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Development of Orally Disintegrating Tablets of Terbinafine Hydrochloride Using Novel Superdisintegrants

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ABSTRACT

The objective of the present study was to design and optimize fast-dissolving tablets of Terbinafine Hydrochloride using different superdisintegrants to enhance the disintegrating properties of the tablets. Fast-dissolving tablets were prepared using direct compression with the help of different super disintegrants such as Kollidon, Vivasol, Tulsion 330, etc., at different concentrations. Pre-formulation studies were done for the drug substance, which included solubility study, calibration curves with λmax at 228 nm, and FTIR studies. Pre compression and post compression studies were done for the tablets. Pre compression studies included flow properties, weight variation, hardness, and friability. Post compression studies included weight variation, hardness, and in vitro disintegration test. Dissolution studies were done using the USP paddle method with phosphate buffer solution pH 6.8. FTIR studies showed that there were no interactions between the drug substance. The powder blends showed good flow properties with an acceptable Carr's index and Hausner's ratio. All the tablets complied with pharmacopoeial standards for physical properties. The disintegration times were within the range of 12.66 to 30.33 seconds. Out of all the formulations studied, F8 with Tulsion 330 showed the best results with approximately 99.8% of the drug dissolved within 4 minutes. The optimized fast-dissolving tablets showed significant improvement in the dissolution rate of Terbinafine Hydrochloride. The study provides an innovative approach to enhance the bioavailability of Terbinafine Hydrochloride.

Keywords: Terbinafine Hydrochloride, Fast-dissolving tablets, Superdisintegrants, Tulsion 330, Direct compression, Dissolution enhancement.

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INTRODUCTION

Oral drug delivery is the most commonly employed and favoured method of drug administration because it is simple, safe, and economical[1]. Still, traditional oral dosage forms like tablets and capsules tend to pose challenges for certain patient groups, i.e., pediatric, geriatric, and bedridden patients, who can have swallowing issues[2]. To counteract these disadvantages and increase patient compliance, fast dissolving tablets (FDTs) have been an innovative dosage form that disintegrates or dissolves instantly within the oral cavity, typically in seconds, without water intake[3]. Fast dissolving tablets possess a number of advantages such as quick onset of action, enhanced bioavailability, and increased patient convenience[4]. These types of preparations are especially useful for drugs that experience vast first-pass metabolism or need to act immediately therapeutically. The quick disintegration of FDTs is made possible by the use of super disintegrants like croscarmellose sodium, sodium starch glycolate, and crospovidone that allow water absorption and induce tablet disintegration by swelling or capillary action[5]. Typical manufacturing methods are direct compression, sublimation, lyophilization, and spray-drying, affecting the mechanical strength, porosity, and dissolution properties of the final product[6,7].

Terbinafine Hydrochloride, an antifungal allylamine agent, is commonly used for the treatment of dermatophytoses and onychomycosis due to Trichophyton, Epidermophyton, and Microsporum species[8,9]. It works its antifungal effect by selectively inhibiting squalene epoxidase, a central enzyme in the ergosterol biosynthetic pathway, a critical cell membrane component of fungi [9, 10]. This inhibition causes intracellular accumulation of squalene and cell death. With all its powerful antifungal activity, Terbinafine Hydrochloride has poor solubility in water and is subject to extensive first-pass metabolism, resulting in low and highly variable bioavailability[11]. Traditional oral drugs, thus, usually cannot bring a quick therapeutic effect. To counter these issues, the design of rapidly dissolving tablets of Terbinafine Hydrochloride presents a good approach to increase drug solubility, dissolution rate, and bioavailability along with patient compliance [12]. Formulation of such a drug ensures that the drug gets easily disintegrated in the oral cavity, leading to quicker absorption and therapeutic effect. In addition, the dosage form may be especially beneficial for swallowing-impaired patients or those who are in need of quick relief from symptoms[6].

