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Formulation And Evaluation Of Fast Disintegrating Tablets Of Herbal Powder Extracts For Headache

Dr. Usha D S[1], Jadav Prakruti Kishorchandra[2], Dr. V. Antony Asir Daniel[3], Shraddha Hrishikesh Dingare[4], Kunal Gupta[5], Dr Dipti Phadtare[6], Dr. Sarthak Bhattacharya[7], Selora Agasti[8*]

[1] Department of Pharmacy Practice, KLE college of pharmacy, Rajajinagar,Bengaluru 560010,KLE Academy of Higher Education and Research, Belagavi 590010,Karnataka, Indiaushads3587@gmail.com

[2] Assistant Professor, C. K. Pithawalla Institute of Pharmaceutical Science and Research Surat. prakruti.jadav@ckpipsr.ac.in

[3] Head of the Department, Associate Professor, Department of ECE, Loyola Institute of Technology and Science, Loyola Nagar, Thovalai, Kanyakumari-629302. asirdaniel1984@gmail.com

[4] Assistant Professor, Department QAT, College TMV Lokmanya Institute of pharmaceutical sciences Pune, shraddhadeshpande2@gmail.com

[5] Associate Professor, Eminent college of Pharmaceutical Technology Barasat, Kolkata, West bengal-700126 kunal_gupta1985@gmail.com

[6] Principal, KCT RG Sapkal Institute of Pharmacy, Nashik aditi24aug@gmail.com

[7] Principal, Raigad College of Pharmacy (Aff. to DR BATU) Ta. Mahad Dist. Raigad, Maharashtradr.sarthak.bhattacharya@gmail.com

[8] Indira Gandhi Institution of Pharmaceutical Science, Salia sahi, Ekamra vihar, Bhubaneswarseloraagasti@gmail.com

Corresponding Author:
Selora Agasti ,Indira Gandhi Institution of Pharmaceutical Science Salia sahi ,Ekamra vihar, Bhubaneswar,seloraagasti@gmail.com

ABSTRACT

Oral medication administration is perhaps the most common method of the dosage form. Researchers have been encouraged by recent technological advancements to produce Fast disintegrating tablets (FDTs) to enhance patient compliance and accessibility. The study was designed to evaluate the composition and efficacy of herbal fast disintegrating tablets for headache care. Herbal powder extracts of Salix alba L (White Willow bark), Tinospora cordifolia (Guduchi), Achyranthes aspera (Latjira), Cyprus rotundus (Nagarmotha), and Withania somnifera (Ashwagandha) are produced and processed into fast disintegrating tablets using a super disintegrant including cross povidone, sodium starch glycolate, and micro-crystalline cellulose in various ratios. Several pre-formulation batches (F1-F9) were formed using the direct compression method with various excipient ratios and evaluated pre and post-compression. Weight variation, hardness, friability, thickness, disintegration time, wetting time, content uniformity, in-vitro release, stability study, and IR compatibility were all evaluated on those tablets. According to ICH standards, a stability study was undertaken, and all formulations were determined to be stable. Increased solubility is observed in the UV absorption spectra. F7 and F9 show excellent performance with a disintegration time of 26sec and 24sec, Content uniformity of 98.75 ± 0.04% and 98.65±0.43%, and greater dissolution rate 97.04% and 98.93% at 30 min.

Keywords: *Fast disintegrating tablet, Herbal formulation, Headache, Cross povidone, Superdisintegrants, Disintegration time.*

INTRODUCTION

Fast disintegrating tablets (FDTs) have attracted a lot of attention over the last three decades because of their higher patient compliance, increased solubility, and stability characteristics compared to traditional tablets and capsules. For quick disintegration, FDTs are solid dosage forms potential implementation ingredients. to increase bioavailability and patient compliance, quick dissolving drug delivery methods

