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Research

Formulation And Evaluation Of Orodispersible Tablets Incorporating Zidovudine Utilizing Natural Superdisintegrants

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Abstract

ODTs are patient-friendly dose forms that quickly disintegrate in the mouth without water. Nine ODT zidovudine antiretroviral medication formulations were produced in this study utilising different natural superdisintegrant. The solubility and dissolving rate of the therapeutic molecules used in this study were improved by using starch tartrate, sodium starch glycolate, and croscarmellose sodium as super disintegrating agents. The formulations were all made utilizing 16-station rotary tablet punching machine and the direct compression method. The next step was to compress the improved mixture into tablets and test their solubility in a controlled laboratory setting. The combination of formulations exhibited favorable flow characteristics, including depth of repose, tapped density, and bulk density. The produced tablets passed all quality control assessment criteria according to I.P. limits and demonstrated good post-compression parameters. Formulation ZF3 was determined to be the most effective since it released the most medicine (100.05 percent) in the shortest duration of time (15 minutes). With a dosage of 75 mg, the ZF3 formulation includes starch tartrate (ST) as a super disintegrant.

Keywords: Zidovudine, Starch tartrate, Sodium starch glycolate, and Croscarmellose sodium.

INTRODUCTION

Oral medication delivery is widely accepted, constituting 50-60% of total dose forms. Patient compliance, ease of administration, accuracy of dosage, self-medication, and pain avoidance are some of the benefits of solid dosage forms. However, swallowing challenges are common, especially when water isn't available, such as during motion sickness or coughing bouts. Oro-dispersible tablets break down rapidly when swallowed, catering to those with dysphagia and active lifestyles[1].

ODTs are commonly referred to by different terms, including "fast-melting, fast-dissolving, oral disintegrating, or oro disperse". As per the European Pharmacopoeia, "oro disperse" denotes a tablet that disperses quickly in the mouth before swallowing. Fast dissolving tablets break down swiftly upon tongue contact, enabling the medicine to dissolve or disperse in saliva. The rate of drug dissolution directly impacts absorption speed and the onset of clinical effect[2].

These pills don't need water to dissolve; they do it in a matter of seconds in saliva. The phrase was just accepted by the European Pharmacopoeia "Oro-dispersible tablet" for tablets that dissolve in the mouth in less than 3 minutes. Some ODTs in the market dissolve in under one minute or even 30 seconds. ODTs are made using methods like lyophilization, moulding, and direct compression. While lyophilization and moulding produce tablets that disintegrate rapidly, they may lack durability and be prone to crumbling. In contrast, tablets produced through direct compression exhibit reduced fragility but have a longer disintegration period[3]. There were some work done on orodispersible tablet formulations such as, orlistat[4], ondansetron[5], zolmitriptan[6], pantoprazol[7], Metformin HCl[8], levocetirizine dihydrochloride and Montelukast sodium[9], omeprazole[10], aceclofenac[11], promethazine HCl[12].

Zidovudine is anti-retroviral drug and creamy white, odourless crystalline solid. Soluble to a small extent in ethanol (96 percent), almost insoluble in water, and readily soluble in methylene chloride. As a nucleoside reverse transcriptase inhibitor (NRTI), zidovudine exhibits anti-HIV-1 (infectious virus) properties[13]. Starch tartrate is newly explored semi synthetic novel superdisintegrants. Very few work was done hence, we did this work. The current research set out to create and assess the efficacy of various super disintegrants in the production of oral dispersible zidovudine tablets.

MATERIALS AND METHODS

Chemicals

Zidovudine was obtained as a gift sample from Cipla Pharmaceuticals, Ahmedabad. Potato starch purchased from Siddharth Starch, Pune. Tartaric acid obtained from Meru Chem Pvt. Ltd., Mumbai. Sodium starch glycolate, croscarmellose sodium, magnesium stearate and microcrystalline cellulose were purchased from Crest Cellulose Pvt. Ltd., Hyderabad. Mannitol, Talc, Sodium saccharin and SLS were purchased from SD Fine-Chem, Mumbai, India. All the used reagents and chemicals were of analytical grade.

Determination of absorption maxima

A UV visible double beam spectrophotometer (EI 1372, Electronics India, Pune, India) was used to obtain the UV spectra of a phosphate buffer with a pH of 6.8 buffer solution containing 10 µg/ml of the zidovudine has been made. The 200-400 range was used to scan the solution[14].

Construction of Zidovudine calibration curve with phosphate buffer pH 6.8

A solution of 1mg/ml (1000µgm/ml) was prepared by dissolving 100mg of Zidovudine in 100ml of phosphate buffer at a pH of 6.8. A concentration of 100µgm/ml was achieved by diluting 10 ml of the aforesaid conventional solution (1000µgm/ml) with 100 ml of a buffered phosphate solution (pH 6.8). A 10 ml volumetric flask was used to transfer 0.2, 0.4, 0.6, 0.8-, and 1-ml portions of this stock solution. Then, a buffered phosphate solution with PH 6.8 was added until the volume reached the mark, yielding 2, 4, 6, 8, and 10 µgm/ml concentrations, respectively. The absorption of each concentration was measured at its maximum wavelength, 265 nm[15].

