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# Development and Assessment of Orally Disintegrating Tablet Containing Montelucast Sodium

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**ABSTRACT:**

Montelukast sodium is widely used in treatment of asthma and other allergic disorders. The Montelukast sodium is a water insoluble drug but need quick action .so we planned a mouth dissolving tablet of Montelukast sodium. Further we evaluated functionality of co-processed super disintegrants over super disintegrant alone. Formulation f1 to f11 were designed to change ratios and amount of Super disintegrants and co-processed super disintegrants. The prepared tablets were evaluated for hardness, friability, weight variation, disintegration time, and in vitro dissolution studies. On the basis of evaluation parameter formulation f9 having co-processed superdisintegrant Crospovidone and SSG (1:3 ratio) in 6% w/w concentration to overage weight of tablet was finally selected as optimized formulation and it was concluded that functionality of co-processed super disintegrant is better than super disintegrant alone.

## 1. Introduction:

Despite of so much of advancements in various delivery system developed for administration of various drugs through different routes such as oral, parental, transdermal and nasal etc., the oral route is considered as the preferred route of administration which includes painless, ease of administration, patient friendly and so on[74].Several new technologies had been developed for oral delivery is being available to address to improve the patient compliance[74]. Fast dissolving drug delivery system (FDDS) is gaining popularity in pharmaceutical companies as they are new drug delivery technique in order to provide the patient with medicine without Corresponding obstacles in swallowing[74]. FDDS include tablets and films. Fast dissolving tablets are designed in such a way that they disintegrate and then swallowed without the need of water as compared to other conventional dosageform[74]. Films are the small polymeric strips which when placed on the mucosal surface rapidly dissolve within a fraction of seconds in order to release the active ingredients without the consumption of water [75].

### 1.2.1 Ideal Characteristics of Fast Dissolving Drug Delivery System[76]

- Require no water for administration
- Cost effective production methods
- Leave minimal or no residue in mouth
- Dissolve within a fraction of seconds
- Have a pleasant mouth feel

### 1.2.2 Advantages of FDDS[77]

- Ease of administration
- Water consumption is not required
- Rapid dissolution and absorption of drug
- Bioavailability is increased

### 1.2.3 Fast Dissolving Tablets

Orally disintegrating dosage forms has to be placed in mouth and then get dispersed insaliva without the need of water. Orally disintegrating tablets are also called as oral disperse, mouth dissolving, rapidly disintegrating, fast melt, and quick dissolve system[77].

### 1.2.4 Patented Technologies for Fast Dissolving Tablets

New FDDS technologies are addressing many pharmaceutical companies to enhance the lifecycle management to convenient dosing for geriatrics and peadiatrics[78.] Various technologies of fast dissolving tablets are:

## 2. Methodology:

### 2.1 Materials Used:

| S. No. | Materials used | Manufactured By |
|---|---|---|
| 1 | Montelukast sodium | Akon Pharma. Pvt. Ltd. |
| 2 | Magnesium Stearate | Titan biotech Limited. |
| 3 | Talc | Loba chemie Pvt. Ltd. |
| 4 | Microcrystalline cellulose(ph 101) | Sd-fine Pvt. Ltd. |
| 5 | Crospovidone | E-Merck Pvt. Ltd. |
| 6 | Sodium starch glycolate | Yarrow Pvt. Ltd. |
| 7 | Flavour | Rankem Pvt. Ltd. |
| 8 | Mannitol | E-Merck Pvt. Ltd. |
| 9 | β -cyclodextrine | Loba chem. Pvt. Ltd. |
| 10 | Methanol | Rankem Pvt. Ltd. |
| 11 | Ethanol | Rankem Pvt. Ltd. |
| 12 | Distilled water | Milli pore water purifired. |
| 13 | SLS | Rankem Pvt. Ltd. |
| 14 | Acetonitrile | Rankem Pvt. Ltd. |
| 15 | Chloroform | Rankem Pvt. Ltd. |
| 16 | Acetone | Rankem Pvt. Ltd. |
| 17 | Methylene chloride | Rankem Pvt. Ltd. |
| 18 | Isopropyl alcohol | Lab chem.Industries.Mumbai |

