ORIGINAL RESEARCH ARTICLE

FORMULATION AND EVALUATION OF FROVATRIPTAN SUCCINATE ORAL MEDICATED JELLIES FOR TREATMENT OF MIGRAINE

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ABSTRACT

The purpose of this study was to create and assess oral medicated jellies containing frovatriptan succinate for the treatment of migraines. A persistent neurological condition, migraine is characterized by severe, recurrent headaches that are accompanied by light, sound, sensitivity. Frovatriptan is a long-half-life selective serotonin receptor agonist that works well for treating acute migraines. However, because of sluggish stomach emptying and first-pass metabolism, traditional pills have a delayed onset. OMJs provide a cutting-edge administration method that guarantees quicker drug absorption and improves patient compliance. Using water-dispersed gelling agents, the heating and congealing method, jellies were made. Their appearance, pH, viscosity (5398–7442 cps), stickiness, homogeneity of content, drug release, and stability were assessed. The physicochemical characteristics of all 17 batches (F1–F17) were excellent, and the drug content ranged from 96.68% to 98.85%. With a 95.45% drug release, optimized batches F3, F13, F14, F15, and F17 demonstrated consistent performance.

Keywords: Medicated Jelly, Frovatriptan Succinate, Gelatin, Pectin, Migraine.

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INTRODUCTION

In recent years, novel drug delivery systems have gained attention for their added therapeutic benefits. Among these, medicated jellies are becoming more and more well-liked for supplying nutraceuticals and active pharmacological ingredients. With a 20% market share in jelly formulations, the United States presently dominates the world market [1]. Compared to conventional dosage forms, medicated jellies have a number of benefits, including being easy to chew, particularly for young and elderly patients; improving compliance due to their soft texture and attractive appearance; relieving xerostomia by promoting saliva; and treating both oral and systemic conditions [2]. Jellies facilitate speedy gastrointestinal entrance or buccal absorption, which speeds up the therapeutic effect [3]. They are especially helpful for those with dysphagia who have trouble swallowing medicines. Carrageenan, pectin, agar, sodium alginate, and gelatin are common gelling agents; pectin is best for acidic medication stability. Japanese Pharmacopeia recommends that medicated jellies be kept at room temperature or in cool, moisture-resistant containers [4].

One of the most incapacitating ailments in the world, headaches, particularly migraines, are widespread neurological disorders that significantly impair quality of life [5]. A recurrent, pulsing headache that lasts 4–72 hours is a common symptom of migraines [6]. Without altering GABA or benzodiazepine pathways, Frovatriptan, a selective 5-$HT_1B/_1D$ receptor agonist, reduces migraines by

narrowing cranial blood vessels and blocking pro-inflammatory neuropeptides.

MATERIALS AND METHODS

Frovatriptan succinate was received as a gift sample from the Chemicea Pharmaceuticals Pvt Ltd, Navi Mumbai. Gelatin and Methyl paraben was received from Analab Fine Chemicals, Mumbai and Pectin and Citric acid was received from Research Lab Fine Chem Industries, Mumbai. All other chemicals and solvents used are of analytical grade and used as procured.

EXPERIMENTAL WORK:

Pre-formulation study

Preformulation is a collection of research investigations that concentrate on a new drug candidate's physicochemical characteristics that may have an impact on the drug's performance and the creation of a dosage form. Preformulation studies cover a variety of research, such as formulation compatibility analysis, stability assessment, and drug characterization. Determining the drug's chemical and physical characteristics, including its solubility, is part of characterization.

1.Physical Evaluation: Color, smell, and appearance are examples of sensory attributes that are perceived by the senses and are referred to as Physical evaluation in APIs. These characteristics can affect patient compliance and are crucial for quality control.

Table I : Organoleptic properties of drug

Physical Evaluation	Observation
Color	White to off-white
Odour	Odourless
Description	White to off-white powder

2.Solubility Study: The capacity of a material to dissolve in a solvent and create a solution is known as solubility. Fill each sterile, labeled test tube with the appropriate amount of medication. After adding each solvent to a test tube and shaking it, the solution's clarity was recorded.

3.Determination of Melting Point: The melting point is the temperature at which a pure liquid and solid are in equilibrium. Often called normal melting points, it is actually believed to be an equilibrium combination at an atmospheric external pressure. The melting temperature was then recorded when the capillary tubes were examined

4.Calibration curve of UV- Visible Spectrophotometer: A phosphate buffer with a pH of 6.8 was used to create a calibration curve. To create a 100 µg/mL stock solution, a 10 mg sample of the medication was dissolved in a small amount of buffer, sonicated, and then diluted to 100 mL. By diluting 0.2–1.2 mL aliquots of the stock with buffer to 10 mL, working solutions ranging from 2–12 µg/mL were created. Each solution's absorbance was determined using a UV-Vis spectrophotometer set to 222 nm.[7]

5.FTIR Spectroscopy study: A Shimadzu IR Affinity-1S FT-IR spectrophotometer (Japan) was used to acquire FTIR spectra. The drug and a 1:1 molar mixture with KBr were compressed into discs to create the samples, which were then scanned over an area of 4000–400 cm^{-1}. Drug-excipient compatibility was evaluated using pre-formulation stability studies using FTIR analysis. To find any interactions and choose the best excipients for a stable formulation, the spectra of the pure medication and its physical mixes with excipients were compared.