are widely employed. A wide range of pharmaceutical and patient requirements are being addressed by new FDT technologies, from improved life-cycle management to comfortable dosing for dysphasic patients in pediatrics, geriatrics, and psychiatry. Because of this, the scientific and industrial communities have been spurred on to develop novel Fast dissolving formulations and technical techniques [1].Fast disintegrating tablets (FDTs) are also known as quick disintegrating, rapid dissolve, fast dissolving, mouth dissolving, quick dissolving, rapimelt, orodispersible, orally disintegrating, effervescent drug absorption system [2].It is estimated that these non-allopathic medical systems are used by more than 70% of India's 1 billion people. The Indian Medications Act currently does not distinguish between herbal drugs and dietary supplements. Many natural medications, on the other hand, have a large body of empirical data to support their efficacy. There is a well-established business that manufactures evidence-based herbals in accordance with pharmacopoeial recommendations. In a number of Institutes/Universities, there has been a significant amount of fundamental and clinical study on medicinal plants and their formulations [3].As the "science of life and longevity" in Sanskrit, Ayurveda is one of the oldest medical systems focused on lifestyle, nutrition and herbs. Ayurveda, Siddha, and Unani, as well as natural goods utilized for their pharmacological activities, have all employed medicinal plants and minerals for thousands of years in various forms. Different powders developed by ayurvedic firms are commonly recommended by ayurvedic doctors [4].

Headache is a continuous symptom in everyone and is an eminent issue in youth and puberty, for what it's worth in adulthood. Headache is originated by cough, sneezing, straining, fever, or sleep; there are unusual signs on assessment and neurological or visual symptoms. An abundance or absence of sleep could cause a headache. Headache is a general and worldwide symptom with a complicated and miscellaneous set of origin. The headache itself could be hurting and disabling aspects that cause substantial levels of incapacity [5, 6]. FDTs were developed in this work to have reasonable mechanical integrity and to disintegrate in the mouth more quickly without water. MCC is utilised as a diluent in tablet formulations to accomplish this purpose. Superdisintegrants like Cross povidone, microcrystalline cellulose (MCC), sodium starch glycolate (SSG), and mixtures of cross povidone, sodium starch glycolate, and microcrystalline cellulose have been used in the formulation of tablets in an attempt to increase the dissolution rate and speed up disintegration. This composition makes use of herbal powder extracts (Table 1). It's a natural remedy for headaches [7].

Plant Name	**Botanical Name**	**Active Constituents**	**Mechanism of Action**	**Reference**
White Willow bark	Salix alba L (Salicaceae)	Salicylic glycosides, salicin, and salicortin	Inhibition of prostaglandins(PGE_2), cyclooxygenase(COX-2)	8, 9, 10
Latjira	Achyranthes aspera (Amaranthaceae)	Linalool, Oleanolic acid glycosides, amino acids ,flavonoids, and saponins	Inhibits phospholipase A, (COX-1, COX-2)	11, 12
Guduchi	Tinospora cordifolia (Menispermaceae)	Tinosporine, isocolumbin, flavonoids, terpenoids, glycosides, and alkaloids	Down-regulation of prostaglandins (PGE_2), and proinflammatory cytokines (IL-1b, IL-6, TNF- α)	13, 14, 15

Nagar-motha	Cyprus rotundus (Cyperaceae)	α-cyperone, salicylic acid, catechin, quercetin,	Inhibition of cyclooxygenase (COX-2), and interleukin (IL-6)	16, 17
Ashwa-gandha	Withania somnifera (Solanaceae)	Withaferin A, withanine, quercetin, kaempferol, and flavonoids	Inhibition of interleukin (IL-6) and tumor necrosis factor (TNF- α)	18, 19

List of commonly recommended Ayurvedic plants in Headache.

MATERIALS AND METHODS

The herbal powder extracts of Salix alba L, Tinospora cordifolia , Achyranthes aspera, Cyprus rotundus, and Withania somnifera was collected from Vital Herbs, Uttam nagar, Delhi, 110059. Cross povidone, Sodium starch glycolate and Microcrystalline cellulose, Citric acid monohydrate, Sodium bicarbonate, Beta-cyclo dextrin, Tartaric acid, Magnesium stearate, and Talc were obtained as gift sample from Loba Chemie Pvt Ltd Mumbai 40002.All other chemicals and reagent was of analytical grade.

