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# FLASH DISSOLVING ALMOTRIPTAN MALATE ORAL DISINTEGRATING TABLETS FOR MANAGEMENT OF MIGRAINE

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## ABSTRACT

The present study was aimed to formulate flash dissolving Almotriptan malate oral disintegrating tablets for management of migraine using direct compression method. Almotriptan malate was highly selective serotonin 5-HT1B/1D receptor agonist used in the treatment of migraine. Almotriptan malate belongs to BCS class III drug i.e. High Solubility and Low Permeability. The Bioavailability is 69.1% somewhat limited after oral dosing so parenterals dosing is an alternative choice but it causes inconvenience to patients so an attempt was made to formulate oral disintegrating tablets in order to enhance the bioavailability All the formulations were subjected to pre-compression and post- compression parameters. The powder blend showed good flow properties for all the formulations. All the formulated tablets were found within the permissible limits for pre and post- compression parameters. F10 is considered has optimized formulation containing combination of 7.5% concentration of crospovidone and fenugreek mucilage powder showed maximum drug release of 98.05 % at the end of 14 mins. Among all the formulations F10 containing higher amount of crospovidone and fenugreek mucilage powder have hardness 2.80 kg/cm$^2$, friability 0.075%, drug content 98.05%, thus fulfilling all the parameters. It has shown least disintegration time 21.25±0.240 sec as compared to other formulations. All the ten formulations showed that disintegration time were less than 50 secs. This indicates rapid disintegration, water absorption ratio showed good absorptive in all the formulations. F10 formulation was compared with selected F6 and F9 and results revealed that F10 showed good *in-vitro* drug release study. Stability studies were carried out at room temperature and accelerated temperature, results revealed that at room temperature F10 formulation was stable. By this study we concluded that

combination of natural and synthetic super disintegrating agents shows synergistic effect by increasing *in vitro* dissolution rate.

**KEYWORDS:** Almotriptan malate, Direct compression method, Super disintegrants, ODT, *in-vitro* drug release study.

## INTRODUCTION

The most preferred route of administration was oral route when compared to all other routes of administration, due to various advantages like easy for administration, low cost, accurate dosing, and self medication and most important is patient compatibility. Even today a tablet was widely used dosage form because they are convenient for self-administration, easy for manufacturing and good compatibility for patients. Oral disintegrating tablets are the best form of tablets because they show their effect in a short period of time for good bioavailability.[1]

For the development of fast dissolving tablets the basic approach used for development of tablets was the use of super disintegrants like (crospovidone) cross linked polyvinyl-pyrrolidone, sodium starch glycolate, Fenugreek mucilage powder etc. In oral cavity superdisintegrants shows rapid onset of action by enhancing the dissolution by releasing maximum amount of medication within a short period of time, hence they were also called as rapidly dissolving tablets.[2] Sometimes they were also named as very rapidly dissolving tablets.

Fast dissolving tablets have gained much more popularity when compared to other drug delivery system because they are easy to administer, has quick onset of action and are economical. From the marketing point of view they show good opportunities for a manufacturer to extend their marketing strategy because for patient population it is more convenient dosage form or dosing regimen.[3] There was so many methods used for manufacturing of fast dissolving tablets but more convenient and less economical is direct compression method when compare to wet granulation process because wet granulation process was not suitable for thermo sensitive and moisture sensitive active ingredients.

Almotriptan Malate was highly selective serotonin 5-HT1B/1D receptor agonist and it binds with high affinity to human 5-$HT_{1B}$ and 5-$HT_{1D}$ receptors and it results in the constriction of cranial blood vessels. At present triptans are the commonly used drugs for patients who fail to

response for NSAID's. The biological half life is 3-4 hours and its water solubility was mentioned has [0.121mg/ml], and pka of 8.77 and the pH of a 1% solution in water is 4.1**.** The bioavailability is 69.1%, somewhat reduced after oral dosing so parenteral dosing was an alternative choice but it is inconvenience to patients, so an attempt was made for oral disintegrating tablets in order to enhance the good bioavailability.[4]

Fenugreek mucilage powder is a natural super disintegrating agent and it was mainly extracted from fenugreek seeds by using soxhelet apparatus extraction process. The fenugreek mucilage extract were added into the oral disintegrating tablets of Almotriptan malate in order to check their natural superdisintegrant property, which may reduce the disintegration time of the tablets allowing faster absorption of the drug and it was also compared with well- known synthetic superdisintegrant like sodium starch glycolate and crospovidone.[5] Hence the present study was aimed at formulation and in vitro evaluation of flash dissolution tablet of Almotriptan malate using natural and synthetic super disintegrants.

## MATERIALS AND METHOD

Almotriptan malate was obtained as gift sample from Apotex Research Pvt. Ltd, Bangalore. Fenugreek mucilage powder was bought from Chemtotal Laboratory Pvt. Ltd. Rajasthan. Crospovidone was procured from S. D. Fine chemicals, Mumbai, India. Sodium starch glycolate was procured from Himedia Labs Pvt. Ltd, Mumbai. All other chemicals were of analytical grade obtained from college laboratory.

