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Formulation and Evaluation of Fast Dissolving Tablet of Dipyridamole

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ABSTRACT

A platelet inhibitor with antiplatelet characteristics is dipyridamole. Variable dissolving rates are caused by the drug's low solubility in water. In the current work, an effort has been made to create oral dipyridamole tablets that dissolve quickly and with a high rate of dissolution. Super disintegrants including Gum Karaya, Agar, and Mannitol were used to create the fast-dissolving Dipyridamole pills. Mannitol was used to create solid dispersions of dipyridamole to enhance its solubility and release characteristics in dissolving fluid. The manufactured fast-dissolving tablets were tested for several characteristics, including weight variation, hardness, friability, disintegration time, drug content, wetting time, in-vitro drug release, FTIR investigations, and short-term stability tests. When compared to other manufactured solid dispersions, it was discovered that the ratio of 1:3 (Drug: PVP K30) demonstrated adequate drug release. According to in-vitro release experiments, 96.86 percent of dipyridamole was released in about 10 seconds. According to the findings, Dipyridamole fast-dissolving tablets with better dissolution may result in increased bioavailability.

INTRODUCTION:

Due to their self-administration easiness, compactness, and ease of production, tablets are the most often used dosage form. However, elderly and young patients have trouble taking regular pills, which results in low patient compliance. Scientists have created novel medication delivery techniques known as "melt in the mouth" or "mouth dissolve (MD)" tablets to address this shortcoming. These unique pill designs melt, dissolve, and scatter in saliva. Their unique benefits, such as the flexibility to be administered anywhere and at any time without the need for water, make them suitable for both elderly and paediatric patients. They are also appropriate for immobile people, suffer from mental illness, or lack simple access to water. The benefits, in terms of patient compliance, rapid onset of action, increased bioavailability, and good stability, make these tablets popular as a dosage form of choice in the current market. [1,2]

Candidates for this dose form include a wide variety of medications (antibiotics, cardiovascular, analgesics, narcoleptics, and analgesics). Techniques including tablet molding, spray drying, lyophilization, sublimation, and the inclusion of disintegrants are used to create fast-dissolving tablets. [7] Zydis,[8,9] OraSolv,[10] DuraSolv, Flash Dose,[11] Wow tab (Without Water), and Flash tab are a few of the patented technology for making fast-dissolving tablets. [12]

Dipyridamole USP, also known as 2,2',2",2"-[(4,8- Dipiperidinopyrimido[5,4-d]pyrimidine-2,6-diyl)dinitrilo]-tetraethanol, is a platelet inhibitor. An odorless, yellow, crystalline powder with a bitter flavor makes up dipyridamole. It is almost completely insoluble in water but is soluble in weak acids, methanol, and chloroform. Dipyridamole is a BCS class II medication that has a high permeability and poor solubility. It has a tiny absorption window and is mostly absorbed in the stomach. Its oral bioavailability is between 37 and 66 percent, and its biological half-life is equally brief. It is soluble at low pH but insoluble at high pH (i.e., the alkaline pH of the small intestine) (40 min). Plasma proteins are very tightly linked to dipyridamole. It is converted to a glucuronide in the liver, where it is eliminated with the bile [13, 14, 15, 16]. Many medications are available in convenient oral dose forms, such as tablets and capsules. However, if the active ingredients have poor solubility or limited bioavailability, they are difficult to manufacture. Better patient compliance is provided by the use of polymer coating in the formulation of medications that dissolve in the mouth and mask harsh tastes [17, 18].

MATERIALS AND METHODS:

Dipyridamole was obtained from Micro Advanced Research Center (Bangalore, India) as a gift sample. Agar and Mannitol were collected from Poona Chemical Laboratory. Other reagents have been bought from S. D. Fine Limited Chemicals (Mumbai, India).

METHODS:

A) IR absorption spectrum: FT-IR spectra of drug samples were recorded using potassium bromide (KBr) pellets at a resolution of $4cm^{-1}$ for its authentication and to study principle peaks using FT-IR spectrophotometer (FT-IR 8400S, Shimadzu). [19]

B) UV absorption maxima of Dipyridamole: [20] UV scanning was done in Shimadzu double beam UV/VIS spectrophotometer using 10 µg/ml drug solutions in the wave length range of(200-400 nm). Phosphate buffer 6.4 used as a blank.