### 2.2 Equipments Used:

| S. No. | Instruments | Manufactured By |
|---|---|---|
| 1 | Electronic weighing balance | SHIMADZU |
| 2 | UV-Vis Spectrophotometer | SHIMADZU |
| 3 | Disintegration test apparatus | VEEGO |
| 4 | Dissolution test apparatus | VEEGO |
| 5 | Test Sieve (no.66) | Sethi standard test sieve |
| 6 | Hot air oven | Servewell Instrument PVT Bangluru |
| 7 | Friabilator USP EF-2 | Rolex.Mumbai |

| | | |
|---|---|---|
| 8 | Tablet punching machine | Codmach machinery |
| 9 | Monsanto Hardness Tester | Rolex.Mumbai |
| 10 | Magnetic stirrer | REMI |
| 11 | Ultrasonic bath sonicater | PCI,Mumbai |

## 3. Preparation of Co-Processed Superdisintegrants:

The co-processed Superdisintegrants were prepared by solvent evaporation method. A blend of Crospovidone and sodium starch glycolate (in the ratio of 1:1, 1:2 and 1:3) was added to sufficient quantity of ethanol. The contents of beaker (250 ml capacity) were mixed thoroughly and stir continuously till most of ethanol evaporated. The wet coherent mass should be passing through 44 mesh sieve. The wet co-processed mass was dried in a hot air oven at $60^0$C for about 20 minutes. The dried mass was passed again through sieve no 44 mesh sieve and stored in airtight container till further use.

## 4. Evaluation of Granules:

### 4.1 Bulk Density (Db)

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume.

**Bulk Density= Mass/Bulk volume**

### 4.2 Tapped Density (Dt)

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by

$$\mathbf{Dt = M / Vt}$$

Where, M is the mass of powder Vt is the tapped volume of the powder.

### 4.3 Angle of Repose (θ)

The friction forces in a loose powder can be measured by the angle of repose (θ). It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane:

$$\mathbf{Tan\ (\theta) = h / r} \quad \text{or } \theta = \mathbf{tan\text{-}1\ (h / r)}$$

Where, θ is the angle of repose, h is the height in cm, r is the radius in cm. The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of

powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel. Relationship between angle of repose and powder flow property.

### 4.4 Relationship between % Compressibility and Flow Ability

| S. No. | Angle of Repose (θ) | Type of Flow |
|---|---|---|
| 1 | 5 – 12 | Excellent |
| 2 | 12 – 16 | Good |
| 3 | 18 – 21 | Fair |
| 4 | > 34 | Very Poor |

### 4.5 Hausner's Ratio:

Hausner's ratio is an indirect index of ease of powder flow. It is calculated by the following equation:

Hausner's ratio = Tapped density/Bulk density

## 5. Evaluation of Tablet

Tablets were subjected to evaluation of properties including drug content uniformity, weight variation, tablet hardness, friability, size and shape, thickness, water uptake test, rupture test and in-vitro drug release.

### 5.1 Weight Variation

The weight of the tablet being made was routinely determined to ensure that a tablet contains the proper amount of drug. The USP weight variation test is done by weighing 20 tablets individually, calculating the average weight and comparing the individual weights to the average. The tablets should met the USP specification that not more than 2 tablets are outside the percentage limits and no tablet differs by more than 2 times the percentage limit.

### 5.2 Tablet Hardness

The resistance of tablets to shipping or breakage under conditions of storage, transportation and handling before usage depends on its hardness. The hardness of each batch of tablet was checked by using Monsanto hardness tester. The hardness was measured in terms of $kg/cm^2$. 3 tablets were chosen randomly and tested for hardness. The average hardness of 3 determinations was recorded.

### 5.3 Friability

Friability generally refers to loss in weight of tablets in the containers due to removal of fines from the tablet surface. Friability generally reflects poor cohesion of tablet ingredients.20 tablets were weighed and the initial weight of these tablets was recorded and placed in Roche

friabilator and rotated at the speed of 25 rpm for 100 revolutions. Then tablets were removed from the friabilator, dusted off the fines and again weighed and the weight was recorded.

$$\% \text{ Friability} = \frac{\textit{Initial weight of tablet} - \textit{Final weight of tablets}}{\textit{Initial weight of tablet}} x100$$

**5.4 Tablet Thickness**

Thickness of the tablet is important for uniformity of tablet size. Thickness was measured using Vernier Calipers. It was determined by checking the thickness of ten tablets of each formulation. The extent to which the thickness of the each tablet deviated from ± 5% of the standard value was determined.

