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FORMULATION AND EVALUATION OF MOUTH DISSOLVING COMBINATION TABLETS OF MONTELUKAST SODIUM AND LEVOCETIRIZINE DIHYDROCHLORIDE USING NATURAL POLYMER

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ABSTRACT

Mouth dissolving tablets are a type of solid dosage form that contains medication that dissolves quickly when pressed on the tongue, usually in a couple of seconds. Due to its simplicity in administration, it is becoming more and more popular among patients who have swallowing issues, particularly children, the elderly, and those who have dysphagia. Objective of this study was to investigate how natural polymers such as Soy polysaccharide, Lepidium sativum mucilage and fenugreek gum could be used as superdisintegrants in mouth dissolving tablets that dissolve in the mouth. Aim of the study was to develop the mouth dissolving combination tablets of Montelukast Sodium and Levocetirizine Dihydrochloride using natural polymers such as Soy polysaccharide, Lepidium sativum mucilage and fenugreek gum as superdisintegrants, optimization and evaluation by comparing them to the formulation containing typical synthetic superdisintegrants Croscarmellose sodium. Mouth dissolving combination tablet was prepared by direct compression method. Blended powder and compressed tablets were subjected to different physicochemical characterization and result revealed that blended powder and tablets had admissible properties. Formulations F3, F5 & F9 containing 8% of Soy polysachharide, 5% of Lepidium sativum mucilage and 9% of fenugreek gum respectively was given promising outcomes and results were comparable with formulation containing synthetic superdisintegrant CCS. Thus, it can be said that the produced mouth dissolving tablets dissolve instantly without the need for water and exhibit rapid dissolution rate.

Keywords: Montelukast Sodium, Levocetirizine Dihydrochloride, mouth dissolving tablets, natural superdisintegrants, Soy polysachharide, Lepidium sativum mucilage, Fenugreek gum, direct compression.

INTRODUCTION

Tablets are the most frequently recommended dosage form due to their manifold superiority in terms of self-administration, handling, affordability, and ease of development. It is nonetheless connected with multi-fold in-commodities viz. discomfort in swallowing, specifically in children and aged group as well as individuals who have troubles in swallowing common tablets and capsules. In circumstance of unapproachable of water this issue could get more escalated while traveling.[1,2]

To handle these challenges, a novel dose form called mouth-dissolving tablets has been evolved. These medications dissolve in the mouth in 20 to 30 seconds as their name implies, and the active ingredient commences to have a therapeutic significance as it comes off in proximity of saliva.[2]

Variant names for this approach entails fast dissolving tablets, fast dispersion tablets, rapid dissolve tablets, rapid melt tablets, quick disintegrating pills, and orally disintegrating tablets. The Food and Drug Administration (FDA) has defined the MDT formulation as a solid dosage form bearing medicinal ingredient that disintegrates promptly within a few of seconds when it is emplaced on the surface of the tongue.[11]

BENEFITS OF MDTs [3,12]

a) MDTs have most important advantage of administration simplicity for the people with inhaling issues, namely those who are kid, aged and possesses dysphagia, odynophagia, globus or psychogenic dysphagia.

b) As there is negligible chance of chocking with MDTs, it is considered to be safe with regard to inhaling.

c) Aspiration of prompt onset of action can be convincingly resolved using MDTs, because tablet gets dissolved and absorbed in no time as soon as it is placed in mouth.

d) Problem of dosing imprecision can be conquered by using MDT unit dose tablets.

e) Since leading fraction of MDT tablet is absorbed in mouth, pre-systemic metabolism of drug is intensely lowered which additionally boosts bioavailability and diminish side effect.

f) As you don't need water to take MDTs, this trait might be very crucial while travelling and in case of unavailability of water.

