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FORMULATION AND *IN VITRO* EVALUATION OF SUMATRIPTAN SUCCINATE FAST DISSOLVING TABLETS

M. Suvarchala*[1], A. M. S. Sudhakar babu[1], P. Venkateswararao[2], G. Lakshmi Devi[1]

[1*]Department of Pharmaceutics, A. M. Reddy Memorial College of Pharmacy, Narasaraopet Guntur, Andhra Pradesh, India.

[2]Department of Pharmaceutical Chemistry, A. M. Reddy Memorial College of Pharmacy, Narasaraopet, Guntur, Andhra Pradesh, India.

ABSTRACT

The objective of the present study was to prepare the Fast Disintegration Tablets of Sumatriptan succinate, an anti-migrane drug. As precision of dosing and patient compliance become an important prerequisite for a migrane treatment, there is a need to develop a formulation for this drug which overcomes problems such as difficulty in swallowing, inconvenience in administration while travelling and patient's acceptability. Hence, the present work was undertaken with a view to develop a Fast Disintegration Tablet of Sumatriptan succinate which offers a new range of product having desired characteristics and intended benefits. Various techniques like direct compression and sublimation technique were used to formulate Fast Disintegration Tablets of Sumatriptan succinate. In direct compression method and sublimation method the effect of various super disintegrants was studied, among these 4% Cross Povidone showed better drug release. The tablets were evaluated for hardness, friability, weight variation, wetting time, disintegration time and uniformity of content. Optimized formulations were evaluated for *in vitro* dissolution test. Between the two techniques sublimation technique was found to be most successful and tablets prepared by this technique (F12) had disintegration time of 30 sec and %CR 52.74±1.42 after 5 min.

KEYWORDS

Sumatriptan succinate, Superdisintegrants, Direct compression technique, Sublimation technique and Fast disintegration tablets.

Author for Correspondence:
M. Suvarchala,
Department of Pharmaceutics,
A. M. Reddy Memorial College of Pharmacy, Narasaraopet, Guntur, Andhra Pradesh, India.
Email: suvarchala.maturu@gmail.com

INTRODUCTION

Drug delivery systems (DDS) are a strategic tool for expanding markets/indications, extending product life cycles and generating opportunities. Oral administration is the most popular route for systemic effects due to its ease of ingestion, pain, avoidance, versatility and most importantly, patient

compliance. Also solid oral delivery systems do not require sterile conditions and are therefore, less expensive to manufacture[1]. Patient compliance, high-precision dosing, and manufacturing efficiency make tablets the solid dosage form of choice. Excipients and equipments choices will be significantly affected should solid dosage form technologies change in response to the unprecedented shifts in the drug discovery such as genomics. Should next generation drugs are predominantly protein or peptide based, tablets may no longer be the dominant format give the difficulty of dosing such moiety. Injections generally are not favored for use by patients unless facilitated by sophisticated auto injectors. Inhalation is one good alternative system to deliver these drugs, but the increased research into biopharmaceuticals so far has generate predominantly chemical entities with low molecular weights. The development of enhanced oral protein delivery technology by Fast dissolving Tablets which may release these drugs in the mouth are very promising for the delivery of high molecular weight protein and peptide[2,3,4]. The oral route remains the perfect route for the administration of therapeutic agents because the low cost of therapy, manufacturing and ease of administration lead to high levels of patient compliance. Many patients have difficulty swallowing tablets and hard gelatin capsules and consequently do not take medications as prescribed. It is estimated that 50% of the population is affected by this problem, which results in a high incidence of noncompliance and ineffective therapy[5, 6]. The demand for solid dosage forms that can be dissolved and suspended in water, chewed, or rapidly dissolved in the mouth is particularly strong in the pediatric and geriatric markets, with further application to other patients who prefer the convenience of a readily administered dosage form. Because of the increase in the average human life span and the decline with age in swallowing ability, oral tablet administration to patients is a significant problem and has become the object of public attention. The problem can be resolved by the creation of rapidly dispersing or dissolving oral forms, which do not require water to aid swallowing. The Center for Drug Evaluation and Research (CDER), US FDA defined Oral Disintegrating Tablets (ODT) as "A solid dosage form containing medicinal substances, which disintegrates rapidly, usually within a matter of seconds, when placed upon the tongue." A fast dissolving tablet can be defined as a solid dosage form that can disintegrates into smaller granules which slowly dissolve in the mouth. The disintegration time for fast dissolving tablet varies from a few seconds to more than a minute depending on the formulation and the size of the tablet.

The dosages forms are placed in the mouth, allowed to disperse or dissolve in the saliva, and then are swallowed in the normal way[7]. Less frequently, they are designed to be absorbed through the Buccal and esophageal mucosa as the saliva passes into the stomach. In the latter case, the bioavailability of a drug from fast dispersing formulations may be even greater than that observed for standard dosage forms.