Determination of drug-polymer compatibility by Fourier Transforms Infra-Red (FTIR) Spectroscopy

To determine whether peaks were present or absent, the infrared spectra of the physical mixture and the pure drug were compared. The FTIR spectrometer (Bruker Alpha II FTIR Spectrometer, Mumbai, India) was used to evaluate the compatibility of the pure medication with the excipients. Using a mortar and KBr press, the solid powder sample was ground with an amount of KBr 100 times higher to create the potassium bromide pellets. After that, the finely ground powder was placed within a stainless steel mould and compressed under polished steel anvils at a pressure of about 8 tonnes per square inch. The spectra were acquired across a wave number range of 400 to 8000 cm^{-1}[16].

Synthesis of starch tartrate

A small amount of water (10 mL) was used to dissolve 10 g of starch tartrate synthesis (TA) and 2 g of sodium hypophosphate (SHP) in a beaker. In a 100 mL glass beaker, 10 g of air-dried potato starch (PS) was added to the tartaric acid (TA) solution, and the mixture was rapidly stirred using a glass rod. For 30 minutes, the mixture was dehydrated at 100°C in a forced air oven. At this stage, TA was applied to the starch particles after all surface moisture had been eliminated. The material was allowed to react for five hours after the oven temperature was increased to 120°C. By altering these parameters in multiple earlier experiments, the

temperature and reaction time were established[17]. The ST reaction's byproducts were combined with 100 milliliters of water and stirred for 30 minutes at 150 rpm using a mechanical paddle stirrer (Remi Electrotechnik Ltd., India). After passing through whatman filter paper, the slurry was rinsed for 30 minutes with 60, 80, and 100 milliliters of water. After one hour of drying at 60° C in an oven, the yield was calculated and the ST was run through ASTM mesh no. 85[18].

Preparation of tablets

Zidovudine dispersible tablets (300 mg) were formulated using the direct compression method, adding talc and magnesium stearate (12.5 mg) as lubricants, SLS (5 mg) as a wetting agent, menthol (5 mg) as a flavouring agent, mannitol (q.s.) as a diluent, and MCC (50 mg) as a binder. The tablet weight was ascertained to be 500 milligrams. Three tablet series were produced using ST (F1–F3), SSG (F4–F6), and CCS (F7–F9) were used as disintegrants at 5%, 10%, and 15% w/w, respectively. Using a 16-station tablet punching machine, all of the materials were carefully weighed, mixed, and compressed into tablets[19].

Table 1: Composition of various tablet formulations

Ingredients (mg)	ZF1	ZF2	ZF3	ZF4	ZF5	ZF6	ZF7	ZF8	ZF9
Zidovudine	300	300	300	300	300	300	300	300	300
Starch Tartrate (ST)	25	50	75						
Sodium starch glycolate (SSG)	-	-	-	25	50	75	-	-	
Croscarmellose sodium (CCS)	-	-	-	-	-	-	25	50	75
Microcrystalline cellulose (MCC)	50	50	50	50	50	50	50	50	50
Magnesium Stearate	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5
Talc	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5	12.5
SLS	5	5	5	5	5	5	5	5	5
Menthol	5	5	5	5	5	5	5	5	5
Mannitol	90	65	40	90	65	40	90	65	40
Total wt.	500	500	500	500	500	500	500	500	500

Precompression parameters

Blend Characterization

Nine different formulations were tested using blend characterization metrics, including bulk and tapped density, compression index, Hausner's ratio and angle of repose.

Post Compression Parameters[20]

Evaluation of uncoated tablets

The pharmacopeial standards were followed to assess each batch of tablet's physical attributes, including the thickness, weight variability, drug content, hardness, friability, and dissolving.

Time of in vitro disintegration[21]

The tablet disintegration test device measured all formulation's disintegration times. Disintegration test tubes held six tablets individually. Tablet disintegration was recorded using a 37 ± 2 °C temperature.

In -vitro dissolution studies[22]

An apparatus (EI -1916, Electronics India, Pune, India) was used for in-vitro release investigations. For every experiment, at a pH of 6.8 of phosphate buffer 500 milliliters was mixed with 50 revolutions per minute of hot water at 37°c. At 2 minute intervals, 5 ml of the dissolving liquid was removed then the absorbance was measured at 265 nm to determine the concentration of zidovudine. At predetermined intervals, 5 ml of each test medium was taken out and swapped out for an equivalent volume of a buffered phosphate solution with a pH of 6.8.