**5.5 Content Uniformity**

10 Tablets were weighed and crushed in a pestle mortar. Powder equivalent to 10 mg of drug was weighed accurately and transferred to a 100 ml volumetric flask and 50ml of ethanol was added to dissolve the drug, finally volume was made up to 100 ml with ethanol. The above solution was filtered and 1 ml of this solution was further diluted up to 10 ml with ethanol and absorbance was taken at 344nm using UV double beam spectrophotometer.

**5.6 Disintegration Time**

Tablet disintegration is an important step in drug absorption. The test fordisintegration was carried out in USP disintegration test apparatus. It consists of 6 glass tubes which are 3 inches long, open at the top, and held against a 10 meshscreen, at the bottom end of the basket rack assembly. To test the disintegration time of tablets, one tablet was placed in each tube and the basket rack was positioned in a 1liter beaker containing distilled water at 37℃ ± 1℃ such that the tablet remains 2.5 cm below the surface of the liquid. The time taken for the complete disintegration of the tablets was noted.

**5.7 *In-vitro* Dissolution Methods**

In vitro drug release studies were carried out using Veego USP XXIII dissolution test apparatus Type II, paddle apparatus (50 rpm, 37+ $0.5^0$C). In vitro release study for tablets was carried out by keeping the tablets for half an hour in 0.5%w/v sod. Lauryl sulphate solution (900 ml).

**5.8 Wetting Time**

Wetting time is closely related to the inner structure of the tablets and to the hydrophilicity of the excipient. It is obvious that pores size becomes smaller and wetting time increase with an increase in compression force or a decrease in porosity. The wetting time was measured by a modification of the described procedure by rawas-qalaji, the tablet was placed at the center of two layers of absorbent paper fitted in to a rounded plastic dish with a diameter of 12cm. After the paper was thoroughly wetted with distilled water, excess water was completely drained out of the dish. The time required for the water to diffuse from the wetted absorbent paper throughout the entire tablet was noted.

## 6. Result and Discussion:

### 6.1 Composition of Montelukast Sodium for Mouth DissolvingTablet

**Table No. 1 Composition of Montelukast sodium for mouth dissolving tablet**

| Formulation Code | F1 | F2 | F3 | F4 1:1 | F5 1:2 | F6 1:3 | F7 1:1 | F8 1:2 | F9 1:3 | F1 0 | F11 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Drug | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| SSG | - | 6 | - | - | - | - | - | - | - | 9 | - |
| Crospovidone | - | - | 6 | - | - | - | - | - | - | - | 9 |
| Co-processed super disintegrant | - | - | - | 6 | 6 | 6 | 9 | 9 | 9 | - | - |
| MCC | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 | 35 |
| Mannitol | 96 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90 | 90 |
| Sodium saccharine | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Flavor | 1.5 | 1.5 | 1.5 | 1.5 | .51 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 | 1.5 |
| Magnesium stearate | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 |
| Talc | 3 | 3 | 3 | 3 | 3 | 3 | 3 | -3 | 3 | 3 | 3 |
| Total weight | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 |

### 6.2 Evaluation of Compression Blend:

**Table No. 2 Pre-compression parameters of prepared granules**

| Formulation Code | Bulk density ($gm/cm^3$) | Tapped density($gm/cm^3$) | Carr's index% | Hasuner's ratio | Angle of repose |
|---|---|---|---|---|---|
| F1 | 0.512 | 0.734 | 30.24 | 1.43 | 15 |
| F2 | 0.432 | 0.597 | 27.63 | 1.38 | 17 |
| F3 | 0.642 | 0.832 | 22.83 | 1.29 | 19 |
| F4 | 0.687 | 0.698 | 1.57 | 1.01 | 22 |
| F5 | 0.784 | 0.812 | 4.18 | 1.03 | 22 |
| F6 | 0.732 | 0.764 | 4.18 | 1.04 | 16 |
| F7 | 0.497 | 0.641 | 22.46 | 1.28 | 25 |
| F8 | 0.645 | 0.774 | 16.66 | 1.2 | 23 |
| F9 | 0.656 | 0.731 | 10.25 | 1.11 | 19 |
| F10 | 0.776 | 0.813 | 4.55 | 1.04 | 21 |
| F11 | 0.576 | 0.585 | 1.53 | 1.01 | 17 |