MATERIAL AND METHODS

Material

Sumatriptan succinate was obtained as a gift sample from Aurobindo pharma ltd. Sodium starch glycolate, Cross carmellose sodium, Cross povidone and Micro crystalline cellulose were obtained from SD Fine chemicals, Mumbai. Camphor, Magnesium stearate was obtained from Central drug house ltd, New delhi. Talc, Aspartame was from SD fine chemicals. All the ingredients used were of analytical grade.

Methods

Preparation of fast dissolving tablets by direct compression method

Six formulations were developed by varying concentration of super disintegrating agents (2-4%). The drug was mixed with proper portion of superdisintegrant. Care should be taken to confirm the proper mixing of drug and superdisintegrant. Then other excipients were added. Then the mixture is passed through sieve (Sieve No.44). The

mixture is blended with flavor, magnesium stearate and microcrystalline cellulose. Finally the blend is subjected for compression using Rotary tablet punching machine (Table No.1).

Preparation of fast dissolving tablets by sublimation method

The basic principle involved in preparing orodispersible tablets by sublimation technique is addition of a volatile salt (Camphor) to the tabletting components. Six formulations were developed by varying concentration of super disintegrating agent (2-4%). Accurately weighed ingredients were sifted through sieve no.44 and thoroughly mixed for 10 min and magnesium stearate and other ingredients were added to the blend and thoroughly mixed. The tablets were compressed using Rotary tablet punching machine. The compressed tablets were subjected to sublimation at 80^{o} C until a constant weight was obtained to ensure complete removal of volatile component (Table No.2).

EVALUATION PARAMETERS

Pre-formulation Studies

Fourier Transform Infrared Spectroscopy

The fourier transform infra-red analysis was conducted for the structure characterization. FTIR spectra of the pure drug, polymers and formulations were recorded by using BOMENMB SERIES FTIR instrument. Approximately 5mg of samples were mixed with 50mg of spectroscopic grade KBr, samples were scanned in the IR range from 500 to 3500 cm^{-1}, with a resolution of 4 cm^{-1}.

Pre-compression studies of fast dissolving tablets

Bulk density

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. It is expressed in g/ml and is given by

$$D_b = M / Vb$$

Where,

M is the mass of powder

Vb is the bulk volume of the powder.

Tapped Density

It is the ratio of the total mass powder to the tapped volume of the powder. It was determined by placing a graduated cylinder, containing a known mass of drug-excipients blend. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 10cm at 2 second intervals. The tapping was continued until no further change in volume was noted.

$$D_t = M / Vt$$

Where,

M is the mass of powder

Vt is the tapped volume of the powder.

Angle of Repose

It is defined as, the maximum angle possible between the surface of the pile of the powder and the horizontal plane. The angle of repose was determined by the funnel method suggested by Newman. Angle of repose is determined by the following formula

$$\text{Tan } \theta = h/r$$

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

Where,

θ = Angle of repose

h = height of the cone

r = Radius of the cone base.

Compressibility Index

The compressibility index has been proposed as an indirect measure of bulk density, size, shape, surface area, moisture content and cohesiveness of materials because all of these can influence the observed compressibility index.

$$\text{Carr's compressibility index (\%)} = [(D_t - D_b) \times 100] / D_t$$

Where,

D_t is the tapped density

D_b is the bulk density

Hauser's ratio

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

$$\text{Hausners ratio} = D_t / D_b$$

Where,

D_t is the tapped density,

Db is the bulk density.

Post compression studies of sumatriptan succinate fast dissolving tablets

Tablet thickness test[8]

Randomly 10 tablets were taken from each formulation trial batch and their thickness was measured using a Vernier caliperse.

Weight variation test[8]

The weight variation test is carried out in order to ensure uniformity in the weight of tablets in a batch. The total weight of 20 tablets from each formulation was determined and the average was calculated. The individual weights of the tablets were also determined accurately and the weight variation was calculated.

Measurement of tablet hardness[8]

The hardness of tablet is an indication of its strength. The force is measured in kg and the hardness of about 3-5 kg/cm2 is considered to be satisfactory for uncoated tablets. Hardness of 10 tablets from each formulation was determined by Monsanto hardness tester.

Friability test[8]

It is measured of mechanical strength of tablets. Roche Friabilator is used to determine the friability by following procedure. Twenty tablets were weighed and placed in Roche Friabilator where the tablets were exposed to rolling and repeated shocks resulting from free falls within the apparatus. After 100 revolutions, tablets are removed, dedusted and weighed again. The friability was determined as the percentage loss in weight of the tablets.

% Friability = (loss in weight / Initial weight) X 100

Disintegration Time

The USP device to rest disintegration was six glass tubes that are "3 long, open at the top, and held against 10" screen at the bottom end of the basket rack assembly. One tablet is placed in each tube and the basket rack is positioned in 1 liter beaker of distilled water at 37± 2ºC, such that the tablets remain below the surface of the liquid on their upward movement and descend not closer than 2.5cm from the bottom of the beaker.