DEMERITS OF MDTs [4,10]

a) It is troublesome to formulate pharmaceuticals with relatively high doses into MDTs.

b) MDTs are spontaneously deteriorated by even mild fluctuation of temperature and relative humidity.

c) MDTs do not have robust physical strength to withstand environmental stress, hence they require special care during manufacturing and packaging and environmental condition should be well maintained.

d) In case of amaroidal drug, if taste covering is not carried out during formulation design MDTs have trend to leave awful taste and coarseness in mouth.

e) MDT may not be preferable for the one who has characteristic dehydrated mouth due to mere production of saliva.

CRITERIA FOR MDTs [8,9,13]

a) MDTs should have peculiar property of disintegrating and dissolving immediately in vocal cavity even if it is taken not having water.

b) MDTs should suit for containing not only the small doses but likewise higher doses of drug.

c) MDT formulation should be robust to combat the inconstant circumstances of temperature and relative humidity.

d) Sweeteners used to hood amaroidal drug used in MDTs should be amicable with formulation.

e) MDTs ought to taste good.

CHALLENGES IN MDTs

a) Palatability:[9]

MDTs conventionally incorporate drugs in taste covering form because most APIs are displeasing to take in. once tablet is administered it dissolves or disintegrates in patient's mouth releasing active constituent that grasp taste buds. Thus enclosing the medication is vital for patient affability.

b) Mechanical strength:[6,9]

In precedence to encounter oral disintegration MDTs are either contrived eminently porous, soft molded matrices or they are compressed into tablets with considerably tiny force which make the tablets frangible, intricate to handle and customarily necessitates profound blister packaging that could augment the cost.

Tablet should not be facilely breakable and it should withhold commensurable mechanical stability with any excipient included.

Pursuing medication that hastily dissolves in oral cavity along with conserving commensurable mechanical strength is difficile.

c) Hygroscopicity:[9]

Chiefly MDTs are hygroscopic in character. Hence they are enormously perceptive to escalated temperature and relative humidity which renders them unable to endorse their physical integrity.

In order to safeguard from such intemperate condition they are prescribed to be packed in special packaging.

d) Amount of Drug:[9]

The amount of drug that can be subsumed in each unit dose impedes the pertinence of technologies used for MDTs. In case of soluble drug extent that can be assimilated in lyophilized dosage form is 400 mg . On other hand, for insoluble drugs it is about sixty milligram.

e) Aqueous solubility:[9]

Water soluble drugs prorates a range of formulation deterrents due to development of eutectic blend, which throw down freezing point and invoke formation of glassy solid which is vulnerable to collapsing upon drying accompanying detriment of supporting structure during sublimation process . Adopting various matrix forming excipient such as mannitol which induce crystallinity and hence give amorphous composite stiffness, might occasionally prevent such collapse.

f) Size of tablet:[9]

Amplitude of the tablets which are contemplated to be easy to swallow is seven to eigh millimeter . Dimension of the tablets which is contemplated to be easy to have grip on is greater than eight millimeters. Consequently, it is visionary to create tablets that are both easy to grasp and effortless to swallow.

g) Mouth feel:[9]

Foremost MDTs should bust into larger particles inside mouth. MDTs after disintegration should generate as slight particles as achievable. Furthermore flavoring and chilling material such as menthol can exaggerate mouth impression.

h) Sensitivity to environmental condition:[9]

Considering majority of the materials used in MDTs is steered to make tablet dissolve in infinitesimal volume of water and they should be lesser perceptive to circumstantial factors like temperature and relative humidity .

i) Drug concentration:[9]

Constitution of MDTs is curbed to potent drugs and those with constricted therapeutic index. Therefore not the entire medications are befitting for MDT dosage form.