Release Kinetics[23]

The results of the in-vitro diffusion study were utilised to look at the drug release kinetics of zidovudine ODT, including their order and mechanism. The zero order, first order, and Higuchi equations were among the kinetic models that were plotted; the Korsmeyer-Peppas equations were employed to determine the release.

Stability Studies[24, 25, 26]

If a drug wants to be registered in the US, EU, or Japan, it must pass certain stability tests that are laid out in the ICH Guidelines, particularly the "Stability testing of new drug substance and products" (QIA). Stability studies for the present research conducted at 40º C ± 2ºC/75% ± 5% RH for the made a selection and used it for three months.

RESULTS AND DISCUSSION

Zidovudine standard calibration curve

In Figure 1, we can see the Zidovudine curve of calibration in phosphate buffer at pH 6.8. Within a concentration ranged from 0 to 10 µg/ml, it was determined that it was linear at 265 nm, with an R2 value of 0.9984.

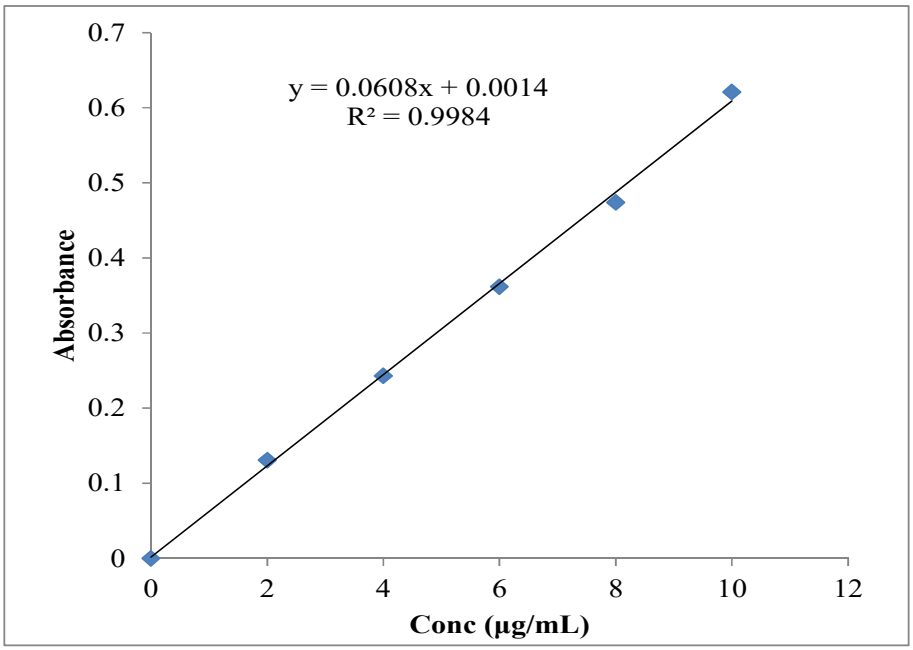

Fig 1: Standard graph of Zidovudine

Studies on drug-excipient compatibility by FT-IR

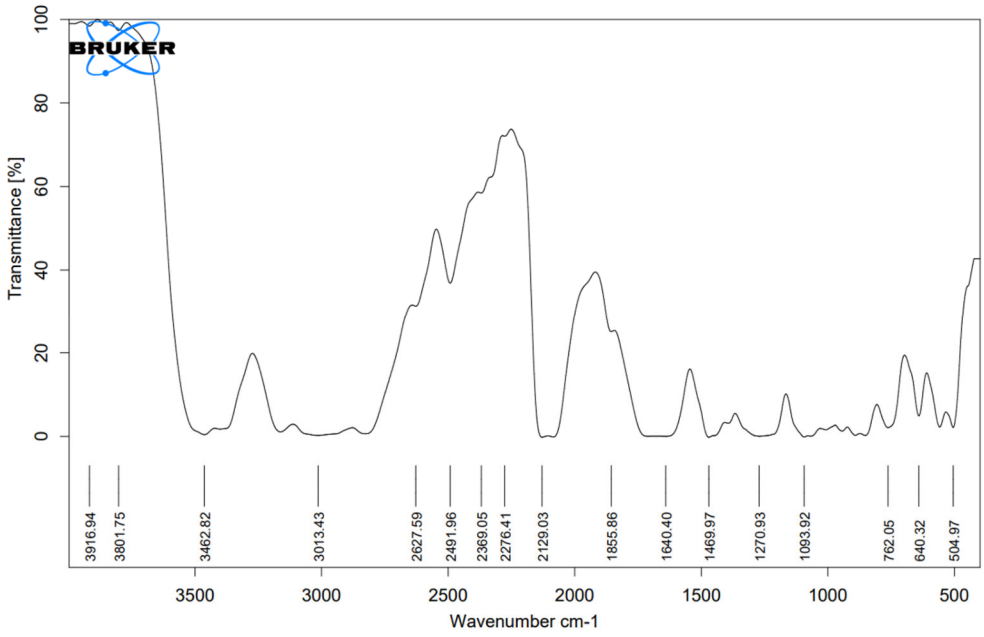

Fig 2: FTIR structure of Pure drug (Zidovudine)

