

Design Formulation and Evaluation of Anti Migraine Mouth Dissolving Tablets Using Different Super Disintegrants

Ravi Shankar Kumar^{1*}, Loveleen², Indu Passi², Amandeep Kaur² and Sandeep Kumar Sharma²

¹Associate Professor, Dasmesh College of Pharmacy, Faridkot, Punjab, INDIA.

²Assistant Professor, Dasmesh College of Pharmacy, Faridkot, Punjab, INDIA.

*Corresponding Author: ravigarg.pharma@gmail.com



www.jrasb.com || Vol. 3 No. 2 (2024): April Issue

Received: 21-04-2024

Revised: 26-04-2024

Accepted: 09-05-2024

ABSTRACT

The main objective of this research was to create and evaluate the efficacy of orally disintegrating tablets containing sumatriptan succinate at a dosage of 25 milligrammes, a medicine commonly prescribed for the treatment of migraines. The tablets are made using the direct compression method. In order to achieve best results, the formulations were enriched with microcrystalline cellulose of varying composition (Avicel PH 102), mannitol as a diluent, crospovidone, croscarmellose, and sodium starch glycolate as superdisintegrants. Carbomer (carbopol 940), Sodium CMC, and Sodium Alginate were among the other excipients that were used. When used at varying doses, these excipients act as disintegrants. In addition, magnesium stearate was used as a substance to reduce friction, while talc was used as a substance to improve flow. We assessed each of the excipients to ascertain their compatibility with the model drug. The findings revealed no occurrence of any physical or chemical interaction. Before compression, the preformulation features of the tablet blend were examined. The criteria considered were bulk density, tapped density, compressibility index, and hausner ratio. An assessment was carried out on central tablets to ascertain their dimensions, firmness, tendency to crumble, variability in weight, rate of disintegration, and uniformity of drug content properties. Furthermore, an investigation was conducted to examine the impact of these variables on the release of the drug. The drug release studies were performed in vitro using the USP dissolving apparatus-II (paddle type) with a phosphate buffer solution at a pH of 6.8. The experiments were conducted at a speed of 50 revolutions per minute at a temperature of 37 degrees Celsius, with a standard deviation of 5 degrees Celsius. The sampling was conducted at consistent intervals of 2, 4, 6, 8, and 10 minutes. After each withdrawal, an equivalent volume of dissolving medium was replaced with the sample. The ultraviolet (UV) method is employed to evaluate the cumulative quantity of medications that have been discharged at different time intervals. Based on the evaluation results, the F-3 trial formulation, which included 6% crospovidone, was selected as the superior formulation among the superdisintegrants. Conversely, the F-10 trial formulation, which included 2% carbopol 940p, was selected as the superior formulation compared to other basic disintegrants.

Keywords: Disintegration, Evaluation, Migraine, Tablet, Carbopol.

I. INTRODUCTION

Undoubtedly, the oral route is the most crucial method of drug delivery. It provides the benefits of easy management and the possibility of reducing manufacturing expenses. Orally administered drugs, especially tablets, are the preferred type of solid oral dose forms. Currently, drug delivery companies are prioritising the development of solid oral medication delivery systems that enhance patient adherence and ensure optimal

dosing. Over the course of ten years, there has been a substantial growth in the demand for the creation of oral disintegrating tablets (ODTs) due to their major influence on patient compliance. Oral disintegrating pills provide a benefit for individuals who experience challenges in swallowing. Dysphagia, or difficulty in swallowing, is prevalent across all age categories, particularly among paediatric and geriatric populations, as well as institutionalised patients and those experiencing symptoms such as nausea, vomiting, and motion sickness.

Orally disintegrating tablets (ODTs) that possess desirable taste and flavour enhance the acceptance of bitter medications among different segments of the population. Migraines have a global prevalence of over 10%. Migraine prevalence is marginally lower in Asia compared to Western countries. The prevalence of chronic migraines is estimated to be around 1.4 to 2.2% of the population. During each episode of migraine, the duration ranges from 15 minutes to 180 minutes. Therefore, it necessitates prompt alleviation. A rapidly disintegrating pill is an optimal option in such instances. Sumatriptan succinate belongs to the subclass of antimigraine drugs. The primary aim of this research was to develop and assess the effectiveness of orally disintegrating tablets containing sumatriptan succinate. Sumatriptan is prescribed for the treatment of migraines. It aids in alleviating headaches, discomfort, and other symptoms associated with migraines, including as sensitivity to light and sound, nausea, and vomiting. Sumatriptan is a potent 5-HT_{1D} receptor agonist that specifically constricts the arteries within the brain and redistributes blood, thereby enhancing cerebral blood flow. The unaltered form of sumatriptan is eliminated in the urine at a rate of just 3% of the total dose. The primary metabolite, which is an analogue of sumatriptan called indole acetic acid, is excreted at a rate of 42% of the dose. The bioavailability of the medicine is 15%. Therefore, it is necessary to enhance its bioavailability by incorporating it into an oral disintegrating dosage form, which can offer a more effective therapeutic outcome compared to the oral administration route.

II. MATERIAL & METHODS

Sumatriptan succinate was obtained from Natco Pharma Ltd. The superdisintegrants used were Crospovidone, Croscarmellose sodium, and Sodium starch glycolate. Common disintegrants such as Carbomer (carbopol 940), Sodium CMC, and Sodium Alginate. Avicel 102 (Microcrystalline cellulose), aspartame, magnesium stearate, mannitol, and talc were acquired from Drug India Pvt. Ltd.

III. PREPARATION OF STANDARD GRAPH

Preparation of Stock solution with 6.8 P^H Phosphate Buffer

The medication was precisely weighed and placed into a 100 ml volumetric flask. The substance was completely mixed with an appropriate amount of phosphate buffer and the volume was adjusted to the desired level with more phosphate buffer in order to obtain a solution with a concentration of 1000 µg/ml. The stock solution used in this experiment had a concentration of 1 mg/ml for the model medication. (Stock I)

UV Absorption Maxima (λ_{\max}) of drug sample in 6.8 P^H Phosphate Buffer

To prepare the stock solution of 10 µg/ml, one ml of the solution mentioned above was diluted with phosphate buffer to a final volume of 100 ml. A UV scan was conducted on a drug solution with a concentration of 10 µg/ml, using a pH 6.8 phosphate buffer as a blank, in a Shimadzu UV 2450 spectrophotometer. The scan covered a wavelength range of 200-400 nm. The peak wavelength was determined to be 226 nm.

Preparation of the calibration curve

The stock II solution was divided into 10 ml volumetric flasks, with 2, 4, 6, 8, and 10 ml being placed into each flask. The flasks were then filled with phosphate buffer up to the mark, resulting in concentrations of 2, 4, 6, 8, and 10 µg/ml, respectively. The absorbance of each solution was quantified at a wavelength of 226 nm. The process of preparing the standard curve was carried out. A plot was created by correlating the absorbances with the concentrations. The resulting graph displayed a straight line equation and a r² value of 0.998, indicating a strong adherence to Beer's Lambert's law.

IV. FORMULATION OF DIFFERENT BATCHES

The primary objective of the current investigation was to develop many batches by using three distinct superdisintegrants and other substances at diverse concentrations. Consequently, various sets of formulations were planned in accordance with specific criteria. F1, F2, F3 were formulated with Crospovidone at concentrations of 1.5%, 3%, and 6%. F4, F5, F6 were formulated with Croscarmellose at concentrations of 1.5%, 3%, and 6%. F7, F8, F9 were formulated with Sodium starch glycolate at concentrations of 1.5%, 3%, and 6%. F10, F11, F12 were formulated with carbopol 940 at concentrations of 2%, 4%, and 6%. F13, F14, F15 were formulated with Sodium CMC at concentrations of 2%, 4%, and 6%. F16, F17, F18 were formulated with Sodium Alginate at concentrations of 2%, 4%, and 6%. The drug's mild bitter flavour was concealed by using aspartame (2.5% to 6%) as the sweetening agent.