6.Physical description: Frovatriptan Succinate: White to off-white powder

Table No. II : Excipients and Properties

Sr.No.	Excipient	Property
1	Gelatin	Gelling agent
2	Pectin	Gelling agent
3	Citric Acid	pH adjuster, saliva stimulant
4	Methyl Paraben	Preservative
5	Stevia	Sweetner
6	Glycerin	Humectant
7	Flavor	Flavoring Agent
8	Color	Coloring Agent

7.Excipient Compatibility Study: The drug-excipient interaction and compatibility were determined using the physical compatibility test. Extracts for each drug and excipient were combined with the drug and excipient in a 1:1 ratio. Glass vials containing the mixture were stored at room temperature. Samples were assessed for color, appearance, and after 15 days, 1 month and any discrepancies were looked for.

Table No. III: Compatibility study description

Drug + Excipient Ratio	Observation	Result
Drug + Gelatin	No change in appearance and color	Compatible
Drug + Pectin	No change in appearance and color	Compatible
Drug + Citric acid	No change in appearance and color	Compatible
Drug + Methyl paraben	No change in appearance and color	Compatible
Drug + Stevia	No change in appearance and color	Compatible
Drug + All Excipients Mixture	No change in appearance and color	Compatible

FORMULATION DESIGN:

- **Composition of Batches:**

Table No. IV: Batches according to DOE (gm)

Run	Factor 1: Gelatin	Factor 1: Pectin	Factor 1: Citric acid
1	1.5	1	0.055
2	2	0.75	0.08
3	1.75	0.75	0.055
4	1.75	0.5	0.03
5	1.75	0.5	0.08
6	1.5	0.75	0.08
7	1.75	1	0.08
8	1.75	1	0.03
9	2	0.5	0.055
10	2	0.75	0.03
11	1.5	0.75	0.03
12	1.5	0.5	0.055
13	1.75	0.75	0.055
14	1.75	0.75	0.055
15	1.75	0.75	0.055
16	2	1	0.055
17	1.75	0.75	0.055

Table No V: Batches according to DOE (gm)

Batches	Gelatin	Pectin	Citric acid	Methyl paraben	Stevia	API	Glycerin	Flavor	Color	Water
1	1.5	1	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
2	2	0.75	0.08	0.03	0.12	0.0025	0.01	0.01	0.01	qs
3	1.75	0.75	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
4	1.75	0.5	0.03	0.03	0.12	0.0025	0.01	0.01	0.01	qs
5	1.75	0.5	0.08	0.03	0.12	0.0025	0.01	0.01	0.01	qs
6	1.5	0.75	0.08	0.03	0.12	0.0025	0.01	0.01	0.01	qs
7	1.75	1	0.08	0.03	0.12	0.0025	0.01	0.01	0.01	qs
8	1.75	1	0.03	0.03	0.12	0.0025	0.01	0.01	0.01	qs
9	2	0.5	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
10	2	0.75	0.03	0.03	0.12	0.0025	0.01	0.01	0.01	qs
11	1.5	0.75	0.03	0.03	0.12	0.0025	0.01	0.01	0.01	qs
12	1.5	0.5	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
13	1.75	0.75	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
14	1.75	0.75	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
15	1.75	0.75	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
16	2	1	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs
17	1.75	0.75	0.055	0.03	0.12	0.0025	0.01	0.01	0.01	qs

FORMULATION OF ORAL MEDICATED JELLIES:

The heating and congealing procedure was used to make oral medicinal jellies. To create a uniform mixture, gelatin was mixed in distilled water at 95°C and swirled for 20 minutes. Pectin and citric acid were then added at 80–85°C. Then, while swirling constantly, the medication, stevia, and methyl paraben were added. To improve suppleness, distilled water, color, flavor, and glycerin were added. After being thickened in a water bath, the liquid was transferred into plastic molds, allowed to cool at ambient temperature, and then chilled for two hours before being stored. The necessity for balanced concentra tions was highlighted by the effects of variations in gelatin, pectin, and citric acid levels on drug release, matrix density, and viscosity.

