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FORMULATION AND EVALUATION OF SUMATRIPTAN IMMEDIATE RELEASE TABLETS

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ABSTRACT

The rationale of this investigation is to design an immediate release oral dosage of Sumatriptan succinate by using microcrystalline cellulose as filler, camphor and menthol as subliming agents by direct compression method .The basic objective of this dissertation is to develop an orodispersible tablet of sumatriptan succinate used in anti-migraine with an aim of reduces the lag time and providing faster onset of action to relief the acute migraine effect immediately. Disintegrates and disperses in oral cavity within 30 seconds without the need of drinking water. Has pleasant mouth feel and there is no after taste or grittiness. Successfully discriminates the ability of three superdisintegrants to promote drug dissolution and proposes a model formulation for disintegrants performance testing and quality control purposes. The formulation F6 containing 8% of CCS and 10% of menthol showed disintegration time of 18seconds after drying. Menthol as subliming agent was found to be most effective of all other subliming agents as it had showed drastic effect on the drug release.

Keywords: Sumatriptan succinate, sublimation, menthol, anti-migraine

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INTRODUCTION

Immediate release drug delivery system

Immediate release drug delivery system is also conventional type of drug delivery system as it is defined as immediate release tablets are designed to disintegrate and release their medicaments with no special rate controlling features such as special coatings and other techniques[1, 2]

Advantages of immediate release drug delivery systems:

- Release the drug immediately.
- More flexibility[2] for adjusting the dose.
- It can be prepared with minimum dose of drug.
- There is no dose dumping problem.
- Immediate release drug delivery systems used in both initial stage and final stage of disease.
- At the particular site of action the drug is released from the system.

Sublimation[3] is the process of transformation directly from the solid phase to the gaseous phase without passing through an intermediate liquid phase. Sublimation is an endothermic phase transition that occurs at temperatures and pressures below a substance's triple point in its phase diagram.

At normal pressures, most chemical compounds and elements possess three different states at different temperatures. In these cases, the transition from the solid to the gaseous state requires an intermediate liquid state. Note, however, that the pressure referred to here is the partial pressure of the substance, not

the total (e.g., atmospheric) pressure of the entire system. So, all solids that possess an appreciable vapor pressure at a certain temperature usually can sublime in air (e.g., water ice just below 0°C). For some substances, such as carbon and arsenical, sublimation is much easier than evaporation from the melt, because the pressure of their triple point is very high, and it is difficult to obtain them as liquids.

Sublimation requires additional energy and is an endothermic change. The enthalpy of sublimation (also called heat of sublimation) can be calculated as the enthalpy of fusion plus the enthalpy of vaporization. The reverse process of sublimation is deposition. The formation of frost is an example of meteorological deposition[4].

The key to rapid disintegration for mouth dissolving tablets[5, 6] is the presence of a porous structure in the tablet matrix. Conventional compressed tablets that contain highly water-soluble ingredients often fall to dissolve rapidly because of low porosity of the matrix. Hence to generate porous matrix, volatile ingredients are used that are later subjected to a process of sublimation. In studies conducted by Heinemann and Rothe, Knitsch et al., and Roser and Blair, inert solid ingredients that displayed high volatility (e.g., ammonium bicarbonate, ammonium carbonate, benzoic acid, camphor, hexamethonium tetramine, naphthalene, phthalic anhydride, urea, and urethane were compressed along with other excipients into a tablet. The volatile material was then removed by sublimation, leaving behind a porous matrix. Solvents such as cyclohexane and benzene were also suggested for the generation of porosity in the matrix.

MATERIALS AND METHODS

Sumatriptan Succinate was obtained as gift sample from Chandra labs, Hyd, menthol, camphor, croscarmelose sodium, crospovidone, SSG, microcrystalline cellulose and magnesium stearate are of laboratory grade and purchased from ESSEL fine chem. Mumbai.

Formulation [7, 8, 9]

Porous tablets of Sumatriptan succinate were prepared by direct compression method employing camphor and menthol as sublimating agents. The concentrations of the above ingredients were optimized as shown in below table on the basis of trial preparation of the tablets. All the ingredients were weighed accurately. The drug was mixed with the release rate enhancing disintegrants and other excipients, except magnesium stearate, in ascending order of their weight. The powder mix was blended for 20 min to have uniform distribution of drug in the formulation. Then, magnesium stearate was added and mixed for not more than 1 min (to ensure good lubrication.) About 200 mg of the powder mix was weighed accurately and fed into the die of single punch machinery and compressed using 8 mm flat- surface punches. The hardness of the tablets was adjusted at 4-6 kg/cm^2 using a Monsanto hardness tester.