**Discussion:** The evaluation parameters of compression blend of drug revealed good flow and compression.

### 6.3 Evaluation Tests of Tablet:

### 6.3.1 Disintegration Time of Different Formulations

**Table No. 3 Disintegration Time of Different Formulations**

| Formulation Code | Disintegration Time | | | |
|---|---|---|---|---|
| | First Time. | Second Time. | Third Time. | Mean± Std. Dev. |
| **F1** | 120 sec | 110sec | 120sec | 116.67±5.77 |
| **F2** | 37 sec | 40sec | 45sec | 40.67±4.04 |
| **F3** | 65 sec | 120sec | 170sec | 118.33±52.52 |
| **F4** | 9 sec | 10sec | 12sec | 10.33±.1.53 |
| **F5** | 65 sec | 120sec | 230sec | 138.33±84.01 |
| **F6** | 30sec | 45sec | 52sec | 42.33±11.24 |
| **F7** | 90 sec | 80sec | 79sec | 83±6.08 |
| **F8** | 7 sec | 12sec | 17sec | 12±5 |
| **F9** | 9 sec | 12sec | 15sec | 12±3 |
| **F10** | 11 sec | 15sec | 25sec | 17±7.21 |
| **F11** | 7 sec | 12sec | 17sec | 12±5 |

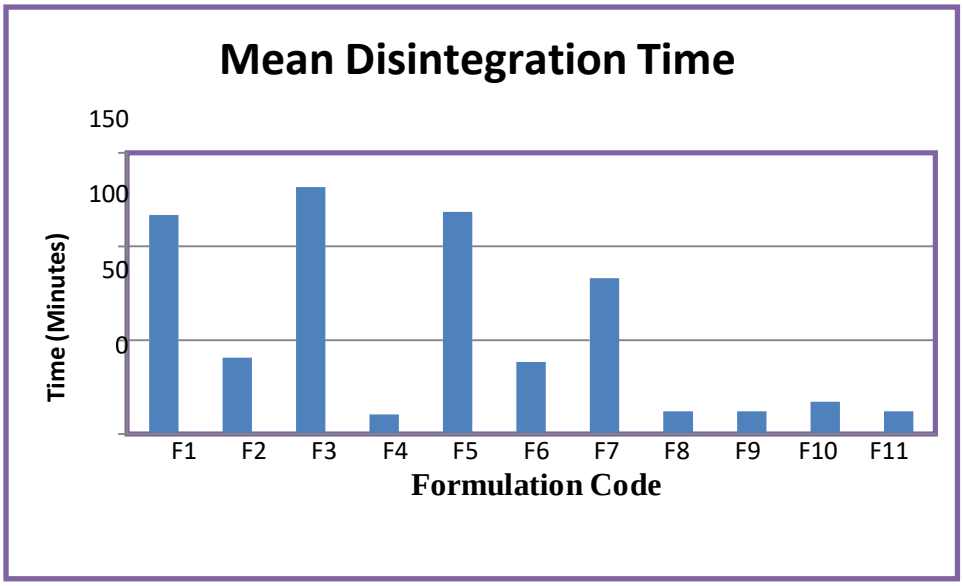



**Figure: 1**

**Discussion:** The minimum disintegrating time was shown by formulation f8 and f9 containingco-processed super disintegrants.as comparison with other formulations.

