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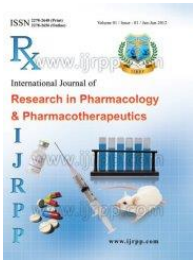

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Fabrication and in-vitro characterization of ORO dispersible tablets of lafutidine

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ABSTRACT

In the present work, oral dispersible tablets of lafutidine were prepared by direct compression method with view to enhance safety and efficacy of drug molecule as well as to achieve better patient compliance. The objective of this present study is to develop orodispersible tablets of lafutidine using superdisintegrant by simple cost effective direct compression technique which increases the rate of dissolution may leads to increase in oral bio availability. Crospovidone, Sodium Carboxy methyl Cellulose and pregelatinized starch were used as superdisintegrant on account of their well established production technology by direct compression. Lafutidine is a namely developed second generation of histamine H_2 receptor antagonist. Lafutidine is having short biological half-life (1.92 ±0 .94 hour), plasma protein binding capability of Lafutidine is 88% and oral bioavailability 22-35%. The prepared tablets were evaluated for thickness, uniformity of weight, content uniformity, hardness, porosity, friability, wetting time, water absorption ratio, *In-vitro* disintegration time within 18 to 65 sec, and the dissolution profile range in 30 minutes was 88.13% to 97.79%. Drug content was estimated spectrophotometrically at 283nm.DSC & IR spectral analysis were proved that reference Lafutidine and its formulations showed similar absorption bands. It was concluded that superdisintegrants addition technique is favorable for preparing oral dispersible tablets by direct compression method.

Keywords: Direct compression, Fabrication, Lafutidine, ODT, Superdisintegrant.

INTRODUCTION

Drug delivery through oral route is the most common and preferred route of drug administration both for solid and liquid dosage forms. However, solid dosage forms are popular because of the ease of administration, accurate dosage, self-medication, pain and avoidance, most importantly the patient compliance. Tablets and capsules are the most popular solid dosage forms. However, many people face dysphasia, especially with pediatric and geriatric populations or any mentally challenged persons [1]. It is immediate and essential to overcome this problem with the oro dispersible tablets which are orally disintegrating tablets, mouth-dissolving tablets, rapid-dissolving tablets, fast-disintegrating tablets and fast-dissolving tablets. These are uncoated tablets intended to be placed in the mouth where they disperse readily within three min before swallowing with rapid bioavailability and quick onset of action [2, 3]. Becaue of its stability, these tablets are better compliance with all patients [4-8].

Lafutidine is a namely developed second generation of histamine H_2 receptor antagonist. It is used in the treatment of gastric ulcers, duodenal ulcers and gastric mucosal lesions associated with acute and chronic gastritis. Lafutidine Has receptors binding affinity which is 20 – 80 times higher than famotidine, ranitidine and cimetidine. Lafutidine is absorbed in the upper part of small intestine, reaches gastric cells via the systemic circulation and rapidly binds to gastric cells H_2 – receptors, resulting in immediate inhibition of gastric acid secretion [9, 10].

MATERIALS AND METHODS

Materials

Lafutidine (Niksan pharmaceutical,Gujarat), Sodium Carboxy Methyl Cellulose (Central Drug House Pvt.,Ltd.,Delhi), Cross Povidone (Madras Pharmaceuticals – Chennai), Pre gelatinished starch (Apex laboratories pvt. Ltd., Chennai).

Compatibility studies

The drug-excipient compatibility studies were carried out using Fourier Transform Infrared Spectrophotometer (FTIR). Infra red spectra of pure drug and mixture of drug and excipients were recorded. The samples were prepared in KBr dish and scanned over 400-4000cm^{-1}.

Differential scanning calorimetry (DSC) for best formulation

Differential scanning calorimetry is used for screening. The specified samples is hermetically sealed aluminium pans at temperature 20^{O}C/min nitrogen were purged at 50ml/min and 100ml/min through cooling unit.

Preparation of oro dispersible tablets of Lafutidine

The oro dispersible tablets of Lafutidine was prepared by direct compression method using super disintegrate crospovidone, sodium carboxy methyl cellulose and Pregelatinize starch, manitol used as mouth feel enhancer,Microcrysstalline cellulose as diluted and binder, lactose as diluents, aspartame as sweetner, talc as glidant and Magnesium stearte as lubricant. All the ingredients were passed through 60 mesh Separately, weighed and mixed in geometrical order in to motor and pestle for 10 min.The blend thus obtained was directly compressed on 12 station rotary punching machine to get 10 mg of lafutidine.Each tablet weighing of 200 mg. F1,F2,F3 formulation are prepared by using sodium carboxy methyl cellulose super disintegrants in 2%,3%,4% respectively.F4,F5,F6 frmulation prepared by using cros povidone superdisintegrant in 2%,3%,4% respectively.F7,F8,F9 formulation prepared by using pregelatinized starch superdisintegrants in 2%,3%,4% respectively. F10.F11,F12 formulation prepared by using combination of SCMC ,pregelatinized starch, cros povidone in 3%,4.5%,12% respectively. The compositions of the different formulation were given in **Table 1a and 1b.** Twelve Formulations (F1 to F12) were prepared formula designed. All the tablets were white color and round in shape having 6 mm diameter. [11-15]**.**

Table: 1 a Composition of oro dispersible tablet of lafutidine

S.NO	Ingredients(mg)	F1	F2	F3	F4	F5	F6
1	Lafutidine	10	10	10	10	10	10
2	Sodium carboxy methyl cellulose	5	10	15	-	-	-
3	Crospovidone	-	-	-	5	10	15
4	Pregelatinzied Starch	-	-	-	-	-	-
5	Scmc + Cross + Press	-	-	-	-	-	-
6	Microcrystalline cellulose	90	90	90	90	90	90
7	Lactose	61	56	51	61	56	51
8	Mannitol	20	20	20	20	20	20
9	Aspartame	10	10	10	10	10	10
10	Talc	2	2	2	2	2	2
11	Magnesium stearate	2	2	2	2	2	2

Table: 2 b Composition of oro dispersible tablet of lafutidine

S.NO	Ingredients(mg)	F7	F8	F9	F10	F11	F12
1	Lafutidine	10	10	10	10	10	10
2	Sodium carboxy methyl cellulose	5	10	15	-	-	-
3	Crospovidone	-	-	-	5	10	15
4	Pregelatinzied Starch	5	10	15	-	-	-
5	Scmc + Cross + Press	-	-	-	10	15	20
6	Microcrystalline cellulose	90	90	90	90	90	90
7	Lactose	61	56	51	61	56	51
8	Mannitol	20	20	20	20	20	20
9	Aspartame	10	10	10	10	10	10
10	Talc	2	2	2	2	2	2
11	Magnesium stearate	2	2	2	2	2	2

Evaluation of Lafutidine oro dispersible tablets

The preparated lafutidine tablets were subjected to pre and post compression evaluation.

Pre compression evaluation

The flow properties of powdered blend were characterized in terms of angle of repose, bulk density, tapped density, Carr's compressibility index and Hausner's ratio as per, [16-17].