***In Vitro* Dispersion Time**[9]

In vitro dispersion time was measured by dropping a tablet in a measuring cylinder containing 6ml of phosphate buffer pH 6.8 (simulated saliva fluid). The time for the tablet to completely disintegrate into fine particles was noted. Three tablets from each batch were randomly selected and *In vitro* dispersion time was performed.

Wetting time[10]

The method reported by yunixia *et al.*, was followed to measure tablet wetting time. A piece of tissue paper (12 cm X 10.75 cm) folded twice was placed in a small petridish (ID= 6.5 cm) containing 6 ml of Sorenson's buffer pH 6.8. A tablet was put on the paper, and the time for complete wetting was measured. Three trials for each batch and the standard deviation were also determined.

Water absorption ratio

A small culture Petri dish can be taken containing 6ml of water and a piece of tissue paper folded twice is placed. A tablet is placed gently on it and the time for complete wetting is measured. The wetted tablet is reweighed. Water absorption ratio R was determined according the following equation:

R = (Wa - Wb) / Wb x100

Where,

Wa is the weight of tablet after water absorption

Wb is the weight of tablet before absorption.

Content uniformity

From each batch of prepared tablets, ten tablets were collected randomly and powdered. A quantity of powder equivalent to weight of one tablet was transferred in to a 100 ml volumetric flask, to this 50 ml pH 6.8 buffer of was added and then the solution was subjected to sonication for about 2 hrs. The solution was made up to the mark with pH 6.8 buffer. The solution was filtered and suitable dilutions were prepared with pH 6.8 buffer. Same concentration of the standard solution was also prepared. The drug content was estimated by recording the absorbance at 282 nm by using UV-Visible spectrophotometer.

***In vitro* dissolution**

Freshly prepared phosphate buffer (pH 6.8) of 900 ml was placed in each dissolution vessels of dissolution test apparatus (USP, II paddle method). The tablets were placed in the dissolution medium. The temperature of the dissolution medium was maintained at 37± 0.5^0C and the paddle was rotated at 50 rpm. 5 ml samples were withdrawn. The sample volume was immediately replaced with the same volume of fresh media as when a sample was taken. The samples withdrawn were filtered, diluted and estimated spectrophotometrically at 282 nm. Cumulative amount of the drug released at each interval was calculated by using standard graph of Sumatriptan succinate.

Stability studies of fast dissolving tablets

It is the responsibility of the manufacturers to see that the medicine reaches the consumer in an active form. So the stability of pharmaceuticals is an important criteria. Stability of medicinal products may be defined as the capability of a particular formulation in a specific container to remain within its physical, chemical, microbial, therapeutic and toxicological specification, i.e. stability of drug is its ability to resists detoriation. 90% of labelled potency is generally recognized as the minimum acceptable potency level. Detoriation of drug may take several forms arising from changes in physical, chemical and microbiological properties. The changes may affect the therapeutic value of preparation or increase its toxicity.

RESULTS AND DISCUSSION

Oral drug delivery system represents one of the frontier areas of drug delivery system. Such a dosage forms are having a major advantage of patient compliance. Orodispersible tablets belong to oral drug delivery system that are capable of disintegrating in the oral cavity and thus rapidly releases the drug. The release rate depends upon the type and concentration of the superdisintegrant that swells, leads to rapid bursting or wicking of the drug. The present study was emphasized to formulate "Sumatriptan succinate Orodispersible Tablets" to improve patient compliance, an attempt was made to prepare the orodispersible tablets of Sumatriptan succinate using superdisintegrants such as Croscarmelose sodium, Sodium starch glycolate, Crospovidone, and Camphor (as subliming agent) in different ratio.

Pre-formulation Studies

Physical mixture of drug and polymer was characterized by FTIR spectral analysis for any physical as well as chemical alteration of the drug characteristics. From the results, it was concluded that there was no interference in the functional groups as the principle peaks of the Sumatriptan succinate were found to be unaltered in the spectra of the drug-polymer physical mixture (Figure No.1 and 2).

Pre-compression Studies

All the formulations prepared by both the methods showed the angle of repose less than 30^{o}C, which reveals good flow property (Table No.3). The loose bulk density and tapped bulk density for the entire formulation blend varied from 0.512 gm/cm^3 to 0.549 gm/cm^3 and 0.647 gm/cm^3 to 0.682 gm/cm^3 respectively (Table No.3). The results of Carr's consolidation index or compressibility index (%) for the entire formulation blend ranged from 16.28 to 20.86%.

Post-compression Studies

The mean thickness was (n=3) almost uniform in all the formulations and values ranged from 2.53 mm to 2.88 mm. The standard deviation values indicated that all the formulations were within the range (Table No.4).