Fig No 1: Optimized Formulation

CELL LINE STUDY:

Activity: In Vitro Cell Viability Assay

Cell line: Caco2 (Human Colon Cancer Cell line)

Media:

- RPMI Medium with high glucose (CatNo-11965-092)
- FBS (Gibco, Invitrogen) CatNo-10270106
- Antibiotic- Antimycotic100Xsolution (Thermo fisher Scientific) CatNo-15240062

Procedure: NCCS Pune's Caco-2 (human colon cancer) cells were cultivated in RPMI medium supplemented with 10% FBS. After being seeded in 96-well plates, cells (1×10^4cells/mL) were exposed to sample concentrations (10–100 µg/mL). The controls were 0.2% DMSO in PBS and untreated cells. Plates were incubated for 4 hours after 20 µL of MTT (5 mg/mL) was added following a 24-hour incubation period at 37°C with 5% CO_2. After dissolving formazan crystals in 200 µL DMSO, an ELISA reader was used to assess absorbance at 570 nm. Three separate tests were performed on each sample [10].

Table No. VI: Effects Of 5-Flurouracil against Caco2 Cell line MTT Assay

Sr. no	concentration (µg/ml)		Absorbance (O D)			Cell viability (%)	IC50 (µg/ml)
		1	2	3	Average		
1.	Control	2.516	2.513	2.514m	2.514		
2.	Standard-5FU 10	1.269	1.268	1.267	1.268	50.43	2.81
	40	0.756	0.751	0.752	0.753	29.94	
	100	0.412	0.415	0.416	0.414	16.47	

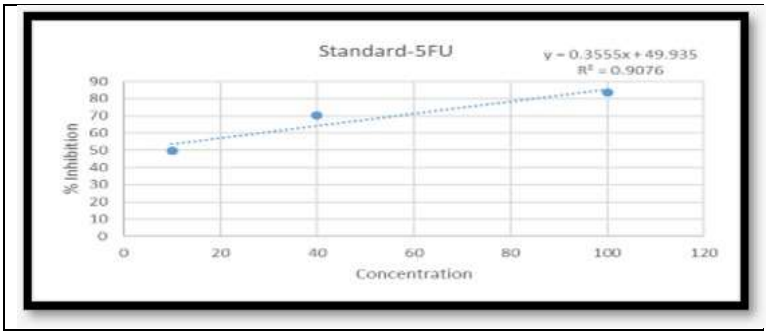

Fig No 2: Calibration Curve of Effect of 5-Flurouracil against Caco2 Cell line MTT Assay

RESULT AND DISCUSSION

1. Calibration curve of UV- Visible Spectrophotometer:

Table No VII: Calibration data of Frovatriptan succinate

Sr. No.	Conc.	Absorbance
1	2	0.322
2	4	0.635
3	6	0.925
4	8	1.238
5	10	1.511
6	12	1.833

