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RESEARCH ARTICLE

Formulation and Evaluation of Oral Disintegrating Tablets of Montelukast Sodium and Desloratidine

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ABSTRACT:
The objective of the present study is to formulate and evaluate oral disintegrating tablets of Montelukast sodium and Desloratadine by direct compression using different concentrations of superdisintegrants like croscarmellose sodium, sodium starch glycolate and crospovidone. Montelukast sodium is a leukotriene receptor antagonist, used in the treatment of asthma and Desloratadine is a drug used to treat allergies the combination formulation is used for the treatment of allergic rhinitis. The Preparation contains 11 formulations by using direct compression method. The prepared batches of oral disintegrating tablets of Montelukast sodium and Desloratadine can be evaluated fort the pre compression parameters like angle of repose, Cars index, Hausner's ratio, tapped and bulk density. The post compression parameters were also studied including the Weight variation, Hardness, friability, Thickness, wetting time, *In vitro* disintegration and the water absorption ratio and *In-vitro* dissolution studies. *In-vitro* dissolution studies showed that formulations F4, F10, F11 showed better dissolution of Desloratidine and Montelukast when compared with marketed formulation and among them F11 was found to be better formulation when compared to others. Based on the formulation development and results, F11 formulation was considered as the desired formulation which contains crospovidone 4 % as a super disintegrant.

KEYWORDS: Active Pharmaceutical Ingredient (API), Oro Dispersible Tablets (ODT), Sodium Starch Glycolate (SSG), Micro Crystalline Cellulose (MCC), Disintegration Time (DT).

1. INTRODUCTION:
Orally disintegrating tablets are also called as oral dispersible tablets, quick disintegrating tablets, mouth dissolving tablets, fast disintegrating tablets, fast dissolving tablets, rapid dissolving tablets, porous tablets, and rapid melts. However, of all the above terms, United States pharmacopoeia (USP) approved these dosage forms as ODTs. Recently, European Pharmacopoeia has used the term orodispersible tablet for tablets that disperses readily and within 3 min in mouth before swallowing. [1-2]

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1.1 Salient Features of Oral disintegrating Drug Delivery System [1-4]
- Ease of administration for patients who are mentally ill, disabled and non co- operative.
- Quick disintegration and dissolution of the dosage form.
- Overcomes unacceptable taste of the drugs.
- Can be designed to leave minimal or no residue in the mouth after administration and also
- to provide a pleasant mouth feel.
- Allows high drug loading.
- Ability to provide advantages of liquid medication in the form of solid preparation
- Cost-effective.

1.2 Ideal Properties of ODTs [4-6]
- Not require water to swallow, but it should dissolve or disintegrate in the mouth in matter of seconds.
- Be compatible with taste masking.

- Be portable without fragility concern.
- Have a pleasant mouth feel.
- Leave minimum or no residue in the mouth after oral administration.
- Exhibit low sensitive to environmental conditions like temperature and humidity.
- Allow the manufacture of the tablet using conventional processing and packaging equipments at low cost.

1. 3 Advantages of ODT [4, 7]

- Administration to the patients who cannot swallow, such as the elderly, stroke victims, bedridden patients, patients affected by renal failure and patients who refuse to swallow such as pediatric, geriatric and psychiatric patients.
- Rapid drug therapy intervention.
- Achieve increased bioavailability/rapid absorption through pre gastric absorption of drugs from mouth, pharynx and esophagus as saliva passes down.
- Convenient for administration and patient compliant for disabled patients and for travelers and busy people, who do not always have access to water.
- Good mouth feel property helps to change the perception of medication as bitter pill particularly in pediatric patients.
- The risk of chocking or suffocation during oral administration of conventional formulations due to physical obstruction is avoided, thus providing improved safety.

1.4 Limitations of oral disintegrating tablets[7-8]

- The tablets may leave unpleasant taste or grittiness in mouth if not formulated properly.
- The tablets usually have low hardness. So, they are friable or brittle, and are difficult to handle. They often requiring specialized peel-off blister packaging careful handling is required.
- Delivery of drug from the fast dissolving formulation would not expect to avoid first pass metabolism since the unit disintegration rapidly and the drug would be swallowed.