### 6.3.2 Weight Variation of Different Formulation:

**Table No. 4 Weight Variation of Different Formulation**

| S. No. | F1 | Deviation from avg. wt. | F2 | eviationfrom avg. wt. | F3 | Deviation from avg. wt. |
|---|---|---|---|---|---|---|
| **1** | 151 | 0 | 150.2 | 0.52 | 149.1 | 1.25 |
| **2** | 149.8 | 0.79 | 149.1 | 1.25 | 150.2 | 0.52 |
| **3** | 148.5 | 1.65 | 148.2 | 1.85 | 148.2 | 1.85 |
| **4** | 152 | -0.66 | 153.4 | -1.58 | 151.4 | 1.58 |
| **5** | 151.2 | -0.13 | 151.4 | -1.58 | 153.4 | -1.58 |
| **6** | 150.8 | 0.13 | 150.2 | -0.26 | 153.4 | -1.58 |
| **7** | 150.3 | 0.46 | 153.4 | 1.58 | 150.2 | 1.58 |
| **8** | 153.2 | -1.45 | 151.4 | -0.13 | 151 | 0 |
| **9** | 149.8 | 0.79 | 150.2 | 1.92 | 149 | 0.79 |
| **10** | 148.1 | 1.92 | 151.2 | -0.13 | 148.5 | 1.65 |
| **11** | 151.2 | -0.13 | 148.1 | 1.92 | 152 | -0.66 |
| **12** | 150.2 | 0.52 | 149.8 | 0.79 | 151.2 | -0.13 |
| **13** | 151.4 | -0.26 | 153.2 | -1.45 | 150.8 | 0.13 |
| **14** | 153.4 | -1.58 | 150.3 | 0.46 | 150.3 | 0.46 |
| **15** | 150.2 | -1.58 | 150.8 | 0.13 | 153.2 | -1.45 |
| **16** | 151.4 | -0.26 | 151.2 | -0.13 | 149.8 | 0.79 |
| **17** | 153.4 | -1.58 | 152 | -0.66 | 148.1 | 1.92 |
| **18** | 148.2 | 1.85 | 148.5 | 1.65 | 151.2 | -0.13 |
| **19** | 149.1 | 1.25 | 149.8 | 0.79 | 150.2 | 1.92 |
| **20** | 150.2 | 0.52 | 151 | 0 | 151.4 | -0.13 |

| S. No. | F4 | Deviation from avg. wt. | F5 | Deviation from avg.wt. | F6 | Deviation from avg.wt. |
|---|---|---|---|---|---|---|
| **1** | 150.2 | 1.25 | 151.2 | 0 | 152.6 | 0.26 |
| **2** | 153.2 | 0.52 | 151.1 | -0.72 | 151.2 | -0.65 |
| **3** | 153.4 | 1.85 | 150.8 | -0.91 | 148.9 | -216 |
| **4** | 151.4 | 1.58 | 152.3 | 0.06 | 151.3 | -0.59 |
| **5** | 148.2 | -1.58 | 154.4 | 1.44 | 152.6 | 0.26 |
| **6** | 150.2 | 0.52 | 150.2 | -1.31 | 151.9 | -0.19 |
| **7** | 149.1 | 1.58 | 150.4 | -1.18 | 149.6 | -1.70 |
| **8** | 150.3 | 0.46 | 151.8 | -0.26 | 148.9 | -2.16 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **9** | 150.8 | 0.13 | 152.6 | 0.26 | 149.2 | -0.01 |
| **10** | 151.2 | -0.13 | 153.4 | 0.78 | 154.6 | 1.57 |
| **11** | 152 | -0.66 | 154.6 | 1.57 | 153.4 | 0.78 |
| **12** | 148.5 | 1.65 | 149.2 | -0.01 | 152.6 | 0.26 |
| **13** | 149 | 0.79 | 148.9 | -2.16 | 151.8 | -0.26 |
| **14** | 151 | 0 | 149.6 | -1.70 | 150.4 | -1.18 |
| **15** | 150.2 | 1.92 | 151.9 | -0.19 | 150.2 | -1.31 |
| **16** | 148.1 | 1.92 | 152.6 | 0.26 | 154.4 | 1.44 |
| **17** | 149.8 | 0.79 | 151.3 | -0.59 | 152.3 | 0.065 |
| **18** | 151.4 | -0.13 | 148.9 | -2.16 | 150.8 | -0.91 |
| **19** | 151.2 | -0.13 | 151.2 | -0.65 | 151.1 | 0.72 |
| **20** | 153.2 | -1.45 | 152.6 | 0.26 | 152.2 | 0 |