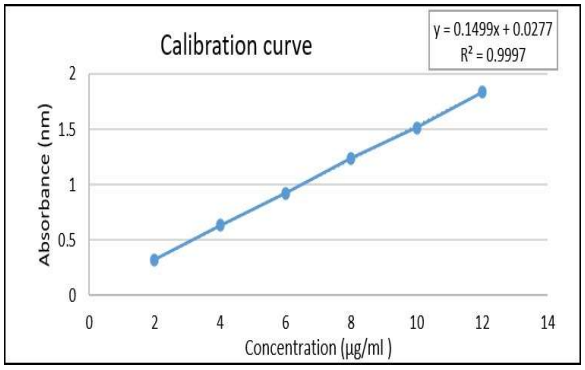

Fig No 3: Calibration Curve of Frovatriptan succinate

2. Fourier infrared spectroscopy (FTIR):

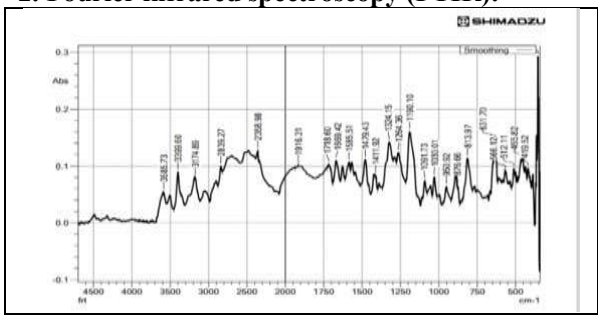

Figure No 4: FTIR Spectrum of Frovatriptan Succinate

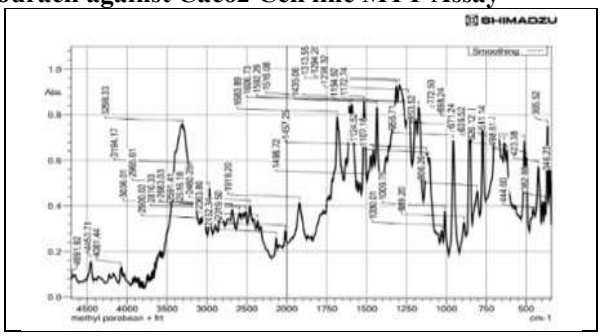

Fig No 5: FTIR Spectrum of Drug + Gelatin

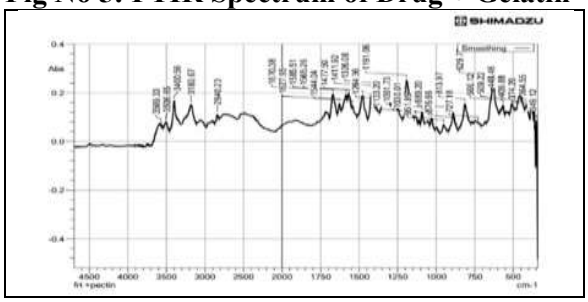

Fig No 6: FTIR Spectrum of Drug+ Pectin

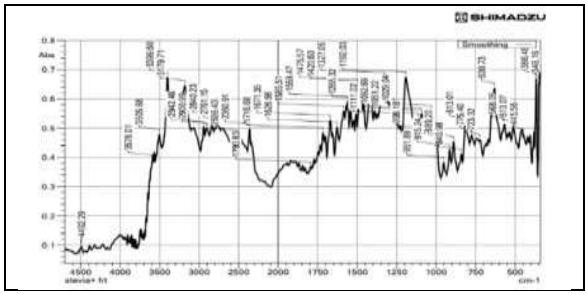

Fig No 7: FTIR Spectrum of Drug + CA

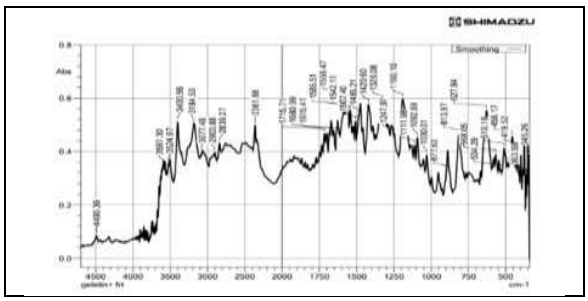

Fig N0 8: FTIR Spectrum Drug + MP

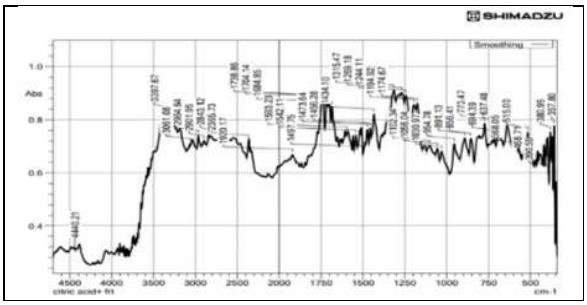

Fig No 9: FTIR Spectrum of Drug +Stevia

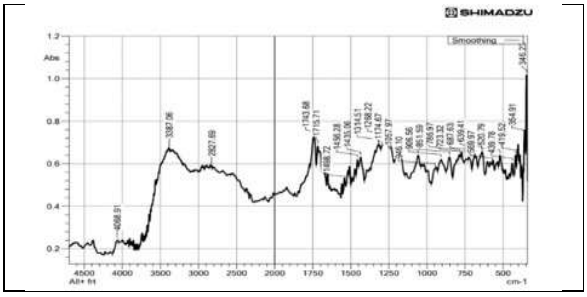

Fig No 10: FTIR Spectrum of Drug +All

3. Differential Scanning Calorimetry (DSC): A crucial method for evaluating the thermal stability of medicinal substances like Frovatriptan is differential scanning calorimetry.

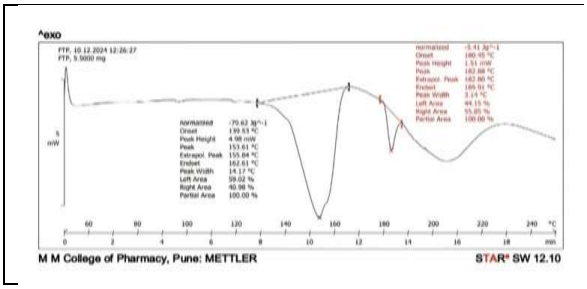

Fig No 11: DSC of Drug

4. Evaluation of Oral Medicated Jellies: Oral medicated jellies containing Frovatriptan were evaluated for quality, stability, and patient acceptability. To guarantee compatibility and integrity, important factors were evaluated, including color, clarity, texture, consistency, pH, viscosity, stickiness, grittiness and syneresis. Weight fluctuation validated proper dosage and UV-Vis spectrophotometry was used to assess the drug concentration. The formulation's effectiveness, stability and patient compliance were demonstrated through in vitro drug release in phosphate buffer, which mimicked gastrointestinal circumstances.