Table 1: Formulation design of Sumatriptan succinate immediate release tablets

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10
Sumatriptan succinate	25mg	25mg	25mg	25mg	25mg	25mg	25mg	25mg	25mg	25mg
Menthol	20mg	20mg	20mg	20mg	20mg	20mg	20mg	20mg	20mg	-
Camphor										20mg
MCC	145	141	137	145	141	137	145	141	137	137
SSG	8mg	12mg	16mg	-	-	-	-	-	-	-
CCS	-	-	-	8mg	12mg	16mg	-	-	-	16mg
CP	-	-	-	-	-	-	8mg	12mg	16mg	-
Mg.stearate	2mg	2mg	2mg	2mg	2mg	2mg	2mg	2mg	2mg	2mg
Total weight	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg

Preformulation:

Organoleptic characters, Solubility, melting point and all other preformulation parameters were evaluated and results were shown.

Drug- Excipient Compatibility studies [10-12]

FT-1R Studies: The IR absorption spectra of the Sumatriptan succinate drug and with different superdisintegrants, natural gums and excipients were taken in the range of 4000-450 cm^{-1} using KBr disc method, 1-2 mg of the substance to be examined was triturated with 300-400 mg, specified quantity, of finely powered and dried potassium bromide. These quantities are usually sufficient to give a disc of 10-15mm diameter and pellet of suitable intensity by a hydraulic press. The scans were evaluated for presence of principle peaks of drug, shifting and masking of drug peaks due presence superdisintegrants, natural gums, polymers and excipients.

Evaluation:

Pre-compression parameters:

- **Angle of repose** [4]

A funnel with 10 mm inner diameter of stem was fixed at a height of 2 cm. over the platform. About 10 gm of sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. A rough circle was drawn around the pile base and the radius of the powder cone was measured.

- **Bulk density and tapped density**[8]

Apparent Bulk density (gm/ml) of the drug was determined by pouring (pre-sieved 40-mesh) gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. Then after pouring the powder bed was made uniform without disturbing. Then the volume was measured directly from the graduation marks on the cylinder as ml. The volume measure was called as the bulk volume and the bulk density was calculated by following formula.

Bulk density = weight of the sample/bulk volume

Tapped densities the drug was determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The cylinder was tapped from height of 2 inches until a constant volume was obtained. In USP TAP DENSITY TESTER, Tap density is measured in 500taps, 750 taps & 1250taps with drop/time-299-302. Volume occupied by the sample after tapping were recorded and tapped density was calculated.

Tapped density = weight of the sample/ volume occupied by the sample after tapping

- **Compressibility (Carr's compressibility index)**

Compressibility is the ability of powder to decrease in volume under pressure. Compressibility is a measure that is obtained from density determinations. It is also one of the simple methods to evaluate flow property of powder by comparing the bulk density and tapped density. High density powders tend to possess free flowing properties. A useful empirical guide is given by the Carr's index or compressibility index calculated from bulk density and tapped density.

- **Hausner's ratio**

Hausner's ratio provides an indication of the degree of densification which could result from vibration of the feed hopper. A lower value of indicates better flow and vice versa.

Post compression parameters

- **Organoleptic properties of tablets**

Organoleptic properties such as taste, color, odour, were evaluated. Ten tablets from each batch were randomly selected and tested for taste, color, odour and physical appearance**.**

- **Thickness**[13]

The thickness of individual tablets of 6 numbers were measured with vernier calipers, it permits accurate measurements and provides information of the variation between tablets. Tablet thickness should be controlled within ± 5% variation of standard value.

- **Hardness**

The tablet hardness of different formulations was measured using the Monsanto hardness tester for 6 tablets. The tester consists of a barrel containing a compressible spring held between two plungers. The lower plunger was placed in contact with the tablet, and a zero was taken. The upper plunger was then forced against the spring by turning a threaded bolt until the tablet fractures. As the spring is compressed, a pointer rides along a gauge on the barrel to indicate the force. The force of fracture is recorded and the zero force reading is deducted from it.