| **S. No.** | **F7** | **Deviation from avg. wt.** | **F8** | **Deviation from avg. wt.** | **F9** | **Deviation from avg. wt.** |
|---|---|---|---|---|---|---|
| **1** | 153.2 | -1.45 | 149.1 | 1.25 | 151.4 | -0.13 |
| **2** | 151.2 | -0.13 | 150.2 | 0.52 | 150.2 | 1.92 |
| **3** | 151.4 | -0.13 | 148.2 | 1.85 | 151.2 | -0.13 |
| **4** | 149.8 | 0.79 | 151.4 | 1.58 | 148.1 | 1.92 |
| **5** | 148.1 | 1.92 | 153.4 | -1.58 | 144.8 | 1.79 |
| **6** | 150.2 | 1.92 | 153.4 | 0.52 | 153.2 | 0.79 |
| **7** | 151 | 0 | 150.2 | 1.58 | 150.3 | 1.45 |
| **8** | 149 | 0.79 | 151 | 0 | 150.8 | 0.46 |
| **9** | 148.5 | 1.65 | 149 | 0.79 | 151.2 | 0.13 |
| **10** | 152 | -0.66 | 148.5 | 1.65 | 152 | -0.13 |
| **11** | 151.2 | -0.13 | 152 | -0.66 | 148.5 | -0.66 |
| **12** | 150.8 | 0.13 | 151.2 | -0.13 | 149 | 1.65 |
| **13** | 150.3 | 0.46 | 150.8 | 0.13 | 151 | 0.79 |
| **14** | 149.1 | 1.58 | 150.3 | 0.46 | 150.2 | 1.58 |
| **15** | 150.2 | 0.52 | 153.2 | -1.45 | 153.4 | 0.52 |
| **16** | 148.2 | -1.58 | 149.8 | 0.79 | 153.4 | -1.58 |
| **17** | 151.4 | 1.58 | 148.1 | 1.92 | 151.4 | 1.58 |
| **18** | 153.4 | 1.85 | 151.2 | -0.13 | 148.2 | 1.85 |

| | | | | | | |
|---|---|---|---|---|---|---|
| **19** | 153.2 | 0.52 | 150.2 | 1.92 | 150.2 | 0.52 |
| **20** | 150.2 | 0.52 | 151.4 | -0.13 | 149.1 | 1.25 |

| S.No. | F10 | Deviation from avg. wt. | F11 | Deviation from avg. wt. |
|---|---|---|---|---|
| **1** | 151 | 0 | 149.1 | 1.25 |
| **2** | 149.8 | 0.79 | 150.2 | 0.52 |
| **3** | 148.5 | 1.65 | 148.2 | 1.85 |
| **4** | 152 | -0.66 | 151.4 | 1.58 |
| **5** | 151.2 | -0.13 | 153.4 | -1.58 |
| **6** | 150.8 | 0.13 | 153.4 | 0.52 |
| **7** | 150.3 | 0.46 | 150.2 | 1.58 |
| **8** | 153.2 | -1.45 | 151 | 0 |
| **9** | 149.8 | 0.79 | 149 | 0.79 |
| **10** | 148.1 | 1.92 | 148.5 | 1.65 |
| **11** | 151.2 | -0.13 | 152 | -0.66 |
| **12** | 150.2 | 0.52 | 151.2 | -0.13 |
| **13** | 151.4 | -0.26 | 150.8 | 0.13 |
| **14** | 153.4 | -1.58 | 150.3 | 0.46 |
| **15** | 150.2 | -1.58 | 153.2 | -1.45 |
| **16** | 151.4 | -0.26 | 149.8 | 0.79 |
| **17** | 153.4 | -1.58 | 148.1 | 1.92 |
| **18** | 18.2 | 1.85 | 151.2 | -0.13 |
| **19** | 149.1 | 1.25 | 150.2 | 1.92 |
| **20** | 150.2 | 0.52 | 151.4 | -0.13 |

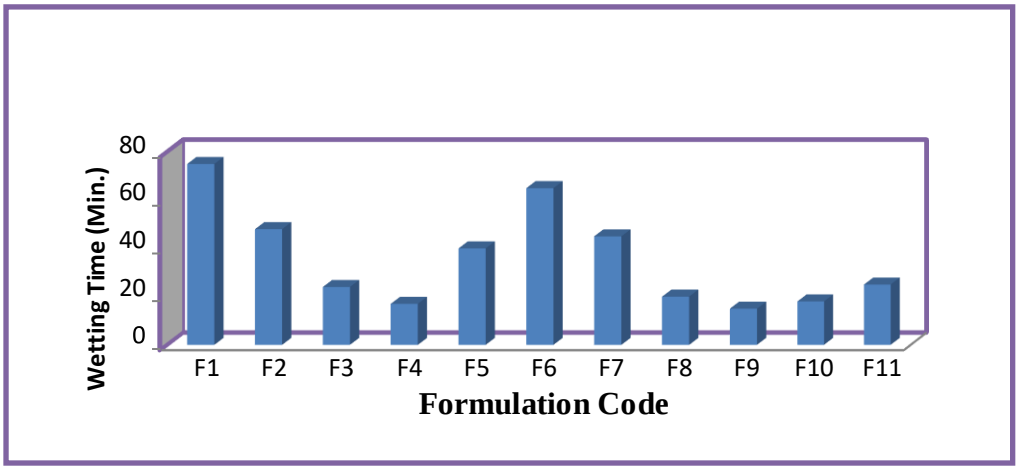
**Discussion:** All the formulated batches of tablet showed weight variation with on acceptance criteria and nod a single tablet found outside the limits.