DIFFERENT TECHNIQUES FOR PREPARATION OF MDTs

a) Freeze drying:[5]

Drying at subsided temperature using sublimation based water riddance is known as lyophilization. API in water soluble matrix is subsequently freeze dried to originate a immensely porous or permeable configuration. When infused into oral cavity lyophilized tablets impulsively dissolve in lesser than 5 sec. as result of saliva's speedy entry into porous or permeable configuration. Heat prone APIs procure benefits from lyophilization.

b) Tablet molding:[5]

There are two different sorts of molding system, one is solvent mode and another is thermal mode. Solvent mode devices lesser compact tablets. They own porous or permeable configuration which contributes them to dissolve vigorously than compressed tablets do. Mechanical durability of tablets that have been molded uplifts substantial interests. It is fundamental to integrate binding agents which strengthen mechanical trait of the tablets. However this practice has consequent dispute of masking flavor of medication particles. To surpass this dispute they are fabricated by spray congealing a molten mixture of ingredients.

c) Direct compression:[5]

Incomplex and especially cost effective practice of producing tablet is direct compression. Due to availability of feasible superdisintegrants and other excipients, the technique of direct compression is universally applied in manufacturing of MDTs.

d) Spry drying:[5]

This technique is entrenched on particulate foundation matrix. Extremely porous configuration is prompted by spray drying an aqueous blend which embraces support matrix and other ingredients. Following mixing with API blend is compressed into tablets.

e) Mass extrusion method:[5]

In this scheme a solution of water soluble polyethylene glycol and menthol is employed to mellow a mixture of API and excipients. The soften bulk is again extruded across an extruder or syringe to give rise to cylinder of product. Finally tablets are reproduced by chopping down this cylinder of products into minute fragments of even sizes by employing hottish cutlass.

f) Sublimation technique:[7]

Prime trait in instituting MDTs employing sublimation process is augmenting a volatile salt to tablet constituents. All the constituents are mixed utterly to yield uniform mixture and then salt is aromatized.

The aromatization of volatile salt lead the tablet permeable which hasten breakdown mechanism when tablet is revealed to saliva.

MATERIAL AND METHOD

Following materials were applied for the formulation of mouth dissolving tablets:

Table 1: Brief of material used

S. No.	Name of Material	Category	Source
1.	Montelukast Sodium	Active Ingredient	Morepen Laboratories Limited
2.	Levocetirizine Dihydrochloride	Active Ingredient	Karunesh Remedies
3.	Soy Polysaccharide	Natural Superdisintegrant	Local Market
4.	Lepidium Sativun Mucilage	Natural Superdisintegrant	Local Market
5.	Fenugreek Gum	Natural Superdisintegrant	Local Market
6.	Croscarmellose Sodium	Synthetic Superdisintegrant	Rosswekk Industries
7.	Microcrystalline Cellulose 102	Diluents	Ankit Pulps and Boards Pvt. Ltd.
8.	Mannitol	Diluents	Anil Starch Ltd.
9.	Aspartame	Sweetener	Parimal Sweetness Pvt. Ltd.
10	Magnesium Stereate	Lubricant	Vimalnath Chem Pvt. Ltd.
11	Aerosil	Glidant	Nippon Aerosil Co. Ltd.

Purified water was employed as solvent amid the formulation process.

Method of preparation of tablets:

a) Mouth dissolving tablets entailing Montelukast Sodium equivalent to 10 mg and Levocetirizine Dihydrochloride equivalent to 5 mg as API were prepared by direct compression fashion.

b) Polymers, viz. Soy Polysaccharide, Lepidium Sativun Mucilage and Fenugreek Gum were engaged as natural superdisintegrants in different fractions as shown in the table no.5. MDTs so generated were assessed and analogized against the formulations integrating conventional synthetic superdisintegrant Croscarmellose Sodium.

c) At first API and other ingredients such as Microcrystalline Cellulose and Mannitol were passed through #60 sieve screen.

d) Sieved Montelukast Sodium, Levocetirizine Dihydrochloride, Microcrystalline Cellulose and Mannitol was mixed precisely.

e) Then claimed quantity of superdisintegrants and aspartame were taken for each formulation and mixed well.

f) Finally, Magnesium Stereate and Aerosil were supplemented and mixed well.

g) Mixed blend was then compressed at average weight of 180 mg using the tablet punching

machine.

h) Finally, blend powder and compressed tablets was assessed for physicochemical depiction.