Analytical Methodology: In the present investigation, Dipyridamole was estimated by UV/Vis spectrophotometry in methanol.

Preparation of Stock Solution: Dipyridamole (10mg) was accurately weighed and transferred into the 1000 ml standard volumetric flask. It was dissolved in methanol and volume was made up to the mark (to get a 1000 µg/ml solution). From this 10 ml was pipette out and then diluted upto 100 ml with methanol. From that solution again 10 ml pipetted out and diluted upto 100 ml in volumetric flask with methanol to get a stock solution of 10µg/ml.

Preparation of Standard Curve: From the stock solution 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 ml were transferred to 10 ml standard volumetric flasks and diluted with methanol upto the mark to obtain dipyridamole concentration of 1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 µg/ml respectively. The absorbance of each solution was measured at 317 nm.

C) DRUG – EXCIPIENT COMPATIBILITY:

The selected polymers were characterized by FT-IR spectroscopy and the FTIR spectra of the pure drug dipyridamole with used excipients like Agar, Tragacanth, Microcrystalline cellulose, PVP K30, Aspartame, Mannitol etc. The instrument was operated under dry air purge and the scans were collected at a scanning speed 2 mm/sec with a resolution of 4 cm^{-1} over the region 4000-400 cm^{-1}. The scans were evaluated for the presence of principle peaks

of drug, shifting and masking of drug peaks and appearance of new peaks due to polymer interaction.

D) DETERMINATION OF FLOW PROPERTIES: [21]

1. Angle of Repose
2. Bulk Density
3. Tapped Density
4. Carr's Index [Compressibility Index] and Hausner's Ratio
5. Hausner's Ratio

E) PREPARATION OF SOLID DISPERSION: [22]

Preparation of Solid Dispersions of Dipyridamole: Solid dispersions of dipyridamole were prepared by solvent evaporation method. Drug was weighed and taken in a china dish, dissolved in methanol and then carrier was added (PVP k30 in ratio of 1:3). The solvent was evaporated at room temperature and dried in hot air oven at 50 °C for 4 hours. The resultant mass was passed through sieve no. 60 and stored in desiccator.

Physical mixture: Physical mixture (PMs) having the same weight ratio was prepared by thoroughly mixing appropriate amounts of dipyridamole and PVP k30 in a morter until a homogenous mixture was obtained. The result was sieved through a 60# sieve and denoted as PM.

F) CHARACTERIZATION OF SOLID DISPERSIONS OF DIPYRIDAMOLE WITH PVP K30:

Drug Content: An accurately weighed quantity of solid dispersion equivalent to 25mg dipyridamole was taken into 100 ml of a volumetric flask. Dissolved in phosphate buffer 6.4 and the volume were made up with the same. An aliquot of the filtrate was diluted and analyzed spectrophotometrically (UV-1700, Shimadzu Corporation, Japan) at 317 nm.

Phase Solubility Studies: Phase solubility studies were carried out by adding excess of drug (20 mg) in screw-capped vials containing 20ml of aqueous solution of different PVP K30concentration. Then suspensions were continuously stirred on electromagnetic stirrer at 250 and 370 and 300 rpm for three days (this duration was previously tested to be sufficient to reach equilibrium). The suspensions were filtered through 0.22µm membrane filter. The filtrate was suitably diluted and analyzed, spectrophotometrically, for the dissolved at 253nm.

Dissolution study: In vitro dissolution studies of Dipyridamole in powder form, SDs, and PMs were performed by using the USP XXIII type-II dissolution apparatus (ElectrolabTDT-06N) employing a paddle stirrer at 50 rpm. 900 ml of pH 6.4 phosphate buffer was used as dissolution medium. The temperature of the dissolution medium was maintained at 37 ±0.5 °C throughout the experiment. Samples of dissolution medium(5ml) were withdrawn for 20 min using syringe fitted with pre-filter at known intervals of time and analyzed for drug release by measuring the absorbance at 253 nm. The volume withdrawn at each time interval was replaced with fresh quantity of dissolution medium. Cumulative percent released was calculated and plotted against time.