The hardness values ranged from 3.36 to 3.96 kg/cm^2 for formulations were almost uniform. Tablet hardness is not as absolute strength (Table No.4).

Friability values were found to be within the limit. Thus tablets possess good mechanical strength (Table No.4).

All the tablets passed weight variation test as the average percentage weight variation was within the pharmacopoeial limits of 7.5%. It was found to be 98.3±0.89 mg to 102.3±0.75mg. The weight of all the tablets was found to be uniform with low standard deviation (Table No.4).

The drug content (Table No.5) of the tablets was found to be between 98 to 101 %. The results were within the range and that indicated uniformity of mixing. The cumulative percentage drug released by each tablet in the *in vitro* release studies was based on the average drug content present in the tablet.

Wetting time is closely related to the inner structure of the tablet. This experiment mimics the action of saliva in contact with the tablet to illustrate the water uptake and subsequent wetting of tablet. This showed that wetting process was very rapid in almost all formulations. This may be due to ability of swelling and also capacity of water absorption and cause swelling (Table No.5).

Water absorption ratio, which is important criteria for understanding the capacity of disintegrants to swell in presence of little amount of water, was calculated. It was found to be in the range of 39.30±1.25 to 87.10±1.02 seconds. The formulations prepared by direct compression technique, formulations containing only 2% of superdisintegrants shows lower water absorption ratio when compared to formulations containing 4% of superdisintegrants. This increase was due to the water up taking ability of the superdisintegrants (Table No.5).

The *in vitro* dispersion time is measured by the time taken to undergo uniform dispersion. Rapid dispersion within several minutes was observed in all the formulations. In sublimation method, formation of pores due to sublimation of camphor may be responsible for the *in vitro* dispersion of tablets (Table No.5).

The internal structure of tablets that is pore size distribution, water penetration into tablets and swelling of disintegration ingredients are suggested to be the mechanism of disintegration. All the formulations showed disintegration time less than 60 seconds. Formulations F6 and F12 showed rapid disintegration compared to other formulations (Table No.5).

All the formulations showed rapid % drug release (90.88% - 99.64%). But the rapid drug dissolution was noticed in F6 and F12 formulations compared to other formulations, which releases 96.53%, and 99.64% respectively at the end of 20 minutes. The fast dissolution might be due to quick disintegration of the tablets to form particles and rapid absorption will take place (Figure No. 3 and 4). Between the two methods the sublimation method shows better drug release (F12, 4% Cros povidone) (Figure No.5).

Stability studies for the developed formulations were carried out by storing the selected formulations at 40°C/75% RH up to one month. The formulations F6 and F12 were selected on the basis of their high cumulative percentage drug release, and also results of *in vitro* disintegration time, wetting time, and *in vitro* dispersion studies. For every 15 days interval, the tablets were analyzed for the hardness, drug content uniformity and cumulative % drug released *in vitro* disintegration time up to one month. These formulations showed no significant changes in the values (Table No.6). From the obtained data of tablet evaluation parameters indicated that stable formulations can be developed using direct compression method and sublimation method.

Table No.1: General composition of formulation prepared by direct compression method

S.No	Ingredients	F1	F2	F3	F4	F5	F6
1	Sumatriptan Succinate	25mg	25mg	25mg	25mg	25mg	25mg
2	SSG	2mg	-	-	4mg	-	-
3	CCS	-	2mg	-	-	4mg	-
4	CP	-	-	2mg	-	-	4mg
5	MCC	67mg	67mg	67mg	65mg	65mg	65mg
6	Magnesium stearate	2mg	2mg	2mg	2mg	2mg	2mg
7	Talc	2mg	2mg	2mg	2mg	2mg	2mg
8	Aspartame	2mg	2mg	2mg	2mg	2mg	2mg

SSG = Sodium starch glycolate; **CCS =** Cros carmellose sodium
CP = Cross Povidone; **MCC =** Micro crystalline cellulose

Table No.2: General composition of formulation prepared by sublimation method

S.No	Ingredients	F7	F8	F9	F10	F11	F12
1	Sumatriptan succinate	25mg	25mg	25mg	25mg	25mg	25mg
2	Camphor	10mg	10mg	10mg	10mg	10mg	10mg
3	SSG	2mg	-	-	4mg	-	-
4	CCS	-	2mg	-	-	4mg	-
5	CP	-	-	2mg	-	-	4mg
6	MCC	57mg	57mg	57mg	55mg	55mg	55mg
7	Magnesium stearate	2mg	2mg	2mg	2mg	2mg	2mg
8	Talc	2mg	2mg	2mg	2mg	2mg	2mg
9	Aspartame	2mg	2mg	2mg	2mg	2mg	2mg

SSG = Sodium starch glycolate; **CCS =** Cross carmellose cellulose;
CP = Cros povidone; **MCC =** Micro crystalline cellulose

Table No.3: Results of flow properties of fast dissolving tablet (F1 to F12)