- **Physical Appearance:** Color, texture, clarity, and consistency were all considered when evaluating medicated jelly. In terms of patient acceptance and compliance, these examinations are crucial. [11]
- **Stickiness and Grittiness:** After gently rubbing the jelly sample between two fingers, the product's texture was assessed visually to determine how sticky and gritty the medicated jelly was. [12]
- **PH:** The pH of the formulation affects the oral jellies' stability and flavor. A digital pH meter was used to measure the generated jellies' pH. The pH was measured after 0.5 g of jelly was dissolved in 50 mL of distilled water to create a 1% solution. [13]
- **Viscosity:** Using a Labman digital rotating viscometer based on spindle torque resistance, the viscosity of the oral medicinal jellies was determined. Once the sample had reached room temperature, a suitable spindle was submerged without coming into contact with the bottom or sides of the beaker. Following the viscometer principle, the spindle was turned at a steady pace after stabilizing and the viscosity was measured. [14]
- **Weight Uniformity:** To guarantee precise dosage, the jellies' weight consistency was evaluated. An analytical balance was used to weigh each of the ten jellies separately and the average weight and percentage change were determined. Consistent fill weight across all units was verified by this test.[15]
- **Syneresis:** At room temperature, syneresis was not observed, most likely as a result of the cosolute's binding of free water. Syneresis, which involves the contraction of the jelly mixture as the liquid is released while being stored, is caused by a lower

concentration of the gelling ingredient. For a full day, each formulation was kept at room temperature and observed for indications of syneresis.[16]

- **In-vitro Dissolution Study:** Using a USP paddle device and 900 mL of pH 6.8 phosphate buffer, an in-vitro dissolving research was carried out at 37 ± 0.5°C and 100 rpm. To maintain sink conditions, 5 mL samples were taken out and replaced with new buffer at 5-minute intervals for a total of 30 minutes. at ascertain the drug content and compute the percentage of drug release, samples were examined using a UV spectrophotometer set at 222 nm. [17]
- **Drug content:** Ten jellies were removed, crushed, and jellies equal to 10 mg of the The medication was dissolved in 100 ml of a volumetric flask with a pH buffer of 6.8. in order to determine the drug content. The final volume was adjusted to the appropriate level. After an appropriate dilution, a UV/visible double beam spectrophotometer was used to measure absorbance at 222 nm. [18]
- **Antimicrobial study:** In order to identify the microbial composition of jellies, these investigations are crucial. Examining the jellies' ability to cultivate diseases such as E. coli, S. aureus, and P. aeruginosa on a particular medium is crucial.
- **Moisture content:** The loss on drying method was used to calculate the moisture content. After preheating the hot air oven to 30°C, the jelly's initial weight was noted. After the samples were dried in the oven, their ultimate weight was determined. The percentage of moisture loss was computed using following formula [19]

%Drying Loss = [W1-W2] * 100 W1

- **Stability study:** Examinations of the generated jelly's stability at room temperature (25 °C ± 5 °C). For three weeks, the formulations were examined for changes in physical properties including pH and appearance as part of the stability studies. A medicinal oral jelly that is physically stable should retain its viscosity, color, clarity, taste and odor during the course of its shelf life. By contrasting the initial samples with those under research, stability studies were conducted on the formulations and the findings are compiled.[20]

5. Color: Orange

6. Physical Appearance: Smooth, Lustrous

Table No IX: Results of Stickiness and Grittiness, Viscosity Study, pH, Weight Uniformity and Syneresis

Sr. No	Batches	Stickiness and Grittiness	Viscosity (cP).	pH	Weight (gm)	Syneresis
1	F1	Slightly-Sticky and Non-Gritty	5618 ± 0.79	6.51 ± 0.04	5.1 ± 0.05	No Water Separation
2	F2	Non-Sticky and Slightly-Gritty	6952 ± 1.25	6.24 ± 0.08	5.2 ± 0.11	No Water Separation
3	F3	Non-Sticky and Non-Gritty	6565 ± 0.55	6.83 ± 0.01	5.0 ± 0.01	No Water Separation
4	F4	Non-Sticky and Non-Gritty	6517 ± 0.98	6.73 ± 0.17	5.3 ± 0.07	No Water Separation
5	F5	Non-Sticky and Non-Gritty	6522 ± 0.72	6.80 ± 0.05	5.0 ± 0.19	No Water Separation
6	F6	Slightly-Sticky and Non-Gritty	5482 ± 0.65	6.32 ± 0.09	5.1 ± 0.04	No Water Separation
7	F7	Non-Sticky and Non-Gritty	6512 ± 0.95	6.51 ± 0.03	5.0 ± 0.06	No Water Separation
8	F8	Non-Sticky and Non-Gritty	6503 ± 0.83	6.45 ± 0.05	5.2 ± 0.05	No Water