In contemporary drug development, optimization methods like factorial design or response surface methodology (RSM) are commonly used to investigate systematically the effect of formulation variables and determine optimum combinations of excipients[12]. These statistical methods not only reduce the number of experimental runs but also increase the reproducibility and stability of the formulation process.

The current research deals with the development of Terbinafine Hydrochloride fast dissolving tablets by optimization and evaluation through proper superdisintegrants and excipients to get rapid disintegration, increased dissolution rate, and better drug release profile. The optimized formulation was tested for physicochemical properties such as hardness, friability, weight variation, disintegration time, drug content uniformity, and in vitro drug release. The aim of the present study is to formulate a patient-compliant and quick-acting oral dosage form of Terbinafine Hydrochloride that overcomes the draw-backs of the traditional tablets and offers enhanced therapeutic efficacy in the treatment of fungal infections.

MATERIALS AND METHOD

Materials

Terbinafine Hydrochloride was obtained as a gift sample from a certified pharmaceutical source. Excipients such as Kollidon, Vivasol, Tulsion 330, magnesium stearate, talc, and microcrystalline cellulose (MCC) were of analytical grade and procured from standard suppliers. All chemicals and reagents used were of analytical or pharmaceutical grade and used as received**.**

Preformulation Studies

The preformulation studies were conducted to assess the physicochemical properties, solubility behavior, and compatibility of Terbinafine Hydrochloride with different excipients. These studies aimed to establish necessary formulation parameters before developing the tablet.

Organoleptic Properties

The colour, taste, and appearance of the pure drug were observed visually.

Solubility Studies

The solubility of Terbinafine Hydrochloride was evaluated in various solvents including distilled water, ethanol, and phosphate buffer (pH 6.8) to determine the best dissolution medium.

Melting Point Determination

The melting point of the pure drug was determined using a capillary method to assess purity.

Formulation of fast dissolving tablets of Terbinafine Hydrochloride:

Preparation of tablets:

Composition of Terbinafine Hydrochloride Fast dissolving Tablet by direct compression method, all the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a polybag. The blend is compressed using rotary tablet machine-8 station with 8mm flat punch, B tooling. Each tablet contains 100 mg Terbinafine Hydrochloride and other pharmaceutical ingredients. Total weight of tablet was found to be 200 mg.

Table 1: Composition of various tablet formulations

Ingredients	F1	F2	F3	F4	F5	F6	F7	F8	F9
Terbinafine Hydrochloride (mg)	100	100	100	100	100	100	100	100	100
Kollidon(mg)	10	20	30	-	-	-	-	-	-
Vivasol(mg)	-	-	-	10	20	30	-	-	-
Tulsion 330 (mg)	-	-	-	-	-	-	10	20	30
Mg Stearate(mg)	2	2	2	2	2	2	2	2	2
Talc(mg)	2	2	2	2	2	2	2	2	2
MCC(mg)	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs	Qs
Total wt(mg)	200	200	200	200	200	200	200	200	200

Determination of Absorption Maximum (λmax)

Ten milligrams of Terbinafine Hydrochloride were accurately weighed and dissolved in phosphate buffer (pH 6.8) in a 100 mL volumetric flask to obtain a stock solution of 1000 µg/mL. A series of dilutions were prepared, and the absorbance of the 10 µg/mL solution was scanned between 200–400 nm using a UV–Visible double-beam spectrophotometer (UV-Labindia, India). The maximum absorption wavelength (λmax) was determined.

Calibration Curve of Terbinafine Hydrochloride

A standard stock solution (1000 µg/mL) was prepared by dissolving 100 mg of the drug in 100 mL of phosphate buffer (pH 6.8). Aliquots corresponding to concentrations of 5, 10, 15, 20, and 25 µg/mL were prepared. The absorbance of each concentration was measured at 228 nm, and a calibration curve was plotted between absorbance and concentration.