Table 2: Composition of different formulations:

S. No.	Name of Ingredient	Quantity (mg)/Tablet											
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
1.	Montelukast Sodium	10	10	10	10	10	10	10	10	10	10	10	10
2.	Levocetirizine Dihydrochloride	5	5	5	5	5	5	5	5	5	5	5	5
3.	Soy Polysaccharide	8	12	16	-	-	-	-	-	-	-	-	-
4.	Lepidium Sativun Mucilage	-	-	-	6	10	14	-	-	-	-	-	-
5.	Fenugreek Gum	-	-	-	-	-	-	10	14	18	-	-	-
6.	Croscarmellose Sodium	-	-	-	-	-	-	-	-	-	8	10	18
7.	Microcrystalline Cellulose	160	156	152	162	158	154	158	154	150	160	158	150
8.	Mannitol	12	12	12	12	12	12	12	12	12	12	12	12
9.	Aspartame	2	2	2	2	2	2	2	2	2	2	2	2
10.	Magnesium Stereate	2	2	2	2	2	2	2	2	2	2	2	2
11.	Aerosil	1	1	1	1	1	1	1	1	1	1	1	1
Average Weight (mg)		200	200	200	200	200	200	200	200	200	200	200	200

EVALUATION

Pre-compression characterization:

Table 3: Pre-compression interpretation for blend powder

Batch Formulation	Bulk Density (g/cm^3)	Tapped Density (g/cm^3)	Compressibility Index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.365	0.427	14.520±0.001	1.170±0.004	27.80±0.012
F2	0.363	0.428	15.187±0.001	1.179±0.002	27.70±0.002
F3	0.362	0.429	15.618±0.002	1.185±0.001	27.50±0.001
F4	0.344	0.415	17.108±0.003	1.206±0.001	28.50±0.003
F5	0.345	0.417	17.266±0.003	1.209±0.004	28.55±0.016
F6	0.347	0.418	16.986±0.002	1.205±0.001	28.61±0.004
F7	0.378	0.449	15.813±0.001	1.188±0.012	28.16±0.003
F8	0.376	0.445	15.506±0.001	1.184±0.004	28.30±0.002
F9	0.373	0.441	15.420±0.004	1.182±0.003	28.20±0.004
F10	0.329	0.381	13.648±0.004	1.158±0.003	26.76±0.004
F11	0.331	0.385	14.026±0.001	1.163±0.005	26.89±0.002
F12	0.333	0.387	13.953±0.003	1.162±0.004	27.12±0.001

Note: All values are expressed as mean±SD.

Post-compression characterization:

All the formulations were evaluated for Weight variation test, Hardness, Thickness, Friability, Disintegration time and wetting time.

Table 4: Post-compression interpretation for compressed tablets

Batch Formulation	Weight Variation (mg)	Hardness (Kg/cm^2)	Thickness (mm)	Friability (%)	Disintegration Time (Sec)
F1	200.1±0.003	4.39±0.002	3.73±0.001	0.24±0.001	26±0.014
F2	200.3±0.004	4.33±0.003	3.71±0.019	0.35±0.006	30±0.003
F3	199.8±0.003	3.90±0.001	3.72±0.002	0.33±0.001	20±0.017
F4	199.9±0.008	3.45±0.004	3.73±0.016	0.31±0.005	29±0.003
F5	201.2±0.001	3.03±0.001	3.77±0.003	0.28±0.001	17±0.009
F6	202.1±0.002	3.40±0.003	3.76±0.002	0.32±0.002	27±0.004
F7	198.9±0.004	3.14±0.004	3.79±0.004	0.25±0.008	24±0.004
F8	200.1±0.007	3.20±0.003	3.75±0.006	0.26±0.004	26±0.002
F9	200.1±0.001	3.98±0.006	3.74±0.008	0.21±0.012	23±0.003
F10	197.8±0.006	3.79±0.001	3.71±0.003	0.28±0.003	30±0.017
F11	202.5±0.001	3.80±0.006	3.74±0.001	0.30±0.005	24±0.016
F12	199.8±0.003	3.47±0.008	3.73±0.003	0.31±0.004	32±0.080

Note: All values are expressed as mean±SD.