### 6.4 Wetting Time:

**Table No. 5 Wetting Time**

| Formulation | Wetting time sec or min | Water absorption Ratio % | Increase in wt. |
|---|---|---|---|
| **F1** | 50 sec | 152 | 172 |
| **F2** | 48 sec | 150 | 180 |
| **F3** | 24 sec | 154 | 174 |

| | | | |
|---|---|---|---|
| **F4** | 17 sec | 152 | 184 |
| **F5** | 40 sec | 153 | 192 |
| **F6** | 17 sec | 155 | 164 |
| **F7** | 45 sec | 154 | 167 |
| **F8** | 20 sec | 150 | 173 |
| **F9** | 27 sec | 152 | 179 |
| **F10** | 20 sec | 153 | 187 |
| **F11** | 15 sec | 154 | 185 |




**Discussion:** Wetting time of all the batches were shown in table .the formulation f1 having no Superdisintegrants have highest wetting time while other tablets having co processed Superdisintegrants have competitively low wetting time.

### 6.5 Physical Attributes of Different Batches:

**Table No. 6 Physical Parameter of Different Batches**

| Code No. | Hardness kg/cm$^2$ | Thickness | % Friability |
|---|---|---|---|
| **F1** | 2.72±0.10 | 4.20 | 0.38±0.15 |
| **F2** | 2.9±0.09 | 4.30 | 0.76±0.11 |
| **F3** | 2.6±0.01 | 4.60 | 0.26±0.19 |
| **F4** | 2.3±0.08 | 4.25 | 0.65±0.54 |
| **F5** | 2.5±0.61 | 4.36 | 0.47±0.15 |
| **F6** | 2.4±0.04 | 4.85 | 0.45±0.54 |
| **F7** | 2.62±0.02 | 4.24 | 0.41±0.24 |
| **F8** | 2.41±0.14 | 4.69 | 0.15±0.54 |

| | | | |
|---|---|---|---|
| **F9** | 2.47±0.25 | 4.36 | 0.12±0.34 |
| **F10** | 2.14±0.35 | 4.85 | 0.21±0.24 |
| **F11** | 2.84±0.54 | 4.24 | 0.51±0.21 |

**Discussion:** Average tablet hardness was found between 2.3 to 2.84 kg/cm$^2$ with a thickness range of 4.2 mm to 4.85 mm. friability of all the batches were found less than 1%.

### 6.6 In-Vitro Release Study

**Table No. 7 *In-Vitro* Release Study for Different Batches**

| Time Interval (Minutes) | Percentage Drug Release of Different Formulations | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **F1** | **F2** | **F3** | **F4** | **F5** | **F6** | **F7** | **F8** | **F9** | **F10** | **F11** |
| **0** | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| **1** | 5.6 | 7.2 | 8.82 | 12.23 | 13.5 | 14.3 | 15.35 | 18.4 | 51.3 | 12.22 | 14.4 |
| **3** | 8.5 | 11.3 | 14.43 | 19.32 | 22.32 | 23.5 | 25.55 | 26.32 | 54.22 | 18.2 | 30.6 |
| **5** | 13.6 | 15.4 | 18.45 | 24.66 | 28.45 | 29.45 | 32.45 | 33.4 | 62.34 | 22.12 | 33.3 |
| **10** | 18.4 | 21.6 | 24.5 | 32.45 | 35.25 | 36.67 | 38.5 | 41.4 | 69.35 | 30.2 | 54.9 |
| **15** | 24.44 | 28.56 | 30.56 | 36.42 | 40.32 | 42.5 | 44.46 | 46.8 | 76.21 | 38.5 | 57.6 |
| **20** | 32.5 | 36.6 | 38.92 | 42.32 | 45.62 | 46.88 | 48.65 | 54.6 | 85.28 | 42.34 | 63.1 |
| **30** | 40.5 | 42.67 | 46.3 | 48.55 | 49.5 | 52 | 55.32 | 63.1 | 92.9 | 58.2 | 79.2 |