- **Weight Variation Test**

Twenty tablets from each batch were weighed with electronic digital balance and average weight was determined. Then individual tablets were weighted and individual weight was compared with the average weight. The percentage deviation was calculated and checked for weight variation. Standard deviation was calculated. Using this procedure weight variation range of all the batches were determined and recorded.

- **In vitro Disintegration time** [8, 9]

The process of breakdown of a tablet into smaller particles is called as disintegration. The in-vitro disintegration time of a tablet was determined using disintegration apparatus as per I.P. specifications.

I.P. Specifications: Place one tablet in each of the 6 tubes of the basket. Add a disc to each tube and run the apparatus using 0.1N HCl maintained at 37±2C as the immersion liquid. The assembly should be raised and lowered between 30 cycles per minute in the 0.1N HCl maintained at 37±2c. The time in seconds taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured and recorded.

- **Drug Content Uniformity Assay**

Ten tablets were selected randomly and powdered. A quantity of this powder corresponding to one tablet was dissolved in 100 ml of 0.1N HCl , stirred for 15 min and filtered. 1 ml of the filtrate was diluted to 100 ml with 0.1N HCl. Absorbance of this solution was measured at 222nm using 0.1N HCl as blank and content of drug was estimated.

- **In vitro Dissolution studies** [10, 11, 13]

Dissolution of the tablet of each batch was carried out using USP type II apparatus (ELECTRO LAB) using paddles at 50 rpm. As per the official recommendation of IP 900ml of 0.1 N HCl used as dissolution medium and the temperature of the medium was set at 37 ± 0.5 ^{0}C. 5 ml of sample was withdrawn at predetermined time interval of 5min., 10min., 15min, 20min, 25min, 30min, 35min and 40min. And same volume of fresh medium was replaced. The withdrawn samples were analyzed by

an UV-visible spectrophotometer at 222 nm using buffer solution as blank solution.

The drug content was calculated using the equation generated from standard calibration curve. The % cumulative drug release was calculated.

RESULTS AND DISCUSSION

Preformulation Studies

- **Description:**

These tests were performed as per the procedure and the results were illustrated in the following table:

Table 2: Table showing the description of Sumatriptan succinate (API)

Test	Description
Color	A white to off white colour crystalline powder
Odor	Odorless

Organoleptic properties such as taste, color, odor were evaluated and the results are within the standards, shown in (Table.9). The drug is showing solubility in methanol and in water.

- **Solubility:**

These tests were performed as per procedure and the results are illustrated in the following table. The drug is showing solubility in methanol and in water.

Table 3: showing the Solubility of Sumatriptan Succinate (API) in various solvents.

Solvents	Solubility
0.1N HCL	Freely soluble
Water	Freely soluble
pH6.8Phosphate buffer	Soluble
Methanol	Freely soluble
Ethanol	Slightly soluble

- **Melting Point:** The melting point of sumatriptan succinate was found to be 170^0c.

Evaluation of tablet blend

Table 4: Evaluation of tablet blend for formulations (F1 – F10)

Formulation	Bulk Density (g/cc)	Tapped Density(g/cc)	Hausner's ratio	Compressibility index (%)	Angle of repose	Flow properties
F1	0.464	0.574	1.23	19.1	29.47	Excellent
F2	0.423	0.501	1.16	15.5	27.63	Excellent
F3	0.456	0.542	1.22	15.8	25.54	Excellent
F4	0.467	0.559	1.25	16.4	26.23	Excellent
F5	0.485	0.593	1.10	18.2	27.21	Excellent
F6	0.460	0.556	1.21	17.2	30.38	Good
F7	0.478	0.575	1.24	16.8	28.46	Excellent
F8	0.450	0.554	1.28	18.7	25.71	Excellent
F9	0.442	0.537	1.27	17.6	31.82	Good
F10	0.467	0.559	1.25	16.4	26.23	Excellent

All the formulations prepared by direct compression method showed the angle of repose less than 34, which reveals good flow property. The bulk density and tapped density for all formulation (F1 – F10) varied from 0.442 - 0.485 gm/cm^3 and 0.501 - 0.593 gm/cm^3 respectively. The results of Carr's consolidate index or % compressibility index and hausner's ratio for the entire formulation (F1 – F10) blend range from 15.5- 19.1 and 1.10-1.28 respectively, shows fair flow properties. The results are shown in the (Table.5).