Method for Preparation of Herbal Fast Disintegrating Tablets:

Direct compression technique was used to prepare herbal tablets of powder extracts using various concentrations of Microcrystalline cellulose (MCC), Cross povidone, Beta-cyclo dextrin, Sodium starch glycolate (SSG), Magnesium stearate, Sodium bicarbonate, Tartaric acid, Citric acid monohydrate, and Talc. In a glass mortar, the materials were evenly mixed. Drug and other components were well mixed before being squeezed with 0.5-mm punches in an automated tableting machine. [20, 21, 22].

Formula for herbal extracts tablet preparation:

Herbal powder extract	**Quantity in mg**
Salix alba L.	85 mg
Tinospora cordifolia	85 mg
Achyranthes aspera	60 mg
Cyprus rotundus	60 mg
Withania somnifera	60 mg
Total	350 mg

Herbal extracts tablet formula

Formulation of herbal tablet by Direct Compression Method:

It is necessary to conduct a formulation design research in order to determine the most suitable excipients for manufacturing tablets. To test the varied concentrations of Microcrystaline cellulose (MCC), Sodium starch glycolate (SSG), Cross povidone, Beta-cyclo dextrin, Tartaric acid, Citric Acid Monohydrate, and sodium bicarbonate, we made a batch of tablets with varying concentrations of these ingredients. The experimental batches of tablets were made utilising the direct compression technique and various excipients that were generally available at the time.

Ingredient	F1	F2	F3	F4	F5	F6	F7	F8	F9
Extract powder of herbs	350	350	350	350	350	350	350	350	350

Cross povidone	100	100	70	60	60	60	50	50	50
Beta-cyclo dextrin	100	80	-	-	70	-	-	-	-
Sodium starch glycolate	-	-	-	-	70	-	-	-	-
Poly vinyl pyrolidone	-	-	-	-	-	-	-	-	-
Tartaric acid	-	-	-	-	-	70	-	-	-
Citric acid monohydrate	-	-	70	80	-	-	80	75	70
Sodium bi carbonate	-	-	70	70	-	70	80	75	70
Micro crystalline cellulose	50	70	40	40	50	50	40	50	60
Magnesium stearate	1%	1%	1%	1%	1%	1%	1%	1%	1%
Talc	1%	1%	1%	1%	1%	1%	1%	1%	1%
Total	600	600	600	600	600	600	600	600	600

Fast-disintegrating tablet ingredients include

After dissolving 100mg of powdered herbal extract in 100ml of water, the final concentration was determined. Aliquots of the stock mixture were diluted to create concentrations between 100 and 500 µg/ml by diluting them with 0.01N HCl. At wavelengths between 200 and 400 nanometers, the absorption peaks were found [23].The final solution, which contained 100 µg/ml, was scanned at wavelengths between 200 and 400 nanometers. The analytical wavelength for lambda max was determined to be 281nm. Preformulation characteristics such as angle of repose, bulk density, tapped density, Hausner ratio, Carr's index, and FTIR investigations were performed on the herbal powder mix. [24, 25, 26].

Hardness test: In a diametric compression test, hardness is defined as the force necessary to crack a tablet. The Monsanto hardness tester was used to measure it. It's measured in kg / cm². In each formulation, three tablets were chosen at random and the mean and standard deviation values were determined.

Friability test: To test a tablet's friability, it is exposed to varied friction and shocks. The tablet was friable using the Roche friabilator. A pre-weighed sample of tablets was placed in the friabilator and spun for 100 revolutions at 25 rpm. The pills were 100 times weighed.