Post compression parameters

The prepared tablets were evaluated for weight variation, hardness, friability, thickness and diameter, drug content estimation and in vitro disintegration time as per Kanaka Durga Devi et al., [18, 19].

In-vitro drug release study

Dissolution rate was studied by using type-II apparatus (at 50rpm) using 500ml phosphate buffer pH 6.8 as dissolution medium.Temperature of the dissolution medium was maintained at 37±0.5ºC, sample was withdrawn at every 5 min interval and diluted suitably and the absorbance of the resulting solution was measured at 283nm by using UV spectrophotometer and concentration of the drug was determined from the standard calibration [20].

In- vitro disintegration time

The test was carried out by using the apparatus specified in IP, tablets were tested for disintegration time at 37±0.5ºC taking distilled water as medium [21].

Water absorption ratio

Water absorption ratio test was used to ensure the capacity of the superdisintegrant and the diluent to absorb the water. A Piece of tissue paper folded twice was placed in a small petri dish containing 6ml of water. A tablet was placed on the paper and time required for complete wetting was measured and wetted tablet was weighed [22].

Wetting time

Wetting time of the tablet was used to assess the capacity of the tablets to disintegrate by swelling in water. A Piece of tissue paper folded twice was placed in a small petri dish containing 6ml of water or eosin dye and a tablet was put on the paper. The time for complete wetting was measured [23].

RESULTS AND DISCUSSION

Determination of λ max

Lafutidine (reference) was estimated by scanning the drug solution (10µg/ml) between 200-400 nm region by using UV spectrophotometer. The obtained spectrum showed absorption maximum (λmax) at 283 nm for the Lafutidine.

Calibration of Lafutidine

Calibration curves of Lafutidine were estimated by using phosphate buffer pH 6 and its absorbance were measured at λmax of 283nm. The correlation coefficient was found to be 0.9994 and obeyed the Beer's law of various concentration of Lafutidine (5-50µg/ml). The results are displaced in **Table 1.**

Table: 1 Calibration of Lafutidine

S.NO	CONCENTRATION (µg/ml)	ABSORBANCE
1	**5**	0.0843 ±0.0019
2	10	0.1606±0.0028
3	15	0.2427±0.0044
4	20	0.3251±0.0186
5	25	0.3982±0.0104
6	30	0.4756±0.0093
7	35	0.5542±0.0135
8	40	0.6311±0.0061
9	45	0.7123±0.0168
10	50	0.7894±0.0214

Regression = 0.9994 ± 0.0001667

Compatability studies by Fourier Transform Infrared Spectroscopic (FT-IR)

FT-IR spectrum of lafutidine, excipients and its formulation were recorded. The spectra of reference Lafutidine showed characteristic peaks at 3282 cm^{-1}, 3118cm^{-} 1656 cm^{1}, 1608cm^{-1}. All the above peaks were also observed in the spectra of mixture of lafutidine and excipients, this indicaties there is no interaction between Lafutidine and excipients used in the formulation. The spectra are displayed in Fig 1-8.

Differential Scanning Calorimetry (DSC) studies

DSC thermogram of lafutidine exhibited a sharp endothermic peak at at 104.18^{o}C which corresponding to its melting temperature. The thermogram of the final best formulation of lafutidine with other excipients show the existence of drug endothermic peak within the range which indicated the absence of interaction between the drug and other excipients. The DSC thermogram of pure drug and the best formulation(F12) and is presented in **Figure no 9** & 10.

Pre compression evaluation of powder blend

Angle of repose

The angle of repose was used to determine the flow properties of powder blend. The angle of repose of the formulations ranged from 24˚05' to 30˚02'.The results indicated that the formulations with synthetic superdisintegrant exhibited good flow properties whereas the natural superdisintegrants had a passable flow property. The results of angle of repose for all the formulations were shown in **Table 3**.

Bulk density

The bulk density is used as an index of the ability of the powder to flow. The bulk density of the formulations was in the range of 0.684 – 0.711 g/ml. The values of bulk density showed that the blend was not tightly packed and indicated good flow properties for synthetic super disintegrants and passable for natural super disintegrants diluents. The results of bulk density for all the formulations were shown in **Table 3**.

Tapped density

The tapped density was used to access the free flowing properties of powder blend. The tapped density of the formulations were in the range of 0.77-0.87 g/cm^3.The results indicated that the blends of the formulation had good flow properties for synthetic superdisintegrants and passable for natural superdisintegrants. The results of tapped density for all the formulations were shown in **Table 3**.

Table: 3 -Evaluation of mixed powder blend of Lafutidine

Formulation Code	Angle of repose (ɵ)mean ± SD	Bulk density (g/ml) mean± SD	Tapped density (g/ml) mean ± SD
F1	28.1 ± 0.09	0.704 ± 0.07	0.775 ± 0.19
F2	26.3± 0.12	0.684 ± 0.18	0.833 ± 0.31
F3	27.34± 0.24	0.693 ± 0.65	0.806 ± 0.23
F4	26.9 ± 0.10	0.687 ± 0.35	0.840 ± 0.24
F5	30.0 ± 0.02	0.707 ± 0.17	0.848 ± 0.09
F6	28.0± 0.03	0.685 ± 0.20	0.824 ± 0.28
F7	24± 0.39	0.711 ± 0.12	0.790 ± 0.19
F8	27.37± 0.24	0.70 ± 0.16	0.875 ± 0.41
F9	25.75± 0.12	0.697 ± 0.35	0.776 ± 0.29
F10	29.40± 0.41	0.70 ± 0.16	0.875 ± 0.41
F11	2.61± 0.41	0.70 ± 0.16	0.875 ± 0.41
F12	27.34± 0.29	0.693 ± 0.65	0.806 ± 0.23

Carr's compressibility index

The Carr's compressibility index was used to access the free flowing properties of powder blend. The compressibility index of all the formulations ranged from 16.9 –23.17%. The value below 16% has a good flow property and good propensity of compression. The results of compressibility for all formulations were shown in **Table 4.**

Hausner's ratio

Hausner's ratio was an indirect index of ease of powder flow. The Hausner's ratio of all the formulations ranged from 1.11-1.25. This indicates better flow property of blend. The results of Hausner's ratio for all the formulations were shown in **Table 4.**

Table: 4 Evaluation of mixed powder blend of Lafutidine

Formulation Code	Carr's index (%) mean± SD	Hausner's ratio Mean ± SD
F1	19.1±0.01	1.10± 0.02
F2	18.1±0.31	1.21± 0.03
F3	16.9 ± 0.03	1.16± 0.01
F4	**18.17± 0.01**	1.22± 0.03
F5	16.66 ± 0.54	1.20± 0.03

F6	21.5 ± 0.02	1.20±0.02
F7	20.8 ± 0.02	1.11±0.01
F8	23.1 ±0.0.01	1.25±0.00
F9	23.7 ± 0.01	1.11±0.02
F10	22.8 ± 0.01	1.25±0.01
F11	18.7 ± 0.02	1.22±0.03
F12	16.9 ± 0.03	1.16±0.01

Post compression evaluation of Lafuditine orodisprsible tablets

General appearance

The tablets were white coloured and round shaped. All tablets were elegant in appearance. The results were shown in **Table 5**.