Drug-excipient compatibility studies

The FT-IR represents the peaks of the Sumatriptan succinate functional groups. These peaks were not affected, they were prominently observed in IR-spectra of Sumatriptan succinate along with superdisintegrants and other excipients. The spectral details of the drug and the excipients are shown in (Figure.8 – 17). There was no difference in the position of the absorption bands, hence providing evidence for the absence of any chemical incompatibility between pure drugs with the excipients.

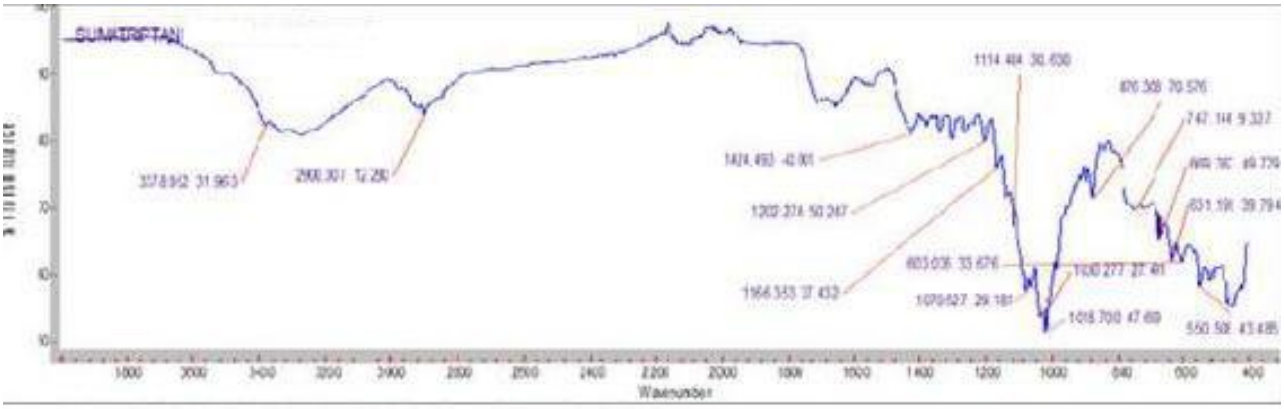

Figure 1: FTIR spectra of pure drug Sumatriptan

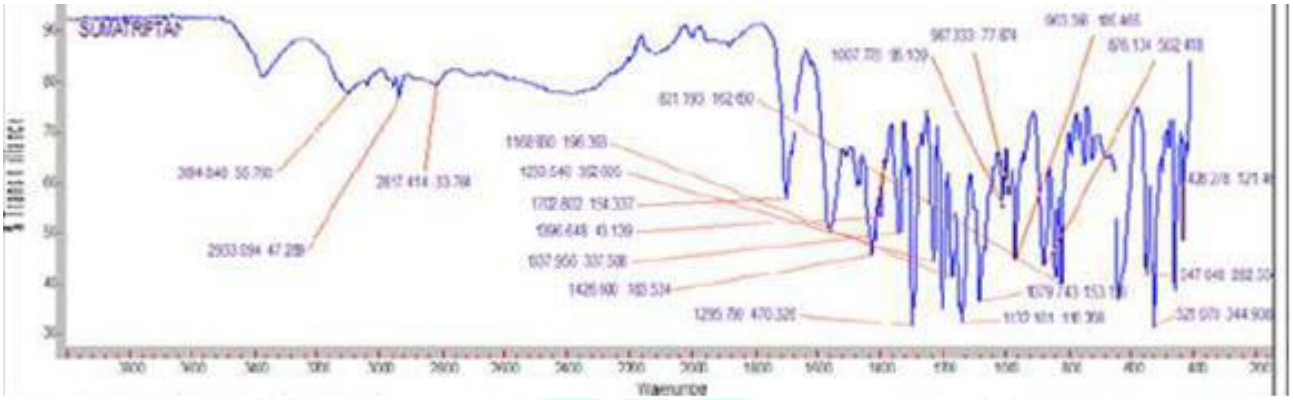

Figure 2: FTIR spectra of Optimized Formulation (F6)

Post compression parameters

Appearance of tablets

All the tablets show similar color, odor, taste and physical appearance. There is no impact of superdisintegrants in their organoleptic properties. The results are shown in the (Table 6).