EVALUATION PARAMETERS FOR ODT

Drug Content Uniformity

A total of twenty tablets were chosen at random and then crushed into powder form. An amount of this powder equivalent to one tablet was dissolved in 100 ml of phosphate buffer with a pH of 6.8, agitated for 15 minutes, and then filtered. The filtrate was diluted by adding 1 ml to 100 ml of a phosphate buffer with a pH of 6.8. The absorbance of this solution was measured at a wavelength of 226nm using a phosphate buffer with a pH of 6.8 as a blank. The concentration of the medication was then determined.

Weight variation²⁶

The process of In-Process (I.P.) was implemented to ensure consistency of weight. Twenty

tablets were selected and their weight was measured individually and collectively using a digital weighing scale. The mean weight of a single tablet was calculated based on the combined weight of all tablets. The weight variation test is a reliable tool for assessing the homogeneity of medication content.

Friability^{27, 28}

Friability is an essential metric used to assess the quality of orally disintegrating tablets (ODT). Efforts to reduce the disintegration time of orally disintegrating tablets (ODTs) result in an increase in their friability compared to regular tablets. Zydis and other dosage formulations are quite delicate. Friability is a quantitative assessment of the tablet's mechanical durability. A tablet with higher friability is more prone to breakage during packaging, transport, or handling. The Roche friabilator is utilised to ascertain the friability using a prescribed process. Pre-measured pills are inserted in the friabilator. The friabilator is comprised of a plastic container that rotates at a speed of 25 revolutions per minute, causing the tablets to fall from a height of 6 inches with each rotation. The tablets undergo rotation in the friabilator for a minimum duration of 4 minutes.

Hardness (Crushing load)^{27, 28}

Tablet hardness is assessed using hardness testers such as Monsanto. A tablet is inserted into the hardness tester and the amount of force needed to crush the tablet is measured. ODTs are often designed to have reduced hardness compared to normal tablets in order to slow down the disintegration process. An optimal balance between mechanical strength and disintegration time is attained for an acceptable oral dissolving formulation.

Wetting time^{28, 29}

The first step in the breakdown of an orally disintegrating tablet (ODT) involves the absorption of water and the saturation of the tablet. Therefore, the determination of wetting time is equally crucial. Additionally, it aids in examining the impact of different additives on the tablet's disintegration. A 6 ml petri dish filled with distilled water is obtained and a folded tissue paper is inserted into it. A tablet with a small amount of amaranth colour is placed on top of this. The soaking time is the duration it takes for the upper surface of the tablet to turn completely red.

Water absorption ratio^{28, 29}

A pre-weighed tablet (W_a) is inserted in a petri dish using the same method as outlined in the wetting time test. Once the tablet has fully absorbed water, it is taken out and its weight is recorded as W_b . The water absorption ratio R is determined using the following formula:

Disintegration Time (DT)³⁰⁻³³

According to the pharmacopoeia, pills are placed within disintegration tubes and the time is recorded. As per the European pharmacopoeia, oral disintegrating/orodispersible pills must break down completely within 3 minutes and should not leave any residue on the screen. Nevertheless, evaluating the rate of

disintegration, even in little quantities of water, proves to be challenging. In contrast, the typical test utilises a quantity of 900 ml of distilled water, although the volume of saliva in people is restricted to a few ml. Therefore, the disintegration rate obtained from traditional tests does not seem to accurately represent the actual disintegration rate in the human mouth. In order to address these issues, a number of novel approaches have been suggested. One of these techniques The disintegration of fast dissolving tablets occurs by the action of saliva in the mouth. However, the amount of saliva available is restricted, and there is currently no tablet disintegration test in the USP and IP that accurately simulates in vivo conditions. A revised iteration of the uncomplicated yet innovative technique was employed to ascertain the disintegration duration of the pills. A cylindrical container was utilised, with a 10-mesh screen positioned in a manner that allowed just 4 ml of disintegrating material to be placed beneath the sieve. In order to measure the time it takes for disintegration to occur, a total of 6ml of Sorenson's buffer with a pH of 6.8 was placed in a vessel. Specifically, 4ml of the buffer was positioned below the sieve, while 2ml was positioned above the sieve. The tablet was positioned on the sieve, and subsequently, the entire assembly was placed onto a shaker. The moment when all the particles traverse the sieve was recorded as the tablet's disintegration time. A random selection of six tablets was made from the composite samples, and the average value was calculated.

In vitro Dispersion Time³¹⁻³³

A tablet was introduced into a 10ml solution of buffer with a pH of 6.8, and the time it took for the tablet to completely disperse was recorded. In the experiment, three tablets were chosen at random from each formulation and subjected to in vitro dispersion time testing.

Dissolution test³¹⁻³³

The dissolution procedure for oral disintegrating tablets is identical to that of conventional tablets. The USP 2 paddle apparatus is the preferred and widely used option for conducting dissolution tests on oral disintegrating tablets. In this test, a paddle speed of 50 rpm is employed. The USP 2 (Paddle) device may have limited utility for particular tablets, mostly due to the tablets' peculiar physical characteristics. Tablet fragments or disintegrating tablet masses are specifically caught on the upper part of the basket spindle, where there is less or no effective stirring. This leads to inconsistent outcomes in disintegration profiles.