Drug–Excipient Compatibility Studies (FTIR Analysis)

Fourier Transform Infrared Spectroscopy (FTIR) was used to evaluate possible interactions between Terbinafine Hydrochloride and excipients. The samples were analyzed using a Bruker FTIR spectrophotometer (Germany, Alpha T). The drug and excipients were blended with KBr (1:100 ratio) and compressed into pellets. Spectra were recorded in the range of 4000–400 cm^{-1}, and characteristic peaks were compared with that of the pure drug.

Evaluation of Flow Properties

Flow properties of the pre-compression blend were evaluated to ensure uniform die filling and compressibility.

Angle of Repose

The angle of repose was measured using the fixed funnel method and calculated using the formula:

$$\theta = tan^{-1}[h|r]$$

where h is the height and r is the radius of the powder cone.

Bulk Density and Tapped Density

Loose bulk density (LBD) and tapped density (TD) were calculated by measuring the volume occupied by the powder before and after tapping in a graduated cylinder.

$$LBD = \frac{M}{v_b}, TD \frac{M}{v_t}$$

Carr's Index and Hausner's Ratio

The compressibility index and Hausner's ratio were calculated using:

$$C = \frac{(\rho b - \rho t)}{\rho b} \times 100$$

RESULTS AND DISCUSSION

Standard Calibration curve of Terbinafine Hydrochloride:

Table 2: Concentration and absorbance obtained for calibration curve of Terbinafine Hydrochloride in pH 6.8 Phosphate buffer

S. No.	Concentration (µg/ml)	Absorbance* (at 228 nm)
1	0	0
2	5	0.277
3	10	0.414
4	15	0.594
5	20	0.739
6	25	0.890

It was found that the estimation of Terbinafine Hydrochloride by UV spectrophotometric method at λ_{max} 228 nm in pH 6.8 Phosphate buffer had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 5- 25µg/ml. The regression equation generated was y = 0.0366x +0.0184.

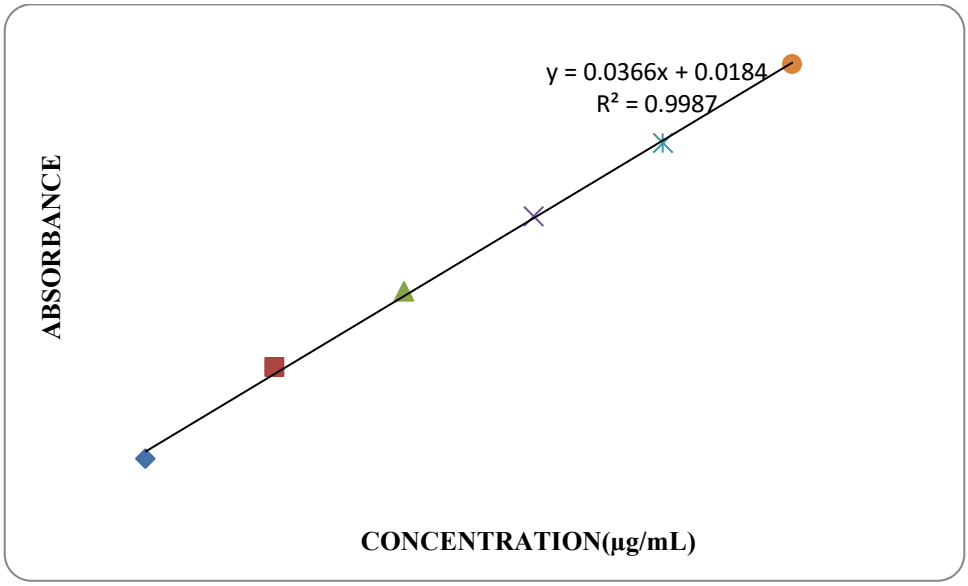

Figure 1: Standard graph of Terbinafine Hydrochloride in pH 6.8 Phosphate buffer

Drug–Excipient Compatibility Studies (FTIR Analysis)

Fourier Transform-Infrared Spectroscopy:

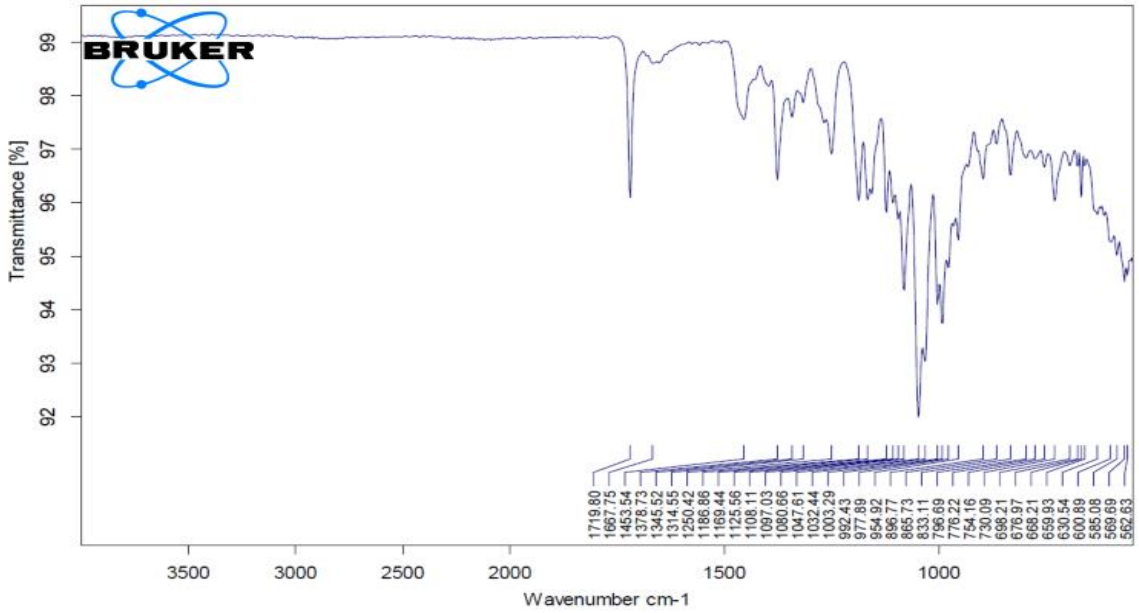

Figure 2: FT-IR Spectrum of Terbinafine Hydrochloride pure drug.