### Determination of λmax[6]

Exactly weighed 50mg of Almotriptan malate was places in a 50ml of volumetric flask and make it upto the mark by adding pH6.8 phosphate buffer to give 1000µg/ml. From the above stock solution 5ml was pipette out into 50 ml of volumetric flask and made upto 50ml mark by adding buffer solution to get 100µg/ml. From this 0.1ml was pipette and included into 10ml of volumetric flask to make 0.1 µg/ml. this sample was analyzed in the range 200-400nm by utilizing UV spectrophotometer Almotriptan malate shows absorbance at λmax227 nm.

### Preparation of Standard Calibration Curve

Exactly weighed 50mg of Almotriptan malate is placed in 50ml volumetric flask and make it upto the mark by adding pH6.8 phosphate buffer to get concentration of 1000µg/ml. From this solution 5ml was pipetted and added into 50ml volumetric flask to make 100 µg/ml.

From the above stock solution take 0.2ml, 0.4ml, 0.6ml, 0.8ml, 1.0ml and add to the 10ml volumetric flask by making upto mark with pH6.8 phosphate buffer to get 2-10µ g/ml. Samples was checked in UV spectrophotometer to determine the absorbance at λmax of 227nm.[7]

**Solubility Analysis**

Solubility of pure drug was checked to determine the suitable solvent for dissolution media. In order to determine the excess amount of drug dissolved in pH6.8 phosphate buffer saturation solubility was carried out. Excess amount of drug is placed in a beaker containing 10 ml of pH6.8 phosphate buffer and placed on magnetic stirrer for 24hrs. After completing 24hrs sample was kept for sonication and finally sample was filtered and analyzed in UV spectrophotometer at λmax227 nm.[8]

**FT-IR Spectroscopy[9]**

All the FT-IR spectra were recorded using an IR spectrophotometer (SHIMADZU) over a scanning range of 4000-500cm$^{-1}$. Compatibility of drug with sodium starch glycolate, fenugreek mucilage powder and crospovidone were determined by mixing sample with KBR powder and compressing into a disk by hydraulic pressure. Test sample readings are compared with the standard in order to confirm stable or not.

**Differential Scanning Calorimetry[10]**

The DSC test of pure Almotriptan malate and physical mixture (drug and super disintegrating agents) were developed in the DSC-60 thermogram. The samples were prepared in the ratio of 1:1 (drug: super disintegrating agents) and were sealed in an aluminum pan before analysis. Under a nitrogen atmosphere, an empty pan was kept as a reference. A heating rate of 10°C/min was employed. The scanning temperature range was 25-250°C.

**Pre-compression characterization parameters[11,12]**

Pre-compression parameters for powder blend like bulk density, tapped density, compressibility index, Hausner's ratio, and angle of repose were determined.

**Preparation of Oral disintegrating tablets of Almotriptan malate**

Ten ODT formulation of Almotriptan malate were prepared by using direct compression method as shown in Table 1. Drug and directly compressible excipients were mixed by adding small portion of each at a time and powder was mixed to get uniform mixture. Drug

equivalent to 12.5 mg of Almotriptan malate was weighed and mixed with super-disintegrants (sodium starch glycolate, crospovidone and Fenugreek mucilage powder). Other ingredients such as mannitol and microcrystalline cellulose (AvicelPH-102) used as diluents, Aspartame as a sweetening agent. All excipients were blended and passed through sieve 60# and then powder blends of batches F1-F10 were tested for powder characteristics. Using remik mini press I unit, the powder blend was then compressed into tablets of 120 mg using a 6 mm flat punch.

**Table 1: Composition of Almotriptan malate Oral disintegrating tablet batches (F1 to F10).**

| Ingredients(mg) | Formulation Code | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 | F10 |
| Almotriptan malate | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 | 12.5 |
| Sodium starch glycolate | 3 | 6 | 9 | - | - | - | - | - | - | |
| Fenugreek mucilage powder | - | - | - | 3 | 6 | 9 | - | - | - | 3.75 |
| Crospovidone | - | - | - | - | - | - | 3 | 6 | 9 | 3.75 |
| Aspartame | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Microcrystalline cellulose | 66.5 | 63.5 | 60.5 | 66.5 | 63.5 | 60.5 | 66.5 | 63.5 | 60.5 | 60.5 |
| Mannitol | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 | 30 |
| Magnesium sterate | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Talc | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

**Post-compression characterization parameters[13,14]**

All the prepared oral disintegrating tablets of Almotriptan malate were subjected to Pharmacopoeial tests. Tablets thickness and hardness were determined using vernier caliper and hardness by Monsanto hardness tester respectively. Friability, disintegration time, wetting time, and *in vitro* dissolution were also performed as per Indian Pharmacopoeial specifications.

**Drug Content**

Five tablets were selected randomly, weighted, and crushed. The drug was extracted in 6.8 pH phosphate buffer. The absorbance of the solution was measured against the blank at $\lambda_{max}$ 227 nm using UV Spectrophotometer.

**Wetting Time[15]**

The tablets were placed in the middle of two layers of absorbent paper mounted into a Petri dish. After the paper was thoroughly wetted with distilled water, Excess water was drained.

The time it took for the water to pass through the entire tablet from the wetted absorbent paper was then monitored using a stopwatch.