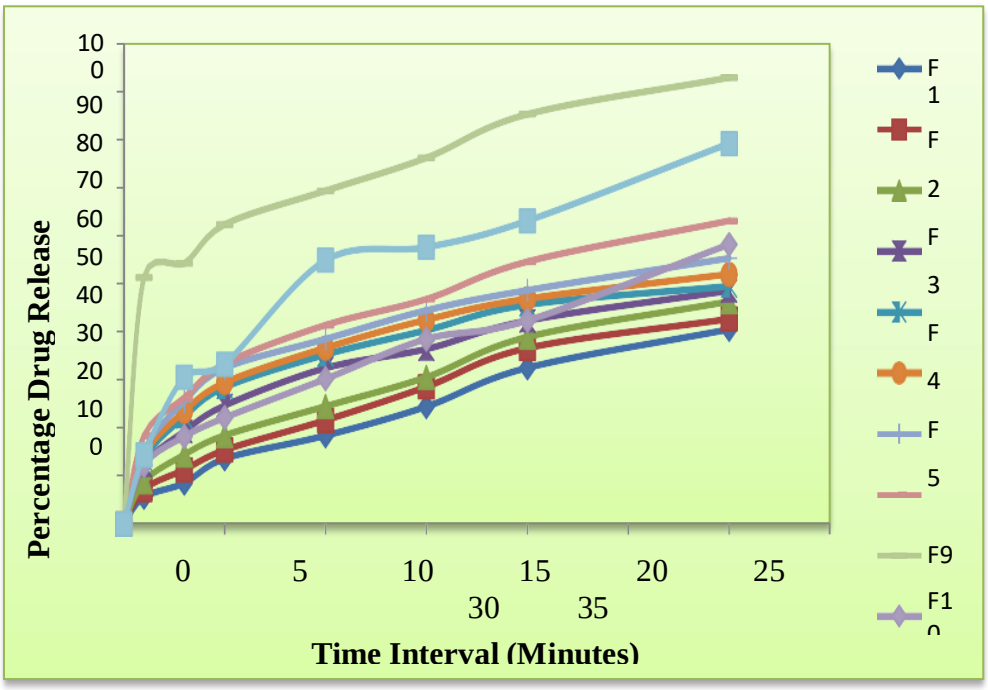



FIGURE NO. 5.19 *In-Vitro* Release Study for Different Batches

**Discussion:** The drug release study of formulation f1 to f11 was performed and data was compared by using one way analysis of variance which revealed that the differences in the mean values among the treatment groups are greater than would be expected by chance; there was statistically significant difference (p=.003) all pair wise multiple comparison procedure (holm-siday method) was adopted which reveal release from f9 formulation is significantly different. f9 formulation was finally selected as optimized formulation based on its in –vitro drug release profile which revealed 92.90% drug release in 30 minutes and disintegration.

## 7. Summary and Conclusion:

The fast disintegrating tablets of Montelukast sodium were prepared firstly by preparing co-processed Superdisintegrants using Cross-povidone and SSG in different ratios and then by using these co-processed Superdisintegrants formulations were designed and compared with other formulations having Superdisintegrants alone .The co-processed Superdisintegrants showed better disintegration time and drug release profile as compared with other formulation as shown an results among different ratios tried,1:3 ratio of Crospovidone and SSG had promising results. The formulation f9 with a concentration of co-processed Superdisintegrants 6% to average weight of tablet was finally selected as optimized formulation as it showed better drug release (92.90% in 30 minutes) and disintegration time (12±3 seconds) as compared to other batches.

So in this project we evaluated functionality of co-processed super disintegrants over a single one and concluded that the co-processed super disintegrates have better capabilities as compared to single one ,this might be due to dispersion of one Superdisintegrants into another one which might increase the surface area and change the functional characteristics.

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