2. MATERIALS AND METHODS:

Montelukast sodium and Desloratadine was obtained as a gift sample from Hetero drugs, Hyderabad. Crospovidone, Cross carmellose sodium, Sodium starch glycollate was obtained from Signet Chemical Corp., Mumbai. All other chemicals used were of analytical grade.

2.1 Formulation of Montelukast sodium and Desloratidine MDTs:

In direct compression method the amount of active ingredient Montelukast sodium and Desloratidine were taken and cross povidone, cross caramellose sodium, sodium starch glycollate were used as superdisintegrants, MCC was used as a diluent and sweetening agent like aspartame were passed through the sieve no.40. These ingredients were mixed well for 5 min after that lubricant such as Magnesium stearate is added to the above blend. Then it was transferred for compression. The efficiency of mixing was verified by the determination of percentage purity. [9-10]

2.2 Preformulation Study[21-22]

2.2.1 Micromeritic properties:[2-4]

2.2.1.1 Bulk density:

Bulk density was determined by pouring gently 25 gm of sample into 100 ml graduated cylinder. The volume occupied by the sample was recorded. Bulk density was calculated as:

Bulk density = weight of sample in gram /volume occupied by the sample

Table 1 Formulations for Montelukast sodium and Desloratidine oral disintegrating tablets:

S. No	Ingredients	Quantity of Ingredients (mg)										
		F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
1.	Montelukast sodium	10	10	10	10	10	10	10	10	10	10	10
2.	Desloratadine	5	5	5	5	5	5	5	5	5	5	5
3.	Sodium starch glycolate	2	4	6	8	-	-	-	-	-	-	-
4.	Cross carmellose sodium	-	-	-	-	4	6	8	-	-	-	-
5.	Crospovidone	-	-	-	-	-	-	-	2	4	6	8
6.	MCC Ph 102	158	156	154	152	156	154	152	158	156	154	152
7.	Mannitol(cyclosel)	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0	20.0
8.	Sillicon dioxide	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
9.	Aspartame	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0	4.0
10.	Magnesium stearate	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
11.	Orange flavor	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5

2.2.1.2 Tapped density:

Tapped density was determined by using Electro lab density tester, which consists of a graduated cylinder mounted on a mechanical tapping device. An accurately weighed sample of powder was carefully added to the cylinder. Typically, the initial volume was noted, and the sample is then tapped (500, 750 or 1250 tapping) until no further reduction in volume is noted or A sufficient number of taps should be employed to assure reproducibility for the material in question. Volume was noted and tapped density is calculated using following formula. [11-12]

Tapped density = Wt. of sample in gm / Tapped volume

2.2.1.3 Compressibility Index and Hausner ratio:-
In recent years the compressibility index and the closely related Hausner ratio have become the simple, fast, and popular methods of predicting powder flow characteristics. Both the compressibility index and the Hausner ratio were determined by using bulk density and the tapped density of a powder.

$$\text{Carr's index} = \frac{\text{Tapped desnity-Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's Ratio = Tapped density (ρt) / Bulk density (ρb0

Table 2 Compressibility index and Hausners Ratio

Compressibility Index (%)	Flow Character	Hausner's Ratio
≤10	Excellent	1.00–1.11
11–15	Good	1.12–1.18
16–20	Fair	1.19–1.25
21–25	Passable	1.26–1.34
26–31	Poor	1.35–1.45
32–37	Very poor	1.46–1.59
>38	Very very poor	>1.60

2.2.1.4 Angle of Repose: - (USP29-NF-24)
The angle of repose has been used to characterize the flow properties of solids. This is the maximum angle possible between surface of pile of powder or granules and the horizontal plane. A funnel was fixed at a height approximately of 2-4 cm over the platform. The loose powder was slowly passed along the wall of funnel, till the cone of the powder formed .Determine the angle of repose by measuring the height of the cone of powder and radius of the heap of powder. [13, 14]

$\text{Tan } \theta = h / r$
$\theta = \text{Tan}^{-1} h / r$

Where
θ = angle of repose,
h = height,
r = radius.

2.2.2 Post compression parameters [8. 10. 11]
2.2.2.1 Thickness:
The thicknesses of the tablets were determined by using Vernier Caliper and the results were expressed in millimeter. A ± 5% may be allowed depending on the size of the tablet.