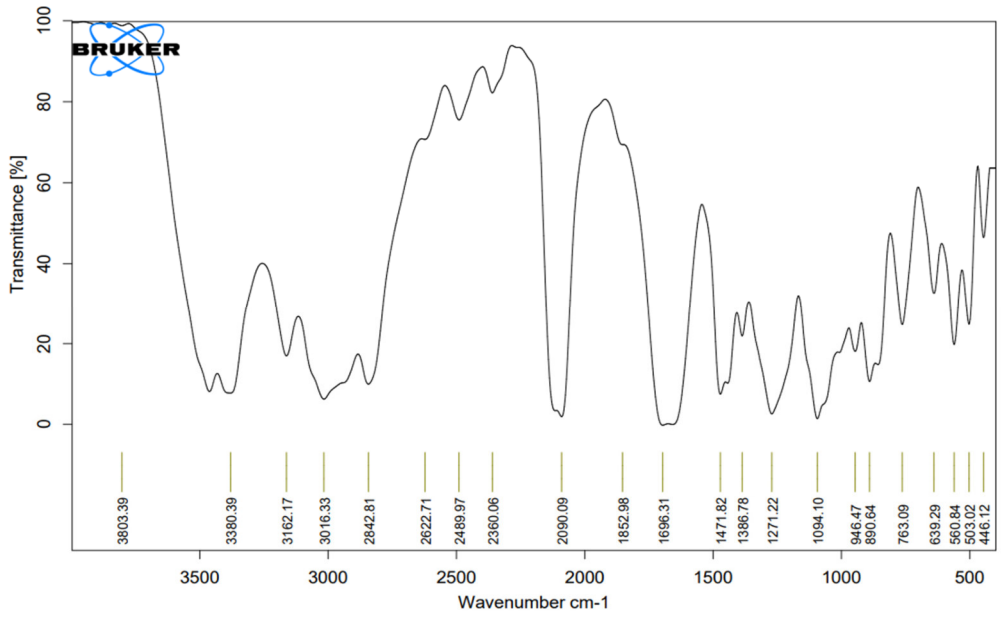

Fig 3: FTIR structure of optimised formulation

The infrared absorption spectra for Zidovudine and its optimized formulation exhibited distinct characteristic peaks corresponding to different functional groups. Zidovudine showed an amine group (N-H stretch) at 3462 cm^{-1}, an acid group (O-H stretch) at 2627 cm^{-1}, a carbonyl group (C=O stretch) at 1640 cm^{-1}, an alcohol group (C-O stretch) at 1093 cm^{-1}, and an azido group at 2129 cm^{-1}. In the optimized formulation, slight shifts in absorption peaks were observed, with the amine group appearing at 3380 cm^{-1}, the acid group at 2622 cm^{-1}, the carbonyl group at 1696 cm^{-1}, the alcohol group at 1094 cm^{-1}, and the azido group at 2090 cm^{-1}. These results showed that there is no interaction between Zidovudine and the formulation.

Pre-compression parameters

This information is displayed in Table 2. Angles of repose were determined to be between 21.33±0.47° and 25.23±0.36°. In terms of bulk density, different formulations exhibited values between 0.46±0.01 and 0.49±0.03 (g/cm^2), while tapped densities ranged from 0.59±0.01 to 0.63±0.04 (g/cm^2). The prepared blends have a Carr's index ranging from 13.26±0.48% to 17.41±0.69%. The Hausner's ratio ranged from 1.06±0.05 to 1.12±0.07 for all the formulations. This points to the mixture enhanced fluidity properties. The results showed that the powder mixtures were suitable for use in tablet production due to their excellent flow characteristics.

Table 2: Pre-compression parameters of Oro dispersible zidovudine tablets

Formulations	Bulk Density (g/cm^2)	Tap Density (g/cm^2)	Carr's Index (%)	Hausner ratio	Angle Of Repose(Ɵ)
ZF1	0.48±0.04	0.61±0.04	14.54±0.59	1.11±0.03	25.23±0.36
ZF2	0.47±0.01	0.60±0.03	15.49±0.62	1.09±0.02	24.42±0.28
ZF3	0.46±0.03	0.59±0.03	13.31±0.53	1.12±0.04	24.31±0.41
ZF4	0.48±0.02	0.62±0.04	14.25±0.58	1.08±0.05	25.26±0.25
ZF5	0.47±0.04	0.59±0.02	16.38±0.63	1.11±0.09	24.18±0.17
ZF6	0.49±0.02	0.63±0.03	13.26±0.48	1.12±0.07	23.43±0.38
ZF7	0.46±0.01	0.62±0.02	17.41±0.69	1.09±0.12	22.39±0.11
ZF8	0.49±0.03	0.63±0.04	15.37±0.54	1.08±0.08	22.14±0.23
ZF9	0.47±0.02	0.61±0.05	13.42±0.49	1.06±0.05	21.33±0.47