### *In vitro* disintegration Time

*In vitro* disintegration study of Almotriptan malate tablets were carried out by using a disintegration tester. The tablets were placed in the disintegration tube which was placed in a pH 6.8 phosphate buffer maintained at 37ºC ±2ºC. The time needed for complete disintegration that is without leaving any residue on the screen is reported as disintegration time.

### *In vitro* dissolution study

In USP dissolution test apparatus the *invitro* release of drug from the formulated tablets were conducted using 900 ml of pH 6.8 phosphate buffer as dissolution medium maintained at 37.0± 0.5°C and stirring rate of 50 rpm. 5 ml samples were withdrawn from the dissolution medium followed by filtrations and analyzed at different time intervals of 2 min. All samples were analyzed at $\lambda_{max}$ 227 nm using UV Spectrophotometer, by maintaining the sink condition.

### Stability studies of optimized formulation F10

The optimized formulation was subjected to stability testing. It was suitably packed in a glass container and was kept in different condition of temperature and humidity for 30 days. The analysis of sample for its physicochemical property was carried out on both at room and accelerated set-up ($40\pm2^0$C / 75±5% RH) and ($25\pm2^0$C / 60±5% RH) respectively for 30 days. After, 15, 30, days the test of hardness, content uniformity, friability and drug release were carried out for optimized formulation.[16]

## RESULTS AND DISCUSSION

### Standard Calibration curve

The linearity range was determined and was identified to be at the range of 2-10 µg/ml at 227 nm. The slope equation was y = 0.162x + 0.015. The correlation coefficient was found to be 0.999 as shown in Fig 1.

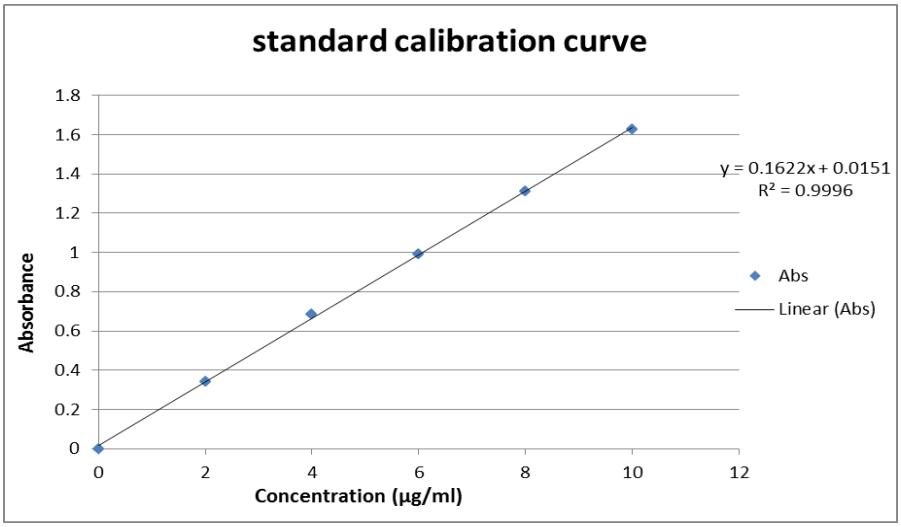


**Figure 1: Standard calibration curve of Almotriptan malate.**

### Solubility study

Solubility study of Almotriptan malate was carried out in pH6.8 and pH6.5 phosphate buffer (simulated salivary fluid). Almotriptan malate showed high soluble in pH6.8 phosphate buffer than in pH6.5 phosphate buffer was shown (0.212±0.0098 mg/ml and 0.1627±0.0047mg/ml).

### FTIR spectroscopy

The FTIR spectra of pure drug and sodium starch glycolate, fenugreek mucilage powder and crospovidone respectively, showed similar peaks at their respective wavelengths with minor differences as shown in Fig 2(a-d) respectively. All the important functional group frequencies for Almotriptan malate were present in the spectral peaks of the drug and polymer mixture, indicating compatibility of drug with the polymers was stable.