Table 3 Flow Properties and Corresponding Angles of Repose

Flow Property	Angle of Repose (degrees)
Excellent	25–30
Good	31–35
Fair - aid not needed	36–40
Passable - may hang up	41–45
Poor - must agitate, vibrate	46–55
Very poor	56–65
Very, very poor	>66

2.2.2.2 Hardness test:
Tablets require a certain amount of strength or hardness and resistance to friability to withstand mechanical shocks of handling in manufacture, packing and shipping. The hardness of tablet was measured by Pfizer hardness tester. Ten tablets from the batch were used for hardness studies and results are expressed in Kg/cm^2.

2.2.2.3 Weight variation test:
Ten tablets were selected at random, individually weighed in a single pan electronic balance and the average weight was calculated. The uniformity of weight was determined according to I.P specification

Table 4 Limits of weight variation

S.No.	Average weight of tablet	Percentage
1	80 mg or less	± 10%
2	More than 80mg and less than 250mg	± 7.5%
3	250 mg or more	± 5%

2.2.2.4 Friability test:
It was performed in Electro lab Friabilator apparatus where the tablets were subjected to the combined effect of abrasion and shock by utilizing a plastic chamber that revolves at 25 rpm dropping the tablets at a distance of six inches with each revolution. Pre weighed samples of 20 tablets were placed in the Friabilator, which is then operated for 100 revolutions. The tablets are then dusted and reweighed. Conventional compressed tablets that loose less than 0.5 to 1% of their weight are generally considered acceptable.

%F = 1- (loss in weight/ initial weight) 100

2.2.2.5 Disintegration:
By using USP device which consists of six glass tubes that are 3inches long, open at one end and held against 10 mesh screen at the bottom end of basket rack assembly. To test for disintegration time, one tablet is placed in each tube and the basket arch is positioned in 1 litre beaker of water at 37°c±2°c. A standard motor driven device is used to move the basket assembly up and down.

2.2.2.6 Water absorption Ratio and wetting time:
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 paper and the time required for complete wetting was measured. The wetted tablet was then weighed.

$$R = 100 \times \frac{Wb - Wa}{Wa}$$

2.2.2.7 Analysis of Active constituents:
A reversed-phase-liquid chromatographic (RP-HPLC) method was developed for the determination of Montelukast Sodium (MON) and Desloratadine (DES) in their marketed formulation. A reversed-phase C-18 column (250 mm × 4.8 mm i.d., particle size 5 μm) column with mobile phase consisting of methanol:

water: Acetic acid (80:20:0.05 v/v/v) was used. The flow rate was 1.0 ml/ min and effluents were monitored at 280 nm. The retention times of Montelukast Sodium and Desloratadine were found to be 7.61±0.2 min and 2.23±0.3 min, respectively.

2.2.2.8 Dissolution studies:

For dissolution of the Montelukast sodium and Desloratidine USP type II paddle type dissolution apparatus is used. One tablet each were placed in each bowl and rotated at 50 rpm in 900ml of the dissolution medium (Distilled water at 37±0.5^{0}C) for 20 minutes and the time intervals for withdrawing the sample are 3,6,10,15,20. min. and was replaced with an equal amount of fresh medium, to maintain the constant volume of dissolution method throughout the experiment. The samples were assayed by HPLC. [15-17]

Dissolution parameters:

Apparatus: USP II Dissolution apparatus;
Medium: Distilled water (900ml);
Speed: 50rpm;
Time: 20min;
Temperature: 37±0.5^{o}C.

HPLC Parameters [18-20]

Column: C18 (250 mm × 4.8 mm i.d., particle size 5 µm)
Mobile phase: Methanol: water: Acetic acid (80:20:0.05 v/v/v)
Flow Rate: 1 ml/min
Detection: UV 280 nm
Injection Volume: 20µl