V. RESULTS AND DISCUSSIONS

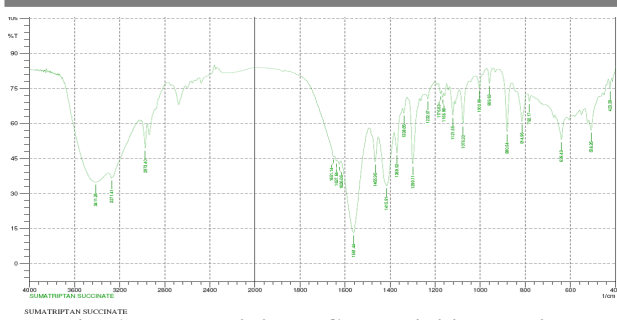


Fig: 1 Drug-excipients Compatibility studies

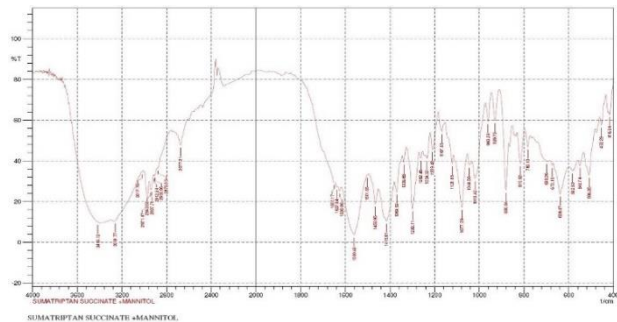


Fig: 2 FT-IR spectra of sumatriptan succinate

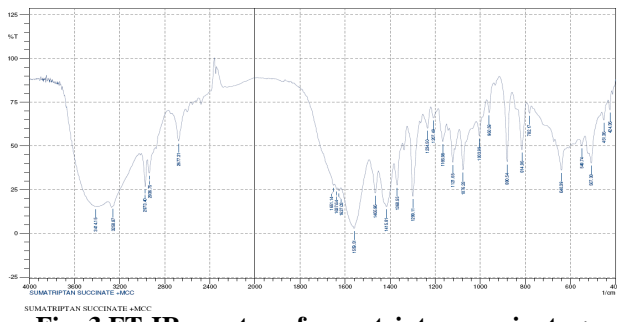


Fig: 3 FT-IR spectra of sumatriptan succinate + Mannitol

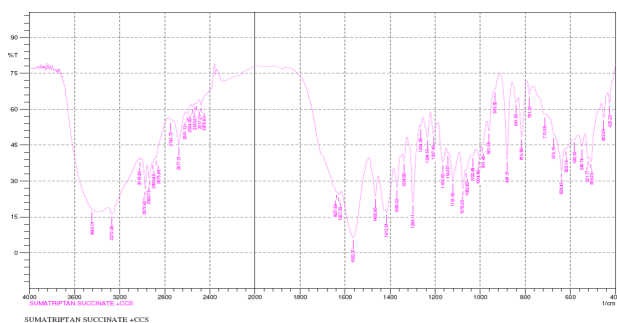


Fig: 4 FT-IR spectra of sumatriptan succinate + MCC

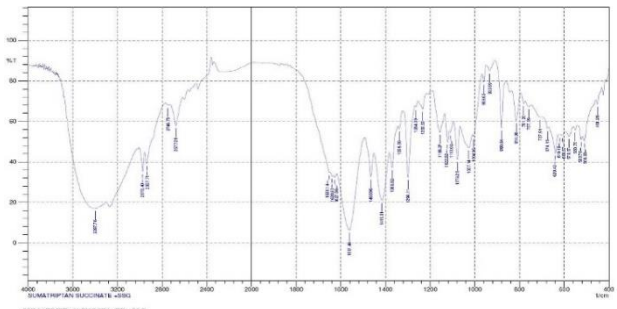


Fig: 5 FT-IR spectra of sumatriptan succinate + CP

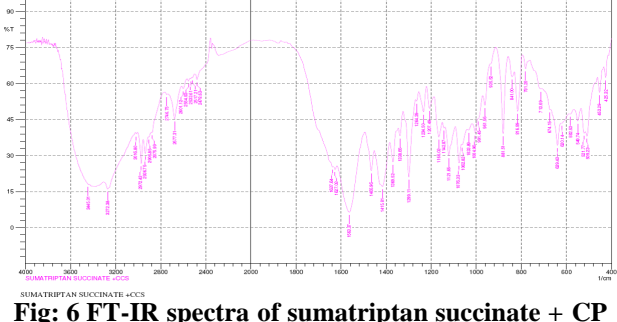


Fig: 6 FT-IR spectra of sumatriptan succinate + CP

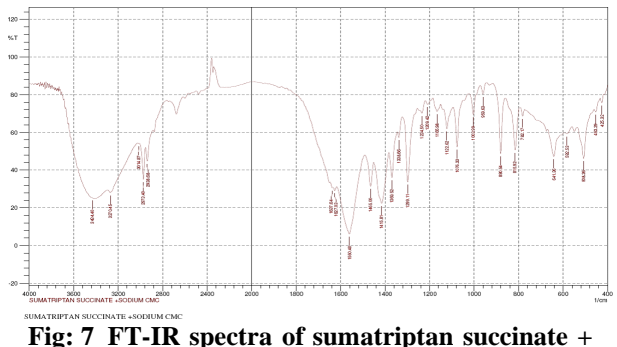


Fig: 7 FT-IR spectra of sumatriptan succinate + Carbopol

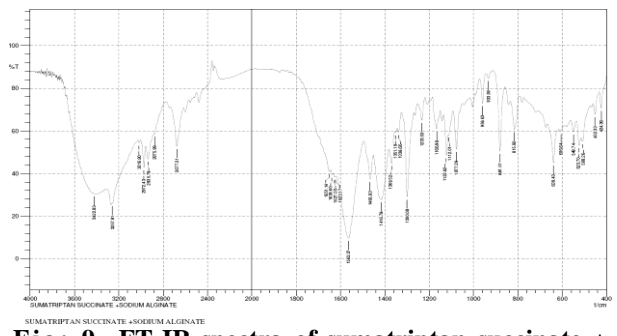


Fig: 9 FT-IR spectra of sumatriptan succinate + Sodium CMC

Table 1: FT-IR spectra of sumatriptan succinate + Mg

IR Spectra	Peaks of functional groups [wavelength (cm ⁻¹)]					
	N-H _{def}	O-H _{str}	C-C _{str} alkanes	C-H _{def} alkenes	S=O	C-H _{def} aromatic
Drug	1561-1651	1415	814-1299	959	1338	782-880
MCC	1559-1651	1415	814-1299	960	1338	782-880
CP	1561-1638	1415	814-1298	959	1338	782-880
CCS	1563-1637	1415	816-1299	935	1338	782-880
SSG	1561-1651	1415	814-1299	959	1338	782-880
Carbopol	1559-1636	1415	814-1299	959	1338	782-880
Sod. CMC	1560-1637	1415	815-1299	959	1338	782-880
Sod. Alginate	1563-1651	1416	815-1300	959	1338	782-881
Mannitol	1560-1650	1415	815-1299	960	1338	783-880
Mg. Stearate	1561-1687	1415	815-1298	961	1338	782-880
SSG	1561-1651	1415	814-1299	959	1338	782-880

Table 2: Evaluation of ODT for formulations (F1 – F9)

Formulation	Hardness ^a (kg/cm ²)	Friability ^b (%)	Weight ^c (mg)	Thickness ^a (mm)	Drug content ^d (%)
F1	3.0±0.17	0.25	201±0.59	3.9±0.05	97.2±0.62
F2	3.1±0.20	0.23	198±0.63	4±0.02	97.72±0.23
F3	3.2±0.18	0.26	201±0.45	3.7±0.07	98.4±0.34
F4	3.0±0.15	0.24	202±0.88	3.8±0.10	97±0.56
F5	3.2±0.16	0.28	203±0.56	3.9±0.03	98.44±0.49
F6	3.1±0.22	0.32	198±0.74	3.9±0.06	100.8±0.27
F7	3.2±0.24	0.27	201±0.67	3.8±0.15	97.2±0.63
F8	3.0±0.22	0.29	201±0.77	3.9±0.03	98.4±0.56
F9	3.1±0.16	0.24	203±0.86	4±0.01	99.32±0.37

a = 6 tablets, b = 33, c = 20, d=10

Table 3: Evaluation of ODT for formulations (F10 – F18)

Formulation	Hardness ^a (kg/cm ²)	Friability ^b (%)	Weight ^c (mg)	Thickness ^a (mm)	Drug content ^d (%)
F10	3.1±0.14	0.31	200±0.91	3.8±0.11	97.08±0.36
F11	3.0±0.16	0.33	201±0.58	3.6±0.04	98.4±0.52
F12	3.2±0.21	0.27	199±0.62	3.6±0.08	99.08±0.48
F13	3.1±0.17	0.29	202±0.84	3.6±0.07	99.4±0.49
F14	3.2±0.23	0.26	203±0.90	3.7±0.05	101.92±0.27
F15	3.0±0.22	0.28	201±0.73	3.6±0.05	97.20±0.47
F16	3.3±0.15	0.30	200±0.75	3.9±0.06	96.76±0.38
F17	3.2±0.15	0.25	201±0.56	3.7±0.12	98.82±0.43
F18	3.2±0.18	0.27	200±0.78	3.9±0.08	100.72±0.61

a = 6 tablets, b = 33, c = 20, d=1

Table 4: Evaluation of ODT for formulations (F1 – F9)

Formulation	Disintegration time ^a (sec)	Wetting time ^a (sec)	Water absorption ratio ^a (%)	In vitro dispersion time ^a (sec)
F1	19±0.54	15±0.23	52±0.42	17±0.79
F2	16±0.63	12±0.47	56±0.47	15±0.82

F3	12±0.48	10±0.35	59±0.78	11±0.64
F4	28±0.57	19±0.32	49±0.13	23±0.63
F5	23±0.72	14±0.49	55±0.27	19±0.71
F6	18±0.41	16±0.28	50±0.17	16±0.92
F7	34±0.68	25±0.16	47±0.32	28±0.87
F8	26±0.43	20±0.25	51±0.47	21±0.83
F9	22±0.60	17±0.51	53±0.92	19±0.75

a = 6 tablets, b = 33, c = 20, d=10

Table 5: Evaluation of ODT for formulations (F10 – F18)