$$F = \frac{W_{initial} - W_{final}}{W_{initial}} \times 100$$

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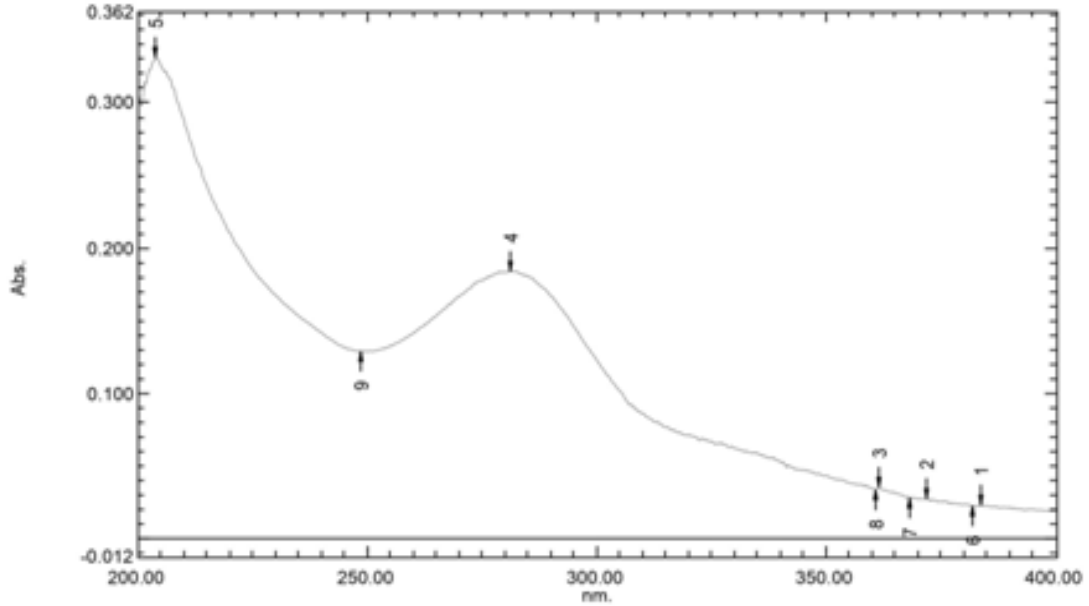
The weight variation test consisted of weighing 20 tablets separately, calculating the average, and comparing the average to the ideal. A vernier calliper from an Electro lab type was used to measure the thickness of the tablets. Five pills are randomly selected from each batch. The units of measurement are millimetres, and average values have been calculated.This test ensures that each batch has the same amount of active medicine. Each batch included 10 crushed pills. Then 100 ml of 0.1N HCl with 100 mg powdered herbal extract. To filter this solution, 1 ml was taken and diluted 100 times with 0.1N HCl. The drug concentration was determined using a UV visible spectrophotometer at 281 nm.The time taken to completely moisten a pill was recorded. Each group had three trials, with the standard deviation computed. The time it took for the FDT to disintegrate completely was used to compute the disintegration time. Water temperature was used to track the disintegration period of six FDTs in each tube of the disintegration test device while it was 37±2°C. Results for each concentration were provided as the mean standard deviation for six pills. At 37±2°C, 50 rpm, and 900 ml distilled water, the release rate of the produced tablets was measured using the USP type 2 (Paddle) procedures. The dissolving medium is replenished with 10 ml of blank media once the samples in 10 ml have been removed. A UV-Spectrophotometer at a wavelength of 281 nm collects samples every five minutes throughout the duration of the experiment and analyses them. Measuring and documenting the rate of disintegration is a need. A standard calibration plot was used to assess the herbal extract's concentration.

RESULTS

Characterization of extract powder: The basic characterization of powder and micromeritic properties of formulations containing polyherbal extracts powder used for preparing fast disintegrating tablets mentioned in table.UV Spectrophotometric study was conducted in 0.1N HCL pH 1.2 and examine range was set between 200-400nm. Absorption maximum (λmax) obtained in 0.1N HCL pH 1.2 was 281nm (Fig.1). The linear correlation was found to be 0.999 (Fig.2).



Measurement Properties	
Wavelength Range (nm.):	200.00 to 400.00
Scan Speed:	Fast
Sampling Interval:	0.2
Auto Sampling Interval:	Enabled
Scan Mode:	Auto
Instrument Properties	
Instrument Type:	UV-1700 Series
Measuring Mode:	Absorbance
Slit Width:	1.0 nm
Light Source Change Wavelength:	340.8 nm
S/R Exchange:	Normal

No.	P/V	Wavelength	Abs.	Description
1	↑	383.80	0.024	
2	↑	371.80	0.028	
3	↑	361.40	0.036	
4	↑	281.20	0.184	
5	↑	203.80	0.331	
6	↓	381.80	0.023	
7	↓	368.20	0.028	
8	↓	360.60	0.034	
9	↓	248.40	0.129	

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Fig.1: λmax scan for DVS at 281nm in 0.1N HCL