3. RESULTS AND DISCUSSION

Table 5 Pre-compression properties

S. No.	Formulation code	Bulk density(gm/ml)	Tapped density (gm/ml)	Angle of repose	Carr's index (%)	Hausner's ratio
1	F1	0.674±0.004	0.780±0.003	27.43±0.47	13.5±0.04	1.157±0.004
2	F2	0.686±0.006	0.787±0.001	24.72±0.43	12.8±0.06	1.147±0.003
3	F3	0.694±0.003	0.796±0.004	24.20±0.52	12.8±0.07	1.146±0.004
4	F4	0.697±0.005	0.803±0.003	22.30±0.25	13.2±0.03	1.152±0.005
5	F5	0.652±0.003	0.760±0.006	27.67±0.54	14.2±0.02	1.165±0.002
6	F6	0.666±0.004	0.774±0.004	25.59±0.29	13.9±0.04	1.162±0.002
7	F7	0.681±0.002	0.793±0.007	24.30±0.28	14.1±0.03	1.164±0.003
8	F8	0.626±0.007	0.724±0.004	28.72±0.33	13.5±0.01	1.156±0.001
9	F9	0.647±0.005	0.743±0.001	24.20±0.54	12.9±0.05	1.148±0.004
10	F10	0.656±0.003	0.753±0.002	23.43±0.48	12.8±0.06	1.147±0.003
11	F11	0.664±0.002	0.768±0.005	24.67±0.51	13.5±0.01	1.156±0.002

3.1 Angle of Repose:

- The angle of repose of all formulations are ranged from 22^o.30 ± 0.25 to 28^o.72 ± 0.33
- All the above formulations have shown good flow properties [Table 5]

3.2 Bulk Density:

- The bulk density of all formulations are ranged from 0.626±0.007 to 0.697±0.005
- All the above formulations have shown good flow properties. [Table 5]

3.3 Tapped Density:

- The tapped density of all formulations are ranged from 0.724±0.004 to 0.803±0.003
- The values of tapped and bulk density shown that the blends are not tightly packed .so it's not affecting the dissolution of the drug. [Table 5]

3.4 Compressibility Index:

- The compressibility index of all formulations are ranged from 12.8±0.06 to 14.2±0.02
- For all the formulations the compressibility index of the formulations were found to show good flow properties [Table 5]

3.5 Hausner's Ratio:

- The Hausner's ratio of all formulations are ranged from 1.146±0.004 to 1.165±0.002
- For all the formulations the Hausners ratio of the formulations were found to show good flow properties. [Table 5]

3.6 Weight Variation:

- The Weight variation of all the formulations was found to be in the range of 199 ± 0.78 to 200± 0.51
- It was found to comply with in the limits specified [Table 6]

3.7 Thickness:

- The thickness of all the formulations was found to be in the range of 3.12±0.01 to 3.80 ± 0.03
- It was found to comply with in the limits specified [Table 6]

3.8 Hardness:

- The hardness of all the formulations was found to be in the range of 3.24 ± 0.05 to 3.79 ± 0.1
- It was found to comply with in the limits specified [Table 6]

3.9 Friability:

- The friability of all the formulations was found to be in the range of 0.156 ± 0.08 to 0.249 ± 0.11
- It was found to comply with in the limits specified [Table 6]

3.10. Disintegration Time:

- The Disintegration Time of all the formulations was found to be in the range of 27± 1 to 34± 1. It was found to comply with in the limits specified [Table 7]

3.11. Water Absorption Ratio:

- The Water absorption Ratio of all the formulations was found to be in the range of 81.04±0.14 to 103.45±0.43 [Table 7]

3.12. Assay:

- The Assay of all the formulations was found to be in the range of 99.1 ± 0.36 to 101.1 ± 0.80
- It was found to comply with in the limits specified.

3.13. Wetting Time:

The wetting time of all the formulations was found to be in the range of 29±2 to 38±1 of all the formulations crosspovidone formulations has shown faster wetting time depicting good dissolution properties. [Table 6]