Table 5: Organoleptic properties of tablets

Color	white
Shape	Round
Texture	Fine

Evaluation of Tablets

- **Before Drying**

Table 6: Evaluation of Immediate Release Tablets For Formulations (F1 – F10) Before Drying

Formulation	Hardness[a] (kg/cm2)	Weight[b] (mg)	Thickness[a] (mm)	Disintegration time[a] (min)	Drug content[c] (%)
F1	6.0±0.17	201±0.59	2.4±0.05	6	98.2±0.62
F2	6.1±0.20	198±0.63	2.4±0.02	5min 24sec	98.72±0.23
F3	6.2±0.18	201±0.45	2.6±0.07	4min	98.4±0.34
F4	6.0±0.15	202±0.88	2.5±0.10	5min 45sec	98±0.56
F5	6.2±0.16	203±0.56	2.4±0.03	4min 34sec	98.44±0.49
F6	**6.1±0.22**	**198±0.74**	**2.45±0.06**	**2min 21sec**	**100.8±0.27**
F7	6.2±0.24	201±0.67	2.5±0.15	5min 32sec	98.2±0.63
F8	6.0±0.22	201±0.77	2.5±0.03	4min	98.4±0.56
F9	6.1±0.16	203±0.86	2.4±0.01	2 min17sec	99.32±0.37
F10	6.1±0.12	198±0.54	2.4±0.05	2min 28sec	98±0.56

a = 6 tablets, b = 20, c=10

- **After Drying**

Table 7: Evaluation of Immediate Release Tablets For Formulations (F1 – F10) After Drying

Formulation	Hardness[a] (kg/cm2)	Weight[b] (mg)	Thickness[a] (mm)	Disintegration time[a] (sec)	Drug content[c] (%)
F1	3.5.0±0.11	181±0.39	2.4±0.03	1min 14sec	98.2±0.62
F2	3.7±0.13	179±0.43	2.4±0.05	47sec	98.72±0.23
F3	3.9±0.15	182±0.47	2.6±0.06	38sec	98.4±0.34
F4	3.8±0.12	183±0.78	2.5±0.09	1min	98±0.56
F5	3.7±0.12	184±0.43	2.4±0.05	42sec	98.44±0.49
F6	**3.6±0.19**	**183±0.51**	**2.45±0.08**	**18sec**	**100.8±0.27**
F7	3.6±0.21	181±0.55	2.5±0.12	45sec	98.2±0.63
F8	3.9±0.25	183±0.57	2.5±0.06	28sec	98.4±0.56
F9	3.8±0.19	184±0.56	2.4±0.07	19sec	99.32±0.37
F10	3.7±0.16	183±0.31	2.4±0.08	22sec	98±0.56

a = 6 tablets, b= 20, c=10

By using the superdisintegrants, the hardness before drying values ranged from 6.0±0.15kg/cm^2 - 6.2±0.24kg/cm^2 for formulations (F1- F10) and hardness after drying ranges from 3.5.0±0.11 kg/cm^2 - 3.9±0.25 kg/cm$^{2.}$

The entire tablet passes weight variation test, as the average % weight variation was within the Pharmacopoeial limit - 7.5%. It was found to be 198±0.54 mg - 203±0.56 mg(before drying),and after drying varies from 179±0.43mg-183±0.78mg. The weight of all the tablets was found to be uniform with less deviation.

Disintegration test carried out in modified dissolution apparatus, Results shows the formulations with F1 (4%), F2(6%), F3(8%) of SSG having disintegrating time(After drying) as 1min 14sec, 47sec and 38sec respectively. F4 (4%), F5 (6%), F6(8%) of CCS having disintegrating time(After drying) as 1min, 42sec and 18sec respectively. F7 (4%), F8(6%), F9(8%) of CP having high disintegrating time(After drying) as 45sec 28sec and 19sec respectively.F10 (8%) of CCS having disintegrating time of 22sec. The concentration of the drug in all the formulations with superdisintegrants was found to be 98±0.56– 100.8±0.27%. It was within the IP limits. The results of drug content of all batches are shown in (Table.8).