Standard Calibration curve of herbal extract (Each value represents mean n=3, ±S.D)

S.No.	Concentration (µg/ml)	Absorbance
1	0	0 ± 0
2	100	0.184 ± 0.01
3	200	0.386 ± 0.014
4	300	0.598 ± 0.016
5	400	0.793 ± 0.019
6	500	1.001 ± 0.02

Standard Calibration curve of herbal extract

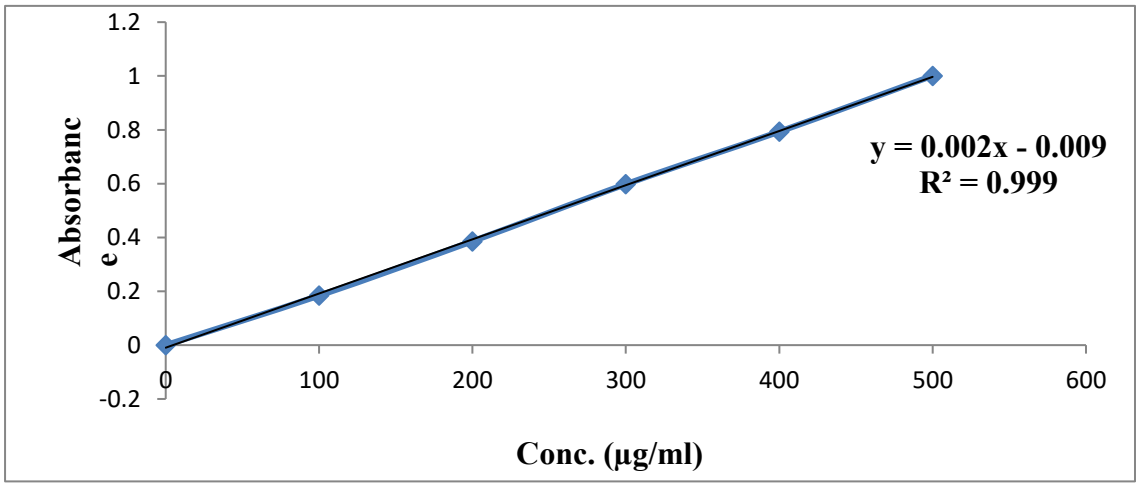


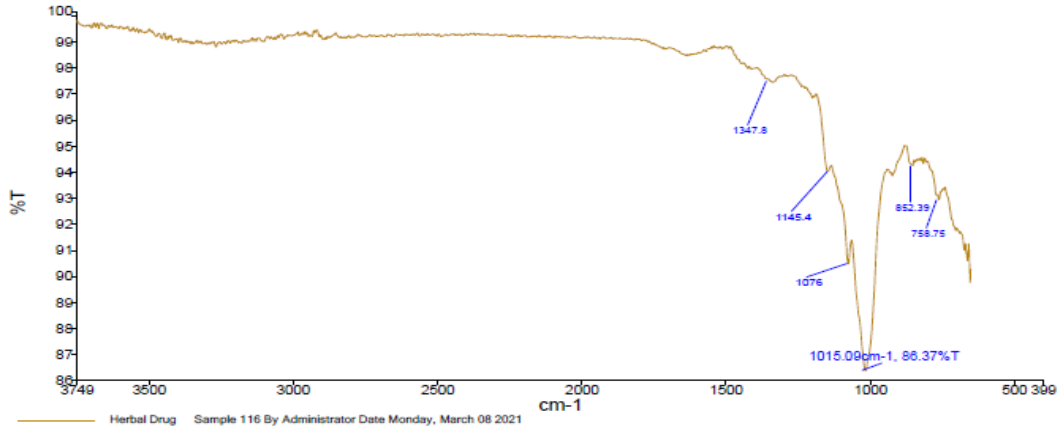
Fig.2 : Calibration curve in 0.1N HCL

FTIR Spectral analysis:

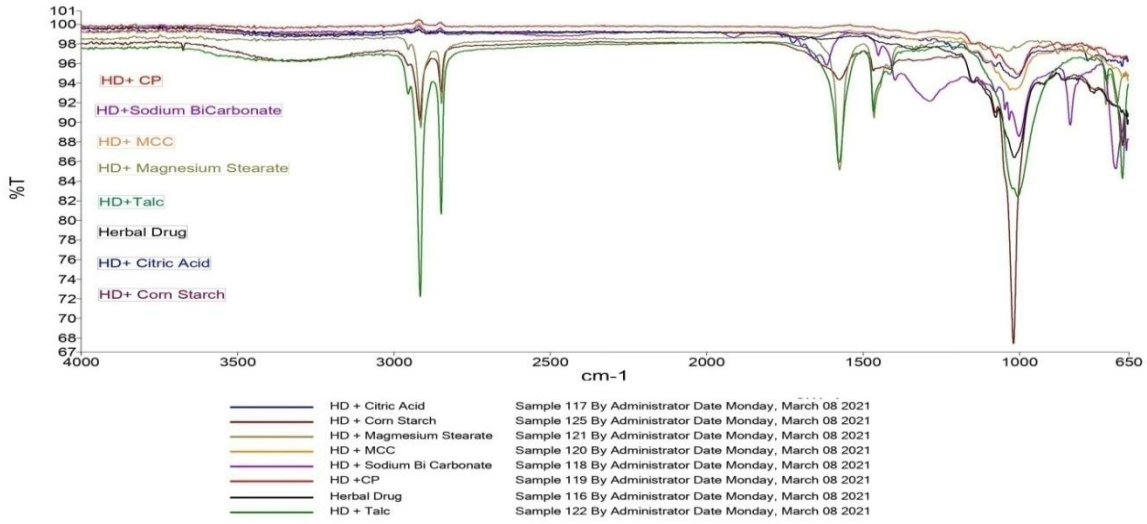
S. no.	Plant name	Chemical Constituent	Functional group Standard range (cm^{-1})	Observed range (cm^{-1})
1	Salix alba (Fig.3)	Salicin, and Salicortin	C-O (1150-1060) O-H (3200-2700) C=C (1650-1566) C-H (2000-1650)	C-O (1013.18) O-H(3243.2) C=C (1614.8) C-H (1670.6)
2	Tinospora cordifolia (Fig.4)	Tinosporine and Isocolumbin	C-O (1150-1060) C=O (1690-1650) O-H(3700-3584) C=C (1650-1566) C-H (2000-1650) CH3 (2830-2695)	C-O (1015.87) C=O (1622.7) O-H(3299.2) C=C (1570) C-H (1680) CH3 (2920)
3	Achyranthes aspera (Fig.5)	Oleanolic acid and Linalool	C-O (1150-1060) O-H(3700-3584) C=C (1650-1566)	C-O (1023.57) O-H(3765.7) C=C (1596.9)

			C-H (2000-1650) COO(1770-1780) CH3 (2830-2695)	C-H (1432) COO(1733.2) CH3 (2824.90)
4	Cyprus rotundus (Fig.6)	Quercetin and Salicylic acid	C-O (1150-1060) O-H(3700-3584) C=C (1650-1566) C-H (2000-1650) C=O (1690-1650)	C-O (1020.02) O-H(3310) C=C (1514.4) C-H (1490) C=O (1618.4)
5	Withania somnifera (Fig.7)	Withaferin A and Withanine	C-O (1150-1060) O-H(3700-3584) C=C (1650-1566) C=O (1690-1650) C-H (2000-1650) CH3 (2830-2695)	C-O (1019.99) O-H(3224.52) C=C (1420.34) C=O (1656.08) C-H (1515) CH3 (2850)

Table: FTIR Spectral analysis



FTIR of all Herbal extract



FTIR of all Herbal extract and Excipients (Cross povidone, Sodium bicarbonate, Micro crystalline cellulose, Magnesium stearate, Talc, Citric acid, and Corn starch)

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Partition coefficient: The partition coefficient of a mixture of Willow bark, Guduchi, Latjira, Nagarmotha, and Ashwagandha were calculated. In the oil phase, the concentration of the herbal extract was found to be 4.69mg while in the aqueous phase was 5.31mg. Hence, the partition coefficient of the herbal extract was 0.883.

pH determination: A pH of herbal extract was 2.8 reported in 1mg/ml concentration in a 0.1N HCl.