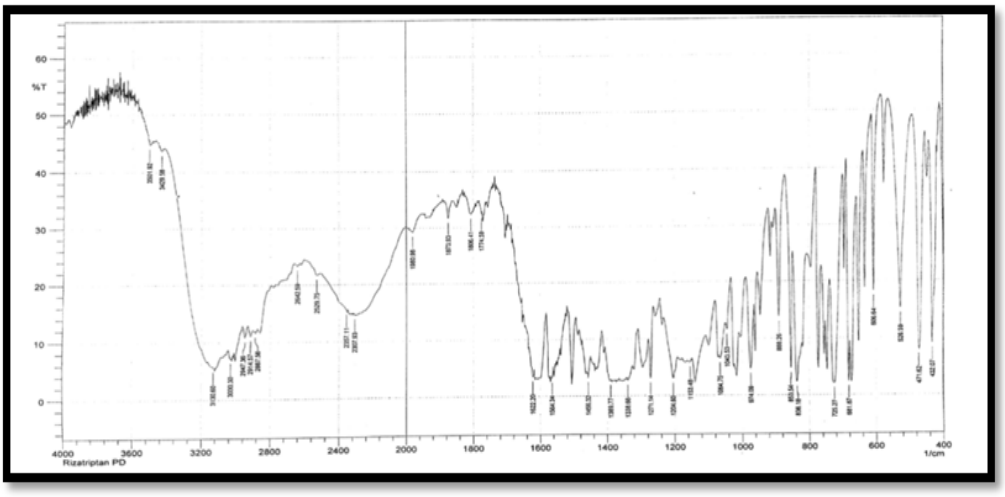


**Fig 2(a): IR spectrum of Almotriptan malate pure drug.**

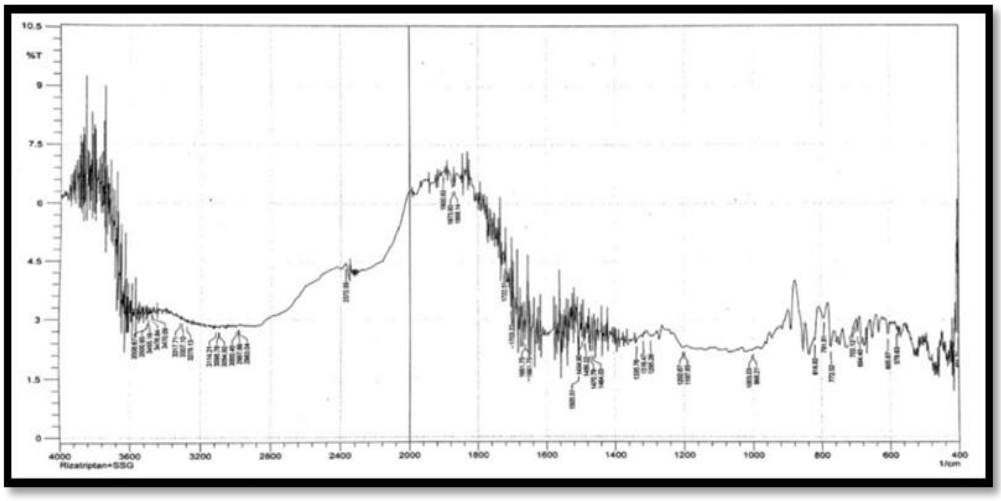


**Fig 2(b): IR spectrum of drug and sodium starch glycolate.**

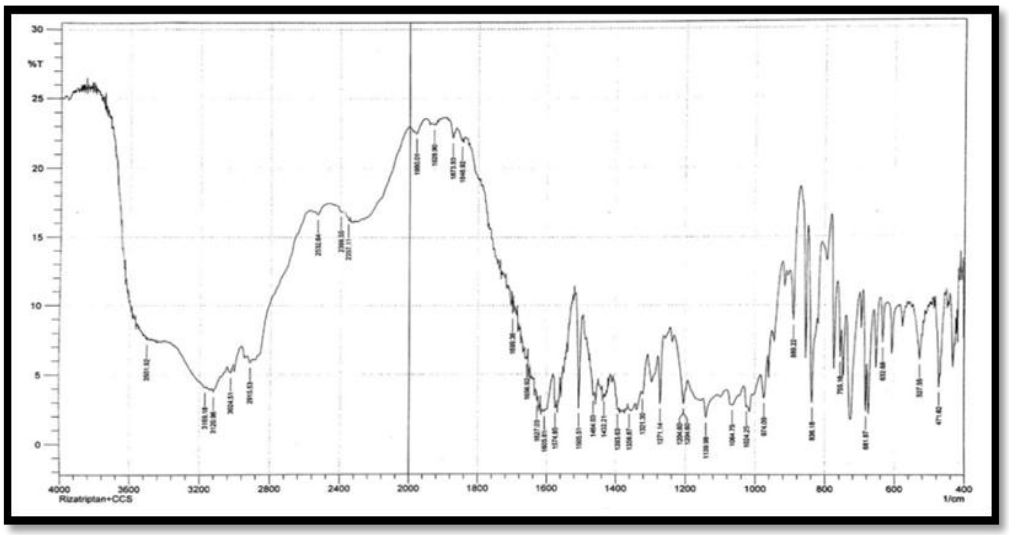


**Fig. 2(c): IR spectrum of drug and fenugreek mucilage powder.**

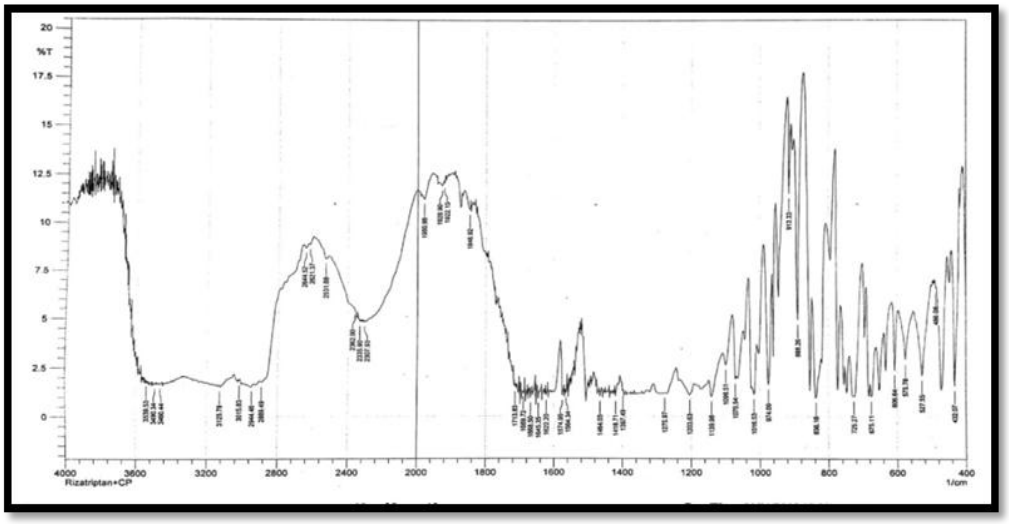


**Fig. 2(d): IR spectrum of drug and crospovidone.**

**DSC study**

The pure drug Almotriptan malate exhibits a sharp endothermic peak at 174.6°C and physical mixture of selected formulation drug, crospovidone and Fenugreek mucilage powder was carried out and Fig 3(a) showed pure drug of DSC study, and Fig 3(b) shows the physical mixture of drug, crospovidone and fenugreek mucilage powder. Melting point of Almotriptan malate was found in the thermograms of physical blends of Fenugreek adhesive powder and crospovidone separately, which shows no interaction between drug and excipients.