G) PREPARATION OF TABLETS CONTAINING SOLID DISPERSIONS OF DIPYRIDAMOLE: [23]

Different dipyridamole mouth dissolving tablets were prepared according to the proportion given in table. The raw materials were passed through a screen (40 mesh) prior to mixing. powdered 1:3 ratio solid dispersion, containing amount equivalent to 25 mg dipyridamole, was mixed with the other excipients and compressed on a rotator tablet punching machine equipped with flat-faced 10-mm punches. The tablet weight was adjusted to ~200 mg.

Direct compression method: Fast dissolving tablets of dipyridamole were prepared by Direct Compression method according to the formulae given in the Tables. All the ingredients were powdered separately and passed through # 60 mesh sieve separately. The solid dispersion and directly compressible excipient were mixed by adding small portion of each at a time and blending it to get a uniform mixture and kept aside. Then the other ingredients were mixed in geometrical order, in an inflated polyethylene pouch magnesium stearate and talc were added last and the tablets were compressed using 8 mm flat round punches to get tablets of 200 mg weight.

Table 1: Composition of Dipyridamole Tablets Prepared by Direct Compression Method

Ingredients (mg)	DFT1	DFT 2	DFT 3	DFT 4	DFT 5	DFT 6
Drug solid dispersion PVP K30 (1:3)	75mg	75mg	75mg	75mg	75mg	75mg
Gum Karaya	-	-	-	10	15	20
Agar	10	15	20	-	-	-
Mannitol	80	75	70	80	75	70
MCC	25	25	25	25	25	25
Aspartame	5	5	5	5	5	5
Magnesium Stearate	3	3	3	3	3	3
Talc	2	2	2	2	2	2
Total	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg

H) POST-COMPRESSION PARAMETERS [24]

Shape and Colour: The tablets were examined under a lens for shape of the tablet and colour by keeping the tablets in light.

Uniformity of Thickness: The crown thickness of an individual tablet may be measured with a vernier caliper, which permits accurate measurements and provides information on the variation between tablets. Other technique employed in production control involves placing 5 or 10 tablets in a holding tray, where their total crown thickness may be measured with a sliding caliper scale. The tablet thickness was measured using vernier caliper.

Hardness Test: The hardness of the tablets was determined using Monsanto Hardness tester. Itis expressed in Kg/cm^2. Three tablets were randomly picked from each formulation and the mean and standard deviation values were calculated.

Friability test: The friability of tablets was determined by using Roche Friabilator. It is expressed in percentages (%). Ten tablets were initially weighed [W (initial)] and transferred

into the friabilator. The friabilator was operated at 25 rpm for 4 mins or run up to 100 revolutions. The tablets were weighed again [W (final)]. The percentage friability was then calculated by,

$$F = \frac{W\ (initial) - W\ (final)\ x\ 100}{W\ (initial)}$$

Acceptable limit of Friability

- <1 Acceptable
- >1 Not acceptable

Weight variation test: The tablets were selected randomly from each formulation and weighed individually to check for weight variation. The U.S Pharmacopoeia allows a little variation in the weight of a tablet. The percentage deviation in weight variation is shown in table no 5.

Drug Content Uniformity: Twenty tablets were weighed and powdered. The blend equivalent to 20 mg of pantoprazole sodium was weighed and dissolved in sufficient quantity of 0.1N HCl. The solution was filtered through Whatman filter paper (No.41), suitably diluted with 0.1NHCl and assayed at 281.5 nm, using a UV-Visible double beam spectrophotometer (UV- 1800 Shimadzu).

***In-vitro* disintegration time:** The disintegration apparatus (Pharma Test, Hainburg, Germany) had to be modified since the standard glass tube is 21.5 mm in internal diameter and the tested tablets have, however, a mean diameter of 25 mm.57 The disintegration was carried out in a beaker consisting of a 200 ml medium. The medium consisted of water at a temperature between 15 and 25°C. Only one tablet at a time was tested and considered disintegrated when completely dispersed fragments were obtained.

***In-vitro* dissolution studies:** In vitro release studies were carried out using a modified USP XXIII dissolution test apparatus. Two objectives in the development of in vitro dissolution tests were to show that,

i) Release of the drug from the tablet is as close as possible upto 100%.

ii)Rate of drug release is uniform from batch to batch and is the same as the release rate from those proven to be bioavailable and clinically effective.

