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RESEARCH ARTICLE
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DEVELOPMENT & EVALUATION OF TASTE MASKED LEVOCETRIZINE DIHYDROCHLORIDE & MONTELUKAST SODIUM FAST-DISSOLVING TABLET

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ABSTRACT
The goal of the current study was to use the direct compression method to create and assess the orodispersible (rapid dissolving) tablets of Montelukast sodium and Taste-masked Levocetrizine dihydrochloride. Ion exchange resins such as Kyron-T-114 and Kyron-T-130 were used to taste mask the medication in order to avoid its unpleasant odor and harsh taste. The substance was identified using a variety of techniques, including stability studies, pH, organoleptic characteristics, drug releasing profiles, and other testing. Kyron-T-114, one of the two resins, was chosen for additional research due to its superior drug release profile, low cost, and high drug loading capacity. Kyron T-114 is a high molecular weight, cross-linked polymer of methacrylic acid that is insoluble in water. Microcrystalline cellulose (MCC) was used as a diluent in the preparation of the tablets, coupled with three distinct superdisintegrants and their varying ratios. Crosspovidone, sodium starch glycolate, and croscarmellose sodium were the super disintegrants used in this investigation. Weight variation, hardness, friability, wetting time, water absorption ratio, disintegration time (DT), and dissolution studies were all assessed for the tablets. Based on the results, it can be said that the tablet formulation made with 1.5% SSG+CP had good drug release and a better disintegration time than other formulations. The major peaks of pure medicines are unaltered, according to the IR spectrum analyses. This further attests to the purity of pharmaceuticals and their compatibility with excipients.

KEYWORDS: FDT, Pre-compression study, post-compression study, Stability study, Similar factor, Difference factor

INTRODUCTION:
Recent years have seen the introduction of a number of new, cutting-edge technologies for the creation of mouth dissolving tablets (MDTs) with intriguing properties, such as incredibly short disintegration times, remarkable taste masking capabilities, a pleasant mouthfeel, and sugar-free tablets for diabetic patients. Increasing porosity and/or adding superdisintegrants and water- soluble excipients to the tablets are the foundations of these methods. Ion exchange resins have been utilized more and more to help make orodispersible tablets and to conceal the taste of harsh medications. Therefore, one of the most important challenges to overcome for the effective creation of oral formulations is the taste-masking of bitter active compounds. The third-generation, non-sedating selective peripheral H1-receptor antagonist levocetrizine dihydrochloride, an oral active R-enantiomer of Cetrizine, is used to treat chronic urticaria,

seasonal allergic rhinitis, and perpetual allergic rhinitis. Unfortunately, it has an extremely disagreeable, bitter taste, which is why taste masking is necessary.

Montelukast sodium is a leukotriene receptor antagonist (LTRA) that is used to treat seasonal allergy symptoms and asthma. Usually, it is taken orally. In the current study, an effort was made to create taste-masked Levocenetrizi dihydrochloride and Montelukast sodium tablets that dissolve quickly in the oral cavity. This would improve patient compliance by increasing the rate of dissolution. It was investigated how co-processed superdisintegrants containing sodium starch glycolate, crospovidone, and croscarmelose sodium were used to create fast-dissolving tablets of these two medications. The current study set out to develop and assess fast-dissolving levocetrizine and montelukast tablets for the treatment of allergic rhinitis.

FORMULATION DEVELOPMENT OF FAST DISSOLVING TABLETS:

Initially, batches of MDTs were formulated using the direct compression technique using DRC equal to 5 mg of levocetirizine HCl. Magnesium stearate was utilized as a lubricant, talc as an anti-adherent, MCC as a diluent, and 10 mg of montelukast sodium. Each component was precisely weighed and combined to create a homogenous mixture. After that, a rotary tablet machine was used to compress the mixture into tablets:

Table 1: Details of Batch1 (LM1-LM6) formulations:

Batch- 1						
Levocetrizine: kyron-T114(1:4)						
	B1LM1	**B1LM2**	**B1LM3**	**B1LM4**	**B1LM5**	**B1LM6**
Levocetrizine Dihydrochloride	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**
Montilukast sodium	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**
MCC	**158mg**	**158mg**	**158mg**	**158mg**	**158mg**	**158mg**
SSG	**2mg**	**-**	**-**	**-**	**-**	**-**
CCS	**-**	**2mg**	**-**	**-**	**-**	**-**
CP	**-**	**-**	**2mg**	**-**	**-**	**-**
SSG+CCS	**-**	**-**	**-**	**2mg**	**-**	**-**
SSG+CP	**-**	**-**	**-**	**-**	**2mg**	**-**
CCS+CP	**-**	**-**	**-**	**-**	**-**	**2mg**
Mg Stearate	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**
Talc	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**

Table 2: Details of Batch2 (LM1-LM6) formulations:

Batch- 2						
Levocetrizine: kyron-T114(1:4)						
	B2LM1	**B2LM2**	**B2LM3**	**B2LM4**	**B2LM5**	**B2LM6**
Levocetrizine Dihydrochloride	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**
Montilukast sodium	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**
MCC	**157**	**157**	**157**	**157**	**157**	**157**
SSG	**3**	**-**	**-**	**-**	**-**	**-**
CCS	**-**	**3**	**-**	**-**	**-**	**-**
CP	**-**	**-**	**3**	**-**	**-**	**-**
SSG+CCS	**-**	**-**	**-**	**3**	**-**	**-**
SSG+CP	**-**	**-**	**-**	**-**	**3**	**-**
CCS+CP	**-**	**-**	**-**	**-**	**-**	**3**
Mg Stearate	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**
Talc	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**

Table 3: Details of Batch3 (LM1-LM6) formulations:

Batch-3						
Levocetrizine: kyron-T114(1:4)						
	B3LM1	**B3LM2**	**B3LM3**	**B3LM4**	**B3LM5**	**B3LM6**
Levocetrizine Dihydrochloride	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**	**5mg**
Montilukast sodium	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**	**10mg**
MCC	**156**	**156**	**156**	**156**	**156**	**156**
SSG	**4**	**-**	**-**	**-**	**-**	**-**
CCS	**-**	**4**	**-**	**-**	**-**	**-**
CP	**-**	**-**	**4**	**-**	**-**	**-**
SSG+CCS	**-**	**-**	**-**	**4**	**-**	**-**
SSG+CP	**-**	**-**	**-**	**-**	**4**	**-**
CCS+CP	**-**	**-**	**-**	**-**	**-**	**4**
Mg Stearate	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**	**2mg**
Talc	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**	**3mg**

Characterizations of Drugs, DRC and Final blend:

To determine their compatibility, FTIR analysis of Levocetrizine Dihydrochloride and Montelukast sodium (mixed & separate), Kyron T 114, Drug - Resin complex, & Blends comprising the Drug, Resin and Additional Excipients were conducted.

RESULTS AND DISCUSSION:

FTIR studies:

FTIR spectroscopy was used to investigate potential interactions b/w drug & excipients used in the formulation development. Since the peaks of the drug and other excipients were visible in the drug-excipients mixture, suggesting that the drug molecule was present in the formulation in an unaltered state, the spectra showed that there was no interaction between the drug and the excipients.