Thickness and diameter

Thickness and diameter of the formulations were used to determine the uniformity of size and shape of the tablets. From the results it was found that the thickness of the tablet in all formulation was 3.3-3.4mm and the diameter of the tablet in all formulation was 6mm.The results indicated that all the formulations had uniform size and shape. The results were shown in **Table 5**.

Hardness

The hardness of the tablets was used to determine the resistance capacity of the tablets to chipping, abrasion or breakage under conditions of storage, transportation and handling before usage. The hardness of the tablets of all the formulations were found to be in the range of 3.16-3.76 kg/cm^2. The result indicated that all the tablets Had good mechanical strength. The results of the hardness for all the formulations were shown in **Table 5.**

Weight variation test

The weight variation test was used to ensure the uniformity of the tablet in all formulations. The weight of all the tablets from each formulation was in the range from 193.4 mg to 200.70 mg. It was found all the tablets passed weight variation test, as the percentage weight variation was within the acceptable limits of ±7.5%. The results were shown in **Table no 5.**

Friability test

Friability test was measured to ensure the mechanical strength of tablet. The results showed that the friability of all the formulation ranged from 0.48% to 0.65%. Friability of all the formulation was lesser than 1 % which indicated the tablets had a good mechanical resistance. The results were shown in **Table 5.**

Uniformity of drug content

The uniformity content test was used to determine the uniform amount of active ingredient present in all formulations. The drug content in the content uniformity of all the formulations was found to be in the range of 98.2 % - 99.70%. The results indicated all the formulations were within the acceptable limits as per USP limits. The results were shown in **Table 5.**

Table 5 Evaluation of mixed powder blend of Lafutidine

Formulation code	General appearance	Thickness (mm)	Hardness kg/m2	Average weight (mg) ± 7.5	Friability (%)	Content uniformity
F1	White	3.56 ± 0.01	3.26 ±0.15	200.0 ± 0.41	0.55 ± 0.51	99.55 ± 0.86
F2	White	3.43± 0.01	3.43 ± 0.05	200.7 ±0.62	0.48 ±0.06	97.15 ±0.95
F3	White	3.42 ± 0.01	3.16 ±0.40	199.56±0.49	0.55 ±0.02	89.06 ±0.75
F4	White	3.32 ±0.11	3.50 ±0.40	199.2 ± 0.18	0.65 ±0.03	87.17± 0.95
F5	White	3.39±0.05	3.50 ±0.40	204.6 ±0.52	0.53 ±0.16	85.78 ±0.78
F6	White	3.32 ±0.00	3.00 ±0.40	201.3 ± 0.63	0.60 ± 0.08	88.62 ±0.40
F7	White	3.42 ±0.00	3.66 ±0.84	202.6 ±0.58	0.57 ± 0.16	90.24 ±0.31
F8	White	3.32 ±0.00	3.33 ±0.23	199.1 ±0.53	0.59 ±0.14	88.71 ± 0.31

F9	White	3.39 ±0.00	3.66 ± 0.84	193.4 ±0.37	0.59 ± 0.01	88.94 ±0.85
F10	White	3.32 ±0.00	3.66 ± 0.84	198.2 ± 0.19	0.52 ±0.01	99.98 ±0.72
F11	White	3.43 ± 0.17	3.76 ± 0.40	199.0 ±0.08	0.53 ±0.07	99.17 ± 0.06
F12	White	3.43 ± 0.05	3.16 ±0.62	199.2 ± 0.48	0.55 ±0.02	99.94 ± 0.06

In-vitro disintegration time

The *in-vitro* disintegration time was determined by disintegration test apparatus. The results were shown in **Table 6.** Formulations F1, F2, F3, F4, F5, F6, F7, F8, F9, F10, F11 and F12 showed the disintegration time 65.0, 50.06, 30.0, 70.6, 45.3, 32.3, 50.0, 40.0, 25.0, 25.6, 20.6 and 18.0 seconds respectively. It was observed that Formulation F12 containing scmc +crospovidone+pre gelatinized starch (3% + 4.5% + 12%) disintegrated rapidly in a short time (18.0 seconds). The results of disintegration of all the tablets were found to be lesser than 180 seconds. So all the formulation satisfied the criteria of oro dispersibile tablets.

Water absorption ratio

The water absorption ratio test was used to ensure the capacity of the superdisintegrant and diluents to absorb the water. The results of water absorption ratio of all the formulation were shown in **Table 6**. Formulation F12 containing scmc +crospovidone+pre gelatinized starch (3% + 4.5% + 12%) as showed highest water absorption ratio (98.78%) when compared to other formulations because of its combination of swelling and wicking of action.

Wetting time

Wetting time of the tablet was used to assess the capacity of the tablets to disintegrate by swelling in water. All the formulations showed quick wetting, this may be due to ability to swelling and also capacity of absorption of water. The results of wetting time of all the formulations were shown in **Table 6**. Formulation F12 showed lesser wetting time than other formulations. This may be due to the combination of wicking and swelling action of superdisintegrant formulations.

Table: 6 Post compression evaluation lafuditine tablet

Formulation Code	Disintegration Time (sec)	Water absorption ratio (%)	Wetting time (sec)
F1	65.0 ±1.63	75.18 ± 0.50	68.1 ± 0.27
F2	50.6 ± 0.47	71.28 ± 1.69	62.0 ±0.81
F3	30.0 ± 1.63	75.18 ± 1.29	69.6 ± 1.2
F4	70.6 ± 2.3	60.58 ± 1.11	72.6 ± 1.2
F5	45.3 ± 1.70	78.53 ± 0.84	73.0 ± 0.8
F6	32.3 ±1.70	85.72 ± 0.43	70.9 ± 0.55
F7	50.0 ± 1.63	71.53 ± 0.43	56.0 ± 1.6
F8	40.0 ± 1.33	71.53 ± 1.07	65.9 ± 0.4
F9	25.0 ± 1.47	96.64 ± 1.89	54.0±1.60
F10	25.6 ± 0.21	81.65 ± 1.78	56.0 ±1.40
F11	20.6 ± 0.96	94.11 ± 1.89	61.2 ± 0.23
F12	18.0 ± 0.4	98.78 ± 1.89	69.1 ± 1.2

In-vitro dissolution studies

The dissolution profile range in 30 minutes was 88.13% to 97.79% **(**Table 5A and 5B**).** The drug release was found to be comparatively less in formulation containing natural superdisintegrant (pre gelatinized starch). The maximum drug release rate 97.79% was observed with the formulation (F12) containing scmc+crospovidone+Pregelatinized starch as a superdisintegrant. The results were shown in **Table 7a-7b and Figure 11 (a, b, c, d)** Among the 12 formulations, the formulation (F12) was selected, as a best formulation because of its desirable character of low disintegration time, highest drug release, high water absorption rate and short wetting time.