						Separation
9	F9	Non-Sticky and Slightly-Gritty	7363 ± 1.21	6.61 ± 0.10	5.0 ± 0.10	No Water Separation
10	F10	Non-Sticky and Slightly-Gritty	6857 ± 1.36	6.73 ± 0.08	5.2 ± 0.14	No Water Separation
11	F11	Slightly-Sticky and Non-Gritty	5398 ± 0.62	6.45 ± 0.03	5.4 ± 0.04	No Water Separation
12	F12	Slightly-Sticky and Non-Gritty	5585 ± 0.78	6.37 ± 0.14	5.3 ± 0.12	No Water Separation
13	F13	Non-Sticky and Non-Gritty	6548 ± 0.41	6.71 ± 0.02	5.0 ± 0.04	No Water Separation
14	F14	Slightly-Sticky and Non-Gritty	6535 ± 0.26	6.65 ± 0.04	5.1 ± 0.02	No Water Separation
15	F15	Non-Sticky and Slightly-Gritty	6512 ± 0.36	6.57 ± 0.06	5.0 ± 0.05	No Water Separation
16	F16	Non-Sticky and Non-Gritty	7442 ± 1.19	6.76 ± 0.07	5.1 ± 0.08	No Water Separation
17	F17	Non-Sticky and Non-Gritty	6529 ± 0.48	6.78 ± 0.03	5.2 ± 0.01	No Water Separation

7. Percent Drug Release Study:

Table No X: % Drug release of Medicated Jellies

Batch	0 min	5 min	10 min	15 min	20 min	25 min	30 min
F1	0	14.56	33.69	51.26	65.68	80.27	89.35
F2	0	13.82	30.11	45.35	61.54	76.73	85.26
F3	0	18.58	39.57	58.76	74.43	84.54	95.45
F4	0	15.87	35.78	54.67	66.92	82.03	91.14
F5	0	16.15	36.13	54.78	67.59	82.03	91.38
F6	0	14.36	33.42	51.12	65.54	80.20	89.11
F7	0	15.58	35.62	54.48	66.32	82.33	91.48
F8	0	15.21	31.57	54.23	66.12	81.42	90.29
F9	0	13.32	30.02	45.14	61.25	75.80	84.22
F10	0	13.76	30.05	45.26	61.44	76.73	85.43
F11	0	14.32	33.25	51.11	65.31	80.21	89.12
F12	0	14.13	33.15	50.86	62.68	79.5	88.50
F13	0	18.14	38.32	58.76	74.43	84.54	95.11
F14	0	18.14	38.32	58.76	74.43	84.54	95.35
F15	0	18.14	38.32	58.76	74.43	84.54	95.19
F16	0	14.21	33.31	51.02	62.71	77.15	85.62
F17	0	18.14	38.32	58.76	74.43	84.54	95.27

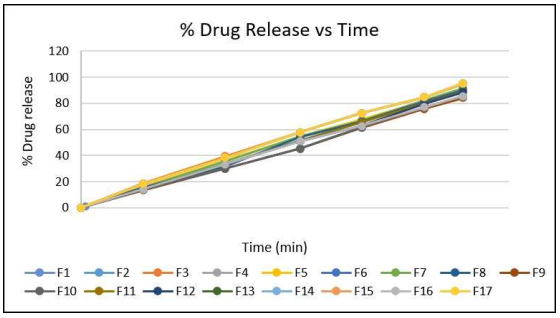

Fig No 12: % Drug release as per time

Aiming for over 90% release for quick migraine treatment, a drug release research was carried out on 17 batches of frovatriptan jelly at intervals of up to 30 minutes. Excellent release (95–96.75%) was demonstrated by batches F3, F4, F5, F7, F8, F13, F14, F15, and F17, most likely as a result of an ideal ratio of plasticizer to gelling agent. Higher viscosity may be associated with batches F1, F2, F6, F9, F10, and F11 having moderate release (91–94%). The somewhat decreased release (\~92%) in batches F12 and F16 may have been caused by formulation changes. The formulation's repeatability was confirmed by

the consistent profiles displayed by the repeated batches (F3, F13, F14, F15, and F17).

8. Percent Drug Content:

Table No XI: % Drug Content of Medicated Jellies

Sr. No	Batches	% Drug Content
1	F1	97.51 ± 0.37
2	F2	96.75 ± 0.79
3	F3	98.85 ± 0.15
4	F4	97.86 ± 0.66
5	F5	97.67 ± 0.51
6	F6	97.38 ± 0.35
7	F7	97.96 ± 0.58
8	F8	97.69 ± 0.45
9	F9	96.68 ± 0.52
10	F10	96.74 ± 0.78
11	F11	97.39 ± 0.34
12	F12	97.12 ± 0.25
13	F13	98.71 ± 0.22
14	F14	98.64 ± 0.34
15	F15	98.52 ± 0.42
16	F16	96.95 ± 0.69
17	F17	98.45 ± 0.60

The drug content analysis of 17 batches of frovatriptan jelly revealed a homogeneous and consistent distribution of API, with values falling between 96.68% and 98.85%, all of which were within acceptable bounds. While optimized batches F3, F13, F14, F15, and F17 demonstrated exceptional consistency (\~98.85%), the majority of batches, including F1, F4, F5, and F7, had content exceeding 97%. Pharmacopoeial criteria were still met by somewhat lower values in F2, F9, and F16. These findings support a carefully monitored formulation procedure that guarantees both safety and therapeutic effectiveness.