FORMULATION CODE:

Table 4: Different formulation codes for Batch 1

	Formulation Blend (containing Levocetrizine and Montelukast sodium)	**Code**
Batch-1	Blend with superdisintigrants Sodium starch glycolate (1%)	B1ML1
	Blend with superdisintigrants Cros carmellose sodium (1%)	B1ML2
	Blend with superdisintigrants Cross povidone (1%)	B1ML3
	Blend with superdisintigrants Sodium starch glycolate + Cros carmellose sodium (1%)	B1ML4
	Blend with superdisintigrants Sodium starch glycolate + Crosspovidone (1%)	B1ML5
	Blend with superdisintigrants Cros carmellose sodium + Crosspovidone (1%)	B1ML6

Table 5: Different formulation codes for Batch 2

	Formulation Blend (containing Levocetrizine and Montelukast sodium)	**Code**
Batch-2	Blend with superdisintigrants Sodium starch glycolate (1.5%)	B2ML1
	Blend with superdisintigrants Cros carmellose sodium (1.5%)	B2ML2
	Blend with superdisintigrants Cross povidone (1.5%)	B2ML3
	Blend with superdisintigrants Sodium starch glycolate + Cros carmellose sodium (1.5%)	B2ML4
	Blend with superdisintigrants Sodium starch glycolate + Crosspovidone (1.5%)	B2ML5
	Blend with superdisintigrants Cros carmellose sodium + Crosspovidone (1.5%)	B2ML6

Table 6: Different formulation codes for Batch 3

Batch-3	Blend with superdisintigrants Sodium starch glycolate (2%)	B3ML1
	Blend with superdisintigrants Cros carmellose sodium (2%)	B3ML2
	Blend with superdisintigrants Crosspovidone (2%)	B3ML3
	Blend with superdisintigrants Sodium starch glycolate + Cros carmellose sodium (2%)	B3ML4
	Blend with superdisintigrants Sodium starch glycolate + Crosspovidone (2%)	B3ML5
	Blend with superdisintigrants Cros carmellose sodium + Crosspovidone (2%)	B3ML6

Table 7: Pre-compression evaluation (Physicomechanical properties) of blends-1:

Formulation Blend	**Pre-compression parameters**		
	Angle of Repose	**Hausner ratio**	**Carrs index**
B1ML1	34.34	1.161	13.29
B1ML2	33.19	1.157	12.32
B1ML3	33.28	1.152	12.94
B1ML4	32.01	1.145	13.87
B1ML5	32.92	1.159	13.75
B1ML6	33.03	1.166	13.32

Table 8: Pre-compression evaluation (Physicomechanical properties) of blends-2:

Formulation Blend	**Pre-compression parameters**		
	Angle of Repose	**Hausner ratio**	**Carrs index**
B2ML1	31.56	1.131	12.78
B2ML2	31.01	1.129	12.56
B2ML3	32.39	1.137	12.43
B2ML4	30.57	1.123	12.11
B2ML5	32.26	1.140	13.02
B2ML6	32.48	1.137	13.14

Table 9: Pre-compression evaluation (Physicomechanical properties) of blends-3:

Formulation Blend	**Pre-compression parameters**		
	Angle of Repose	**Hausner ratio**	**Carrs index**
B3ML1	33.32	1.156	13.89
B3ML2	33.24	1.149	12.76
B3ML3	32.67	1.151	13.64
B3ML4	32.12	1.143	13.47
B3ML5	32.30	1.140	13.28
B3ML6	33.59	1.144	13.62

Post-compression parameters-

The Direct Compression technique was used to compress the powder blend. It has been Discovered that tablets made using the direct compression method are good and do not chip, cap, or stick. To assess tablets, a number of physical characteristics were measured, including Thickness, hardness, weight variation, friability, hardness, and disintegration time.

Table10: Parameters Evaluation of Post-compression of Batch 1

Formulation	Post Compression Evaluation Parameters				
	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm^2)	Wt. variation	Friability
B1ML1	3.11±0.12	3.0±0.28	3.2±0.56	200.12±1.04	0.50±0.056
B1ML2	3.12±0.15	3.0±0.31	3.1±0.67	200.67±0.54	0.49±0.062
B1ML3	3.11±0.15	3.1±0.30	3.3±0.52	201.21±1.01	0.51±0.059
B1ML4	3.12±0.16	3.0±0.43	3.3±0.60	200.34±0.34	0.48±0.038
B1ML5	3.12±0.18	3.0±0.39	3.2±0.71	200.14±0.83	0.55±0.031
B1ML6	3.11±0.13	3.0±0.40	3.1±0.66	201.25±0.65	0.39±0.032