Results of in-vitro release profile

Table 8: In-Vitro Release Profile of Sumatriptan succinate from formulations F1-F10

Time (min)	Cumulative % drug release									
	F1	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8**	**F9**	**F10**
5	13±0.0021	17±0.011	24±0.023	17±0.023	20±0.019	**37±0.011**	13±0.017	17±0.021	23±0.011	32±0.021
10	23±0.019	27±0.014	38±0.025	32±0.019	38±0.014	**55±0.017**	27±0.021	31±0.025	37±0.009	53±0.019
15	35±0.011	42±0.025	54±0.019	45±0.021	57±0.017	**70±0.021**	38±0.025	45±0.023	53±0.008	68±0.001
20	56±0.016	59±0.021	67±0.023	56±0.025	65±0.018	**86±0.022**	51±0.019	57±0.026	68±0.012	82±0.007
25	62±0.011	70±0.017	78±0.021	69±0.022	76±0.021	**99±0.023**	64±0.017	76±0.023	78±0.017	91±0.011
30	77±0.021	83±0.022	91±0.017	86±0.021	93±0.023	**102±0.027**	79±0.016	84±0.021	97±0.019	99±0.021
35	89±0.014	92±0.017	99±0.021	93±0.021	99±0.025		92±0.018	99±0.019	101±0.021	102±0.021
40	101±0.013	98±0.021		101±0.018			99±0.021	102±0.017		

n=3

Dissolution is carried out in USP apparatus type-2 apparatus at 50rpm in 900ml dissolution media (0.1N HCl) for 40 minutes. At the end of 30 minutes almost total amount of the drug is released (i.e. 102±0.027 %), from the formulation prepared by the direct compression method with 8% crospovidone.

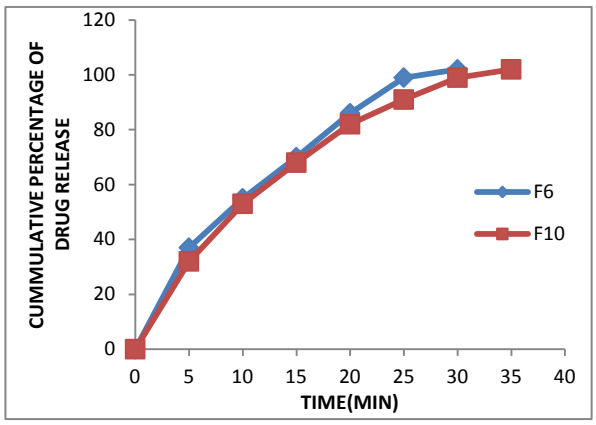

Figure 3: Linear graph comparison between cumulative % drug releases for formulations (F6 & F10)

From the above Table 7, it is observed that the thickness, hardness, weight variation and drug content of the immediate release tablets were in the passable range. The F1,F2 and F3 formulations containing menthol as the subliming agent, SSG as super disintegrating agent in the percentage of 4%, 6% and 8% didn't show much effect on the Disintegration time i.e., 1min 14sec,47sec 38sec respectively and dissolution time i.e., 101% in 40min,98% in 40min and 99% 35min respectively .

The F4, F5 formulations containing menthol as the subliming agent, CCS as super disintegrating agent in the percentage of 4%, 6% didn't show much effect on the Disintegration time i.e., 1min, 42sec respectively and dissolution time 101% in 40min and 99% in 35min respectively. Whereas F6 containing menthol as sublimating agent and 8% menthol as sublimating agent showed good disintegrating time i.e.,18sec and dissolution of 102% in 30min.

The F7, F8 and F9 formulations containing menthol as the subliming agent, CP as super disintegrating agent in the percentage of 4%, 6% and 8% didn't show much effect on the Disintegration time I.e., 45sec,28sec and 19sec respectively, dissolution time of 99% in 40min,102% in 40min and 101% in 35min respectively.

The formulation F10 containing camphor as sublimating agent and 8% CCS as super disintegrating agent showed 22sec disintegration time and 102% drug release in 35min.

Among the formulations F6 and F10 F6 was optimized as it showed less disintegration time and highest percentage of drug release (102%) in 30 min where as F10 showed disintegrating time of 22sec and 102% of drug release in 35min.

CONCLUSION

By studying all the experimental results it was conclusively demonstrated that the formulated immediate release tablets of sumatriptan succinate exhibited good physical parameters and rapidly disintegrating without affecting the release profile and is very effective. The overall results indicated that formulation with cross caramellose sodium (8%) as super disintegrants and menthol (10%) as sublimating agent had a higher edge compared to other formulations. They satisfy all the criteria for immediate release tablets and the direct compression process is simple, reproducible and robust to prepare immediate release tablets of other anti-migraine drugs. The formulation F6was the optimized formulation and can be easily scaled up and can be easily employed in large scale production because the process is simple, cost effective and precise and also yields reproducible good results for manufacturing the tablets.

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