9. Antibacterial Study: Using the agar well diffusion method, the antibacterial study sought to determine if the prepared jellies inhibit *E. coli* (ATCC 8739). Zones of inhibition showed antibacterial activity after test substances were incubated for 24 to 48 hours in wells on agar plates. This evaluated the formulation's potential unintended preservative effect.

Table No XII: Results of antibacterial activity

Sample	Concentration	Zone of Inhibition
Control (DMSO)	-	0 mm (no activity)
Streptomycin	1 mg/mL	25 mm (high activity)
Sample FT	100 µL	10 mm (good activity)
Sample FT	200 µL	14 mm (better activity)

Fig No.13: Antibacterial Activity of Oral Medicated Jelly Formulation against *Escherichia coli* ATCC No. 8739

Using the agar well diffusion method, the test verified that sample FT had dose-dependent antibacterial activity against *E. coli*. It displayed 10 mm (100 µL) and 14 mm (200 µL) inhibitory zones, whereas streptomycin displayed a 25 mm zone. The absence of any effect from the control (DMSO) demonstrated that the sample was the cause of the activity and suggested that it have antibacterial qualities at greater doses.

10. Moisture content: Moisture content in jelly formulations was determined using the loss on drying method. To determine moisture loss, jellies were weighed, dried in a hot air oven that had been prepared to 30°C, and then weighed again. Water loss was controlled (0.1–0.2 g) in all 17 batches. The optimized batches (F3, F13, F14, F15, and F17) showed very good water retention and stability with very little moisture loss (~2%). The general stability of the formulation was confirmed by further batches that also stayed within acceptable bounds.

11. Stability study: Examinations of the generated jelly's stability at room temperature (25 °C ± 5 °C). For three weeks, The formulations were examined for changes in physical properties including pH and

appearance as part of the stability studies. A physically stable medicated oral jelly should retain its viscosity, color, clarity, taste, and odor during the course of its shelf life.. By contrasting the initial samples with those under research, stability studies were conducted on the formulations, and the findings are compiled.

Table No XIII: Stability study data of the Optimized formulation

Sr. No.	Days	General appearance	Weight (gm)	Syneresis	pH	Viscosity	Drug content
1	Initial	Non-Sticky and Non-Gritty	5.0 ± 0.01	No Water Separation	6.8 ± 0.01	6565 ± 0.55	98.85 ± 0.15
2	7	No Change	5.0 ± 0.02	No Water Separation	6.8 ± 0.01	6578 ± 0.42	98.85 ± 0.21
3	14	No Change	5.0 ± 0.02	No Water Separation	6.8 ± 0.02	6592 ± 0.38	98.84 ± 0.20
4	21	No Change	5.0 ± 0.04	No Water Separation	6.8 ± 0.03	6620 ± 0.45	98.82 ± 0.14
5	28	No Change	5.0 ± 0.01	No Water Separation	6.7 ± 0.01	6647 ± 0.31	98.72 ± 0.19
6	35	No Change	4.9 ± 0.01	No Water Separation	6.7 ± 0.04	6672 ± 0.24	98.69 ± 0.26

The optimized frovatriptan jelly batch's high physical, chemical, and functional stability was confirmed by a 35-days stability analysis. Good environmental stability was indicated by the weight remaining constant at 5.0 g and the absence of syneresis, grittiness, or stickiness. Changes in viscosity and pH (6.7–6.8) were slight and within tolerable bounds. The drug content remained well within pharmacopeia norms, declining marginally from 98.85% to 98.69%. Overall, throughout the research time, the formulation stayed stable and usable.

12. Results of Cell Line Study:

Table no. XIV: Effects of Sample against Caco2 Cell line by MTT assay

Sr. no	concentration (µg/ml)		Absorbance (O D)			Cell viability (%)	IC50 (µg/ml)
		1	2	3	Average		
1	Control	2.516	2.513	2.514	2.514		
2	Standard-5FU 10	1.753	1.752	1.752	1.752	69.69	61.21
	40	1.426	1.423	1.422	1.423	56.62	
	100	0.905	0.908	0.909	0.907	36.08	