Parameters after compression

The results, including the percentage deviation are displayed in Table 3. The tablet's weight is around 497.7±3.8 to 503.8±5.6 mg. The results indicated that the tablet's hardness fell within the accepted IP limits, ranging from 2.6±0.4 to 2.9±0.6 kg/cm^2. The tablet's thickness ranged from 3.29±0.21 to 3.52±0.24, according to

the results. All the formulations had an average friability ranging from 0.49±0.03 to 0.72±0.06%, which is below the statutory limit of 1% for IP and suggests that the tablets have acceptable mechanical resilience. The assay investigations indicated that the medication content percentages in each formulation ranged from 97.58±3.22% to 100.02±2.29 %.

Table 3: Post-Compression parameters of Oro dispersible zidovudine tablets

F code	Weight variation (mg)	Hardness (kg/cm^2)	Thickness (mm)	Friability (%)	Assay (%)
ZF1	502.6±5.4	2.7±0.3	3.52±0.24	0.59±0.03	98.32±4.24
ZF2	498.3±4.5	2.8±0.4	3.34±0.17	0.61±0.05	99.87±3.18
ZF3	500.6±4.7	2.9±0.2	3.41±0.15	0.67±0.04	100.02±2.29
ZF4	503.8±5.6	2.6±0.4	3.48±0.12	0.55±0.03	98.16±5.36
ZF5	501.2±4.2	2.9±0.6	3.52±0.19	0.68±0.06	97.58±3.22
ZF6	498.5±5.5	2.7±0.3	3.42±0.23	0.71±0.05	98.47±5.42
ZF7	497.7±3.8	2.6±0.6	3.29±0.21	0.59±0.04	98.36±3.31
ZF8	499.2±4.2	2.7±0.4	3.38±0.23	0.49±0.03	99.64±6.12
ZF9	502.4±4.9	2.9±0.5	3.49±0.22	0.72±0.06	98.29±4.26

In vitro disintegration time

Table 4 displays the results of the in vitro time to disintegration evaluations performed on each batch of tablets. The findings indicated that the duration required for the tablets to dissolve varied between 32.28±1.61 and 59.56±3.34 seconds.

Duration of wetting operations

Table 4 displays the wetting time data for each formulation. The wetting time of prepared tablet formulations was less than 79.62 seconds respectively. The findings demonstrated that the concentration impacted the wetting duration of the super disintegrant. Formulation ZF3, which includes ST, had a shorter wetting time compared to the other formulations.

Table 4: Time of disintegration and wetting

F code	Disintegration Time (sec)	Wetting time (sec)
ZF1	54.36±2.32	73.82±0.06
ZF2	47.51±3.44	67.45±0.07
ZF3	32.28±1.61	54.39±0.03
ZF4	57.33±4.39	79.62±0.05
ZF5	53.32±2.29	68.41±0.04
ZF6	44.19±2.13	63.69±0.07
ZF7	59.56±3.34	75.27±0.03
ZF8	54.37±1.41	64.32±0.05
ZF9	47.54±2.26	57.54±0.06

Studies on in vitro dissolution Utilising a USP dissolving device and the paddle method, 500 ml of pH 6.8 phosphate buffer was utilised for in vitro dissolution tests. The duration of the dissolution experiments was approximately thirty minutes.

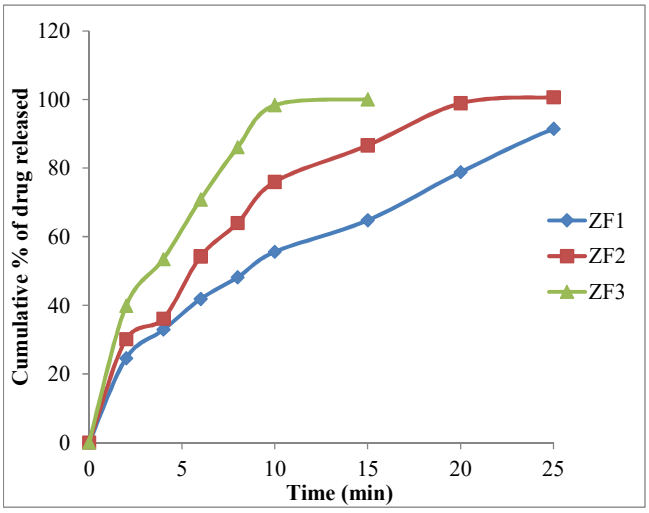

Fig 4: Dissolution profile of formulations prepared with starch tartrate (ST)