Modification: The normal USP XXIII dissolution apparatus was chosen in which a beaker was placed. This beaker is an elongated one generally used for TLC and another purpose. Another modification was that basket was used in place of paddles because of the narrow mouth opening of the beaker. Outside this beaker water was putted at a level till the dissolution fluid in the beaker reaches. The temperature was validated and kept at 40.1°C and the rotation of the basket was kept at 75 RPM. Only 190 ml dissolution fluid was used. A summary of general in vitro dissolution conditions employed throughout the study to determine the in vitro dissolution rate for all the formulations is given in the following table.

Summary of general dissolution conditions

- Dissolution medium 190 ml 0.1 N HCl
- Temperature 40.1°C ± 5°C
- Rotation speed 75 rpm
- Volume withdrawn 5 ml every 30 seconds for 10 mins
- Lambda max 281.5nm
- Beer‘s range 2 – 100µg/ml
- Tablet taken 1 tab (known drug content)

I) Stability studies:

In the present study, the ODTs where packed in suitable packaging material and stored under the following conditions for a period of 90 days at 40 ± 1 °C and RH 75 ± 5%The tablets were withdrawn after period of 15, 45 and 90days and analyzed for physical characterization (Visual defects, hardness, friability, disintegration, dissolution etc.) and drug content.

RESULTS AND DISCUSSION:

A) Infrared Spectrum: The IR spectrum of the obtained sample was done acc. to the procedure mention in the material and method and complied with IR spectra of sample drug showing similar characteristic peaks. Figure 1 shows the IR spectra of sample drug.

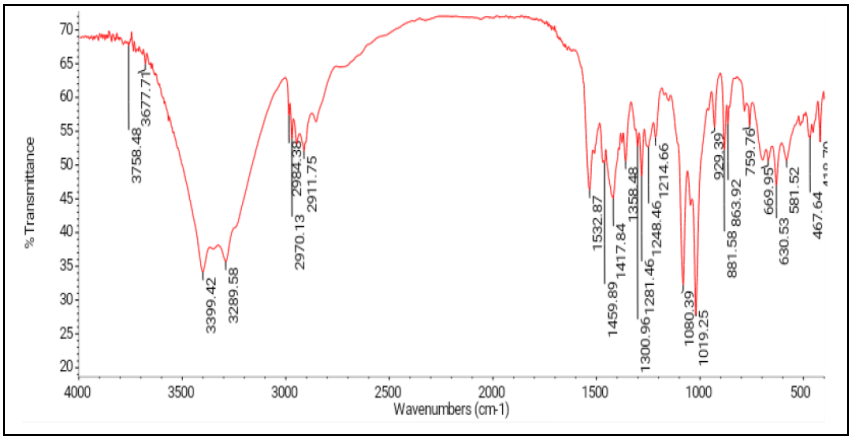

Figure 1: IR spectra of pure dipyridamole

B) UV Spectroscopy:

i) UV Spectrum of dipyridamole: The UV spectrum of dipyridamole in methanol and distilled water was scanned and λ_{max} was found to be typical peaks at 317 nm in methanol and340 nm in distilled water in the spectral range 200-400 nm respectively. The UV spectrum report is given in figure 2 as given below.