Solubility analysis: 0.1N HCl, ethanol, and methanol are all solvents that can dissolve herbal extract powder samples.

Observation of morphological characters:

Name of the plant	Nature	Color	Odour	Taste
Salix alba L	Fine powder	Pale yellow	Characteristic	Bitter
Tinospora cordifolia	Fine powder	brown	Characteristic	Astringent
Achyranthes aspera	Fine powder	Pale green	Characteristic	bitter
Cyprus rotundus	Fine powder	Brown	Characteristic	Astringent
Withania somnifera	Fine powder	Yellow	Characteristic	Astringent

Evaluation of powder characteristics:

Formulation	Angle of repose (θ)	Bulk density (gm/cm^3)	Tapped density (gm/cm^3)	Carr's index (%)	Hausner's ratio
F1	19.40±0.25	2.74±0.14	3.31±0.56	17.22±0.25	1.20±1.45
F2	19.53±0.78	2.67±1.56	3.23±0.86	17.33±0.89	1.20±0.36
F3	19.92±1.56	2.73±0.28	3.30±0.78	17.27±0.25	1.20±0.85
F4	19.50±1.29	2.68±1.56	3.25±0.71	17.53±1.03	1.21±1.15
F5	19.48±0.93	2.61±0.45	3.16±1.02	17.40±0.57	1.21±1.09
F6	19.26±0.37	2.64±0.52	3.19±1.58	17.24±1.01	1.20±1.15
F7	19.29±0.69	2.60±1.08	3.15±1.84	17.46±1.59	1.21±1.64
F8	19.54±0.53	2.69±1.43	3.26±0.98	17.48±0.14	1.21±0.95
F9	19.23±0.41	2.66±0.82	3.21±0.29	17.13±0.54	1.20±0.83

Data as expressed as mean ± S.D. (n = 3)

Post compression evaluation of tablets:

Formulation	Weight variation (mg)	Hardness kg/cm2	Friability (%)	Thickness (mm)	Content uniformity (%)	Wetting time (sec)
F1	574±3.25	4.3±0.35	0.17±0.12	6.58±0.12	90.23±0.09	134
F2	559±1.65	4.0±1.25	0.29±0.02	6.61±0.23	90.52±0.23	109
F3	594±5.23	4.2±1.02	0.74±0.68	6.45±0.12	96.24±0.02	81
F4	589±1.47	3.3±0.27	0.51±0.74	6.38±0.03	95.63±0.08	61
F5	600±1.32	3.9±0.22	0.73±0.96	5.33±0.36	94.26±0.19	49
F6	602±0.57	3.2±0.52	0.64±0.85	6.40±0.19	96.69±0.67	41
F7	598±1.65	3.6±0.84	0.89±0.92	6.31±0.07	98.75±0.04	26
F8	593±0.98	3.4±0.91	0.75±0.74	6.38±0.13	97.67±0.28	30
F9	600±0.82	3.8±0.43	0.93±0.28	6.32±0.16	98.65±0.43	23

Data as expressed as mean ± S.D. (n = 3)

Stability study of herbal fast disintegrating tablets:

Parameter	Initial	1 Month	2 Month
Avg. weight (mg)	600 ± 0.82	601 ± 0.75	601 ± 0.98
Hardness (kg/cm2)	3.8 ± 0.43	3.9 ± 0.52	3.9 ± 0.79
Friability (%)	0.93 ± 0.35	0.94 ± 0.48	0.94 ± 0.43
Disintegration time (sec)	24	25	25
Wetting time (sec)	23	25	26
% Content uniformity	98.65 ± 0.43	98.78 ± 0.58	98.86 ± 0.67

Data as expressed as mean ± S.D. (n = 3)

DISCUSSION AND CONCLUSION

Medicinal plants are considered to gold mine of components that are considered to be therapeutically active. These medicinal herbs are used since ancient time for treatment of many ailments. In most of the cases weather we are discussing traditional system of medicine, folklore practice or, Ayurveda combination of herbal components is one on of the widely used preparation. These preparations are intended to be used for treatment of various ailments and are considered to be polyherbal formulations.Headache is one of the most common disorders in today's lifestyle. In this concern present study was designed to investigate analgesic potential of a polyherbal formulation consisting of three medicinal plant's extract that are reported to have good analgesic potential. Salix alba L, Tinospora cordifolia, Achyranthes aspera, Cyprus rotundus, and Withania somnifera were the medicinal plants that were selected for present study. A different combination of these medicinal plants plays an important role, providing synergistic activity against the disorders. Selected combination was fabricated to fast dissolving tablet and it was further evaluated and characterized on various parameters.