S.No	Formulation code	Angle of repose(θ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Compressibility index (I)	Hausner's ratio
1	F1	25.16	0.512	0.647	20.86	1.26
2	F2	23.74	0.549	0.673	18.42	1.22
3	F3	28.70	0.532	0.650	18.15	1.22
4	F4	26.65	0.545	0.651	16.28	1.19
5	F5	24.72	0.541	0.655	17.40	1.21
6	F6	22.89	0.535	0.668	19.91	1.24
7	F7	30.01	0.541	0.682	20.67	1.26
8	F8	29.72	0.532	0.670	20.59	1.25
9	F9	27.54	0.529	0.665	20.45	1.25
10	F10	28.45	0.532	0.667	20.23	1.24
11	F11	27.89	0.530	0.661	19.81	1.24
12	F12	24.13	0.533	0.650	18.50	1.22

Table No.4: Uniformity of Thickness, Hardness, Friability, and Weight variation of fast disintegrating tablets (F1 to F12)

S.No	Formulation code	Weight Variation (n=10) (mg)	Uniformity of Thickness (n=3) (mm)	Hardness (n=3) (kg/cm^3)	Friability %
1	F1	101.6±0.20	2.71±0.04	3.62±0.17	0.15
2	F2	102.3±0.75	2.73±0.03	3.79±0.34	0.27
3	F3	101.5±0.89	2.76±0.03	3.76±0.25	0.16
4	F4	100.1±0.23	2.83±0.04	3.84±0.20	0.18
5	F5	101.1±0.2	2.53±0.01	3.53±0.15	0.24
6	F6	101.0±0.25	2.65±0.01	3.96±0.12	0.37
7	F7	100.1±0.20	2.79±0.06	3.43±0.22	0.14
8	F8	100.5±0.75	2.68±0.07	3.36±0.31	0.23
9	F9	98.3±0.89	2.88±0.05	3.71±0.26	0.16
10	F10	99.71±0.23	2.75±0.07	3.67±0.14	0.18
11	F11	102.1±0.2	2.79±0.04	3.62±0.15	0.24
12	F12	101.0±0.25	2.81±0.01	3.56±0.25	0.23

± S.D, † **n=3** average of three Observations, ‡ mm- Millimetre

Table No.5: Wetting Time, Water Absorption Ratio, *In vitro* Disintegration Time, *In vitro* Dispersion Time, Drug Content Uniformity (F1 to F6)

S.No	Formulation code	Wetting Time (n=3)	Water Absorption Ratio (n=3)	In-vitro Disintegration Time (sec)	In-vitro Dispersion Time (sec)	Drug Content (%)
1	F1	42.76±1.56	39.30±1.25	52.40±0.46	74.57±1.23	98.0
2	F2	35.52±1.73	37.16±1.41	50.71±0.67	72.74±1.36	99.1
3	F3	34.38±1.75	36.92±1.25	48.07±1.20	70.12±1.20	98.7
4	F4	34.19±1.85	68.64±1.51	51.81±1.03	71.71±1.51	98.57
5	F5	33.38±1.58	79.45±1.20	48.13±1.06	68.17±1.43	98.32
6	F6	31.46±1.25	87.10±1.02	42.19±0.96	66.12±1.15	99.15
7	F7	38.66±0.99	38.01±1.30	48.19±0.15	70.17±1.51	99.9
8	F8	33.72±0.12	35.31±1.11	41.91±1.24	65.18±1.62	101.2
9	F9	32.65±1.72	33.71±1.01	39.46±0.97	63.16±1.19	98.4
10	F10	36.87±1.01	65.46±1.12	44.12±1.12	69.16±1.03	99.9
11	F11	30.76±1.02	79.02±0.52	38.72±0.15	62.19±1.24	98.7
12	F12	29.74±1.00	86.71±1.10	30.17±1.21	59.21±1.05	99.79

Table No.6: Stability study of tablet properties of optimized formulations (F6 & F12)

S.No	Parameters	Controlled		F6		F12	
		F6	F12	After 15 days	After one month	After 15 days	After one month
1	Hardness (kg/cm)	3.96±0.12	3.86±0.25	3.95±0.29	3.92±0.16	3.85±0.21	3.83±0.78
2	Drug Content (%)	99.15	99.75	99.01	98.56	99.12	99.01
3	In-vitro disintegration time (sec)	42.19±0.96	30.17±1.21	42.76±0.94	43.07±0.91	31.32±1.26	32.12±1.52
4	Wetting time (sec)	31.46±1.25	29.74±1.00	31.99±1.25	32.04±1.06	30.12±1.23	31.52±1.15
5	%CDR	96.53±1.02	99.64±1.05	95.96±1.26	94.29±1.36	99.01±1065	98.56±1.14