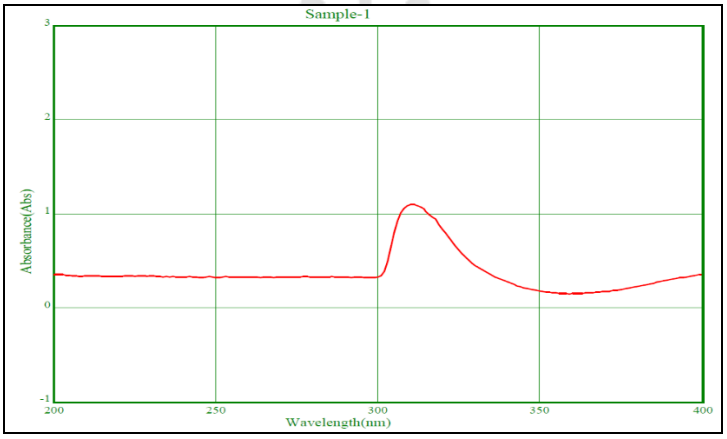

Figure 2: UV Spectra of drug in methanol

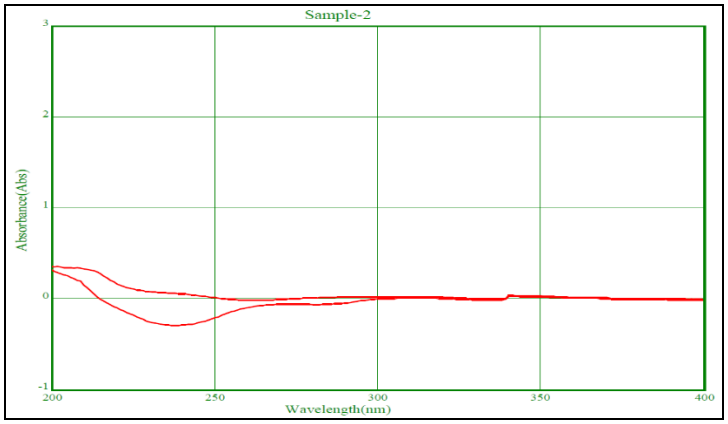

Figure 3: UV Spectra of drug in distilled water

Preparation of Calibration Curve: Calibration curve of dipyridamole revealed that the graph obeyed Beers Lambert Law in the concentration range (0-10µg/ml). A regression equation was found to be: y =0.0481x + 0.0025 and high coefficient correlation of 0.9998 was also observed.

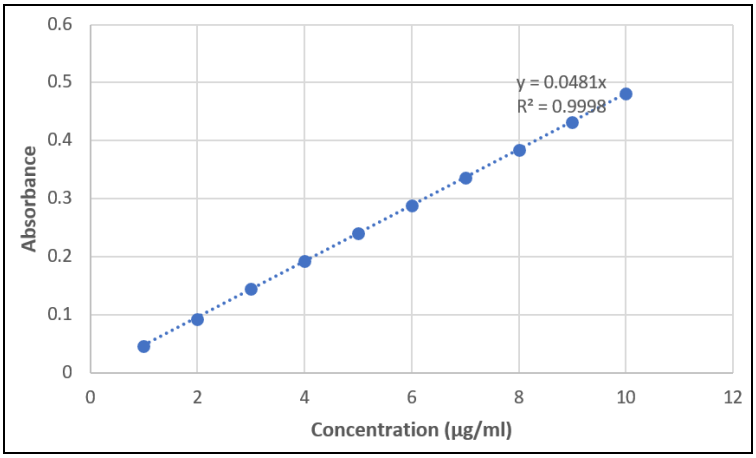

Figure 4: Calibration curve of dipyridamole in methanol

C) COMPATABILITY STUDIES

FTIR Studies: Drug- excipient interactions play a crucial role concerning the stability and-potency of the drug. FTIR techniques have been used here to study the physical and chemical interaction between drug and excipients used.

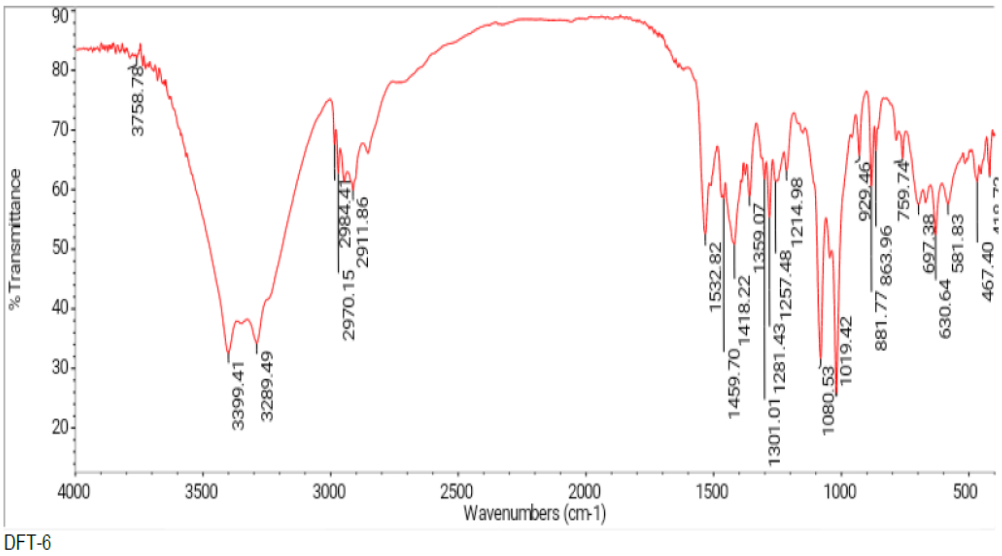

Figure 5: FTIR Spectra of Formulation (Solid dispersion)