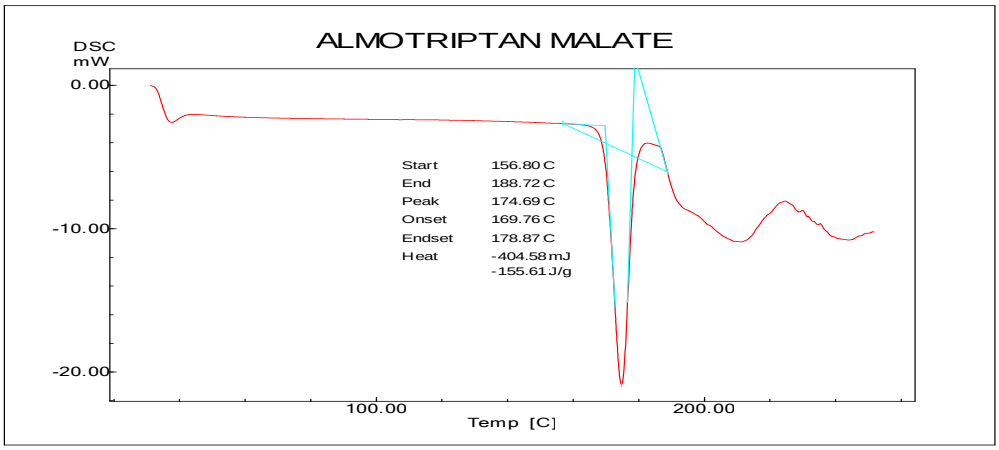


**Fig. 3(a): DSC thermogram of Almotriptan malate pure drug.**

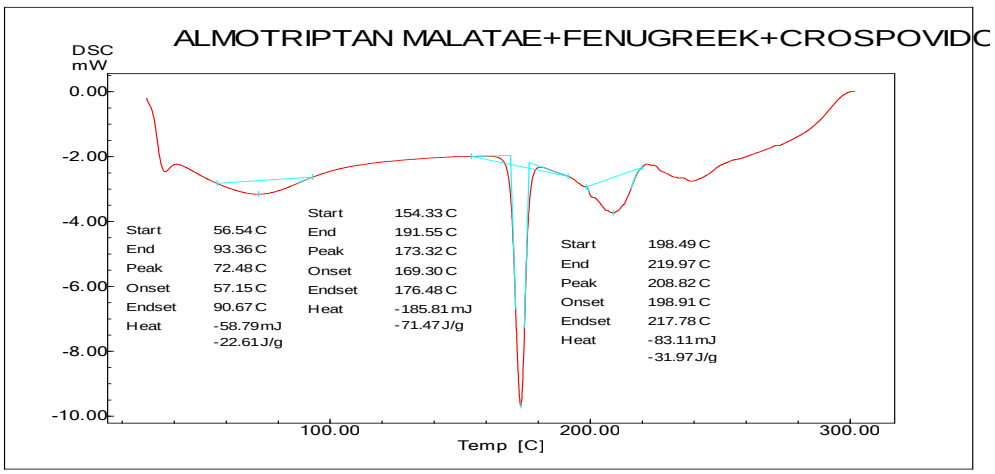


**Fig. 3(b): DSC of Almotriptan malate, and its Excipients.**

**Evaluation of pre-compressed blend**

The Micromeritics properties of Almotriptan malate oral disintegrating tablets from F1-F10 formulations for bulk density and tapped density, for all the formulations ranges from 0.38 ± 0.04 g/cm$^3$ to 0.44 ± 0.08 g/cm$^3$ and 0.42 ± 0.02 g/cm$^3$ to 0.46 ±0.04 g/cm$^3$ individually. The percent compressibility for the whole preparation are exist in the range of 3.213 ± 1.16 to

4.531 ± 1.741. The Hausner's proportion for all the preparations exists in the range of 1.021 ± 0.014 to 1.047± 0.057. Angle of repose readings were seen as in the range of 26°.93′± 0.65t30°.05′ ± 0.37 which shows great flow property of the powder. All the readings of pre compression blend were shown in Table 2.