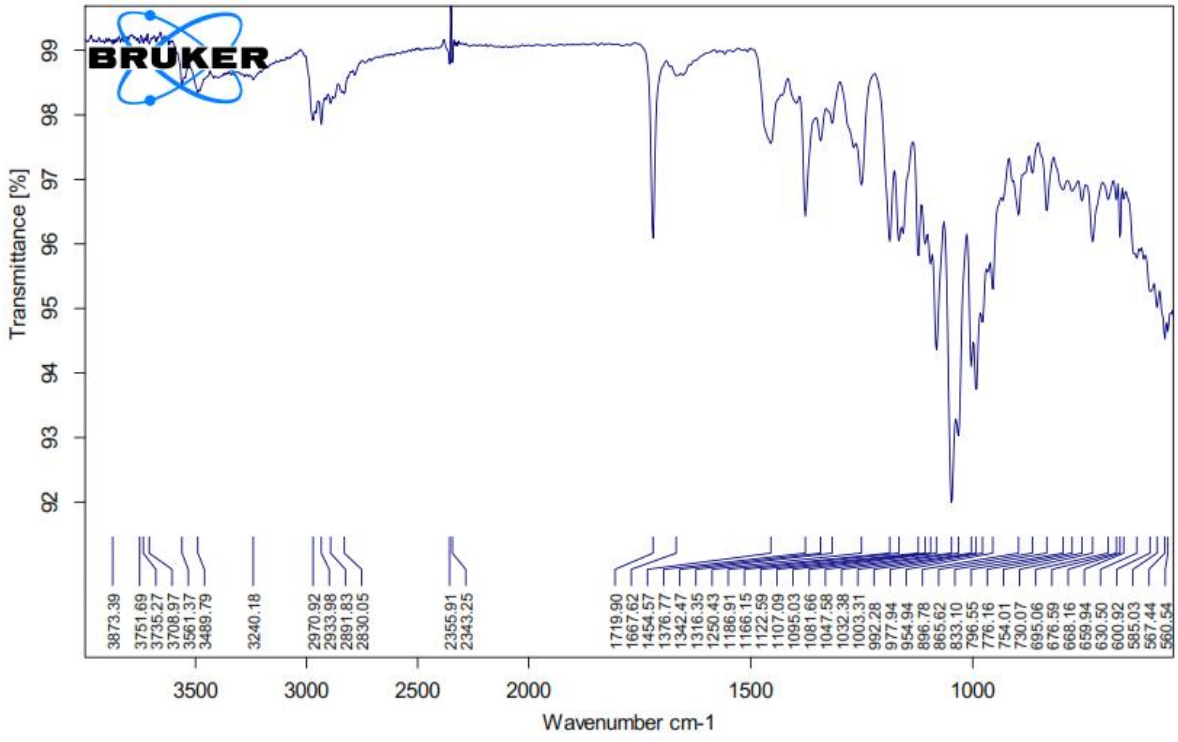

Figure 3: FT-IR Spectrum of Optimized Formulation

From the FTIR data it was evident that the drug and super disintegrates, other excipients doses not have any interactions**.** Hence they were compatible.

Evaluation Parameters for Fast Dissolving Tablets of Terbinafine Hydrochloride:

Pre-compression parameters:

The data's were shown in Table 2. The values for angle of repose were found in the range of 25°-30°. Bulk densities and tapped densities of various formulations were found to be in the range of 0.41 to 0.50 (gm/cc) and 0.50 to 0.58 (gm/cc) respectively. Carr's index of the prepared blends fall in the range of 13.06% to 18.18%. The Hausner ration fall in range of 1.14 to 1.22. From the result it was concluded that the powder blends had good flow properties and these can be used for tablet manufacture.

Table 3: Pre-compression parameters

Formulations	Bulk Density(gm/cm^3)	Tap Density(gm/cm^3)	Carr's Index %)	Hausner ratio	Angle Of Repose(Ɵ)
F_1	0.45	0.55	18.18	1.22	27.91
F_2	0.47	0.55	14.54	1.17	28.23
F_3	0.50	0.58	13.79	1.16	29.34
F_4	0.46	0.55	16.36	1.19	26.71
F_5	0.50	0.58	13.79	1.16	29.34
F_6	0.47	0.55	14.54	1.17	28.23
F_7	0.50	0.58	13.79	1.16	29.34
F_8	0.41	0.50	18	1.21	26.78
F_9	0.41	0.50	18	1.21	26.78

Post-compression Parameters:

Weight variation test:

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet and was shown in the Table 3. The average weight of the tablet is approximately in range of 196 to 208, so the permissible limit is ±7.5% (110-220mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

Hardness test:

Hardness of the three tablets of each batch was checked by using Monsanto hardness tester. The results showed that the hardness of the tablets is in range of 2.5 to 3.00 kg/cm^2, which was within IP limits.

Thickness:

Thickness of three tablets of each batch was checked by using Vernier Calipers. The result showed that thickness of the tablet is raging from 3.56 to 3.64.

Friability:

Tablets of each batch were evaluated for percentage friability. The average friability of all the formulations lies in the range of 0.30 to 0.51% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets.

In vitro disintegration time:

Tablets of each batch were evaluated for in vitro disintegration time, The results showed that the disintegration time of prepared tablets were in the range of 12.66 to 30.33 seconds.

Assay:

Assay studies were performed for the prepared formulations. From the assay studies it was concluded that all the formulations were showing the % drug content values within 97.23 -99.2%.