Table: 7a - Invitro release profile of Lufutidine orodispersible tablets

Time (min)	**Cumulative Percentage drug release ± SD**					
Formulation	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**
5	41.75 ±0.29	30.43± 0.86	32.35 ±0.87	33.40 ± 0.29	26.42 ± 0.32	17.68 ± 1.04
10	54.45 ±0.22	48.66±1.49	59.58 ± 1.49	58.70 ± 0.18	37.85 ± 0.42	32.78 ± 0.45
15	62.49 ±0.96	60.76±2.16	65.28 ± 2.47	67.13 ± 0.41	50.58 ± 0.51	53.47 ± 1.13
20	79.35 ±2.77	76.84±2.72	76.76 ± 3.32	78.49 ± 0.29	67.44 ± 1.81	64.89 ± 1.19
25	77.39 ±2.09	83.66±1.53	85.62 ± 2.76	87.21 ± 0.44	72.84 ± 0.41	72.84 ± 0.41
30	87.13 ±1.05	86.51±0.52	94.44 ± 1.82	94.05 ± 0.47	90.20 ± 1.50	86.20 ± 1.50

Table: 7 b - Invitro release Profile of Lufutidine oro dispersible tablets

Time (min)	**Cumulative Percentage drug release ± SD**					
Formulation	**F7**	**F8**	**F9**	**F10**	**F11**	**F12**
5	17.90 ± 1.04	33.40±0.29	12.93 ± 0.23	3165 ± 0.20	33.40 ± 40	59.22 ± 1.19
10	25.82 ± 0.45	58.70 ± 0.18	26.43 ± 0.54	5142 ± 0.46	58.70 ± 0.18	80.31 ± 1.18
15	33.24 ± 1.13	67.13 ± 0.41	40.61 ± 0.94	6589 ± 1.19	67.13 ± 0.41	89.67 ± 0.34
20	43.89 ± 1.19	78.49 ± 0.29	55.54 ± 1.47	7621 ± 1.50	78.49 ±0.29	91.12 ± 0.33
25	58.70 ± 0.41	87.21 ± 0.44	71.42 ± 4.61	8321 ± 1.42	87.49 ± 0.44	95.49 ±1.41
30	88.87 ± 1.50	94.05 ± 0.47	88.55 ± 1.19	9238 ± 0.45	94.05 ± 0.47	97.79 ± 0.88