**Table 2: Micrometric properties of mixed blend and excipients.**

| Formualtion | Thickness (mm) | Uniformity of weight (mg) | Hardness (kg/cm$^2$) | Friability (%) | Drug content (%) |
|---|---|---|---|---|---|
| F1 | 2.80 ± 0.05 | 118.2 ± 1.84 | 2.84 ± 0.05 | 0.068± 0.02 | 93.17 ± 0.11 |
| F2 | 2.60 ± 0.08 | 118.6 ± 1.90 | 2.67 ± 0.25 | 0.051 ± 0.02 | 95.83 ± 0.20 |
| F3 | 2.71 ± 0.02 | 118.5 ± 1.04 | 2.87 ± 0.05 | 0.061 ± 0.03 | 96.13 ± 0.10 |
| F4 | 2.70 ± 0.05 | 117.4 ± 0.40 | 2.63 ± 0.25 | 0.081± 0.04 | 94.89 ± 0.05 |
| F5 | 2.83 ± 0.02 | 118.5 ± 1.75 | 2.53 ± 0.15 | 0.011 ± 0.04 | 96.10 ± 0.11 |
| F6 | 2.55 ± 0.05 | 118.8 ± 1.78 | 2.40 ± 0.10 | 0.061 ± 0.03 | 97.81 ± 0.10 |
| F7 | 2.70 ± 0.05 | 119.2 ± 1.55 | 2.73 ± 0.23 | 0.082± 0.02 | 95.12 ± 0.05 |
| F8 | 2.68 ± 0.02 | 118.4 ± 1.20 | 2.50 ± 0.20 | 0.062 ± 0.02 | 96.63 ± 0.11 |
| F9 | 2.59 ± 0.05 | 118.8 ± 1.77 | 2.60 ± 0.22 | 0.081 ± 0.04 | 97.88 ± 0.20 |
| F10 | 2.52 ± 0.01 | 119.3 ± 1.77 | 2.80 ± 0.21 | 0.075 ± 0.04 | 98.05 ± 0.10 |

*Resulted data is an average of triplicates (mean ± SD).

**Evaluation of prepared Oral disintegrating tablets**

The tablet's thickness and diameter range was found to be2. 52 ±0.010 mm to 2.83±0.020 mm and 6.02±0.0577 mm respectively. Tablet hardness ranged from 2.40 ± 0.01 to 2.87 ± 0.02 kg/cm$^2$ for all formulations which are indicative of good mechanical strength. Percent friability ranged from 0.011 ± 0.04 to 0.082 ± 0.02% which was within the IP limit. Weight variation was found to be in the range of 117 ± 4.77 to 119.3 ±1.77 which was within the acceptable limit as per IP. Percentage drug content of all formulations was found to be in range of 93.17 ± 0.11% to 98.63 ± 0.10% of Almotriptan malate which was within acceptable IP limit. All the results were tabulated in Table 3.

The wetting time and *in vitro* disintegration time for all the formulations were within the range of 22.21 ± 0.18 to 36.20 ± 0.16 seconds and 21.25 ± 0.41 to 44.39 ± 0.04 seconds respectively Table 4. The results concluded that the wetting time and disintegration period decreased with an increase in super disintegration concentration due to its faster swelling and capillary action in the disruption of the tablet system.

*In vitro* dissolution profile results revealed that formulation containing combination of crospovidone and fenugreek mucilage powder showed higher drug release as compared to the formulation containing individual crospovidone and fenugreek mucilage powder. Among all

formulation, F10 containing 7.5% crospovidone and fenugreek mucilage powder showed the highest drug release of 98.63 ± 0.10% within 14 minutes, hence considered as optimal formulation and drug release pattern from F1 to F10 were shown in Fig 4(a-c). Here it was also concluded that combination of natural and synthetic superdidintegrating agents shows synergestic effect and *in vitro* drug dissolution increased with an increase in the concentration of super-disintegrating agents.

**Table 3: Post compression parameters of Almotriptan malate Oral disintegrating tablets F1-F10.**

| Formulation | Post compression parameters | | | | |
|---|---|---|---|---|---|
| | Thickness (mm) | Weight variation (mg) | Friability (%) | Hardness (kg/cm$^2$) | Drug content (%) |
| F1 | 2.80±0.05 | 118.2±1.84 | 0.068±0.02 | 2.84±0.05 | 98.17±0.11 |
| F2 | 2.60±0.08 | 118.6±1.90 | 0.051±0.02 | 2.67±0.25 | 95.83±0.20 |
| F3 | 2.71±0.02 | 118.5±1.04 | 0.061±0.03 | 2.87±0.05 | 96.13±0.10 |
| F4 | 2.70±0.05 | 117.4±0.40 | 0.081±0.04 | 2.63±0.25 | 94.89±0.05 |
| F5 | 2.83±0.02 | 118.5±1.75 | 0.011±0.04 | 2.53±0.15 | 96.10±0.11 |
| F6 | 2.55±0.05 | 118.8±1.78 | 0.061±0.03 | 2.40±0.10 | 97.81±0.10 |
| F7 | 2.70±0.05 | 119.2±1.55 | 0.082±0.02 | 2.73±0.23 | 95.12±0.05 |
| F8 | 2.52±0.02 | 118.4±1.20 | 0.062±0.02 | 2.50±0.20 | 96.63±0.11 |
| F9 | 2.59±0.05 | 118.8±1.77 | 0.081±0.04 | 2.60±0.22 | 97.88±0.20 |
| F10 | 2.52±0.01 | 119.3±1.77 | 0.075±0.04 | 2.80±0.21 | 98.05±0.10 |

Resulted data is an average of triplicates (mean ± SD).

