determined by placing each tablet diagonally between the two plungers of tablet hardness tester (with the nozzle) and applying pressure until the tablet broke down into two parts completely and the reading on the scale was noted down in kg/cm^2. The results are presented in Table 3.

Thickness [8]

The thickness of three randomly selected tablets from each formulation was determined in mm using a vernier calliper (Pico India). The average values were calculated. The results are presented in Table 3.

Uniformity of weight [9]

Weight variation test was done as per standard procedure. 20 tablets from each formulation (F1-F9) was weighed using an electronic balance, and the average weight was calculated. The results are shown in Table 3.

Friability[9]

The friability of tablets was measured using six tablets using a Roche friabilator. Tablets were rotated at 25 rpm for 4 minutes or up to 100 revolutions. The tablets were taken out, dedusted, and reweighed. The percentage friability was calculated from the loss in weight as given in equation below. The weight loss should not more than 1%. The results are shown in Table 3.

Friability (%) = ([Initial weight − Final weight]/initial weight) × 100

Drug content [10]

10 tablets were powdered and the powder equivalent to 15 mg was dispersed in phosphate buffer pH 6.8. Volume of the solution made up to 10 mL by media. The mixture was filtered and 1 ml of the filtrate was diluted to 10 mL using phosphate buffer pH 6.8. The absorbance of the sample preparations was measured at λmax 352.0 nm for montelukast sodium and 231.0 nm for levocetirizine dihydrochloride. The results are presented in Table 4.

Wetting time [11]

A piece of tissue paper folded twice was placed in a small petridish containing 6 ml of phosphate buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined. The results are presented in Table 4.

Water absorption ratio [11]

A piece of tissue paper folded twice was placed in a small petri dish containing 6 ml of water. A tablet was put on the tissue paper and allowed to wet completely. The wet tablet was then weighed. Water

Table 1: Composition of montelukast sodium and levocetirizine dihydrochloride sublingual tablets formulations

Ingredients	Quantity for tablet (mg)								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Montelukast sodium	10	10	10	10	10	10	10	10	10
Levocetirizine dihydrochloride	5	5	5	5	5	5	5	5	5
CP	5	10	-	-	10	5	10	10	-
SSG	10	5	10	5	-	-	10	-	10
CCS	-	-	5	10	5	10	-	10	5
MCC	25	25	25	25	25	25	25	25	25
Sodium saccharine	2	2	2	2	2	2	2	2	2
Talc	4	4	4	4	4	4	4	4	4
Magnesium stearate	2	2	2	2	2	2	2	2	2
Mannitol	137	137	137	137	137	137	132	132	132

CP: Crospovidone, SSG: Sodium starch glycolate, CCS: Croscarmellose sodium, MCC: Microcrystalline cellulose

Table 2: Evaluation of montelukast sodium and levocetirizine dihydrochloride sublingual tablets (pre-compression parameters)

Formulation code	Bulk density* (g/ml)	Tapped density* (g/ml)	Compressibility/ Carr's index* (%)	Hausner's ratio*	Angle of repose*(°)
F1	0.472±0.71	0.549±0.16	14.026±0.23	1.163±0.07	28.56±0.31
F2	0.481±0.33	0.539±0.45	10.761±0.15	1.120±0.06	29.53±0.24
F3	0.441±0.46	0.514±0.06	14.202±0.08	1.165±0.05	27.95±0.19
F4	0.452±0.19	0.526±0.15	14.068±0.14	1.163±0.04	26.57±0.32
F5	0.471±0.55	0.547±0.22	13.894±0.24	1.161±0.06	28.75±0.27
F6	0.462±0.09	0.543±0.43	14.917±0.16	1.175±0.07	29.64±0.17
F7	0.456±0.54	0.537±0.17	15.084±0.22	1.177±0.03	26.37±0.11
F8	0.451±0.05	0.501±0.14	9.980±0.11	1.110±0.05	22.56±0.12
F9	0.445±0.61	0.521±0.18	14.587±0.12	1.170±0.07	28.53±0.22

*Values represented as mean±SD (n=3), SD: Standard deviation

Table 3: Evaluation of montelukast sodium and levocetirizine dihydrochloride sublingual tablets (post-compression parameters)

Formulation code	Thickness* (mm)	Hardness* (kg/cm^2)	Weight variation* (mg)	Friability* (%)
F1	2.3±0.02	3.5±0.31	200.03±0.09	0.394±0.02
F2	2.3±0.01	3.4±0.16	199.94±0.13	0.426±0.05
F3	2.2±0.03	3.3±0.17	199.52±0.06	0.532±0.01
F4	2.3±0.01	3.6±0.23	199.37±0.14	0.511±0.06
F5	2.2±0.01	3.2±0.28	199.46±0.22	0.346±0.03
F6	2.3±0.03	3.7±0.14	199.87±0.24	0.372±0.05
F7	2.2±0.01	3.3±0.23	199.73±0.09	0.416±0.04
F8	2.2±0.03	3.4±0.26	200.10±0.16	0.513±0.06
F9	2.3±0.02	3.7±0.23	199.79±0.23	0.379±0.05

*Values represented as mean±SD (n=3), SD: Standard deviation

Table 4: Evaluation of montelukast sodium and levocetirizine dihydrochloride sublingual tablets