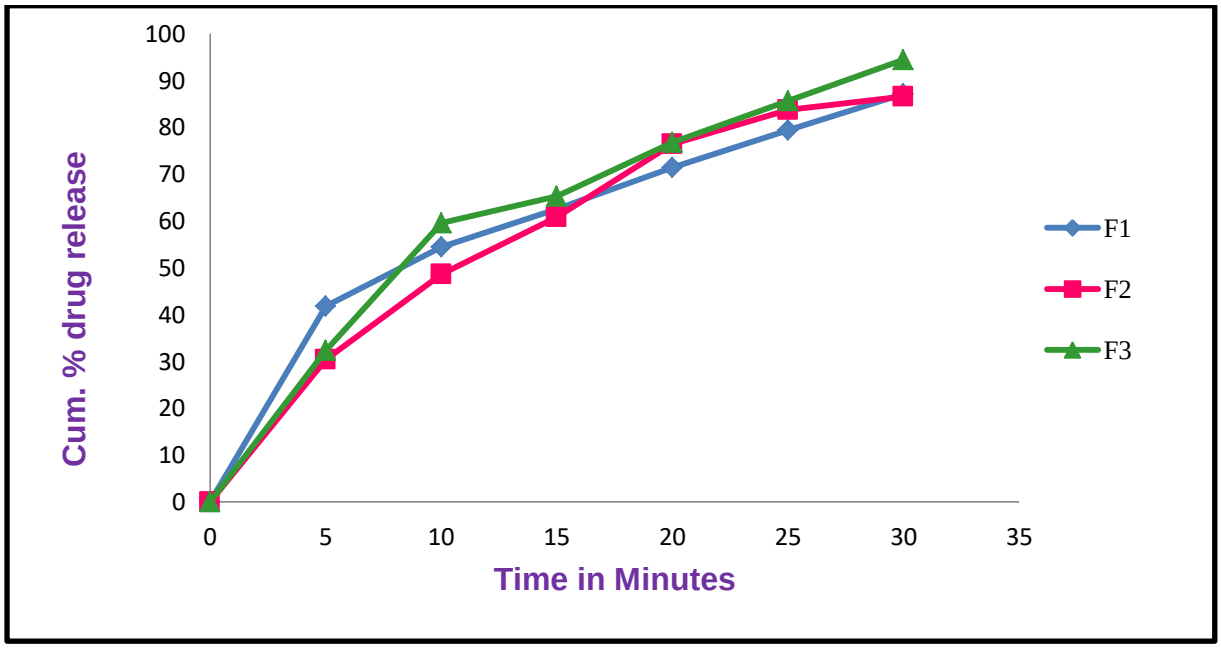

Figure: 11 a- Invitro release profiles of Lafutidine orodispersibile tablets

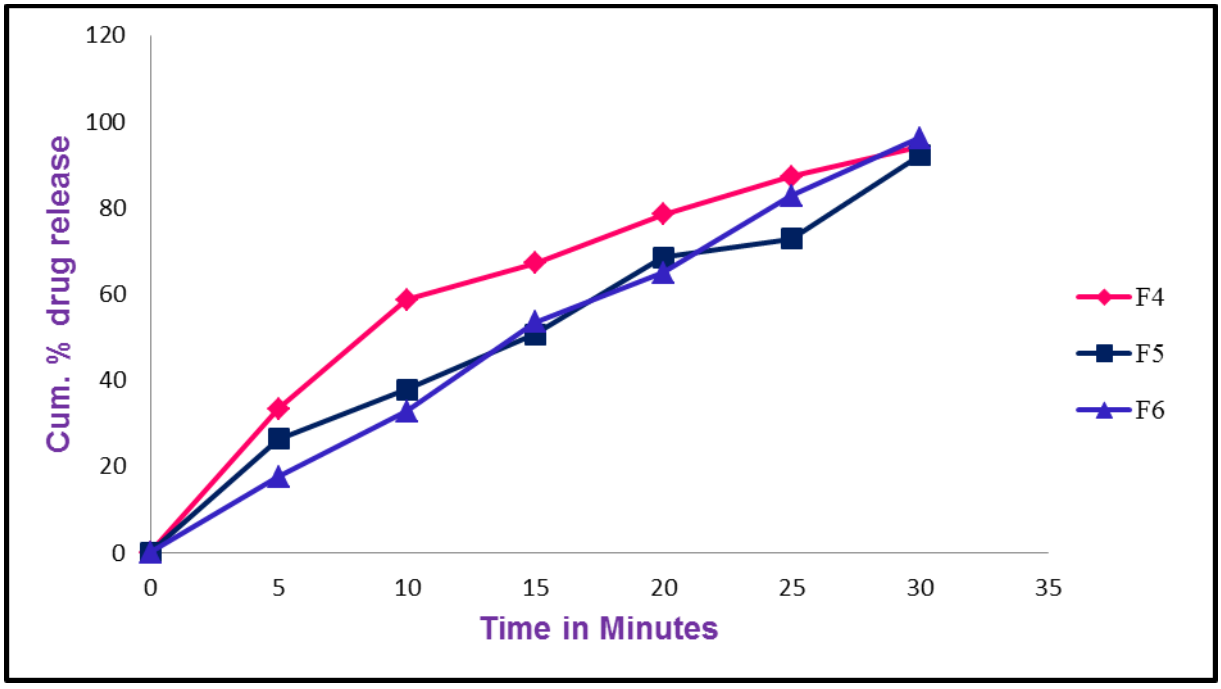

Figure: 11 b-Iinvitro release profiles of Lafutidine orodispersibile tablets

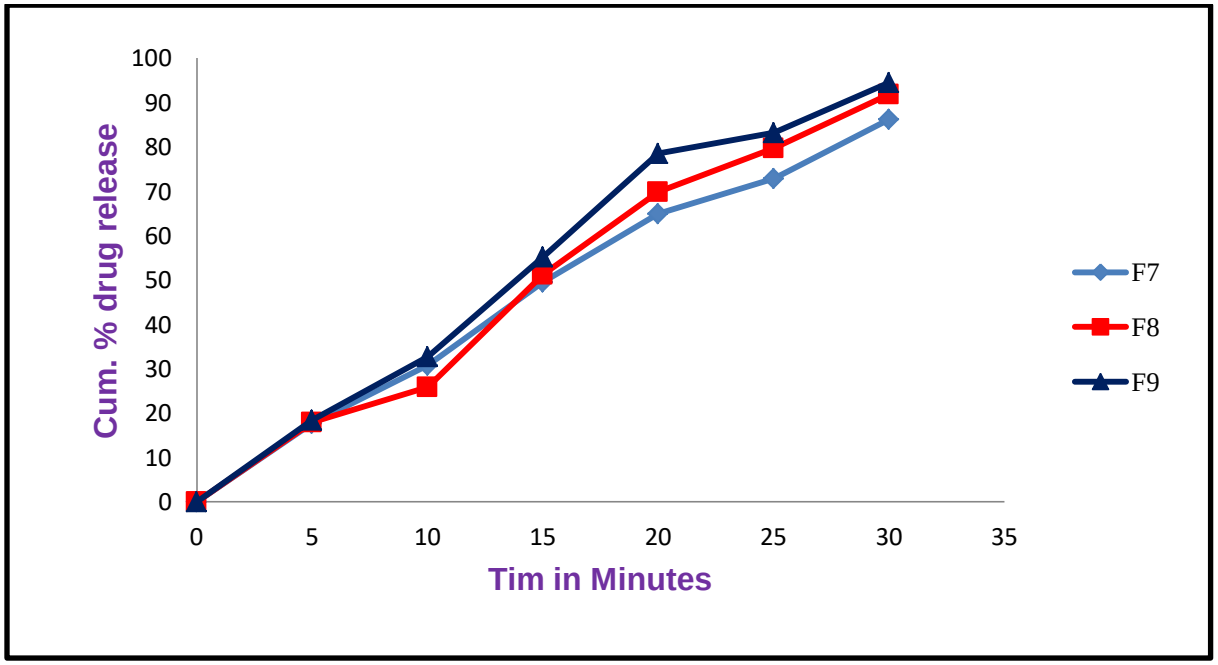

Figure: 11 c- Invitro release profiles of Lafutidine orodispersibile tablets

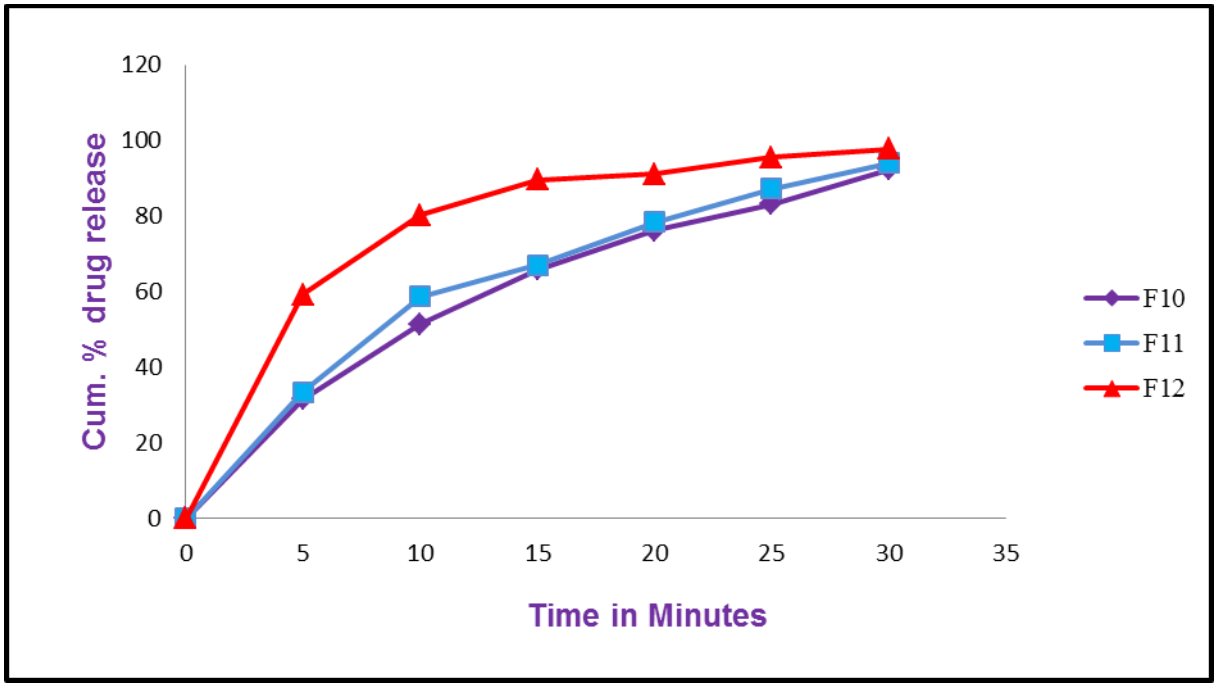