Table 6 Showing different post compression properties

Formulation	Thickness (mm)	Hardness (kg/cm^2)	Weight variation (mg)	Wetting time (sec)	Friability (%)
F_1	3.80±0.03	3.24±0.05	200±0.13	38±1	0.249±0.11
F_2	3.74±0.03	3.33±0.15	200±0.51	36±2	0.234±0.01
F_3	3.26±0.02	3.45±0.11	199±0.15	35±2	0.238±0.08
F_4	3.14±0.01	3.63±0.15	200±0.04	33±2	0.233±0.02
F_5	3.41±0.02	3.48±0.14	199±0.78	36±1	0.238±0.08
F_6	3.46±0.01	3.61±0.15	200±0.25	35±2	0.242±0.01
F7	3.74±0.03	3.66±0.05	200±0.13	32±1	0.253±0.11
F8	3.62±0.03	3.53±0.14	200±0.51	34±2	0.232±0.01
F9	3.27±0.02	3.58±0.13	200±0.15	32±1	0.224±0.08
F10	3.12±0.01	3.64±0.12	200±0.04	31±1	0.219±0.02
F11	3.47±0.02	3.79±0.12	199±0.68	29±2	0.222±0.08

Table 7 Showing Water absorption ratio and Disintegration time

Formulation Code	Water absorption Ratio	Disintegration Time (sec)
F_1	81.04 ± 0.14	34± 1
F_2	86.61 ± 0.25	31± 2
F_3	94.53 ± 0.44	28± 1
F_4	100.22 ± 0.32	27± 1
F_5	93.45 ± 0.43	32± 1
F_6	96.63 ± 0.60	29± 2
F7	98.04 ± 0.14	27± 1
F8	96.61 ± 0.25	31± 1
F9	99.53 ± 0.44	29± 2
F10	101.22 ± 0.32	28± 2
F11	103.45 ± 0.43	28± 1

Table 8 Cummulative percent *in-vitro* drug release of Desloratidine in different Formulations

Time (mins)	Cumulative percent drug release										
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
0	0	0	0	0	0	0	0	0	0	0	0
3	18.3±1.2	23.4±2.1	25.6±0.3	31.2±0.7	16.2±2.3	20.2±2.4	22.3±0.8	22.4±1.4	27.3±2.4	32.4±2.1	36.2±0.9
6	39.7±0.6	46.9±2.4	51.8±0.6	54.4±1.2	34.3±2.1	39.4±0.4	40.6±2.4	43.6±2.2	49.7±3.1	59.5±2.7	63.4±1.4
10	51.4±3.2	59.8±1.3	72.4±0.5	79.3±2.9	47.2±0.9	57.4±1.3	54.3±3.2	55.4±2.7	68.4±2.2	80.1±2.4	87.2±2.7
15	67.7±2.6	74.6±3.1	87.3±0.3	96.2±2.2	61.2±0.6	74.6±2.8	71.4±1.7	72.6±3.1	81.2±2.5	90.4±1.3	98.4±0.9
20	76.9±2.4	87.2±2.4	99.8±0.4	99.6±0.6	78.4±2.6	91.4±1.6	85.6±1.5	83.5±1.6	92.4±1.7	99.7±0.7	100.2±0.3

Table 9 Cummulative percent drug release of Montelukast in different formulations

Time (mins)	Cumulative percent drug release										
	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11
0	0	0	0	0	0	0	0	0	0	0	0
3	14.7±2.2	19.8±2.6	22.8±1.4	25.6±1.6	15.6±1.4	17.9±0.8	23.3±2.1	20.8±1.4	23.4±1.2	25.7±2.3	29.5±2.2
6	36.3±3.2	41.3±3.2	44.2±3.4	46.7±2.3	31.7±2.3	37.2±2.4	41.8±1.6	39.7±0.5	40.8±2.3	47.9±0.6	50.7±1.6
10	49.3±3.6	55.4±1.8	58.4±2.2	64.3±3.1	44.3±0.4	54.3±3.1	56.4±0.8	54.1±2.2	59.6±1.8	61.2±0.5	69.8±3.2
15	66.2±2.6	71.2±2.8	74.9±1.8	81.2±2.4	58.4±2.2	70.9±2.2	74.8±2.4	70.6±2.6	74.7±1.5	78.7±2.4	90.4±1.8
20	74.3±3.4	83.4±3.1	87.2±2.3	99.4±0.4	76.8±2.1	83.7±1.5	91.2±1.1	81.7±1.4	82.4±1.8	92.3±1.8	99.8±0.3

