 28.56°. All formula proven inside and close by 30°, which suggests superb free flowing properties. The bulk density and Tap density consequences have been proven with inside the Table. No.06. Bulk density become observed to be in variety of 0.483 gm/ml to 0.593 gm/ml, and Tapped density become observed to be 0.523 gm/ml to 0.652 gm/ml, for Lafutidine formulations. The values received lies with inside the applicable variety and now no longer a lot difference have been observed.

The % compressibility of all of the formulations lies inside the variety of 6.118% to 14.86%. It is an oblique index of ease of powder flow. The values had been lies inside the variety of 11 to 15 which shows all formulations had been displaying the best flow properties and consequences had been proven in Table No.6.

The tablet thickness became observed to be 2.06±0.018

mm to 3.03 ± 0.033 mm and the tablet hardness became observed to be 2.03 ± 0.012 kg/cm2 to 3.21 ± 0.003 kg/cm2 and the consequences became observed to be inside the limits. Prepared drugs had been evaluated for weight version. Percentage deviation from the common weight became observed to be inside the prescribed reputable limits.

The weight version became observed to be $199.2\pm1.$ forty two mg to 201.3 ± 1.23 mg. Thefriability of all of the formulations became observed to be among $0.10\pm0.12\%$ to $0.80\pm0.03\%$. which became observed to be inside the reputable requirement (i.e now no longer extrathan 1%).

The wetting time of all of the formulations become discovered to be48 sec to 125 sec. The water absorption ratio of all of the formulations become discovered to be 39.6 ± 0.75 % to 56.7 ± 1.0 %. The disintegration time of all of the formulations become discovered to be 33.6 ± 1.00 sec to 150 ± 1.00 sec. The drug content material estimation statistics for all of the formulations have been discovered to be 91.6% to 98.1%. The formulation (F2) become taken into consideration to be efficient many of the all kind formulations.

The disintegration and dissolution time profile confirmed first-class end result for the solid dispersion (PEG 4000) containing Plantago ovata mucilage Drug release profile become studied the usage of percent drug launch versus time (hr) plot. The effects have been depicted in Table No.09. Formulations F1, F2, F3 and F4 confirmed 77.86%, 85.69%, 72.67% and 82.73%.

Release of drug respectively at 30min. Formulations F5, F6, F7, F8 and F9 confirmed 71.58%, 79.86%, 78.55%, 83.49% and 40.32%. respectively.

Among all formulations, F2 confirmed quicker launch of drug. On the premise of drug content material, in- vitro launch study, disintegration time and wetting-time effects, formulations F2 become subjected for balance research as in line with ICH guidelines. The effects determined have been now no longer tons numerous in integrity of the drugs at exceptional temperature conditions. There become no full-size extrade in hardness, friability, disintegration-time, drug content material and in-vitro launch study. The effects have been depicted in Table No. 09.

CONCLUSIONS

The role of this investigation has been achieved by preparing fast drug delivery technique of Lafutidine with aid of super disintegrating agents like Dehydrated Banana powder and plant *Plantago ovate* mucilage. Fast dissolving tablets of Lafutidine were successfully formulated and evaluated. The work is carried out using natural polymers with different concentrations. FTIR studies proved that there is no chemical interaction between Lafutidine and polymers. Formulations were found to be complying with all the properties of tablets and the formulations were satisfactory.

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