Figure: 11 d- Invitro release profiles of Lafutidine orodispersibile tablets

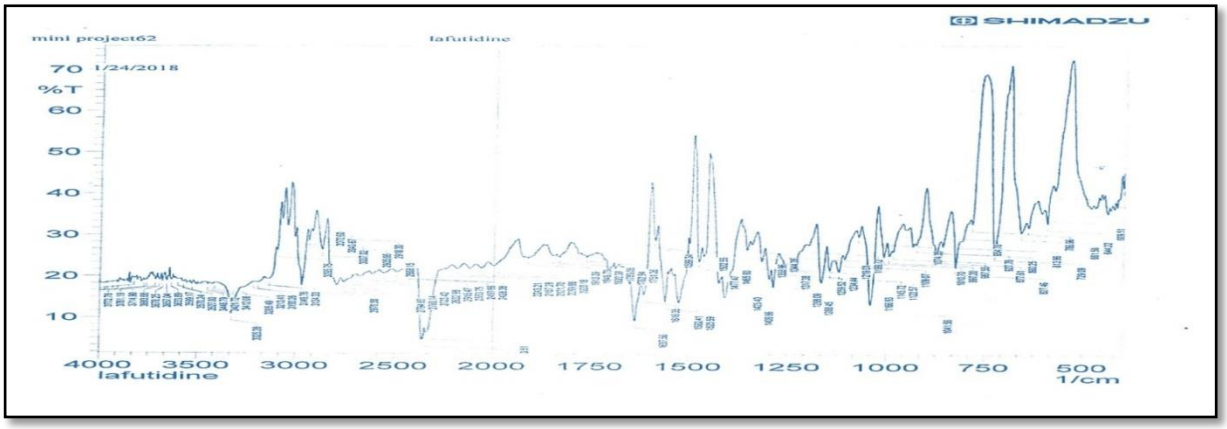

Figure: 1- FT-IR studies of Lafutidine

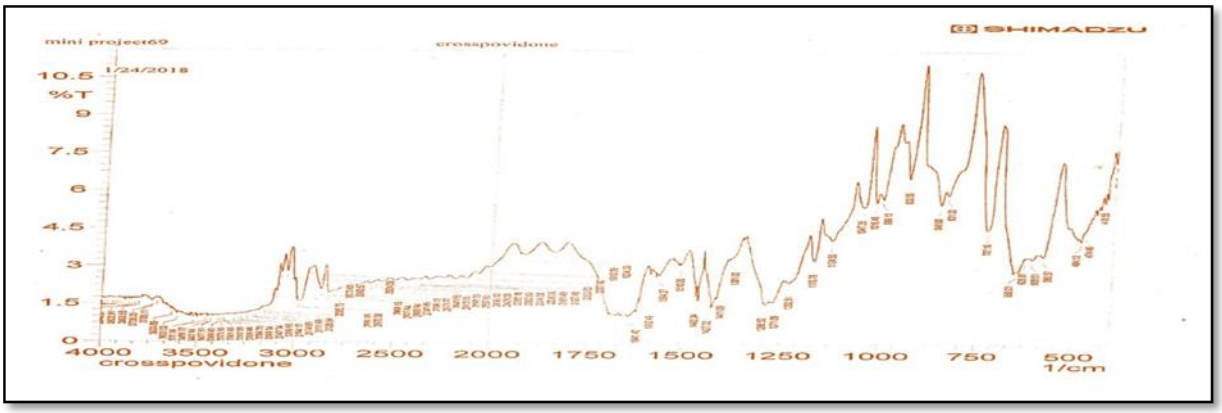

Figure: 2- FT-IR studies of Crospovidone

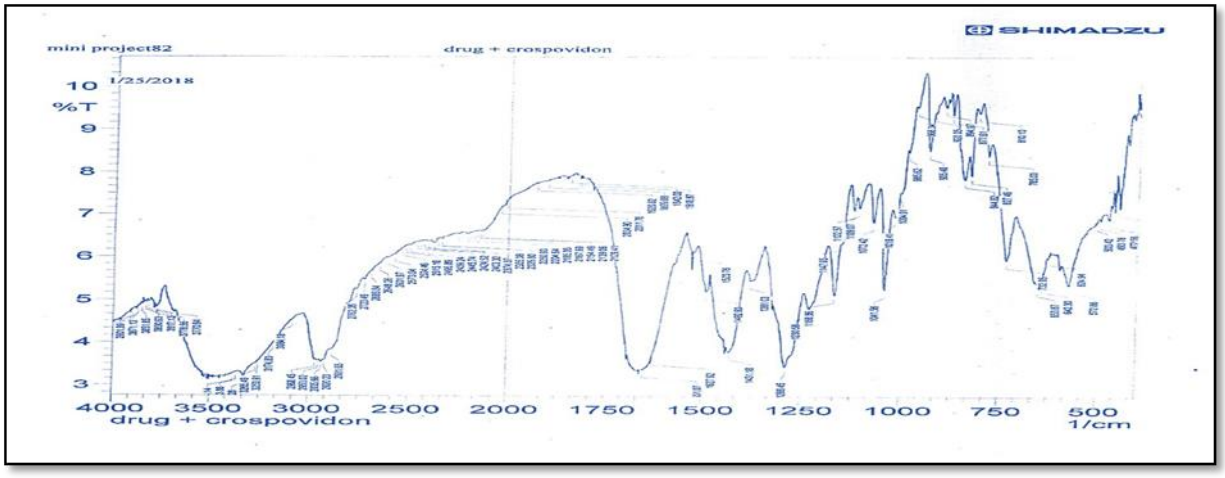

Figure: 3- FT-IR studies of Drug +Crospovidone

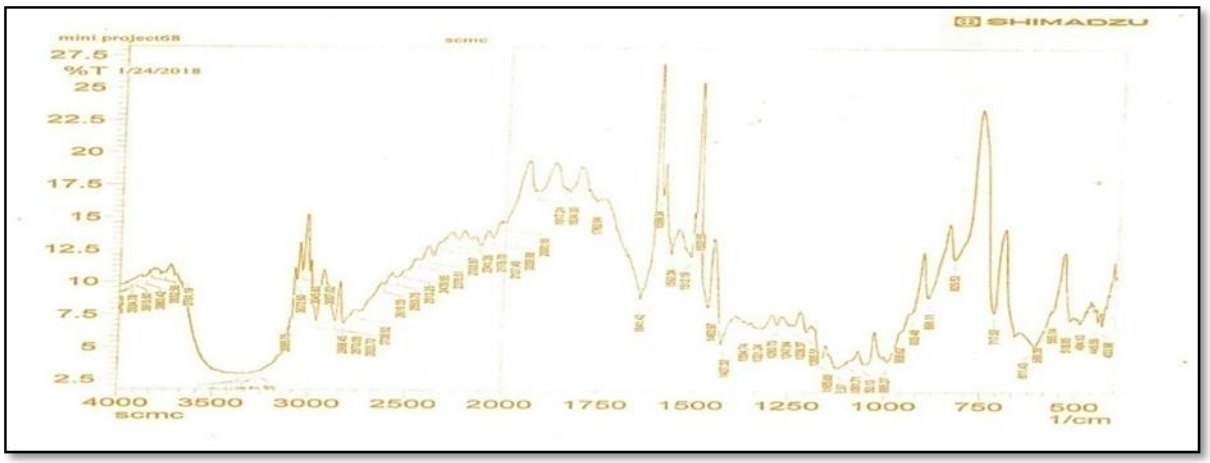

Figure: 4- FT-IR studies of SCMC