Table11: Parameters Evaluation of Post-compression of Batch 2

Formulation	Post Compression Evaluation Parameters				
	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm^2)	Wt. variation	Friability
B2ML1	3.12±0.19	3.0±0.27	3.2±0.56	200.11±1.04	0.52±0.076
B2ML2	3.14±0.16	3.0±0.49	3.1±0.78	201.35±0.89	0.51±0.045
B2ML3	3.12±0.11	3.1±0.52	3.3±0.64	200.63±1.18	0.56±0.093
B2ML4	3.11±0.12	3.0±0.16	3.1±0.82	200.19±0.76	0.49±0.032
B2ML5	3.11±0.15	3.0±0.40	3.1±0.79	200.35±0.93	0.50±0.066
B2ML6	3.13±0.14	3.0±0.38	3.1±0.12	201.59±0.47	0.47±0.064

Table12: Parameters Evaluation of Post-compression of Batch 3

Formulation	Post Compression Evaluation Parameters				
	Thickness (mm)	Diameter (mm)	Hardness (Kg/cm^2)	Wt. variation	Friability
B3ML1	3.11±0.14	3.0±0.45	3.1±0.46	200.17±0.19	0.51±0.045
B3ML2	3.13±0.56	3.1±0.34	3.2±0.62	201.24±0.34	0.50±0.034
B3ML3	3.12±0.31	3.1±0.66	3.2±0.57	200.43±1.05	0.54±0.034
B3ML4	3.12±0.22	3.1±0.32	3.1±0.43	200.18±0.67	0.50±0.022
B3ML5	3.13±0.17	3.0±0.21	3.1±0.89	200.27±0.38	0.51±0.063
B3ML6	3.12±0.43	3.0±0.78	3.2±0.23	201.34±0.43	0.49±0.055

Table 13: Evaluation of Post-compression Parameters of Batch 1:

Formulation	Wetting time(sec.)	% Water absorption
B1ML1	24.42±0.312	86.21±0.879
B1ML2	25.39±0.225	87.56±0.993
B1ML3	24.54±0.564	91.34±0.866
B1ML4	21.57±0.218	94.44±0.645
B1ML5	22.59±0.300	92.33±0.943
B1ML6	23.15±0.467	92.67±0.798

Table 14: Evaluation of Post-compression Parameters of Batch 2:

Formulation	Wetting time(sec.)	% Water absorption
B2ML1	26.23±0.435	88.24±0.867
B2ML2	25.43±0.432	89.18±0.456
B2ML3	21.45±0.568	87.43±0.996
B2ML4	21.68±0.545	93.09±0.818
B2ML5	20.12±0.469	95.34±0.622
B2ML6	21.98±0.654	91.89±0.469

Table 15: Evaluation of Post-compression Parameters of Batch 3:

Formulation	Wetting time(sec.)	% Water absorption
B3ML1	25.20±0.564	87.19±0.967
B3ML2	23.22±0.469	88.46±0.375
B3ML3	22.56±0.586	90.87±0.955
B3ML4	21.06±0.418	93.22±0.768
B3ML5	21.98±0.654	93.11±0.222
B3ML6	22.93±0.745	91.45±0.546

Table 16: Evaluation of Post-compression Parameters of Batch 1:

Formulation	Dispersion time(sec.)	Drug content By dilution method		Drug content by petridish method	
		Levocetrizine	Montelukast	Levocetrizine	Montelukast
B1ML1	29.34±0.46	93.63±1.12	92.44±1.67	96.02±1.26	95.14±1.14
B1ML2	30.28±0.67	94.13±1.24	93.21±1.49	95.28±1.23	93.04±1.19
B1ML3	28.13±0.54	94.75±1.29	93.78±0.34	96.41±1.19	94 .53±1.26
B1ML4	21.89±0.43	95.37±0.87	95.02±1.33	96.74±1.16	95.78±1.16
B1ML5	22.75±0.38	96.20±1.15	95.78±1.23	97.10±1.24	95.92±1.28
B1ML6	23.19±0.86	95.29±1.23	93.02±1.11	96.68±1.18	95.11±1.17