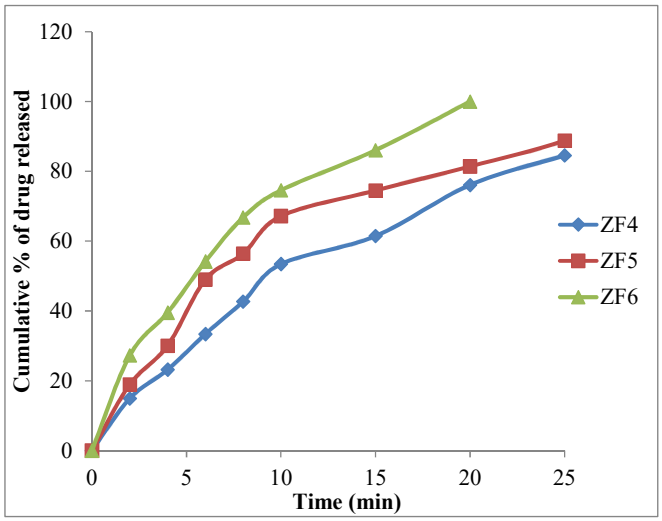

Fig 5: Dissolution profile of formulations prepared with SSG

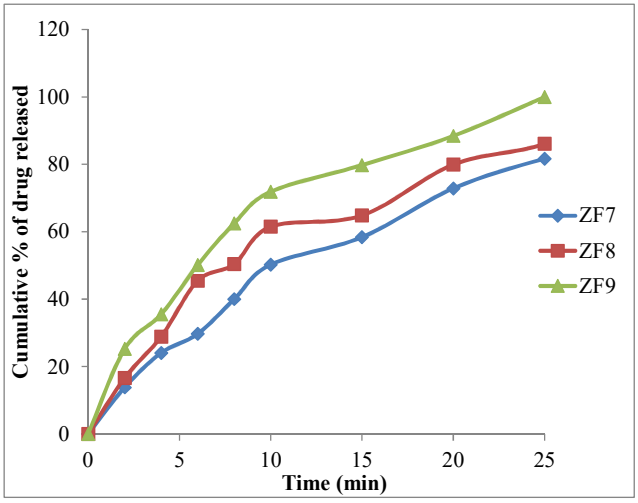

Fig 6: Dissolution profile of formulations prepared with CCS

Formulations made with super disintegrant ST demonstrated the fastest drug release rate in 15 minutes, at 100.05 percent (ZF3 formulations with a super disintegrant concentration of 75 mg), as shown in Figure 4. So, it was determined that the super disintegrant principle may be utilized to create oro-dispersible tablets. For optimization purposes, the ZF3 formulation was deemed appropriate.

Utilizing Kinetics of Release Rate for Dissolution

Various models were utilized to examine the drug release kinetics. A number of release of drug models, including first-order, zero-order, Higuchi, and Korsmeyer-Peppas, were fitted to the collected data to examine the mechanism underlying the rate kinetics of the dose form.

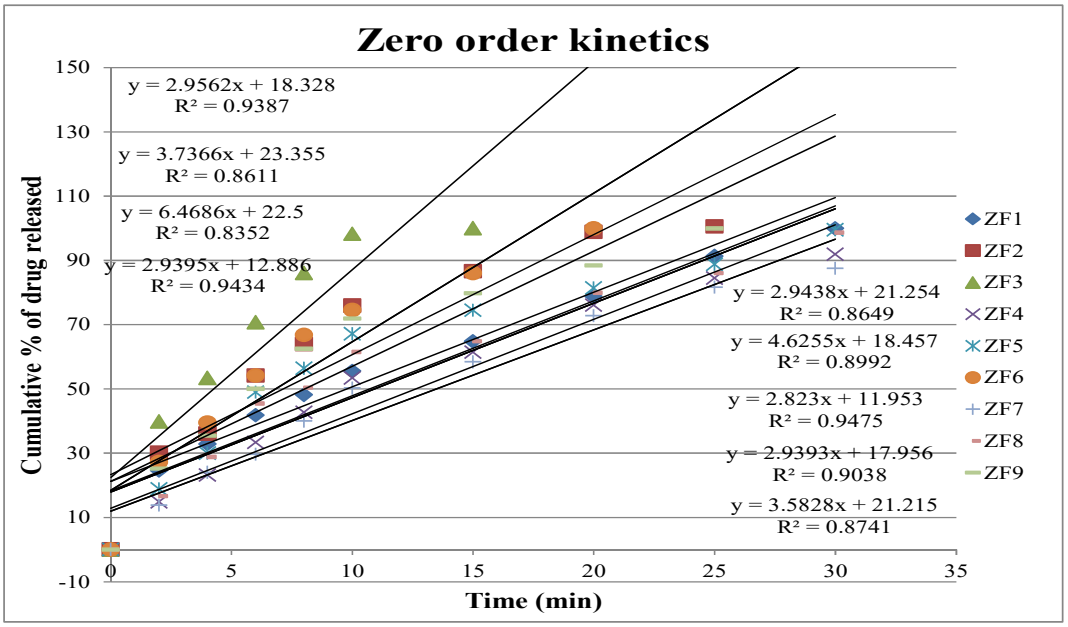

Fig 7: Zero order release kinetics graph of zidovudine formulations.