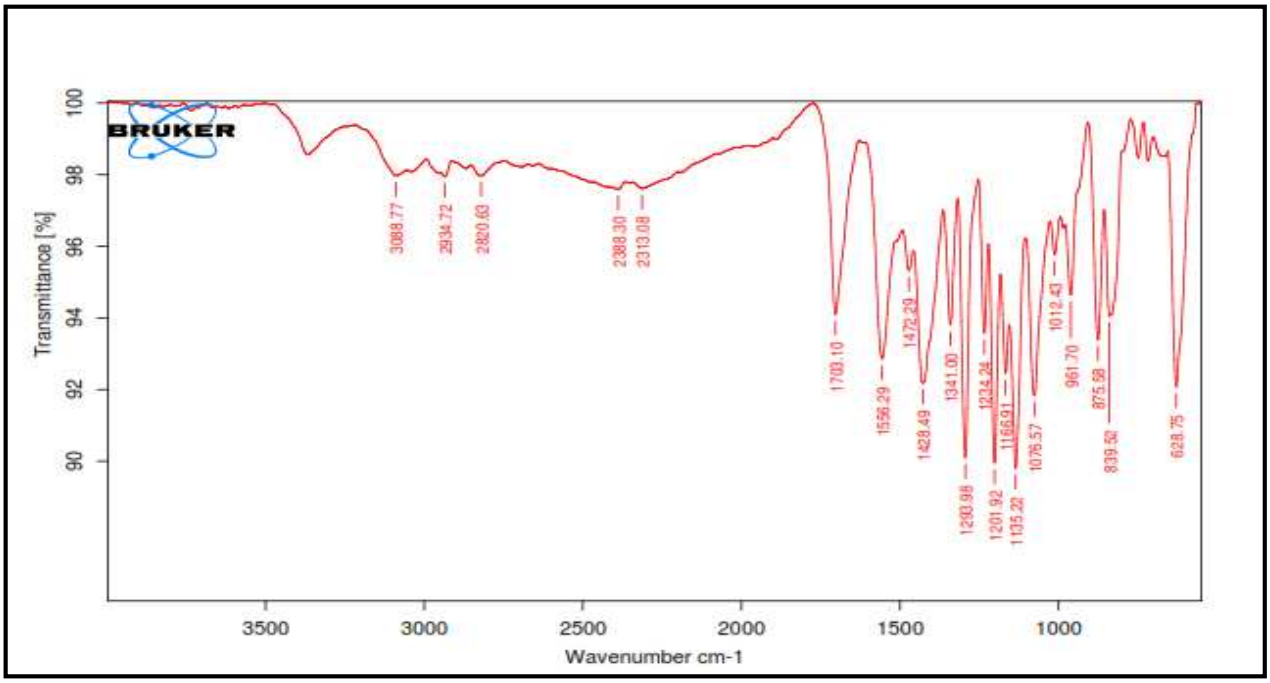

Figure No.1: FT-IR spectra of pure Sumatriptan succinate

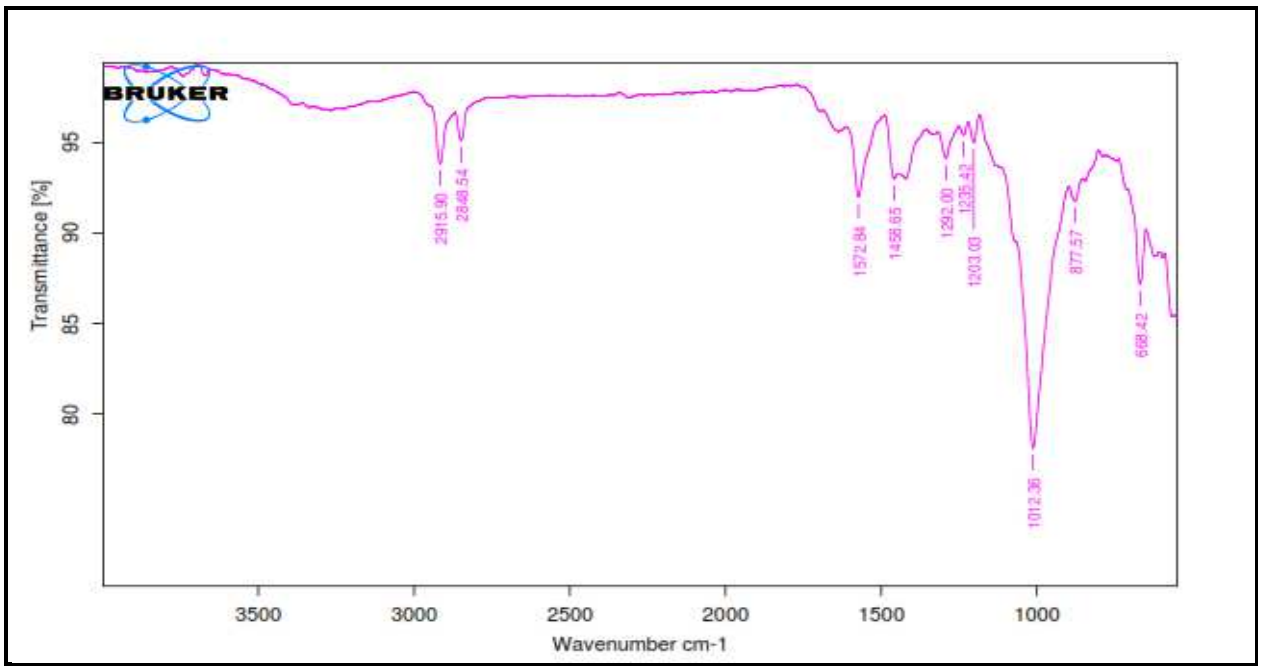