Compatibility studies were performed using FTIR spectrophotometer. The IR spectrum of pure dipyridamole and physical mixture of drug and polymers were studied. The FTIR scan shows characteristic absorption peaks of dipyridamole at 3399.41 cm^{-1}, 1459.70 cm^{-1} (N-H stretching and bending vibrations); 1359.07 &1301.01 cm^{-1} (C-N stretching vibration); 1532.82 cm-1 (C=C stretching vibration); 2970.15 cm^{-1} (Aromatic C-H stretching and bending vibrations) respectively.

The peaks obtained in the spectra of the pure drug correlate with the peaks obtained when the drug and excipients were scanned together, thus indicating that the drug was compatible with the formulation excipients. Based on this study it was concluded that there is no chemical interaction between drug and the excipients used and thus it can be safely used in the formulations.

D) DETERMINATION OF FLOW PROPERTY:

Bulk Density: BD of the formulation blend plays an important role in the compression of the powder the BD of the formulation was found to be 0.25 g/cm^3.

Tapped Density: TD also plays an important role in knowing the compressibility of the formulation blend it was found to be 0.34 g/cm^3. It was noted that the TD of the formulation where greater than their respective BD thus indicating that all the powder formulations had a good compressibility.

Angle of Repose (θ): The angle of repose for the formulated blend was carried out and the results were shown in Table 2. It was concluded that the entire formulation blend was in the range.

Carr's Index: CI was calculated based on the BD and TD and the results were shown in table 3.5. It was found to 13.45% which lies in the official limits i.e. 5% to 15%, indicating the granules blend has excellent flow property for compression.

Hausners Ratio: HR was calculated based on the BD and TD. It is a ratio between TD and BD and was found to be 1.13 thus indicating that the formulation blend have free flowing property which is ideal for ODTs.

Table 2: Determination of Flow Properties of powder

Drug	Angle of repose	Bulk density	Tapped density	Carr's index	Hausner Ratio
Dipyridamole	26°.65	0.25	0.34	13.45	1.13

E) CHARACTERIZATION OF SOLID DISPERSION OF DIPYRIDAMOLE

i) Drug content: The percentage of the drug content for physical mixture and solid dispersion was found to be in range 94.98% to 96.79 and 96.86 to 98.65% respectively. The percentage of the drug content for formulation PMD3 and SDD3 was found to be between96.79 %w/w and 98.65 %w/w. The results were shown in **table 3**.

Table 3: Drug content in physical mixture and solid dispersions.

Solid dispersion (drug to PVP mass ratio)	Drug content (%)	Physical mixture (drug to PVP mass ratio)	Drug content (%)
SDD1 (1:1)	96.86	PMD1 (1:1)	94.98
SDD2 (1:2)	97.75	PMD2 (1:2)	95.43
SDD3 (1:3)	98.65	PMD3 (1:3)	96.79

ii) Dissolution studies of solid dispersions and physical mixtures: The percentage release of dipyridamole at various time intervals from the physical mixture and solid dispersions made by using various concentrations of PVP K30. Dissolution of pure drug is very low,

about 30.56% of drug being dissolved in 20 min. In the 20 min SD containing 1:3 of drug and PVP K30 showed better drug release 98.76% than other ratios of SD's.

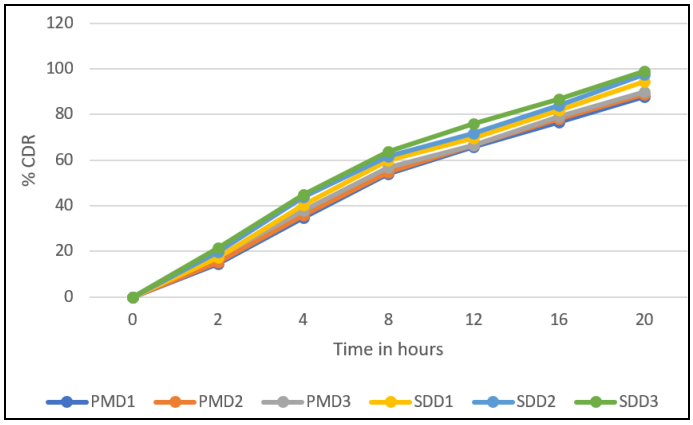

Figure 6: Comparison study of physical mixture and solid dispersion

Table 4: *In-vitro* dissolution profile of Dipyridamole, physical mixture and solid dispersions