Formulation	Disintegration time ^a (sec)	Wettingtime ^a (sec)	Water absorption ratio ^a (%)	<i>In vitro</i> dispersion time ^a (sec)
F10	25±0.33	48±0.46	45±0.21	24±0.40
F11	34±0.49	54±0.48	42±0.30	28±0.64
F12	45±0.51	52±0.35	40±0.76	41±0.61
F13	58±0.27	58±0.43	34±0.15	53±0.52
F14	43±0.32	46±0.54	38±0.37	42±0.43
F15	39±0.29	33±0.32	41±0.74	30±0.45
F16	48±0.47	36±0.29	33±0.48	38±0.33
F17	52±0.30	40±0.38	36±0.35	46±0.67
F18	59±0.37	44±0.28	42±0.27	48±0.58

a = 6 tablets, b = 33, c = 20, d=10

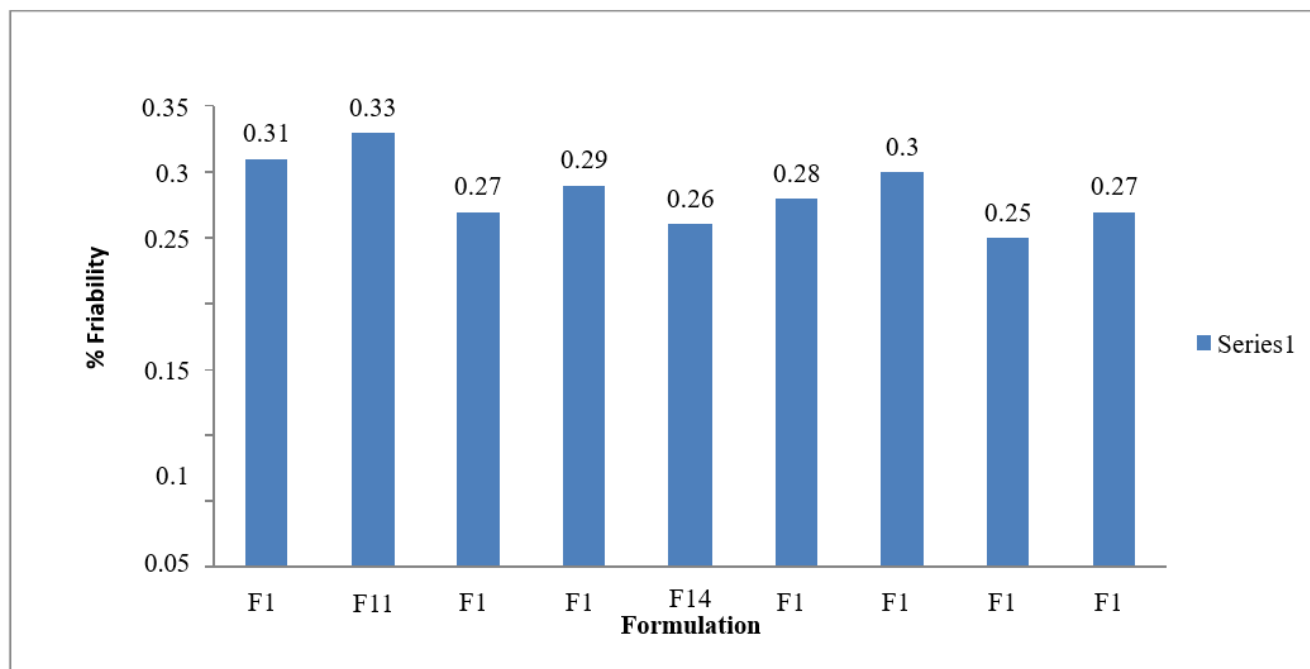


Figure 11: Bar graph comparison between friability for formulations (F10- F18)

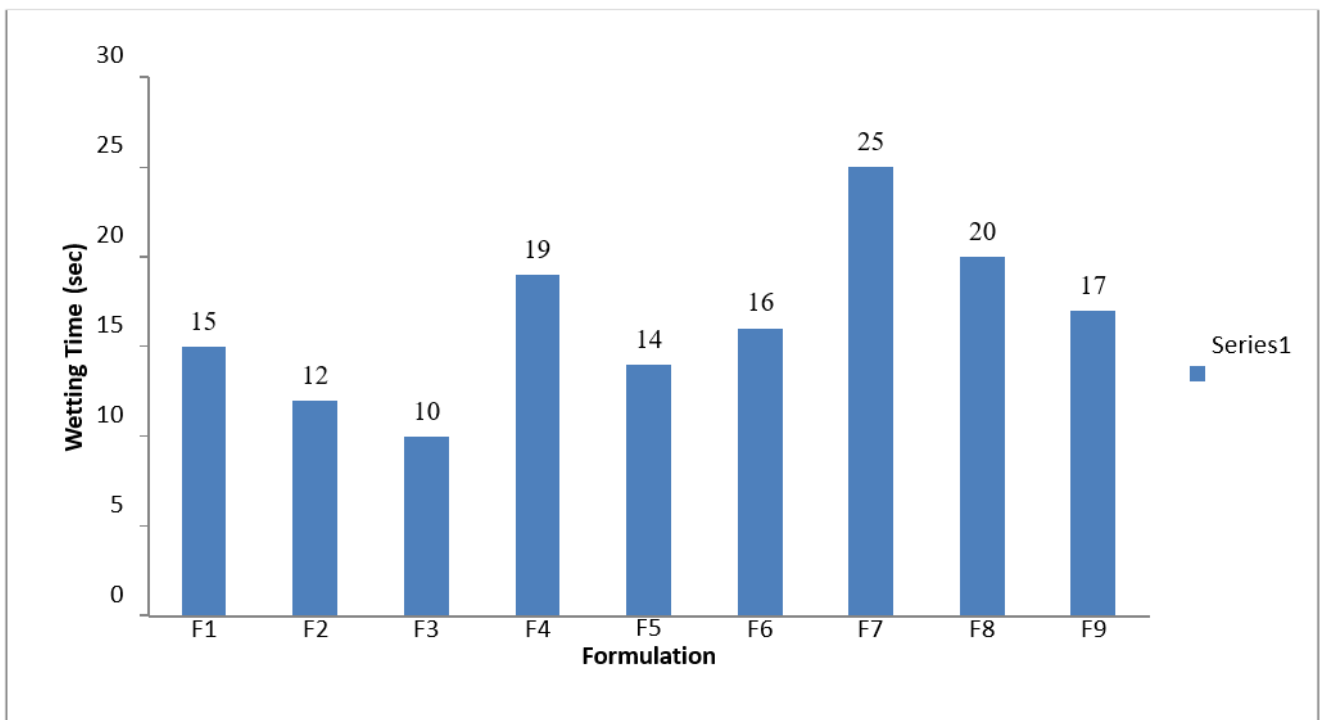


Figure 12: Bar graph comparison between wetting time for formulations (F1- F9)