Percent drug content or assay test:

Table 5: Percent drug content or assay

Batch Formulation	**Assay/Drug Content (%)**	
	Montelukast Sodium	**Levocetirizine Dihydrochloride**
F1	97.10±1.05	94.50±1.43
F2	97.50±1.20	96.70±1.03
F3	94.48±1.02	91.51±1.08
F4	96.56±1.10	97.65±1.70
F5	100.10±0.07	99.97±0.89
F6	97.89±1.10	97.48±1.41
F7	98.87±0.16	97.57±0.89
F8	97.21±1.50	97.31±1.08
F9	100.98±0.20	98.98±0.06
F10	106.65±0.14	96.46±1.05
F11	96.92±0.19	97.78±1.21
F12	95.54±1.02	96.32±1.51

Note: All values are expressed as mean±SD.

In vitro dissolution or drug release test:

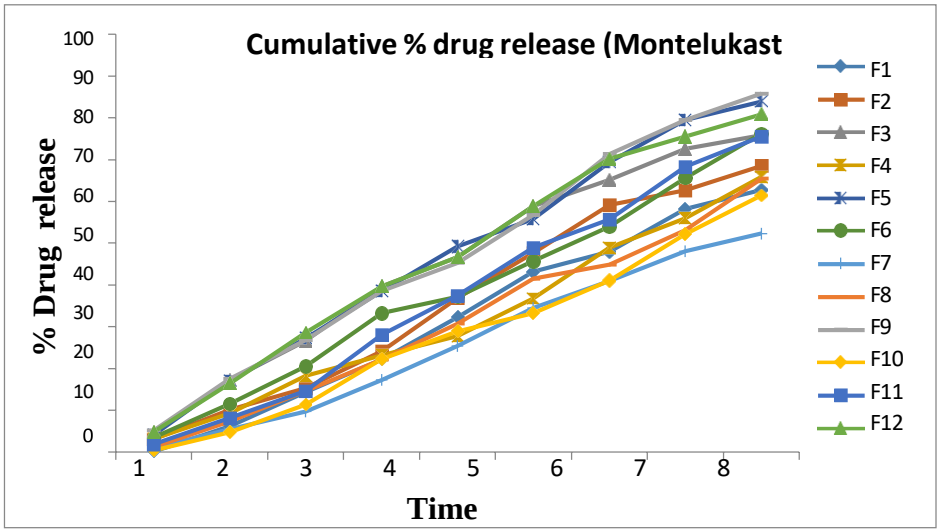
Table 6: In vitro dissolution/drug release of tablets (Montelukast Sodium)

Cumulative % drug release (Montelukast Sodium)												
Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0.5	0.15	3.12	4.89	3.21	4.12	3.48	1.01	1.21	5.21	0.48	1.89	4.89
1	6.21	10.21	17.25	9.26	17.16	11.54	5.47	7.38	17.61	4.85	8.14	16.49
1.5	14.31	15.31	26.68	18.27	27.18	20.51	9.78	14.58	26.75	11.47	14.68	28.68
2	22.15	24.21	39.75	23.15	38.51	33.24	17.32	22.15	38.61	22.32	28.12	39.75
3	32.25	36.87	46.65	27.85	49.25	37.21	25.45	30.71	45.29	28.98	37.45	46.65
4	43.16	47.65	58.85	36.78	55.85	45.65	34.52	41.47	56.78	33.25	48.94	58.85
6	47.98	59.12	65.25	48.98	69.36	53.93	40.89	44.85	71.36	41.14	55.68	70.25
8	58.12	62.65	72.55	55.98	79.51	65.65	48.11	53.21	79.45	52.21	68.32	75.55
10	62.74	68.52	75.85	65.86	83.89	76.25	52.36	65.45	85.82	61.45	75.52	80.85