S. No.	Formulation	Cumulative % drug release after 20 min
1	SDD1	94.37 ± 2.65
2	SDD2	97.63 ± 2.45
3	SDD3	98.76 ± 3.05
4	PMD1	87.65 ± 3.17
5	PMD2	88.83 ± 2.99
6	PMD3	89.75 ± 3.34

F) EVALUATION OF POST-COMPRESSION PARAMETER

i. Thickness of tablets: The average thickness for all the formulations (DFT1-DFT6) was found in the range of 3.54-4.9 mm respectively which is within the allowed limit of deviation i.e. 5% of the standard value.

ii. Weight Variation Test: As the powder material was free-flowing, tablets obtained were uniform in weight due to uniform die fill with acceptable variation as per IP standards. The weight variation for all formulations (DFT1-DFT6) was found in the range of 202 to 206 mg, results were dissipated in **table 5**.

iii. Drug content: The percentage of the drug content for formulation DFT1 to DFT6 was found to be between94.56%w/w and 97.34%w/w. The results were shown in **table 5**.

iv. Hardness: Hardness test was performed by "Monsanto hardness tester". All the formulations (DFT1-DFT6) have an average hardness in between 4.3 to 5.1 kg/cm^2 respectively. This ensures good handling characteristics of all formulation batches.

v. Friability: The average percentage friability for all the formulations was found in between 0.123% to 0.161%, which is found within the pharmacopoeial limit (i.e. less than 1%). So, the maximum friability was 0.161% observed for DFT6 and the minimum friability 0.123% observed for DFT1.

Table 5: Post-compression parameters results

Formulation	Thickness (mm)± SD	Weight variation (mg)	Drug content (%)	Hardness (kg/cm^2)	Friability (%)
DFT1	3.54 ±0.12	200 ± 5	96.09 ± 0.15	4.5 ± 0.11	0.123± 0.14
DFT 2	3.65 ±0.11	203 ± 5	96.23 ± 0.14	4.3 ± 0.13	0.139± 0.17
DFT 3	4.99 ±0.12	202 ± 5	97.34 ± 0.15	4.9 ± 0.12	0.136± 0.18
DFT 4	4.65 ±0.14	206 ± 5	94.56 ± 0.14	5.1 ± 0.11	0.143± 0.19
DFT 5	3.89 ±0.12	203 ± 5	94.99 ± 0.13	4.8 ± 0.13	0.151± 0.22
DFT 6	3.55 ±0.12	205 ± 5	96.72 ± 0.15	4.4 ± 0.12	0.161± 0.21

vi. Disintegration Test: Disintegration time of 3 min (180 sec) was fixed as the upper limit for branding formulations as ODTs as specified by European Pharmacopoeia. Therefore, formulations having a disintegration time greater than 180 sec were not selected for further studies such as in vitro dissolution etc. The disintegration time for Batch DFT1-DFT6 ranged from 1-180 seconds (**Table 6**).

Table 6: Disintegration time of batch (DFT1-DFT6)

S. No.	Formulation code	Disintegration time (Second)
1	DFT1	119.03 ± 0.34
2	DFT 2	134.45± 0.54
3	DFT 3	109.18± 0.34
4	DFT 4	138.17± 0.24
5	DFT5	142.18± 0.87
6	DFT6	129.98± 0.27

vii. *In-vitro* Dissolution Study: All the formulations which passed the in vitro disintegration where subjected to in vitro dissolution studies. This study also plays an important part in the selection of the best formulation among all.