Table 4: Post-Compression parameters

Formulation code	Average Weight(mg)	Hardness (kg/cm^2)	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
F1	205	2.5	3.59	20.33	0.43	97.23
F2	204	2.6	3.64	22.66	0.34	98.55
F3	199	2.5	3.59	30.33	0.49	98.16
F4	201	2.6	3.58	19.00	0.47	99.34
F5	199.4	2.3	3.59	30.33	0.49	98.16
F6	202	2.7	3.64	22.66	0.34	98.55
F7	201	2.5	3.59	30.33	0.49	98.16
F8	201	2.6	3.56	17.00	0.34	99.25
F9	202	2.5	3.56	19.00	0.44	97.25

Table 5: In vitro Dissolution studies

Time (Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9
2	25.4	31.7	30.8	24.3	39.5	14.9	48.3	68.16	80.45
4	39.6	34.5	36.72	31.6	76.3	28.4	82.9	99.8	95.33
6	48.6	41.9	56.16	49.3	96.2	33.1	98.7		
8	64.3	62.4	87.4	58.3	99.7	59.7			
10	76.4	89.1	98.5	74.3		79.3			
15	97.1	99.5		88.1		88.9			
20	97.6			94.6		93.5			
25				98.1		98.1			
30									

In vitro dissolution studies were carried out by using 500ml of pH 6.8 Phosphate buffer in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min. The dissolution data for all the formulations were given in Table.

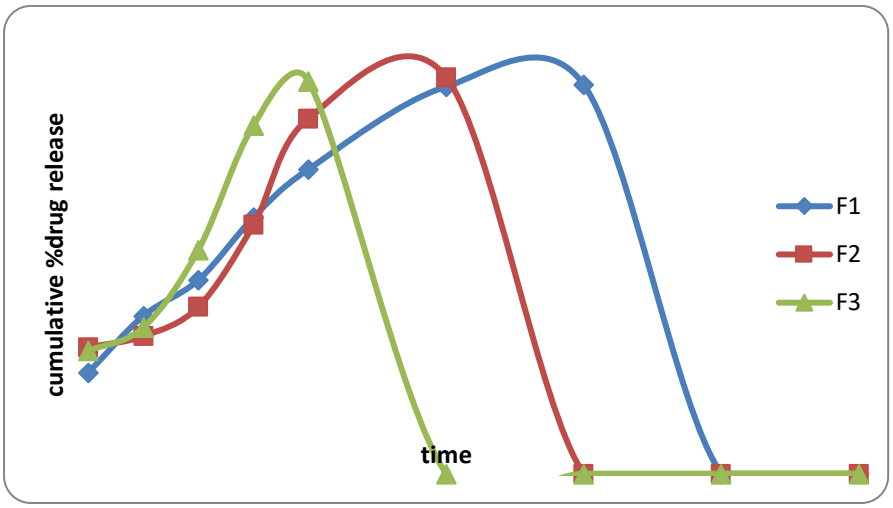

Figure 4: Dissolution profile of formulations prepared with Kollidon as super disintegrate