Table 17: Evaluation of Post-compression Parameters of Batch 2:

Formulation	Dispersion time(sec.)	Drug content By dilution method		Drug content by petridish method	
		Levocetrizine	Montelukast	Levocetrizine	Montelukast
B2ML1	30.22±0.40	93.61±1.14	93.53±1.15	95.17±1.32	94.67±1.22
B2ML2	29.23±0.23	94.54±1.37	94.17±1.06	94.65±1.43	93.34±1.65
B2ML3	27.13±0.76	94.89±1.44	93.88±0.98	96.23±1.32	94.39±1.78
B2ML4	23.16±0.47	96.12±0.45	94.63±0.92	96.64±1.56	94.89±1.37
B2ML5	21.02±0.12	97.77±1.33	95.85±1.02	98.31±1.12	96.90±1.13
B2ML6	23.59±0.38	96.12±1.32	92.98±1.13	96.56±1.42	95.33±1.24

Table 18: Evaluation of Post-compression Parameters of Batch 3:

Formulation	Dispersion time(sec.)	Drug content By dilution method		Drug content by petridish method	
		Levocetrizine	Montelukast	Levocetrizine	Montelukast
B3ML1	29.12±0.45	93.11±1.28	93.46±1.32	95.04±1.34	95.22±1.27
B3ML2	26.56±0.74	94.32±1.31	94.21±1.23	94.67±1.23	94.67±1.41
B3ML3	27.11±0.49	94.87±1.27	93.56±0.78	96.57±1.29	95.48±1.37
B3ML4	24.18±0.77	96.22±0.19	94.14±0.76	97.45±1.22	94.61±1.82
B3ML5	22.69±0.58	96.39±1.48	94.43±1.09	97.19±1.67	95.88±1.43
B3ML6	23.55±0.47	95.78±1.11	93.72±1.22	95.88±1.32	95.23±1.46

Table 18: Evaluation of Post-compression Parameters of Batch 1:

Formulation	Disintigration by disintegration apparatus (sec.)	Disintegration Time in the Oral Cavity (DT).	Disintigration by petridish method (sec.)	Disintigration by dissolution apparatus with basket (sec.)
B1ML1	31±0.56	28±0.23	30±0.46	29±0.76
B1ML2	30±0.43	27±0.18	31±0.82	31±0.23
B1ML3	32±0.32	30±0.76	30±0.37	28±0.21
B1ML4	29±0.44	27±0.43	29±0.45	30±0.88
B1ML5	26±0.76	25±0.62	27±0.71	28±0.64
B1ML6	27±0.65	28±0.49	28±0.12	29±0.86

Table 19: Evaluation of Post-compression Parameters of Batch 2:

Formulation	Disintigration by disintegration apparatus (sec.)	Disintegration Time in the Oral Cavity (DT).	Disintigration by petridish method (sec.)	Disintigration by dissolution apparatus with basket (sec.)
B2ML1	28±0.33	29±0.22	27±0.65	26±0.11
B2ML2	27±0.82	27±0.53	26±0.41	28±0.47
B2ML3	25±0.62	26±0.65	29±0.85	27±0.88
B2ML4	24±0.39	23±0.43	25±0.49	26±0.55
B2ML5	21±0.43	22±0.13	22±0.20	23±0.53
B2ML6	22±0.66	23±0.98	25±0.69	25±0.28

Table 20: Evaluation of Post-compression Parameters of Batch 3:

Formulation	Disintigration by disintegration apparatus (sec.)	Disintegration Time in the Oral Cavity (DT).	Disintigration by petridish method (sec.)	Disintigration by dissolution apparatus with basket (sec.)
B3ML1	29±0.76	28±0.19	32±0.49	31±0.29
B3ML2	30±0.44	27±0.49	30±0.91	28±0.58
B3ML3	28±0.21	30±0.26	28±0.74	29±0.54
B3ML4	25±0.71	26±0.39	27±0.50	27±0.52
B3ML5	24±0.59	24±0.76	25±0.73	25±0.23
B3ML6	25±0.30	26±0.55	26±0.50	26±0.38

The fast disintegration tablet formulation demonstrated a disintegration time of less than or equal to 60 seconds in accordance with the Pharmacopoeial requirement. All batches met this time requirement. All of the prepared formulations showed disintegration times of less than 60 seconds, as can be seen from the above. The formulation with the shortest disintegration time was B2ML5. Based on the aforementioned observation, the optimal B2ML5 formulation has the highest drug content and the shortest disintegrant time. Every formulation' s wetting time, water absorption capacity, and other parameters were adequate and within acceptable bounds.

IN-VITRO DRUG RELEASE:
Dissolution parameter:
Medium: pH6.8 Buffer,
Volume: 900 ml,
Apparatus: USP Type II (Paddle),
Speed: 50 rpm,
Time Point: 0, 5,10,15,20,25,30,35…. minutes,
Temperature: 37^{o}C

Identification: At 231 nm for Levocetrizine and 352.20 nm for Montelukast sodium in UV-Visible spectrophotometer
Differences in the particle size generated in the disintegrated tablets could affect drug dissolution since breaking tablets into finer fragments may promote drug dissolution by providing larger total surface areas for drug dissolution to take place. B2ML5 formulation was selected for drug release study in different medium.

Table: 21 Comparative *In-Vitro* Drug Release Profile of Levocetrizine and Montelukast sodium (B2ML5) in different medium

Kyron T-114 (SSG+CP) (%CDR)								
Dissolution media→	**water**		**Water +SLS**		**0.1N HCl**		**pH 6.8 PBS**	
Time(min)↓	**L**	**M**	**L**	**M**	**L**	**M**	**L**	**M**
5	28.23	29.11	34.37	36.28	33.32	8.19	25.09	27.22
10	43.17	38.54	56.43	59.34	45.56	18.26	39.34	38.31
15	58.27	57.26	80.58	77.45	61.65	22.34	58.61	51.48
20	76.64	78.65	90.61	87.48	79.89	29.15	80.56	64.16
25	90.81	91.79	97.27	93.88	84.61	38.78	94.08	81.90
30					96.11	42.26		93.45
35						46.12		

STABILITY STUDIES OF OPTIMIZED BATCH:

Table 22: Stability data for optimized formulation B2ML5

Formulation	**Parameters Evaluated**	**Time interval (months)**							
		0		**1**		**2**		**3**	
B2ML5	**Hardness (kg/cm2)**	3.1±0.33		3.0±0.46		3.0±0.29		3.1±0.52	
	Friability (%)	0.50±0.027		0.49±0.067		0.46±0.077		0.45±0.045	
	Dispersion time (sec)	21.34±0.27		20.38±0.45		20.76±0.30		21.01±0.37	
	% Drug content	L	M	L	M	L	M	L	M
		96.4	94.6	95.2	93.5	97.1	94.4	96.9	93.5
	Disintegration time (sec)	18±0.12		20±0.16		18±0.07		19±0.21	

Table 23: Stability data of Dissolution profile of optimized batch B2ML5

Kyron T-114 (SSG+CP) (%CDR) pH 6.8 PBS(K4)								
Month→	**0**		**1**		**2**		**3**	
Time(min)↓	**L**	**M**	**L**	**M**	**L**	**M**	**L**	**M**
5	22. 32	20. 27	23. 18	21. 56	23. 34	24. 91	23. 17	22. 15
10	39. 56	37. 88	41. 43	38. 69	39. 69	40. 86	40. 44	43.3 4
15	58. 34	49. 22	64. 73	58. 37	59. 44	58. 12	58. 38	55. 73
20	76. 79	60. 72	84. 86	71. 43	78. 67	70. 49	80. 11	71. 48
25	92. 80	79. 59	94. 11	84. 91	94. 54	87. 58	93. 07	82. 66
30		92. 19		93. 44		92. 09		92. 14

Stability study revealed that the formulations were physically stable when stored at 40±20 c and 75±5 % RH till 3 months and there was no significant difference in dissolution for optimized formulation.