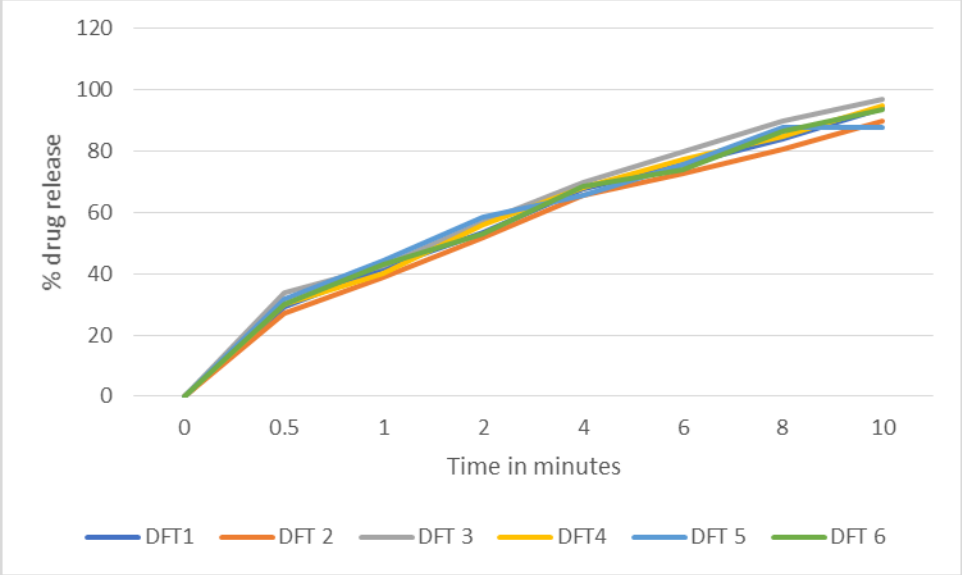

Figure 7: In-vitro drug release (DFT1-DFT6)

Table 7: *In-vitro* drug release profile of DFT3 Formulation

Time (Min)	√T	Log T	Abs*	Conc. (µg/ml)	CDR (mg)	CDR (%)	Log % CDR	Cumulative % drug release remaining	Cumulative Log % Drug release remaining
0	0	0	0	0	0	0	0	100	1.369
0.5	1.143	0.277	0.076	2.564	31.83	31.73	1.112	68.27	1.476
1.0	1.245	0.323	0.141	4.543	43.33	42.99	1.198	57.01	1.542
2.0	1.343	0.476	0.210	6.324	58.38	57.87	1.287	42.20	1.749
4.0	1.698	0.567	0.281	8.544	68.27	69.83	1.376	30.17	1.654
6.0	2.987	0.798	0.351	10.371	77.89	78.78	1.542	21.22	1.732
8.0	2.121	0.899	0.422	12.632	88.71	88.43	1.652	11.57	1.548
10	2.132	0.987	0.499	14.621	97.56	97.78	1.789	2.22	1.748

*Each reading is an average of three determinations.

√T= Square root of time, Log T= Log Time, Conc.= Concentration, CDR= Cumulative drug release

Table 8: Release exponent values and release constant value for different formulations

Batch no.	Zero order	First order	Higuchi	Peppas	
	R^2	R^2	R^2	R^2	N
DFT3	0.9294	0.9543	0.9456	0.9965	0.594

G) STABILITY STUDIES: Based on the results of *in-vitro* drug release best formulations DFT3wereselected for three-month stability studies at 25ºC/60% RH. Three months of stability studies revealed that; there was not any significant degradation of the drug. Thus, prepared formulations were physically and chemically stable. The result of stability studies was tabulated in **table 9**.

Table 9: Stability Study of DFT3

Formulation	Initial	1 month	2 months	3 months
Hardness kg/cm^2	4.9 ± 0.20	4.9 ± 0.22	4.8 ± 0.32	4.7 ± 0.42
Friability %	0.136	0.136	0.135	0.132
Drug content %	97.34 ± 0.54	96.49 ± 0.54	96.15 ± 0.43	95.99 ± 0.32

CONCLUSION:

Based on the aforementioned findings, it can be said that the Dipyridamole FDT (Fast Dissolving Tablet) with increased dissolution may result in better bioavailability and efficient treatment employing a solid dispersion approach. Based on in-vitro dissolution and disintegration investigations, formulation DFT3 was identified as promising. It had a disintegration time of 10 min and a 96.86 percent drug release. It was determined that fast-dissolving Dipyridamole tablets were effectively created by combining a solid dispersion strategy with the direct compression method.

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