Formulation code	Wetting time* (seconds)	Disintegration time* (seconds)	Water absorption ratio*	Drug content *(%)	
				Montelukast sodium	Levocetirizine dihydrochloride
F1	26.54±0.87	56.52±1.43	78.69±2.11	97.21±1.49	95.31±0.91
F2	34.16±1.84	61.34±1.85	78.61±1.34	99.89±2.16	100.31±0.75
F3	30.83±1.69	74.35±1.64	84.53±1.86	95.47±0.65	96.56±1.29
F4	26.51±2.01	67.51±0.76	75.61±1.77	98.61±1.35	97.81±1.46
F5	25.64±1.74	61.34±1.82	83.65±2.12	97.56±1.75	99.69±0.45
F6	33.56±1.65	55.26±1.47	85.67±1.76	95.70±0.91	101.88±1.64
F7	20.34±2.03	48.33±1.75	91.22±1.65	96.98±1.22	95.94±2.13
F8	18.36±1.55	45.42±1.49	94.42±1.44	101.63±0.79	99.06±1.32
F9	21.03±1.72	49.67±2.05	90.34±1.85	97.32±1.54	98.13±1.47

*Values represented as mean±SD (n=3), SD: Standard deviation

Table 5: Comparative dissolution data of oral marketed immediate release formulation and optimized formulation

Time (minutes)	Cumulative % drug release (optimized formulation)		Cumulative % drug release (oral marketed immediate release formulation)	
	Montelukast sodium	Levocetirizine dihydrochloride	Montelukast sodium	Levocetirizine dihydrochloride
0	0	0	0	0
5	21.94	28.8	15.44	16.93
10	27.12	33.20	19.39	20.99
15	32.34	37.18	23.57	24.08
30	57.70	53.25	32.19	33.56
45	76.03	78.14	41.54	42.69
60	95.48	94.59	50.32	52.35

absorption ratio, R was determined using the following equation. The results are presented in Table 4.

Water absorption ratio (R) = $([W_a - W_b]/W_b]) \times 100$

In-vitro disintegration time [12]

Disintegration time for sublingual tablets was determined using USP tablet disintegration apparatus with phosphate buffer of pH 6.8 as medium. The volume of medium was 900 ml and temperature was 37±0.5°C. The time in seconds taken for complete disintegration of the tablets with no palatable mass remaining in the apparatus was measured. The results are presented in Table 4.

In-vitro dissolution studies [13]

Dissolution study was conducted for all the formulations using USP dissolution test apparatus Type-II (Electrolab, Mumbai, India). 900 ml of phosphate buffer (pH 6.8) was taken as the dissolution medium and rotated at 50 rpm. Temperature was maintained at 37°C±0.5°C for 60 minutes. Five ml of aliquots were periodically withdrawn, and the sample volume was replaced with an equal volume of fresh dissolution medium. The samples were filtered, diluted suitably and analyzed at λmax 231.0 nm for levocetirizine dihydrochloride and 352.20 nm for montelukast sodium. The results obtained for all the formulations are represented in Figs. 1 and 2.

Drug-excipient compatibility studies by Fourier transform infrared (FTIR)

The FTIR studies were performed to study drug-excipient interaction in the range 4000-400/cm using an FTIR spectrometer (IR AFFINITY-1 CE, Shimadzu, Japan) equipped with a pyroelectric detector. Data were acquired using IR solution software. The FTIR spectra of montelukast sodium, levocetirizine dihydrochloride, and optimized formulation are shown in Figs. 3-4.

RESULTS AND DISCUSSION

The bulk densities of the blend were found to be in the range of 0.445-0.481 g/ml. The angle of repose varied from 22.56° to 29.64°.

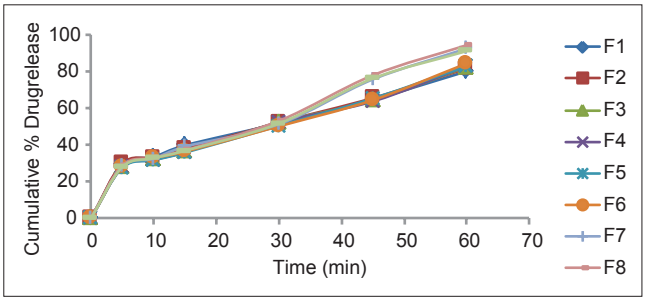

Fig. 1: *In vitro* dissolution profile of all formulations (montelukast sodium)

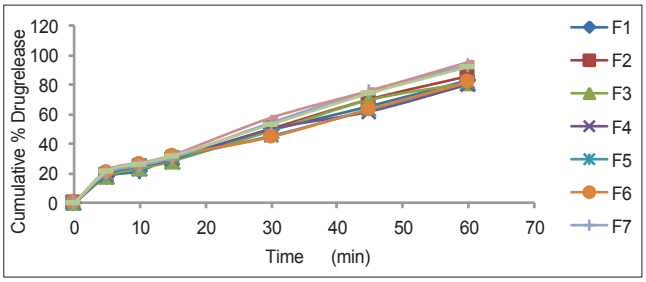

Fig. 2: *In vitro* dissolution profile of all formulations (levocetirizine dihydrochloride)

The low values of angle of repose indicate the free flowing nature of the blend. The tapped densities ranged from 0.501 to 0.549 g/ml, and the Carr's indices were in the range of 9.98-15.084. Hausner ratio was found in the range of 1.11-1.177. The values of compressibility index further confirmed the good compressibility of the prepared blends.

The prepared tablets were evaluated for their hardness, thickness, weight variation, friability, and the results are presented in Table 3. The weight variation was found to be within the prescribed limits, and it