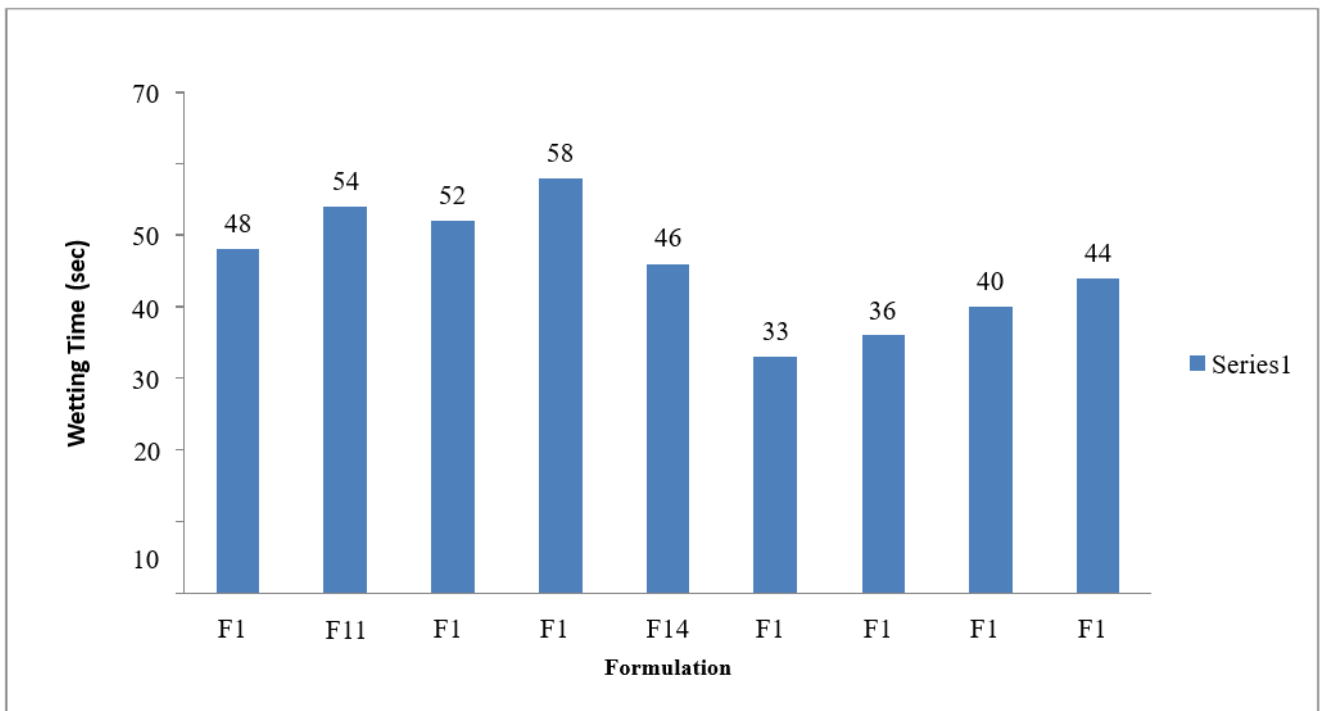


Figure 13: Bar graph comparison between wetting time for formulations (F10- F18)

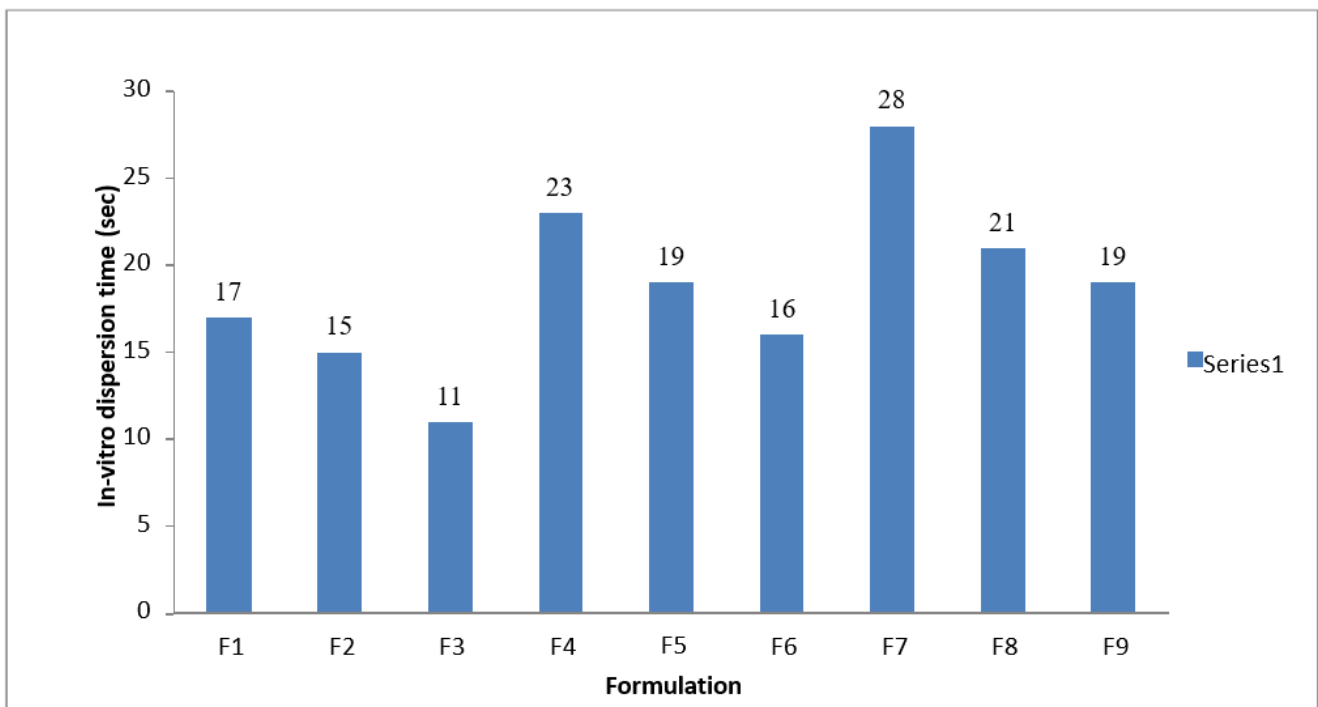


Figure 14: Bar graph comparison between In-vitro dispersion time for formulations (F1- F9)

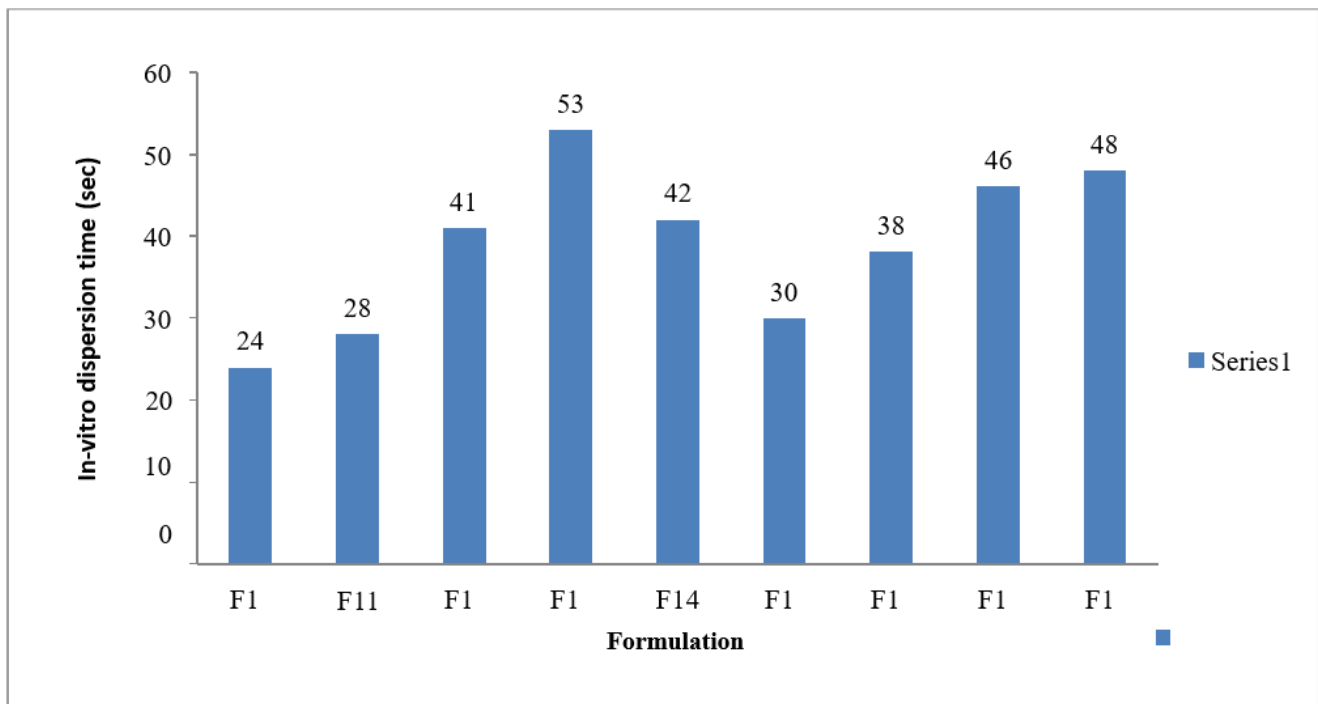


Figure 15: Bar graph comparison between In-vitro dispersion time for formulations (F10- F18)