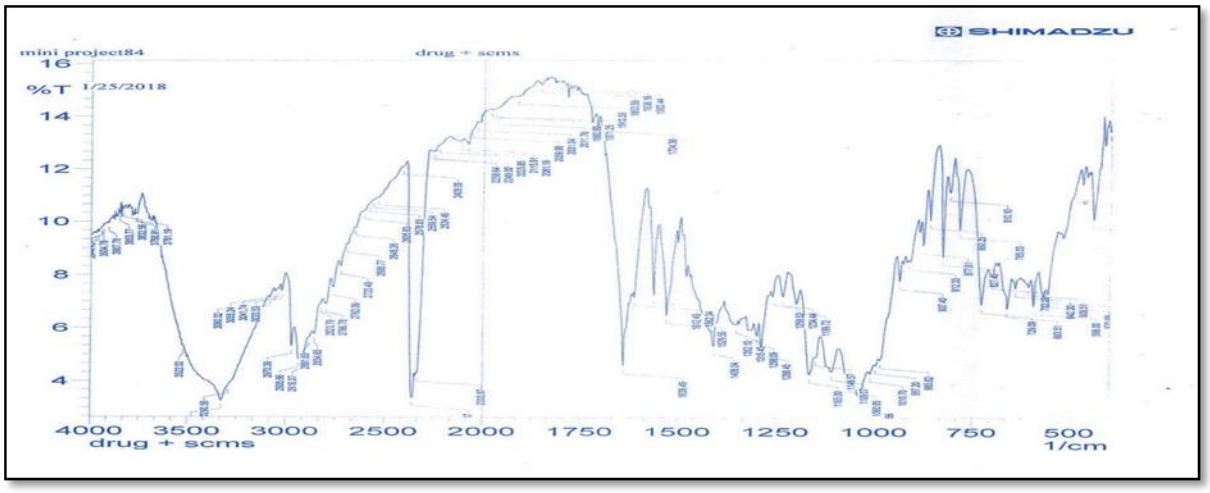

Figure: 5- FT-IR studies of Drug + SCMC

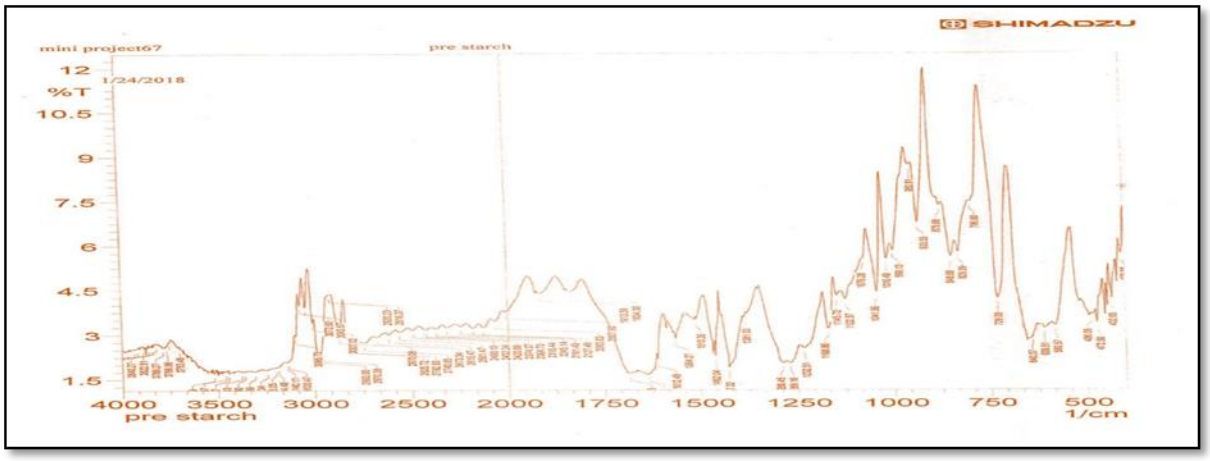

Figure: 6- FT-IR studies of Pre Gelatinized Starch

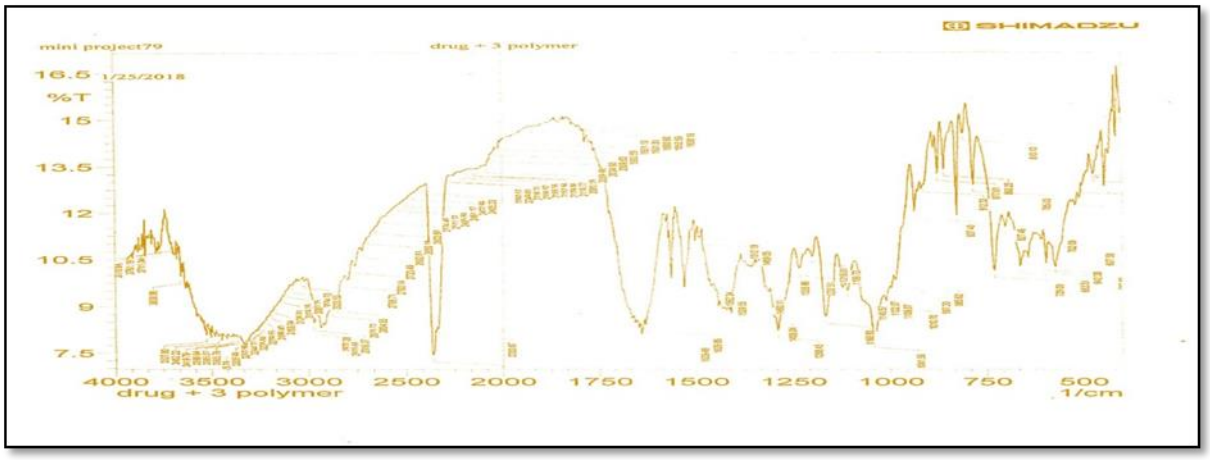

Figure: 7- FT-IR studies of Lafutidine + SCMC +Pre Gelatinized Starch

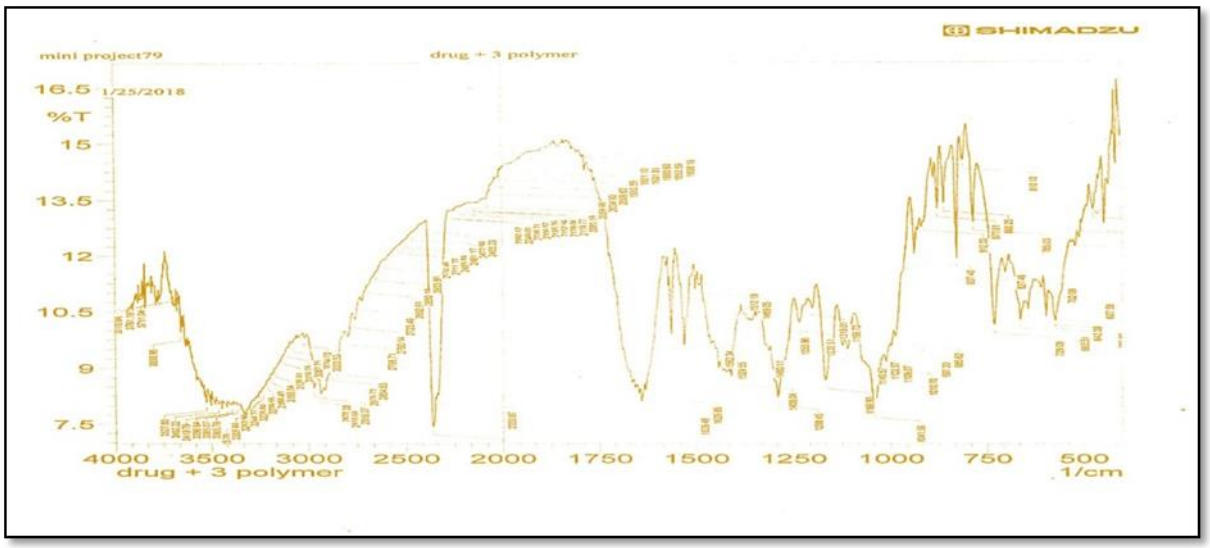

Figure: 8- FT-IR studies of best formulation of Lafutidine (F12)