Figure No.2: FT-IR spectra of optimised formula (F12)

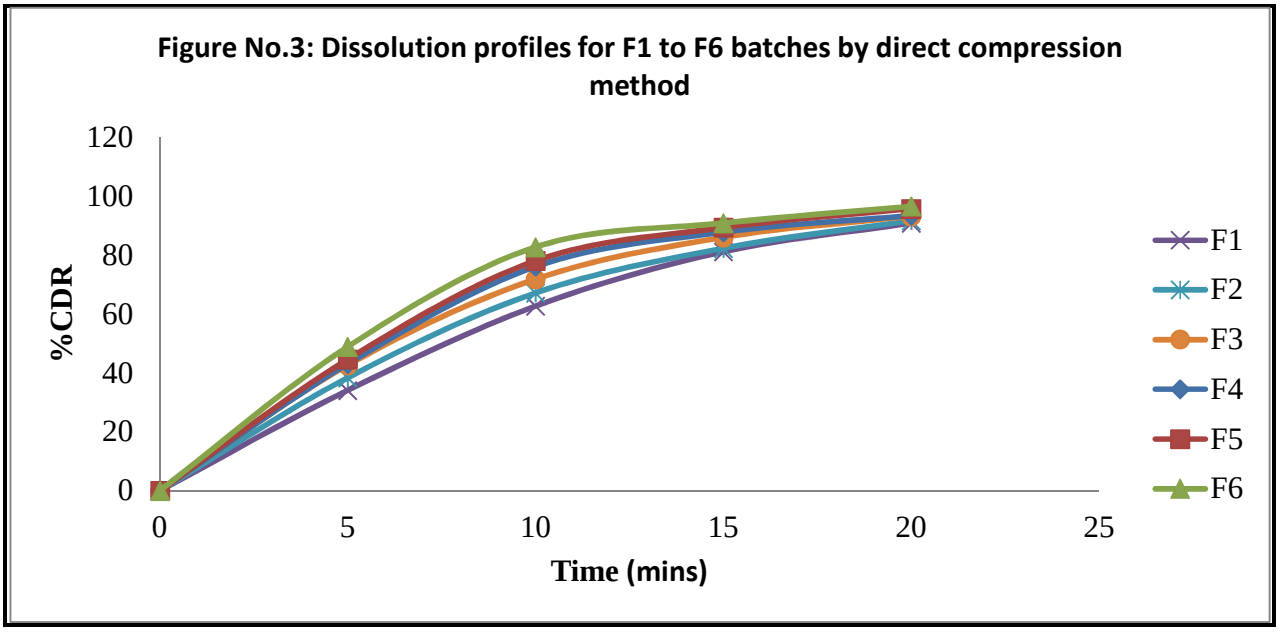

Figure No.3: Dissolution profiles for F1 to F6 batches by direct compression method