Similarity factor and difference factors:

Formulations showed (f2) value between 50 to 100 and (f1) value below 15 indicating similar release profiles of the formulations before and after stability studies.

Table:24 Similarity factor and difference factors of Levocetrizine dihydrochloride in B2ML5 before and after stability study

Time (min) n	Drug release of before Stability study (Rt)	Drug release of after Stability study (Tt)	L with (SSG+CP)	
	Lwith (SSG+CP)	Lwith (SSG+CP)	f_1	f_2
5	25. 43	27. 11	1.82	87.66
10	39. 24	41. 42		
15	58. 62	62. 37		
20	85. 12	77. 80		
25	93. 67	91. 33		

Table:25 Similarity factor and difference factors of Montelukast sodium in B2ML5 before and after stability study

Time (min) n	Drug release of before Stability study (Rt)	Drug release of after Stability study (Tt)	Mwith (SSG+CP)	
	Mwith (SSG+CP)	Mwith (SSG+CP)	f_1	f_2
1	23. 17	22. 08	3.41	85.09
2	41. 54	45. 66		
3	57. 73	59. 49		
5	73. 14	70. 21		
8	87. 32	81. 29		
12	93. 88	92. 03		

CONCLUSION:

Comes about appear that with Kyron T-114, medicate proportion of 1:4 gave greatest sum of sedate stacking. These drug-resin complexes encourage assessed for taste concealing and diverse condition of medicate stacking and after optimization Kyron T-114 resinate with sedate in proportion 1:4 chosen for definition advancement on the premise of most extreme medicate stacking and fetched viability. All the Clumps (1, 2 & 3) for detailing shown palatable values for point of rest and bulk thickness, tapped thickness, hausner proportion and cars file and appeared great stream properties. All the tablets pass the weight variety test, Friability test, Hardness test and variety as % variety is inside the pharmacopoeial restrain. Medicate substance estimation appeared more than 90% of the drugs (Levocetrizine dihydrochloride and Montelukast sodium) display. The scattering delivered was smooth with charming mouth feel and the sharp taste was completely veiled in all details. The deterioration tests conducted on all these details appeared that, there' s quicker crumbling of the tablets occurred, which is much less than the official constrain for quick deteriorating tablets (1 minutes). Least time for crumbling was appeared by the definition B2ML5 so this definition at long last chosen for sedate discharge ponders. In vitro sedate discharge profile of tablet appeared over 90% drugs (Levocetrizine dihydrochloride and Montelukast sodium) discharge in 25-35 minutes in 6.8phosphate buffer showing that the sedate will be ingested speedier within the mouth, pharynx and throat and hence improve the bioavailability by pregastric retention through mouth, pharynx and throat. Soundness thinks about was conducted for 3 months. Likeness (f2) and distinction components (f1) for B2ML5 were calculated. Definition appeared (f2) esteem between 50 to 100 and (f1) esteem underneath 15 demonstrating comparative discharge profiles of the definitions some time recently and after soundness thinks about. There was no noteworthy alter in taste and color at optimized temperature. There was no noteworthy variety within the deterioration time, hardness, friability and in-vitro disintegration profiles for the optimized definition. In conclusion, the objective of detailing advancement and assessment of mouth dissolving tablets of taste conceal Levocetrizine dihydrocloride and Montelukast sodium had been accomplished. On the premise of drug release B2ML5 was considered as optimized definition.

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