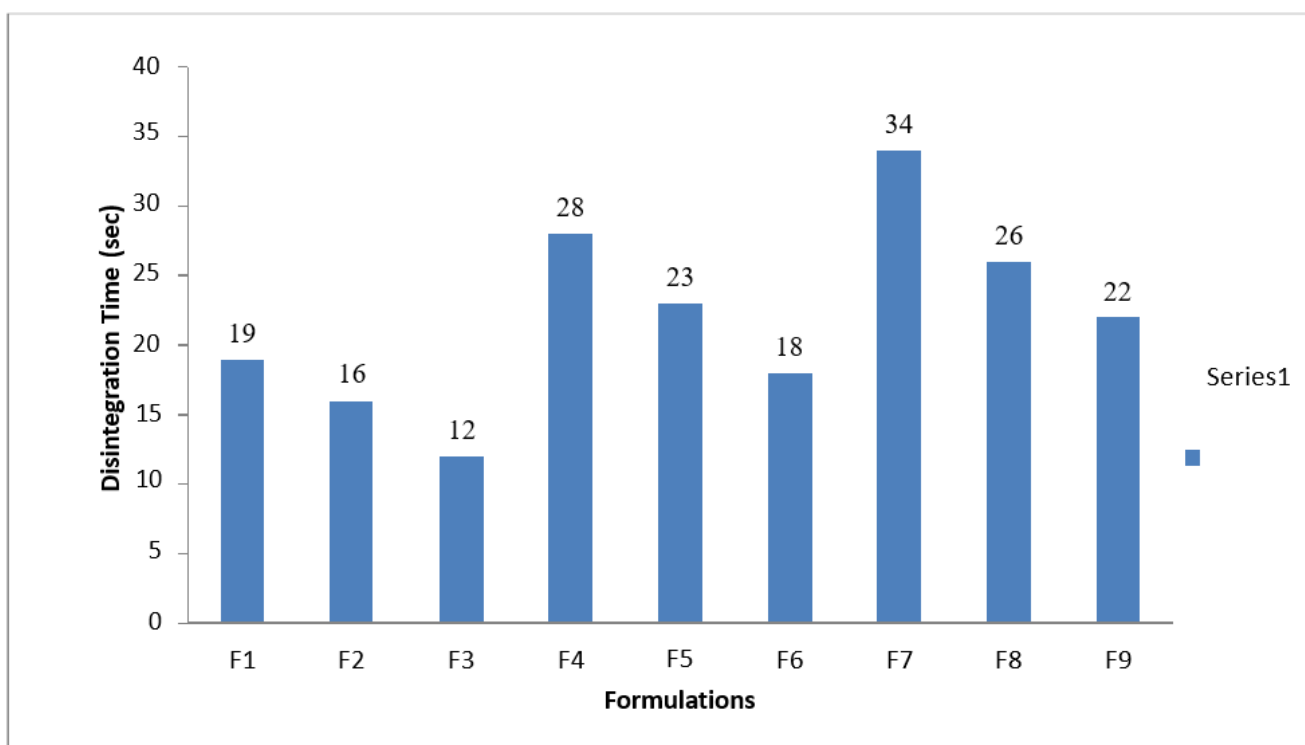


Figure 16: Bar graph comparison between Disintegration time for formulations (F1- F9)

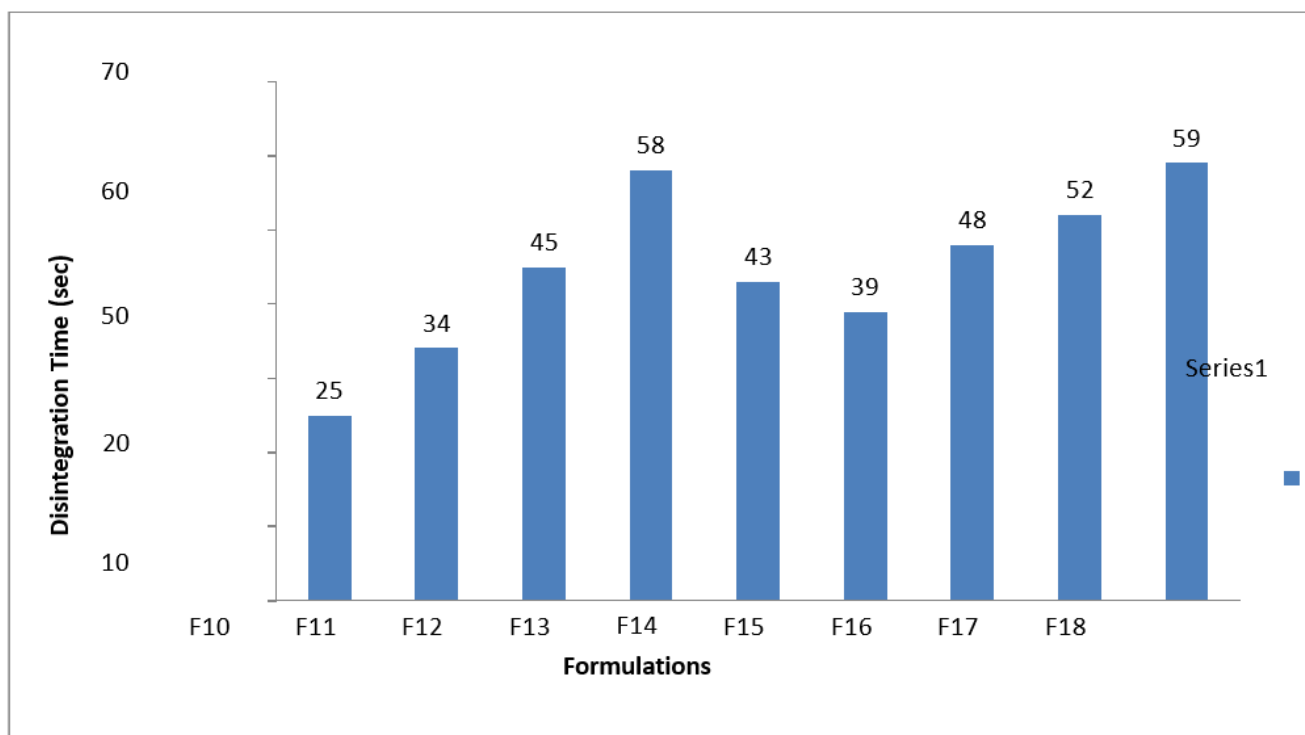


Figure 17: Bar graph comparison between Disintegration time for formulations (F10- F18)

Table 6: Cumulative % drug release for formulations (F1 – F9)

Cumulative % drug release									
Time	F1	F2	F3	F4	F5	F6	F7	F8	F9
2 Min	55.81±0.89	58.11±0.98	63.69±0.52	48.4±0.53	51.59±0.55	62.71±0.65	45.93±0.88	50.86±0.61	56.58±0.65

4 Min	68.4±0.32	72.01±0.27	74.65±0.58	57.28±1.0	62.12±0.54	71.97±0.56	55.74±0.49	61.23±0.34	64.72±0.53
6 Min	71.73±0.46	80.75±0.65	82.38±0.46	72.58±0.54	76.74±0.63	81.92±0.77	71.89±0.74	73.5±0.44	77.51±0.50
8 Min	82.13±0.72	85.06±0.98	88.82±0.58	79.06±0.67	85.33±0.89	86.45±0.83	76.83±0.89	82.15±0.87	84.23±0.55
10 Min	91.7±0.93	94.58±0.57	96.96±0.54	88.51±0.75	92.54±0.84	93.12±0.63	85.74±0.40	87.11±0.33	89.02±0.74

n=6

VI. DISCUSSIONS

The FT-IR spectroscopy displays the characteristic peaks corresponding to the functional groups present in sumatriptan succinate. The peaks in the IR spectra of sumatriptan succinate were not impacted and were clearly detected, along with super disintegrants, simple disintegrants, and other excipients. The spectrum characteristics of the medication and the excipients are presented in Table 7 and Figure 2-11, respectively. The absence of any chemical incompatibility between the pure medication and the excipients was confirmed by the lack of variation in the position of the absorption bands.

Determination of λ_{max}

The synthetic drug sample (sumatriptan succinate) was analyzed using a UV-2450 Shimadzu spectrophotometer to perform UV scanning. The wavelength maxima was determined to be 226nm. Since it aligns with the usual values, it has been verified as sumatriptan succinate.