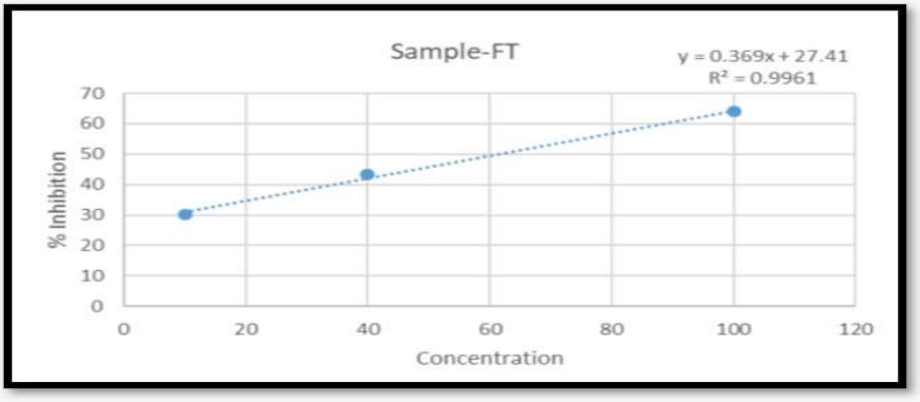

Fig No. 14: Calibration Curve of Effect of Sample against Caco2 Cell line MTT Assay

Sample FT demonstrated dose-dependent cytotoxicity against Caco2 (human colon cancer) cells, according to the MTT assay. Cell viability dropped from 69.69% at 10 µg/mL to 36.08% at 100 µg/mL, and absorbance values showed that larger dosages resulted in greater cytotoxicity. A moderate yet encouraging anticancer activity is shown by an IC_{50} value of 61.21 µg/mL.[21]

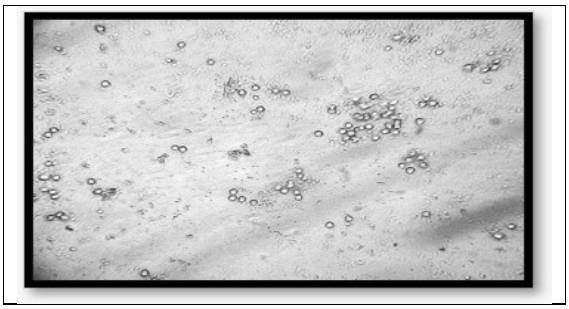

Fig No 15: Control

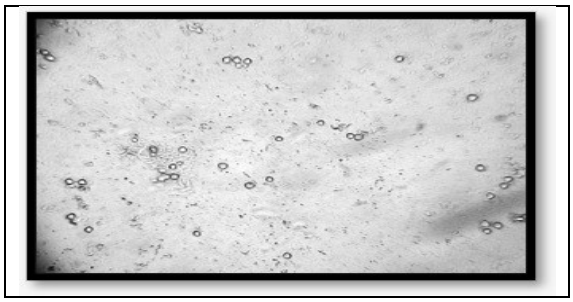

Fig No 16: Standard

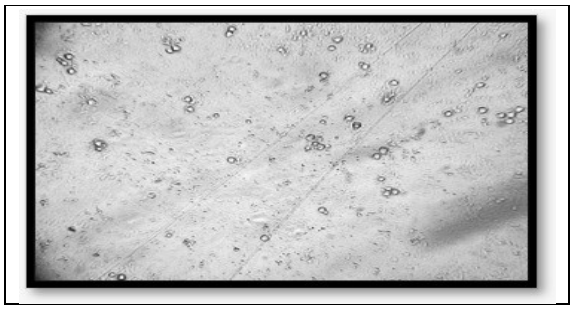

Fig No 17: Sample

The Caco-2 cell line study demonstrates that the Frovatriptan oral medicated jelly formulation is safe and well-tolerated by cells, showing minimal cytotoxicity compared to the standard drug. These results support the biocompatibility of the developed formulation.

CONCLUSION

In order to improve patient compliance and therapeutic results in the treatment of migraines, this study effectively illustrated the viability and efficacy of developing Frovatriptan as an oral medicated jelly. The perfect gelling matrix with the desired texture, stability, and quick drug release was made possible by a combination of gelatin and pectin. Batches F3, F13, F14, F16, and F17, out of the 17 formulations, continuously satisfied pharmacopeial requirements, exhibiting superior physical characteristics, a high drug content (\~98.85), and a rapid drug release within 30 minutes. Over a period of 35 days, stability tests validated the formulation's integrity. Additionally, sample FT demonstrated E. coli -specific dose-dependent antibacterial activity, with significant inhibition at higher doses. Caco-2 cell cytotoxicity assay revealed good biocompatibility with moderate activity (IC_{50} = 61.21 µg/mL) and above 69% cell viability at therapeutic doses. All things considered, this study demonstrates that Frovatriptan oral jelly has the potential to be a quick-acting, patient-friendly dosage form, opening the door for further clinical research and business growth.

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Data Availability: The data supporting the findings of this study are available from the corresponding author upon reasonable request. The accompanying author can provide the data that support the study's conclusions upon reasonable request.

Declaration Of Competing Interest: The authors declare that there are no conflicts of interest.

Consent To Publish: The authors attest that ready give consent to publish the data and conclusions in this study. Both co-author shave given their approval for the paper to be submitted and consents to its publication.

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