A. *In vitro* Dissolution Profiles of Desloratidine

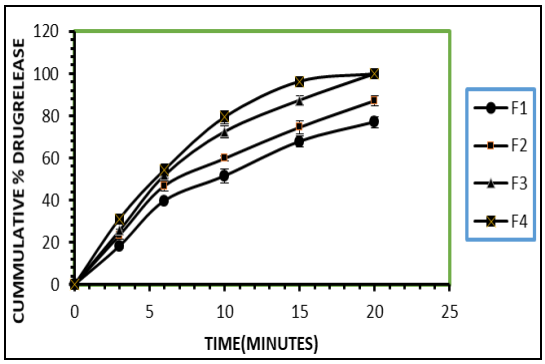

Figure 1 Dissolution profile comparision of formulations made using SSG as superdisintegrant

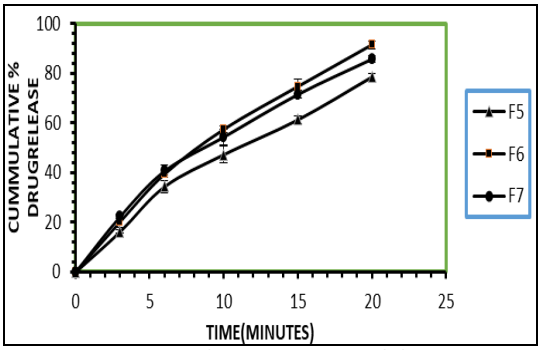

Figure 2 Dissolution profile comparision of formulations made using CCS as superdisintegrant

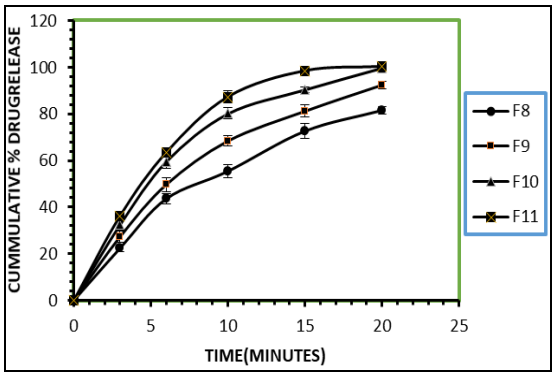

Figure 3 Dissolution profile comparision of formulations made using CP as superdisintegrant

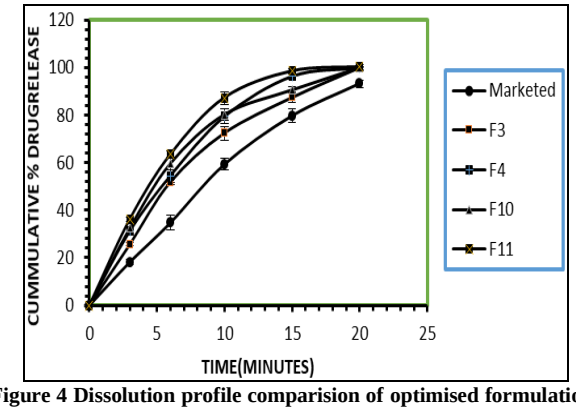

Figure 4 Dissolution profile comparision of optimised formulations (F3,F4,F10,F11) with marketed formulation

B. *In vitro* Dissolution Profiles of Montelukast Sodium:

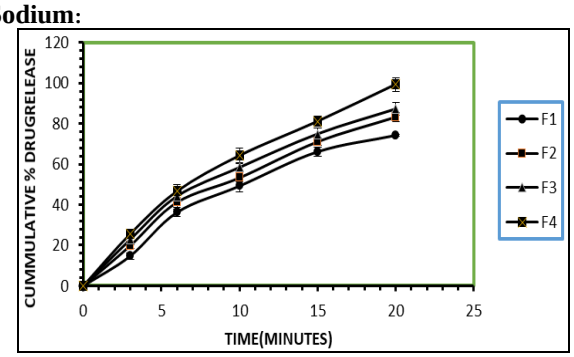

Figure 5 Dissolution profile comparision of formulations made using SSG as superdisintegrant.