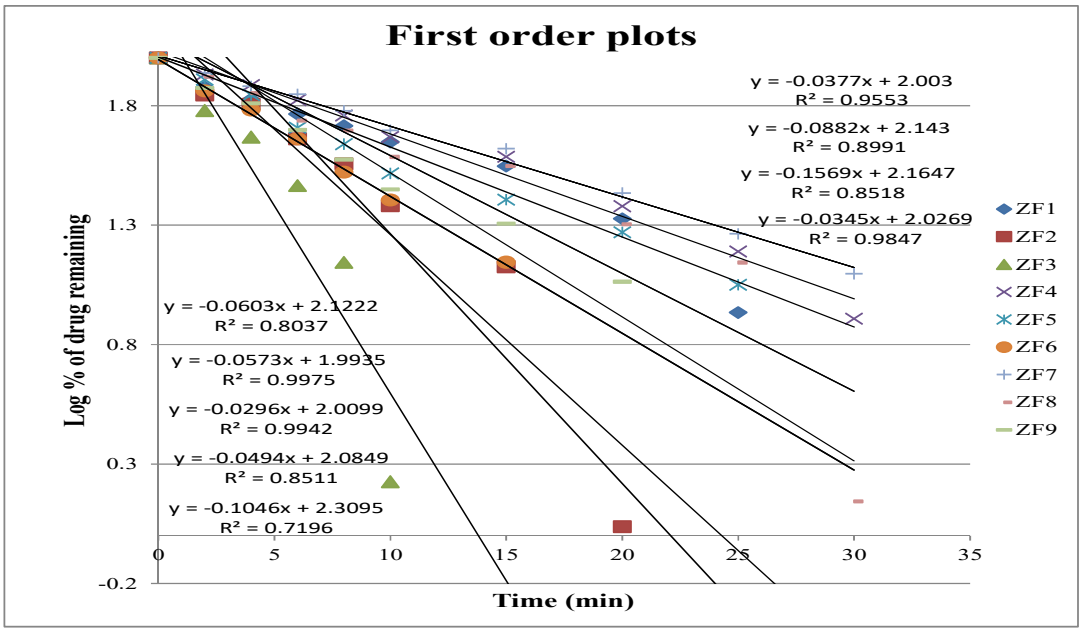

Fig 8: First order release kinetics graph of zidovudine formulations

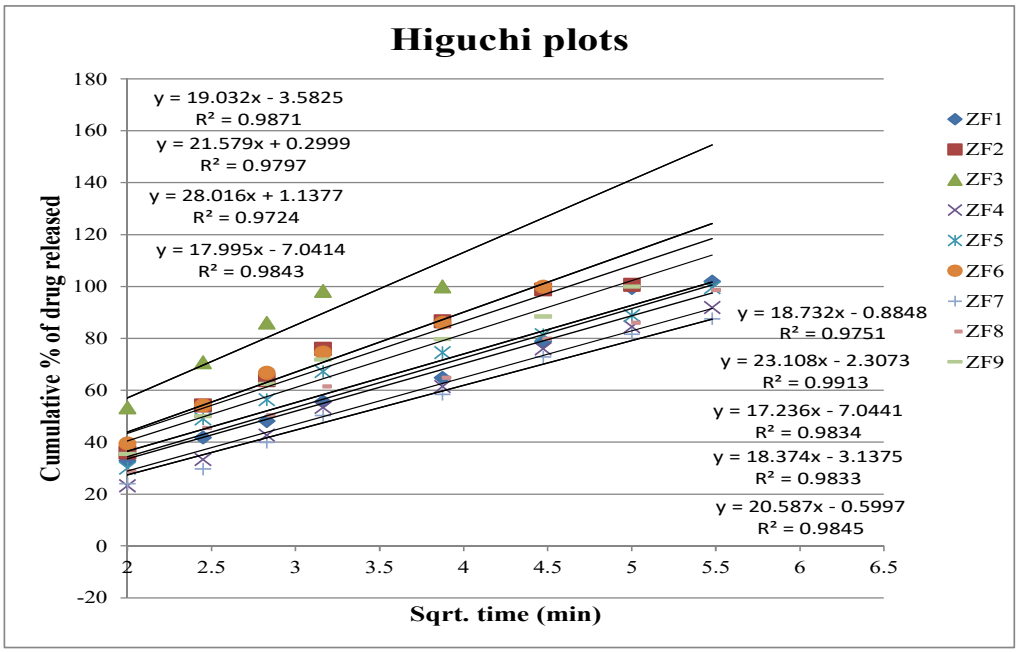

Fig 9: Higuchi release kinetics graph of zidovudine formulations

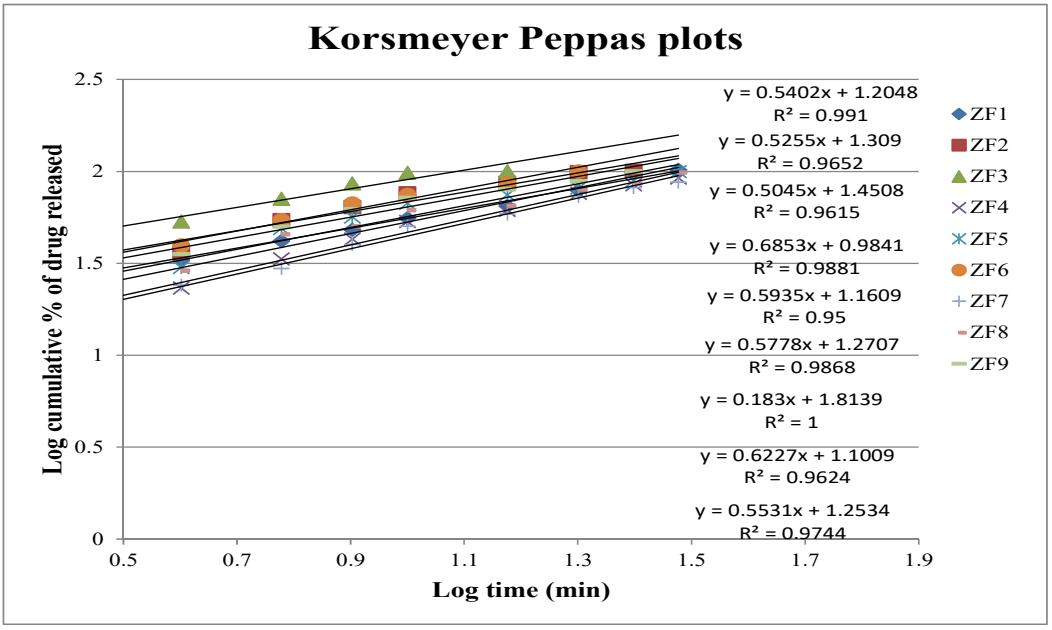

Fig 10: Korsmeyer-Peppas kinetics graph of zidovudine formulations.

The R^2 values presented in the first-order kinetic graphs exceeds in contrast to the zero-order kinetic graphs, indicating that the drug release adheres to first-order kinetics. The regression equations of Higuchi plots provide R^2 values exceeding 0.9, showing that drug release adheres to diffusion kinetics. The Korsmeyer-Peppas model is applicable when drug release entails many processes or when the precise mechanisms are indeterminate. The model can additionally ascertain if the release is governed by diffusion. Here "n" is between 0.45 and 0.89, it signifies the medication release is caused via non-fickian diffusion process.

Selection of Best Formulation

Out of nine potential formulations, the one with the best combination of characteristics was selected: rapid drug release, short wetting time, high water absorption ratio, and minimal disintegration time. With a disintegration time of just 32.28 seconds, a drug release rate of 100.05% within 15 minutes, and a wetting time of just 54.39 seconds, Formulation ZF3 stood out from the others. According to these considerations, the ZF3 formulation is the best one to use.

Stability Studies