Development of calibration curve with 6.8pH phosphate buffer

The UV scanning of the solution revealed a peak absorbance at 226nm, leading to the development of the calibration curve at this specific wavelength. The calibration curve exhibited a linear relationship within the concentration range of 2 - 10µg/ml. The calibration curve is presented in Table 3 and Figure 1.

EVALUATION OF TABLETS:

Hardness test

The utilization of super disintegrants resulted in hardness values ranging from 3.0±0.15 kg/cm² to 3.2±0.24 kg/cm² for formulations (F1-F9), as indicated in Table 8. The use of basic disintegrants resulted in hardness values ranging from 3.0±0.16 - 3.3±0.15 kg/cm² for formulations F10 - F18, which were nearly identical (Table 9).

There is no discernible difference in hardness between tablets containing superdisintegrants and tablets containing basic disintegrants. They fall inside the allowed range.

Test for measuring variations in weight

The pill passed the weight variation test, as the average percentage weight fluctuation remained within the allowed limit of 7.5% stipulated by the Pharmacopoeia. The measured value varied between 198±0.63 mg and 203±0.90 mg. The tablets displayed uniform weight with negligible variation, as shown in Table 8 and 9.

Friability test

The friability values were found to be within the limit (0.5 - 1%). The above evaluation parameter showed no significant difference between F1-F18 formulations, details were given in (Table.8, 9) and comparative profile in (Figure.12, 13).

Drug content uniformity

The drug concentration in all formulations using superdisintegrants was determined to be between 97±0.56% and 100.8±0.27%. The activity fell within the prescribed IP restrictions. The drug composition of all batches is presented in Table 8. The drug concentration in all formulations using basic disintegrants ranged from 96.76±0.38% to 101.92±0.27%. The drug content results for all batches are displayed in Table 9.

Wetting time

The experiment replicates the interaction between saliva and the tablet to demonstrate the absorption of water by the tablet and its subsequent saturation. This indicates that the wetting process occurred quickly in nearly all of the formulations. This phenomenon may be attributed to the potential for expansion followed by rupture, as well as the ability to absorb water, which ultimately leads to swelling. The utilisation of superdisintegrants resulted in wetting time ranging from 10±0.35 to 25±0.16 seconds. The data presented in Table 10 and Figure 14 demonstrate that crospovidone formulations have a shorter wetting time compared to crosscarmellose and sodium starch glycollate formulations. Wetting time for basic disintegrants ranged from 33±0.32 to 58±0.43 seconds. The data presented in Table 11 demonstrates that carbomer (carbopol 940) formulations exhibit shorter wetting times compared to those of sodium CMC and sodium alginate. The comparative profile is depicted in Figure 15. The wetting time was reduced when superdisintegrants were used, as compared to the formulation containing ordinary disintegrants. Due to the presence of superdisintegrants, the substance disintegrates rapidly because of the wicking and swelling features of these superdisintegrants.

Water absorption ratio

The water absorption ratio is a crucial factor for determining the disintegrants' capacity. The tablet undergoes water absorption, resulting in a loss of structural integrity. The use of superdisintegrants resulted in a water absorption ratio ranging from 47±0.32 to 59±0.78 (Table 10). The water absorption ratio of the simple disintegrants was determined to be within the range of 36±0.35 - 45±0.21 (Table 11). This demonstrates that all the formulations exhibit excellent water

absorption capacity and can readily breakdown in the oral cavity within a brief timeframe, hence enhancing bioavailability. The utilisation of superdisintegrants resulted in a higher water absorption ratio in comparison to the formulation using only simple disintegrants.

In-vitro dispersion time

The in vitro dispersion time is determined by the duration required for achieving a homogeneous dispersion. The in vitro dispersion time of superdisintegrants ranged from 11 ± 0.64 to 28 ± 0.87 seconds. The results indicated that the in vitro dispersion duration of F1, F2, and F3 formulations was superior than that of F4, F5, F6, F7, F8, and F9 formulations, as shown in Table 10. This comparison is also depicted in Figure 16.

The dispersion time in vitro, using basic disintegrants, ranged from 24 ± 0.40 to 53 ± 0.52 seconds. The results indicated that the in vitro dispersion duration of formulations F10, F11, and F12 is superior to that of formulations F13, F14, F15, F16, F17, and F18, as shown in Table 11. This comparative profile is also depicted in Figure 17. The use of superdisintegrants resulted in a shorter dispersion time compared to the formulation with ordinary disintegrants.

In-vitro Disintegration test

A disintegration test was conducted using a modified dissolve equipment. The results indicate that formulations containing 1.5%, 3%, and 6% of SSG exhibited longer disintegration times of 34, 26, and 22 seconds, respectively. The disintegration time of F1, F2, and F3 formulations with 1.5%, 3%, and 6% CP concentrations respectively is 19, 16, and 12 seconds. These disintegration times are much shorter compared to the disintegration times of F4, F5, F6, F7, F8, and F9 formulations as shown in Table 10. This is also evident in the comparative profile displayed in Figure 18. The disintegration test results for formulations containing 2%, 4%, and 6% sodium alginate indicated significantly longer dissolving times of 48, 52, and 59 seconds, respectively. The findings indicated that the disintegration time of F10, F11, F12 formulations containing 2%, 4%, and 6% carbomer (carboplo 940) respectively, were 25, 34, and 45 seconds. These results demonstrate that these formulations have a significantly shorter disintegration time compared to F13, F14, F15, F16, F17, and F18 formulations, as shown in Table 11 and Figure 19. The incorporation of superdisintegrants resulted in a reduced disintegration time compared to the formulation containing only simple disintegrants.

In-vitro Dissolution studies

The dissolution process is conducted using a USP apparatus type-2 at a rotation speed of 50 revolutions per minute in 900 millilitres of dissolution media (phosphate buffer with a pH of 6.8) for a duration of 10 minutes. After 10 minutes, the formulation created using the direct compression method with 6% crospovidone releases practically the entire amount of the medicine ($96.96\pm 0.54\%$). Similarly, the formulation with 2%

carbomer (carbopol 940) releases $94.83\pm 0.52\%$ of the drug. The percentage of medication release for all formulations can be seen in Table 12 and 13, while the comparative release profile is displayed in Figure 20 to 28. The utilisation of superdisintegrants resulted in a greater drug release in comparison to the formulation including basic disintegrants. Crospovidone and carbopol 940 provide higher drug release compared to other formulations of superdisintegrants and ordinary disintegrants, respectively. When compared to other superdisintegrants, carbopol at a concentration of 2% exhibits a similar release profile. However, at greater concentrations, it further decreases the release profiles of the medication due to its gelling property.

VII. CONCLUSION

The aforementioned findings indicate that the developed orally disintegrating tablets containing sumatriptan succinate shown favourable physical characteristics and swiftly disintegrated without impacting the release pattern. Moreover, these tablets proved to be very efficacious for elderly and paediatric patients. The comprehensive findings revealed that the formulation incorporating crospovidone at a concentration of 12% exhibited a superior performance compared to other formulations comprising superdisintegrants. Additionally, the formulation using Carbopol at a concentration of 2% demonstrated a higher efficacy compared to formulations consisting of basic disintegrants such as cabomer (at concentrations of 4% and 6%), Sod. CMC, and Sod. Alginate. They meet all the requirements for oral disintegrating pills. The direct compression procedure is a straightforward, consistent, and strong method for preparing orally disintegrating tablets of sumatriptan succinate and other anti-migraine medications. Carbopol can function as a superdisintegrant when used at a lower dose (2%). However, at larger concentrations, it can impede the release of the medicine due to its gelling tendency.