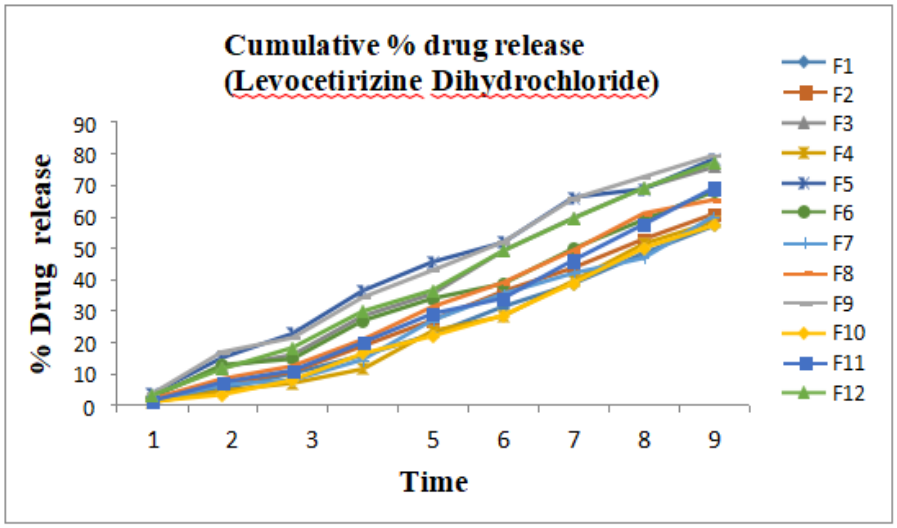
Table 7: In vitro dissolution/drug release of tablets (Levocetirizine Dihydrochloride)

Cumulative % drug release (Levocetirizine Dihydrochloride)												
Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
0.5	1.85	1.89	2.73	0.78	3.45	2.32	1.08	1.89	3.45	1.05	1.2	3.01
1	5.12	6.58	11.92	4.42	14.87	12.68	6.26	8.12	16.78	3.25	7.15	11.37
1.5	9.87	10.45	15.85	6.87	22.54	14.54	7.87	12.35	21.25	7.82	10.75	18.19
2	15.75	18.68	28.15	11.45	36.15	26.72	14.45	20.78	34.12	16.32	19.78	29.69
3	22.32	26.84	35.35	23.54	45.38	33.78	26.79	31.21	42.75	21.79	28.96	36.37
4	31.23	36.12	48.85	28.12	51.45	38.48	35.25	38.78	51.78	28.32	33.85	48.87
6	38.54	43.45	59.42	39.45	65.87	49.65	41.75	49.12	65.45	38.59	45.98	59.22
8	48.12	52.69	68.98	51.12	68.45	58.75	46.65	60.78	72.49	49.89	57.25	68.89
10	56.85	60.63	75.54	58.21	78.1	67.75	59.96	65.12	79.25	56.98	68.87	76.88

Cumulative percentage of drug released was determined for each tablet formulation (F1 to F12) by sampling and analyzing at different time intervals under the similar dissolution test conditions. Dissolution profile is presented in table no. 6, 7 and graph no. 1,2. On evaluation of results it was found that F5 exhibit the better percentage of drug released in comparison to other formulations.



Graph 1: Graph-Cumulative percent drug release (Montelukast Sodium)



Graph 2: Graph-Cumulative percent drug release (Levocetirizine Dihydrochloride)

Comparison of dissolution profile of optimized formulations containing natural superdisintegrants with formulation containing conventional superdisintegrant CCS:

Table 8: Difference factor (*f1*) and Similarity factor (*f2*) of dissolution of optimized formulation F3, F5, F9 and F12.

S.N.	Formulations	Montelukast Sodium		Levocetirizine Dihydrochloride	
		f1	*f2*	*f1*	*f2*
1	F3 & F12	3.73	74.91	2.09	89.67
2	F5 & F12	4.18	77.95	9.83	62.87
3	F9 & F12	4.24	76.55	9.88	65.23

Since the difference factors (f1) for the formulation F3, F5 & F9 were found to be in the range of 3.73 to 9.88 and similarity factor (f2) in the range of 62.87 to 89.67, dissolution profiles of formulations containing natural superdisintegrants are comparable with formulation containing synthetic superdisintegrant CCS.