A three-month stability investigation was carried out on the ZF3 refined compounds in a controlled environment with a 40°C temperature and a 75% relative humidity. Every thirty days, the tablets were tested for a variety of properties, including thickness, diameter, hardness, consistency of content, friability, weight change and disintegration time. All of the metrics were within the predetermined range, and there was no discernible change from the original data. Measurements were taken every 30 days throughout the three-month in-vitro dissolving research. Exposure to elevated temperatures and controlled humidity levels had no effect on the release patterns.

CONCLUSION

The study sought to make Zidovudine tablets dissolve quickly. This study used super disintegrating agents starch tartrate, SSG, and CCS to improve the solubility and dissolving rate of a medication. Every formulation was directly compressed with a 16-millimeter punch on an eight-station rotary tablet punching machine. The combined formulations had good tapped density, bulk density, and angle of repose. FTIR confirmed drug-polymer compatibility. According to FTIR data, the pure drug and excipients have no chemical interaction. Direct compression method was used. Starch tartrate, SSG and CCS were super disintegrant, talc flow promoters, magnesium stearate lubricants, and mannitol sweeteners and diluents were used in this method. Several parameters were evaluated after compression and found satisfactory, including thickness, friability, hardness, wetting time, in vitro drug release, and disintegration.

Formulation ZF3 was determined to be the most effective since it released the most medicine (100.05 percent) in the shortest duration of time (15 minutes). With a dosage of 75 mg, the ZF3 formulation includes starch tartrate (ST) as a super disintegrant.

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