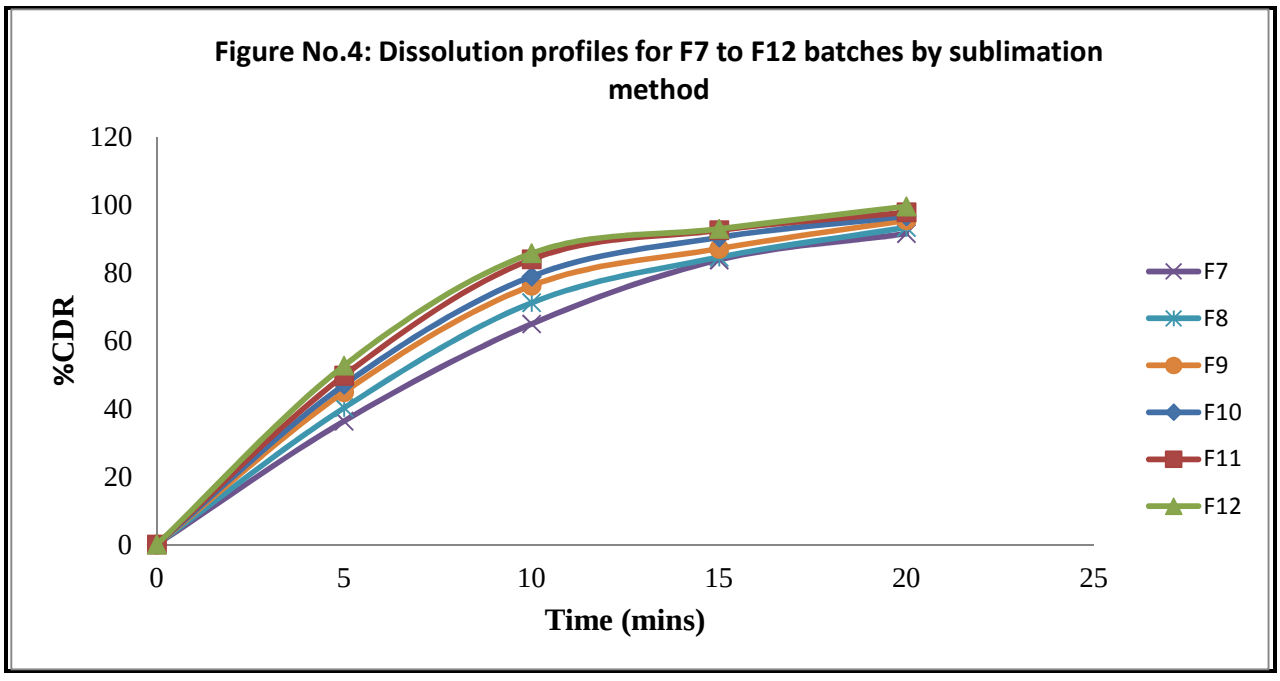

Figure No.4: Dissolution profiles for F7 to F12 batches by sublimation method

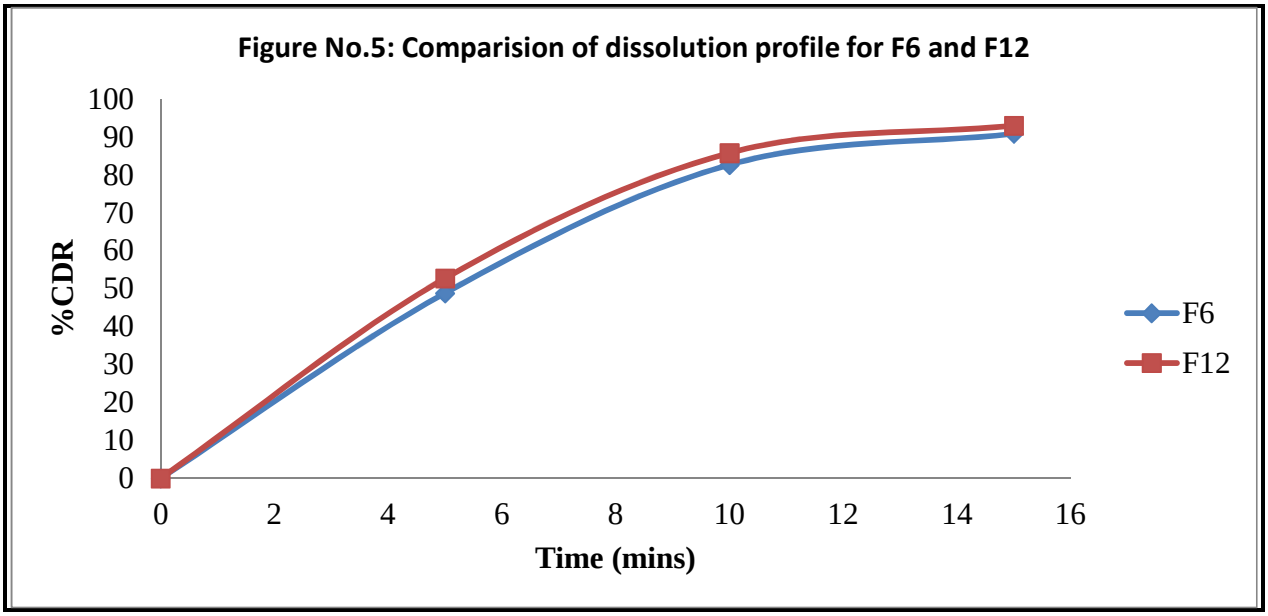

Figure No.5: Comparison of dissolution profile for F6 and F12

CONCLUSION

Sumatriptan succinate (Anti-migrane) can be efficiently and successfully formulated by employing direct compression method and sublimation method. It can be concluded that between the two techniques, sublimation method is best suitable in the preparation of Fast Disintegration Tablets of Sumatriptan succinate. The developed formulations have suitable characteristics. Among the three superdisintegrants, Crospovidone (F12) showed good disintegrants property. It has also shown good water absorption ratio. Further detailed investigation is required to establish bioavailability studies and efficacy including pre-clinical studies and clinical studies of these novel orodispersible tablets.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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