REFERENCES

- [1] Awuchi, C. G., Ondari, E. N., Ogbonna, C. U., Upadhyay, A. K., Baran, K., Okpala, C. O. R., ... & Guiné, R. P. (2021). Mycotoxins affecting animals, foods, humans, and plants: Types, occurrence, toxicities, action mechanisms, prevention, and detoxification strategies—A revisit. *Foods*, 10(6), 1279.
- [2] Saha, P., Nyarko, R. O., Lokare, P., Kahwa, I., Boateng, P. O., & Asum, C. (2022). Effect of Covid-19 in Management of Lung Cancer Disease: A Review. *Asian Journal of Pharmaceutical Research and Development*, 10(3), 58-64.
- [3] Saha, P., Kumar, A., Bhanja, J., Shaik, R., Kawale, A. L., & Kumar, R. (2022). A review of

- immune blockade safety and antitumor activity of dostarlimab therapy in endometrial cancer. *International Journal for Research in Applied Sciences and Biotechnology*, 9(3), 201-209.
- [4] Saha, P., Kumar, A., Bhanja, J., Shaik, R., Kawale, A. L., & Kumar, R. (2022). A review of immune blockade safety and antitumor activity of dostarlimab therapy in endometrial cancer. *International Journal for Research in Applied Sciences and Biotechnology*, 9(3), 201-209.
- [5] Singh, Y., Paswan, S. K., Kumar, R., Otia, M. K., Acharya, S., Kumar, D., & Keshamma, E. (2022). Plant & Its Derivative Shows Therapeutic Activity on Neuroprotective Effect. *Journal for Research in Applied Sciences and Biotechnology*, 1(2), 10-24.
- [6] Singh, Y., Paswan, S. K., Kumar, R., Otia, M. K., Acharya, S., Kumar, D., & Keshamma, E. (2022). Plant & Its Derivative Shows Therapeutic Activity on Neuroprotective Effect. *Journal for Research in Applied Sciences and Biotechnology*, 1(2), 10-24.
- [7] Keshamma, E., Paswan, S. K., Kumar, R., Saha, P., Trivedi, U., Chourasia, A., & Otia, M. (2022). Alkaloid Based Chemical Constituents of Ocimum santum & Cinchona Bark: A Meta Analysis. *Journal for Research in Applied Sciences and Biotechnology*, 1(2), 35-42.
- [8] Amle, V. S., Rathod, D. A., Keshamma, E., Kumar, V., Kumar, R., & Saha, P. (2022). Bioactive Herbal Medicine Use for Eye Sight: A Meta Analysis. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 42-50.
- [9] Nyarko, R. O., Roopini, R., Raviteja, V., Awuchi, C. G., Kumar, R., Faller, E. M., ... & Saha, P. (2022). Novel Sars-CoV-2 Variants & Therapeutic Effects. *Journal for Research in Applied Sciences and Biotechnology*, 1(2), 25-34.
- [10] Kumar, R., Saha, P., Keshamma, E., Sachitanadam, P., & Subramanian, M. (2022). Docking studies of some novel Hetrocyclic compound as Acat inhibitors: A meta analysis. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 33-41.
- [11] Patel, R. K., Gangwar, D., Gupta, H., Sharma, N., & Kumar, R. (2023). Plants Alkaloids Based Compound as Therapeutic Potential for Neurodegenerative. *Journal for Research in Applied Sciences and Biotechnology*, 2(2), 14-26.
- [12] Awuchi, C. G., Saha, P., Amle, V. S., Nyarko, R. O., Kumar, R., Boateng, E. A., ... & Asum, C. (2023). A Study of various medicinal plants used in ulcer treatment: A review. *Journal for Research in Applied Sciences and Biotechnology*, 2(1), 234-246.
- [13] Sultana, A., Singh, M., Kumar, A., Kumar, R., Saha, P., Kumar, R. S., & Kumar, D. (2022). To identify drug-drug interaction in cardiac patients in tertiary care hospitals. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 146-152.
- [14] Sultana, A., Singh, M., Kumar, A., Kumar, R., Saha, P., Kumar, R. S., & Kumar, D. (2022). To identify drug-drug interaction in cardiac patients in tertiary care hospitals. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 146-152.
- [15] Nyarko, R. O., Awuchi, C. G., Kumar, R., Boateng, E., Kahwa, I., Boateng, P. O., ... & Saha, P. (2022). Evaluation of cafeteria diet in experimental animal with plant extract of calotropis procera for obesity parameter. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 107-113.
- [16] Subramanian, M., Keshamma, E., Janjua, D., Kumar, D., Kumar, R., Saha, P., ... & Rao, S. (2022). Quality risk management approach for drug development and its future prospectives. *Journal for Research in Applied Sciences and Biotechnology*, 1(3), 166-177.
- [17] Prajapati, A. K., Sagar, S., & Kumar, R. (2022). Past and Current Prospectives of Herbal Product for Skin Care. *Journal for Research in Applied Sciences and Biotechnology*, 1(5), 145-160.
- [18] Butola, K., Bisht, V., & Kumar, R. (2023). Recent Approaches of Ocular Disease and Its Herbal Product Treatment: An Updates. *Journal for Research in Applied Sciences and Biotechnology*, 2(2), 102-114.
- [19] Kohli, A., & Kumar, R. (2023). Role of Antioxidants of Natural Herbs in Management of Male Infertility. *Journal for Research in Applied Sciences and Biotechnology*, 2(1), 55-80.
- [20] Kashyap, N., Kumar, R., Rana, V., Sood, P., & Chauhan, T. (2023). Role of Terpenoids Active Ingredients Targeting for Neuroprotective Agents. *Journal for Research in Applied Sciences and Biotechnology*, 2(3), 22-40.
- [21] Chaudhary, H., Sagar, S., Kumar, R., Bisht, V., & Butola, K. (2022). Herbal Essential Oil use as Ulcer Protective Activity: A Systematic Review. *Journal for Research in Applied Sciences and Biotechnology*, 1(5), 86-101.
- [22] Kumar, A., Uniyal, Y., & Kumar, R. (2022). Recent Advancement of Colorectal Cancer and Their Herbal Essential Oil Treatment. *Journal for Research in Applied Sciences and Biotechnology*, 1(5), 133-144.
- [23] Awuchi, C. G., Ondari, E. N., Eseoghene, I. J., Twinomuhwezi, H., Amagwula, I. O., & Morya,

- S. (2021). Fungal growth and mycotoxins production: Types, toxicities, control strategies, and detoxification. *Fungal reproduction and growth*, 100207.
- [24] Raj, R., Kumar, A., Sood, P., Kumar, R., & Rana, V. (2023). Randomized Phase III Trial Comparing Epirubicin/Doxorubicin Plus Docetaxel and Epirubicin/Doxorubicin Plus Paclitaxel as First Line Treatment in Women with Advanced Breast Cancer. *Journal for Research in Applied Sciences and Biotechnology*, 2(3), 55-63.
- [25] Keshri, S., Kumar, R., Kumar, D., Singhal, T., Giri, S., Sharma, I., & Vatsha, P. (2022). Insights Of Artificial Intelligence In Brain Disorder With Evidence Of Opportunity And Future Challenges. *Journal of Pharmaceutical Negative Results*, 10853-10867.
- [26] Kumar, S., Kumar, A., Kumar, R., Kumar, V., Kumar, N., & Tyagi, A. (2022). Phytochemical, Pharmacognostical and Pharmacological Activities of Carica papaya. *International Journal for Research in Applied Sciences and Biotechnology*, 9(2), 310-315.
- [27] Saini, A., Parkash, V., Kumar, V., Gaur, A., & Chirag, H. (2021). Detection of mycotoxins from some micro and macro endophytic ascomycetes fungi. *International Journal of Environment, Agriculture and Biotechnology*, 6(3).
- [28] Upadhyay, J., Sonaji, A. V., Trimbak, K. S., Ganesh, C. S., Pawar, K. V., & Kumar, R. (2024). Role of Herbal Active Compound in Cardiac Failure Treatment. *Journal for Research in Applied Sciences and Biotechnology*, 3(2), 83-102.
- [29] Upadhyay, J., Sonaji, A. V., Trimbak, K. S., Ganesh, C. S., Pawar, K. V., & Kumar, R. (2024). Role of Herbal Active Compound in Cardiac Failure Treatment. *Journal for Research in Applied Sciences and Biotechnology*, 3(2), 83-102.
- [30] Awuchi, C. G., Amagwula, I. O., Priya, P., Kumar, R., Yezdani, U., & Khan, M. G. (2020). Aflatoxins in foods and feeds: A review on health implications, detection, and control. *Bull. Environ. Pharmacol. Life Sci*, 9, 149-155.