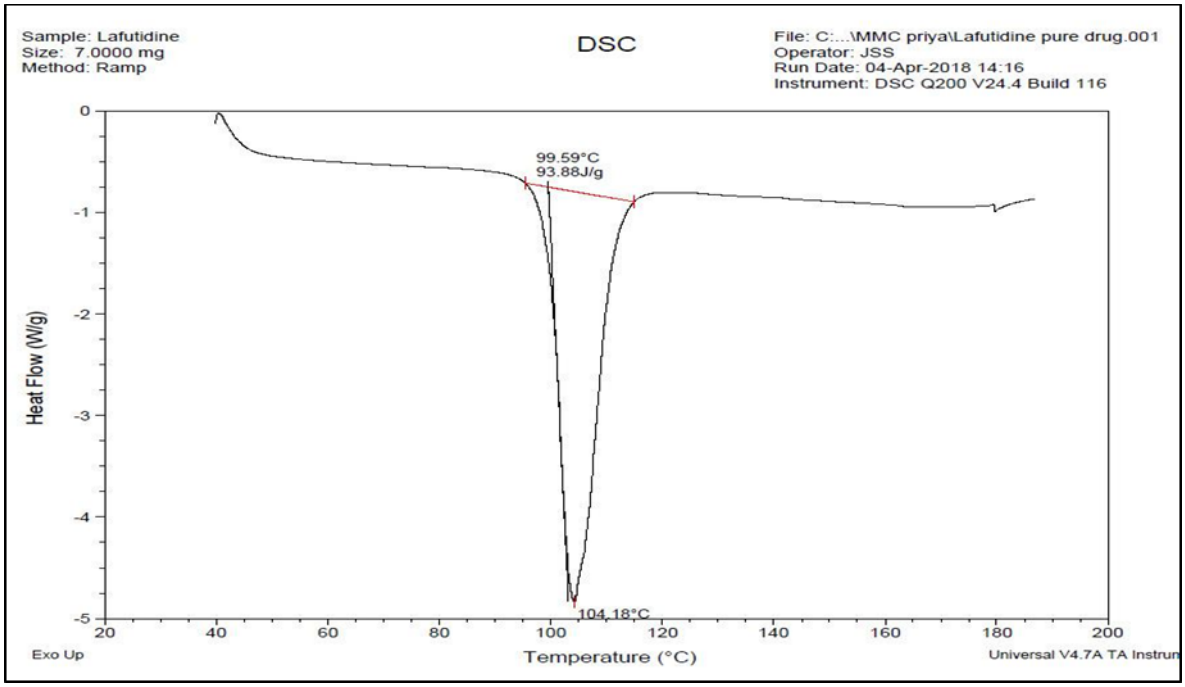

Figure: 9- DSC thermogram of Lafutidine

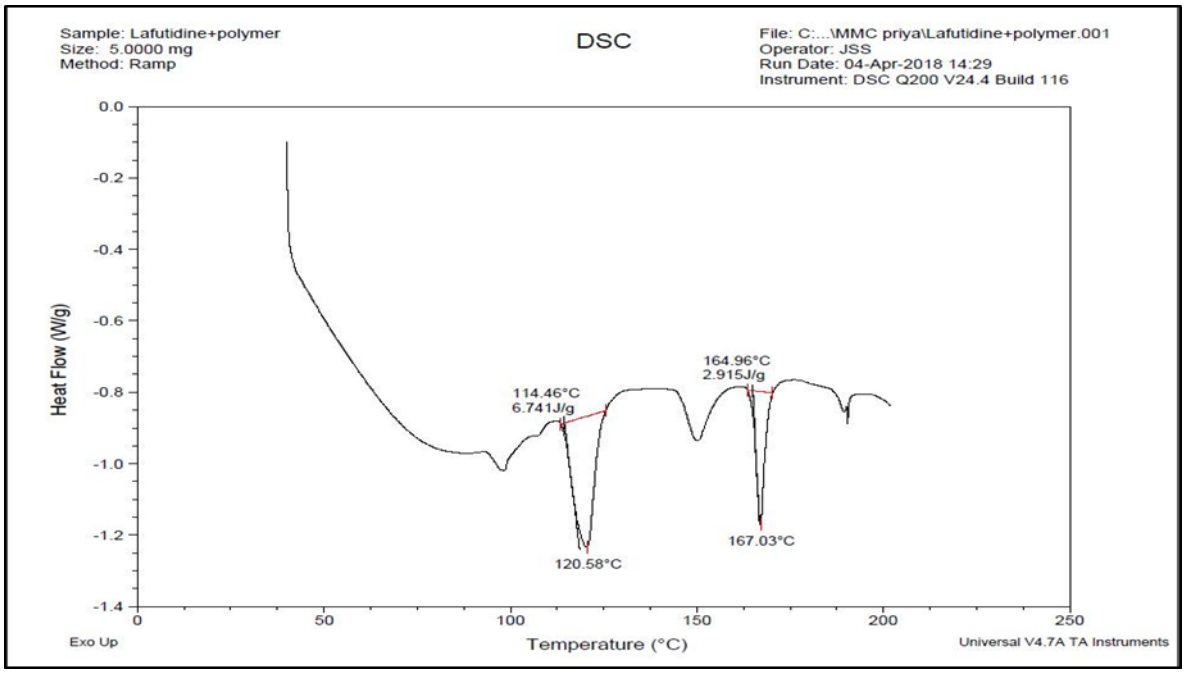

Figure: 10 –DSC thermogram of best formulation of Lafutidine (F12)

CONCLUSION

Oro dispersible tablets is a promising approach with a view of obtaining faster action of drug and would be advantageous in comparison to currently available conventional forms. In this study oro dispersible tablets of lafutidine were prepared by direct compression method using crosspovidone, sodium carboxy methyl cellulose and pregelatinized were used in formulation. Formulation F12 containning 4.5% crospovidone has shown the better results for disintegration time of 18 seconds. In-vitro dissolution study showed 97.79% of drug release at the end of 30 minutes. From the study, it can be conclude that the oro dispersible tablet of lafutidine

could perform better bioavailability, effectiveness and hence better patient compliance.

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