FDTs formulation containing 600 mg of all-herbal powder extract for headaches was the primary goal of this study, which included the development of FDTs containing excipients like Cross povidone, Citric acid monohydrate, Magnesium stearate, Beta-cyclo dextrin and Sodium starch glycolate as well as Talc as excipients. Fast disintegrating drug delivery system improved the bioavailability and therapeutic efficiency of herbal extract powder.In the pre-formulation step, an FTIR analysis of pure herbal extract powder and excipients was performed. There hasn't been any interaction. As a result, it was discovered that herbal extracts powder is acceptable with excipients.The direct compression method was used to prepare twenty-one batches of the formulation. The formulation angle of repose values ranges from 19.40±0.25 to 19.23 ±0.41. The compressibility index was calculated using bulk and tapped densities. Formulation bulk and tapped values vary from 2.74±0.14 to 2.66±0.82 and 3.31±0.56 to 3.21±0.29, consequently. For formulas, the car's index and Hausner's ratio values vary from 17.22±0.25 to 17.13±0.54 and 1.20±1.45 to 1.20±0.83, consequently. As a result, all of the formulations had good flow characteristics.The thickness, weight variation, hardness, friability, and drug content consistency of the manufactured FDTs were all examined. Tablet thickness varied between 6.58±0.12 to 6.32±0.16 in all formulations. In all formulations, the weight variation of tablets ranged from 574±3.25 to 600±0.82. All of the formulations F1-F9 had hardness and friability of 4.3±0.35 to 3.8±0.43 and 0.17±0.12 to 0.93±0.28, consequently. All of the formulations had drug content varying from 90.23±0.09 to 98.65±0.43. All of the formulations had different wetting times, varying from 23 sec to 134 sec. Compared to all formulations F7 and F9 showed the best, the disintegration time for F7 and F9 were found to be 26sec and 24sec containing cross povidone, Citric acid monohydrate, Sodium bicarbonate, and Micro crystalline cellulose. The manufactured tablets were then put through a dissolution test to see how well they released the medication in-vitro. The dissolution tests were performed at 37±0.5°C. in 0.1N HCl in a USP type-2 apparatus. The dissolution investigations revealed that the conc. of excipients had a significant impact on the herbal extracts release from the tablets. In comparison to the other formulations, F7 and F9 had better herbal extracts release and disintegration performances. It took 24 sec and 26 sec for this formulation to disintegrate.The drug release followed zero-order kinetics followed by non-fickian diffusion in the F7 and F9 formulations, according to the kinetic analysis. The formulation stability tests were carried out for two months at 45°C and 175 % RH. There was no discernible difference, according to the data.

According to the results of the study, F7 and F9 were the best formulations, with disintegration times of 26 sec and 24 sec, and drug release rates of 98.93 % and 97.04 % in 30 minutes, consequently. Yet, more in-vivo research can be done to back up the findings.When compared to a Clove analgesic tablet [24], our herbal tablet has a disintegration time of 24 sec and a drug content of 98%, whereas the clove tablet has a disintegration time of 142 sec and a drug content of 95%.When comparing the Diclofenac potassium fast dissolving tablet [27] to our five herbal extract tablets, the diclofenac potassium fast dissolving tablet dissolves in 25.33 sec with serious side effects, whereas our five herbal extract tablet dissolves in 24 sec with no or minor health consequences.Overall, the FDTs are made from a combination of Salix alba L, Tinospora cordifolia, Achyranthes aspera, Cyprus rotundus, and Withania somnifera extract powder and excipients give a stable formulation that meets performance standards. In in-vivo studies, this formulation has strong analgesic promise for headaches.

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