**Table 4: Post compression parameters of Almotriptan malate Oral disintegrating tablets F1-F10.**

| Formulations | Wetting time (sec) | Water absorption ratio | *In-vitro* disintegration time (sec) |
|---|---|---|---|
| F1 | 36.20 ± 0.16 | 68.24 ± 0.05 | 44.39 ± 0.04 |
| F2 | 34.76 ± 0.02 | 65.04 ± 0.02 | 39.16 ± 0.23 |
| F3 | 33.07 ± 0.06 | 61.43 ± 0.11 | 33.68 ± 0.50 |
| F4 | 30.76 ± 0.20 | 64.57 ± 0.06 | 40.12 ± 0.40 |
| F5 | 29.01 ± 0.04 | 59.13 ± 0.01 | 36.44 ± 0.81 |
| F6 | 27.52 ± 0.50 | 56.13 ± 0.01 | 28.36 ± 0.52 |
| F7 | 28.76 ± 0.02 | 58.56 ± 0.02 | 29.46 ± 0.69 |
| F8 | 27.01 ± 0.01 | 55.78 ± 0.01 | 26.65 ± 0.45 |
| F9 | 26.28 ± 0.02 | 53.34 ± 0.04 | 23.65 ± 0.45 |
| F10 | 22.21 ± 0.18 | 51.43 ± 0.11 | 21.25 ± 0.41 |

Resulted data is an average of triplicates (mean ± SD)

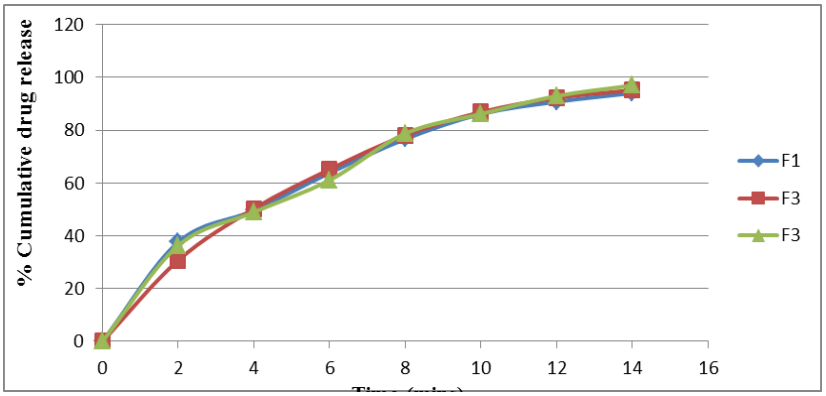


**Fig. 4(a): *In vitro* drug release profile of F1-F3 formulation.**

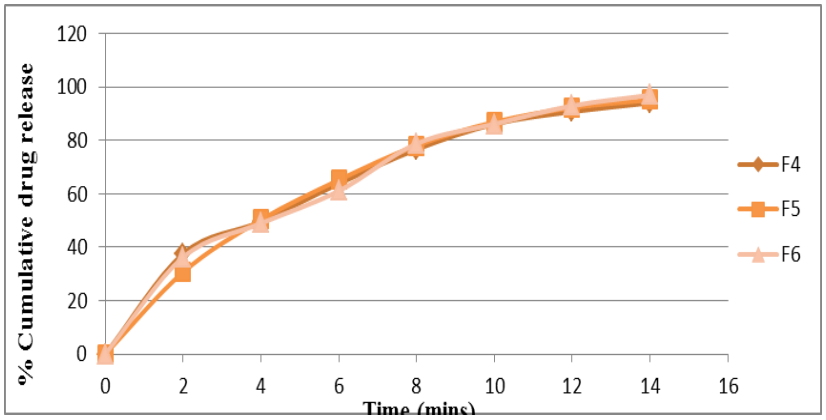


**Fig. 4(b): *In-vitro* drug release profile of F4-F6 formulation.**

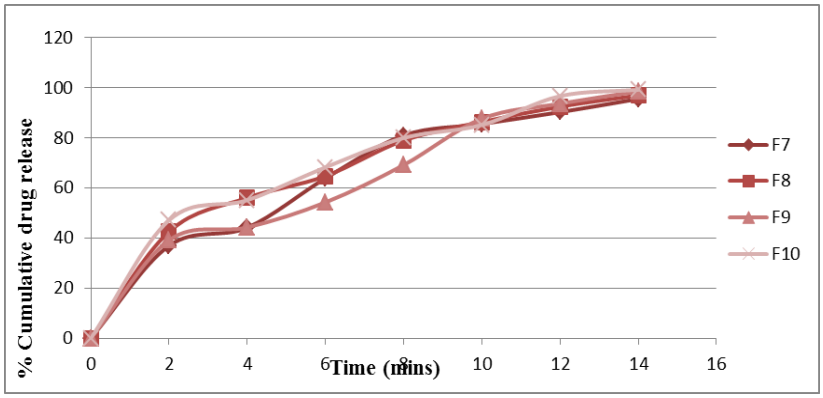


**Fig. 4(c): *In-vitro* drug release profile of F7-F10 formulation.**

**Comparison of Dissolution profile of F6, F9, and F10 Formulation**

F6 formulation containing 7.5% fenugreek mucilage powder showed a drug release of 97.0±0.00 at the end of 14 minutes. And formulation F9 containing the 7.5% concentration of crospovidone showed drug release of 98.5±0.005 at the end of 14minutes. In combination of 7.5% concentration of fenugreek mucilage powder and crospovidone showed highest drug release of 99.1±0.002 compared to F6 and F9 formulation. Among these three formulations