Stability Study:

Stability evaluation of optimized formulations F3, F5 & F9 was executed for the term of three months. Batches were kept in ACC Stability Chamber under the Temperature of 40±2ºC and Relative Humidity of 75±5% . After 3 months of storage tablets were ascertained for the distinct physicochemical particularities as follows:

Table 9: Stability study assessment result

S. No.	Parameter	F3	F5	F9
1.	Appearance	Complies	Complies	Complies
2.	Weight Variation (mg)	199.25±0.125	200.5.±0.003	198.45±0.008
3.	Hardness (kg/cm2)	4.21±0.002	3.98±0.021	3.85±0.005
4.	Thickness (mm)	3.72±0.003	3.75±0.002	3.8±0.001
5.	Friability (%)	0.6±0.002	0.5±0.005	0.4±0.087
6.	Disintegration Time (Sec)	40±0.287	20±0.045	29±0.009
7.	% Drug Content			
	Montelukast Sodium	96.78±1.35	97.10±1.06	95.10±1.89
	Levocetirizine Dihydrochloride	94.50±1.14	98.10±0.89	98.10±1.65
8.	% Drug Release			
	Montelukast Sodium	76.25	85.80	75.25
	Levocetirizine Dihydrochloride	77.35	80.15	76.87

Note: All values are expressed as mean±SD.

CONCLUSION

In the currently study, mouth dissolving combination tablets of Montelukast Sodium and Levocetirizine Dihydrochloride was successfully developed, optimized and analogized by comparing them to the formulation comprising typical synthetic superdisintegrants (CCS). Mouth dissolving combination tablet was generated by direct compression scheme .

The characteristic peak in the physical mixture of individual API and polymer as well as excipient indicates that there was not any interference in peak of drugs. Hence, it can be contemplated that troublesome of drug-excipient incompatibility did not endure.

Outcome of pre-compression blend powder exploration such as BD, TD, Angle of Repose, Hausner's Ratio proclaimed that entire the formulations (F1-F12) possessed good flow property, which attributed uniformity of average weight in course of compression activity.

Weight variation of entire formulation batches was befallen within Pharmacopoeial extremity. Hardness of tablets was found within the range of 3.03±0.001 to 4.39±0.002 kg/cm^2 and percent friability less than 1%, which demonstrated that tablets had commensurable mechanical solidity and physical integrity.

Percent drug content value of all formulations of tablet was resulted in the range of 94.48±1.02 % to 106.65±0.14 % (MS) and 91.51±1.08% to 99.97±0.89 % (LD) concluding that each tablet encompasses almost equivalent amount of drug contents.

Optimized formulation F3 containing 8% of Soy polysachharide showed % drug release of 75.85 % (MS) and 75.54 %(LD) within 10 minutes disintegration time 20 sec with wetting time of 15 seconds. Optimized formulation F5 containing 5% of Lepidium Sativun Mucilage showed % drug release of 83.89 % (MS) and 78.10 %(LD) within 10 minutes and disintegration time 17 sec with wetting time of 12 seconds. Similarly, Optimized formulation F9 containing 9% of Fenugreek Gum showed % drug release of 85.82 % (MS) and 79.25 %(LD) within 10 minutes and disintegration time 23 sec with wetting time of 16 seconds. From these results it was concluded that formulation F3, F5 and F9 had the satisfactory drug release profile along with favorable disintegration time.

Values of difference factor and similarity factors for percent drug release of optimized formulation F3, F5, F9 against formulation F12 was found to in the range of 3.73 to 9.88 and 62.87 to 89.67 respectively, referring that dissolution profiles of these formulations comprising natural superdisintegrants are comparable with formulation comprising synthetic superdisintegrant CCS.

Stability study of optimized formulations endorsed that formulations were invariable at prescribed constraint of Temperature and Relative Humidity as per ICH guideline.

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