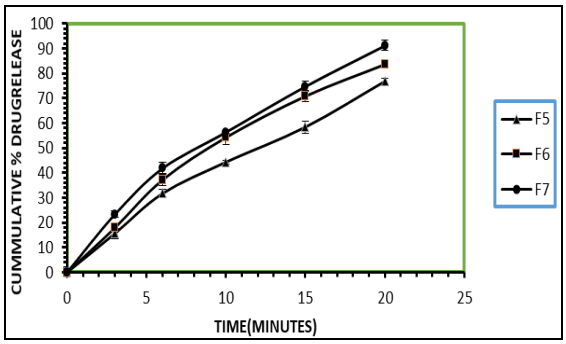

Figure 6 Dissolution profile comparision of formulations made using CCS as superdisintegrant.

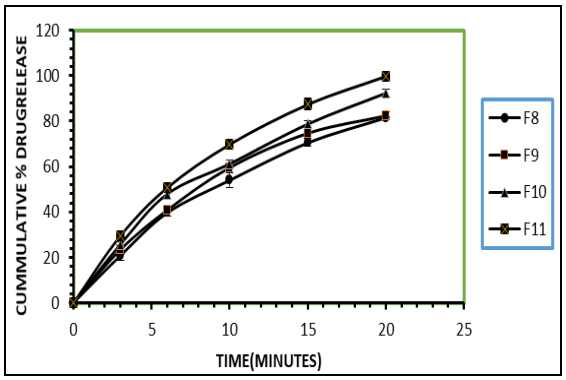

Figure 7 Dissolution profile comparision of formulations made using CP as superdisintegrant.

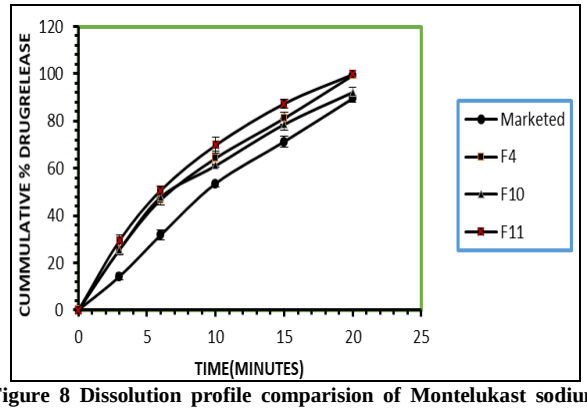

Figure 8 Dissolution profile comparision of Montelukast sodium optimised formulations (F4,F10,F11) with marketed formulatio

3. 14. *In- vitro* dissolution studies:

- Total eleven formulations were formulated using three superdisintegrants like SSG, CCS, and CP. Dissolution studies were performed for these formulations to find the percent drug release of Desloratidine and Montelukast sodium.
- In case of Desloratidine the formulations F3 (SSG 3%), F4 (SSG 4%), F10 (CP 3%), F11 (CP 4%) have shown better dissolution than marketed formulation. Of them F4 showed 96.2±0.4% dissolution in 15 minutes and F11 showed 98.4±0.4 dissolution in 15 minutes. [Table 8]
- In case of Montelukast sodium the formulations F4 (SSG 4%), F10 (CP 3%), F11 (CP4%) have shown better dissolution than marketed formulation. Of them F11 showed 90.4±0.5 dissolution in 15 minutes. [Table 9]
- The formulations F11, F10, F4 the dissolution rate was found to be more for F11 formulation and dissolution rate was in the order of F11>F4 >F10.
- By considering the above discussions F11 (CP 4%) was found to be optimized formulation.
- The data for dissolution profiles compared with marketed formulations were shown in the figures 7.4.4 and 7.4.8 to show that optimized formulations of Desloratidine and Montelukast sodium were effective and suitable than conventional tablets.

4. SUMMARY AND CONCLUSION:

The pre compression parameters like angle of repose, Cars index, Hausner's ratio, tapped and bulk density were performed and were found to be within the limits. The post compression parameters were also studied including the Weight variation, Hardness, friability, Thickness, wetting time, *In vitro* disintegration and the water absorption ratio and the values were found to be within the limits.

In-vitro dissolution studies showed that formulations F4, F10, F11 showed better dissolution of Desloratidine and Montelukast when compared with marketed formulation and among them F11 was found to be better formulation when compared to others. Based on the formulation development and results, F11 formulation was considered as the desired formulation which contains crospovidone 4 % as a super disintegrant

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6. DECLARATION OF INTEREST:

Nil.

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