F10 formulation showed synergistic effect by increasing the dissolution rate at the end of the 14 minutes. F10 formulation proved that combination of natural and synthetic disintegrating agents may enhance the dissolution and disintegration time compared to individual formulation as shown in Table 5 and *in-vitro* drug release comparision pattern of F6,F9 and F10 were shown in Fig 5.

**Table 5: Comparison of dissolution profile of F6, F9, and F10 Formulation.**

| **Media** | ***In vitro* dissolution (%)** | | |
|---|---|---|---|
| | **F6** | **F9** | **F10** |
| Phosphate buffer pH6.8 | 97.0±0.001 | 98.5±0.005 | 99.1±0.002 |

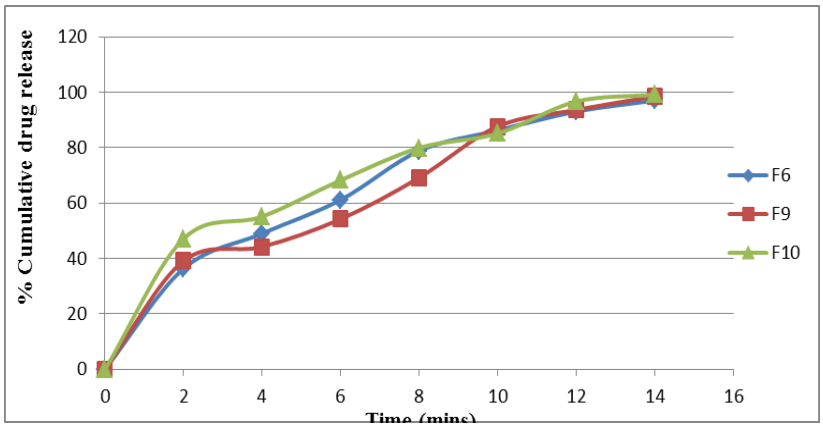


**Fig 5: Comparison of F6, F9 and F10 formulation.**

**Stability study**

Stability testes of F10 formulation showed no significant change. The hardness of tablet was 2.76kg/cm$^3$. The % drug release at (25±60°C/RH 60±5%/) on 15th day was found to be 99.10% and on 30th day percent drug release at (25±60°C/RH 60±5%) is 98.93%. There was minor variation in tablet hardness and tablet drug content on 15th day at (40±2°C and 75±5%). The hardness of the tablet was 2.90 kg/cm$^3$. The % drug release at (40±2°C and 75±5%) on 15th day was 96.82% and on 30th day the % drug release at (40±2°C and 75±5%) is 98.90%. At the 30th day the hardness of tablet was 2.89 kg/cm$^3$ and drug content was 97.22%. Drug content of tablets of accelerated study reduced may be due to drug degradation. The results were shown in Table 6.

**Table 6: Stability studies of selected formulation F10.**

| Parameters | Optimized formulation F10 | | | | |
|---|---|---|---|---|---|
| | | Room temperature 25°C ± 2°C / RH 60 ± 5% | | Accelerated temperature 40°C ± 2°C / RH 75 ± 5% | |
| | Initial | 15 days | 30 days | 15 days | 30 days |
| Hardness (kg/cm$^2$) | 2.80 | 2.80 | 2.76 | 2.90 | 2.98 |
| % Drug content | 98.05% | 97.54% | 96.86% | 96.82% | 97.22% |
| % Drug release at 14mins | 99.14% | 99.10% | 98.93% | 99.05% | 98.90% |

## CONCLUSION

In this study, an attempt was made to formulate Almotriptan malate oral disintegrating tablets for management of migraine treatment. Based on experimental investigation it can be concluded that combination of natural and synthetic super disintegrating agents enhances the dissolution by *in vitro* drug release and disintegration time study. And study was proved that using combination of natural and synthetic super disintegrating agents shows synergistic effect rather than antagonistic effect.

Compare to all the prepared formulations from F1 to F10, formulation F10 oral disintegrating tablets prepared via combination of natural and synthetic super disintegrating agents showed the highest *in vitro* drug dissolution of 99.11% ±0.4% at the end of 14 minutes and a rapid disintegration time of 21.25 ± 0.41 seconds. Formulation F10 exhibits a good wetting time of 22.21 ± 0.18 seconds. Hence formulation F10 containing 7.5% concentration, combination of crospovidone and fenugreek mucilage powder was selected as the optimized formulation. Thus, it can be concluded that the formulation of a oral disintegrating tablet of Almotriptan malate seems to be a promising formulation for safe and effective delivery via oral route for the treatment of migraine providing instant action.

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## Conflict of interest

There are no conflicts of interest.

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