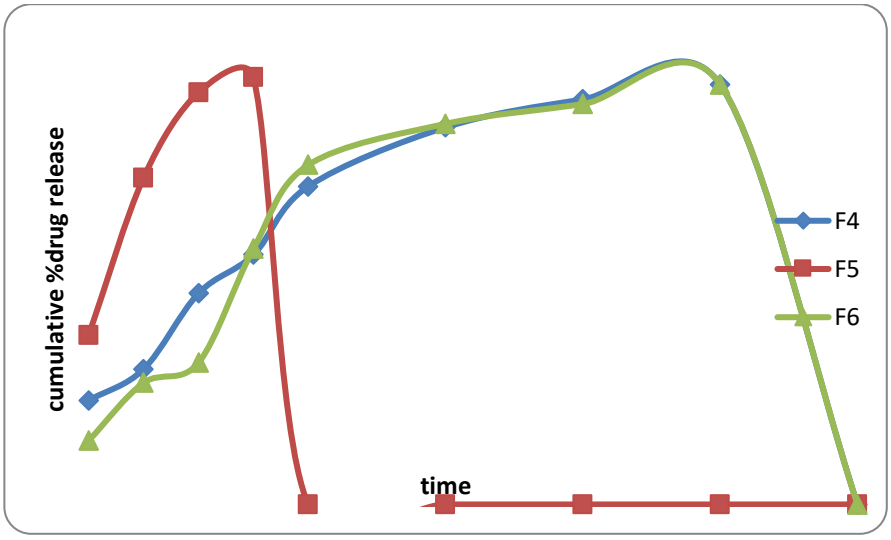

Figure 5: Dissolution profile of formulations prepared with Vivasol as super disintegrate

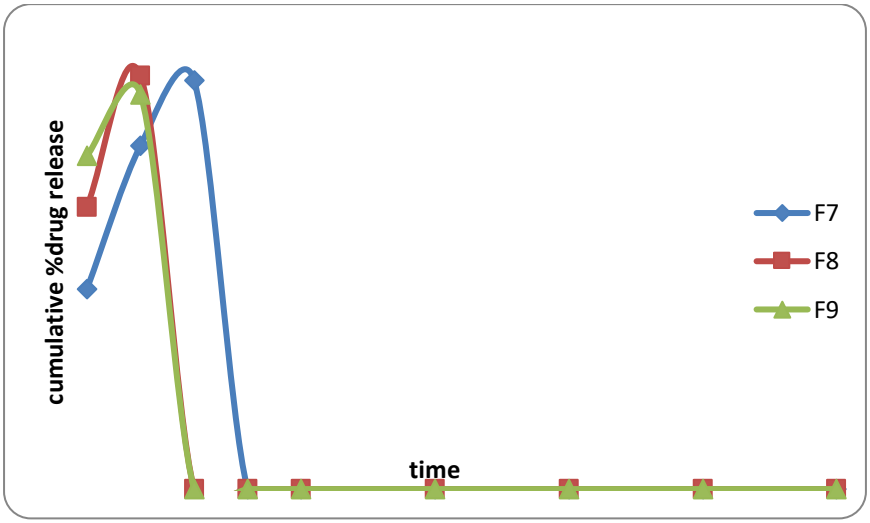

Figure 6: Dissolution profile of formulations prepared with Tulsion 330 as super disintegrate

From Table 4 it was evident that the formulations prepared with super disintegrate Tulsion 330

showed maximum % drug release in 4 min i.e.99.8% and 95.33% (F8, F9 formulations and the concentration of super disintegrate is 20mg,30 mg). So the principle of super disintegrates was found to be useful to produce oro- dispersible tablets. F8 formulation was considered as optimized formulation as it contains less concentration of super disintegrate (Tulsion 330,Ion exchange resin).The formulation followed zero order release mechanism. As the time increases the percentage drug release was increased.

DISCUSSION

The current research successfully formulated fast dissolving tablets of Terbinafine Hydrochloride with acceptable physicochemical characteristics and improved drug dissolution rate. The UV spectroscopic technique exhibited excellent linearity within a concentration range of 5-25 µg/mL, thus confirming its reliability, as reported by previous research. FTIR results showed no considerable drug-excipient interaction, thus signifying acceptable drug compatibility with excipients, as reported. Results of pre-compression tests, including angle of repose, Carr's index, and Hausner ratio, signified acceptable flow characteristics of the drug powder mix, thus suggesting acceptable efficiency of the direct compression method of tablet production, as reported by previous research. Results of the post-compression tests of the formulations showed acceptable pharmacopoeial limits of weight variation, hardness, friability, and drug content. Results of hardness and friability tests were consistent with those reported. For fast dissolving tablets, thus signifying acceptable mechanical strength of the tablets.

One of the most significant findings from this study was the rapid disintegration time, which ranged from 12.66 to 30.33 seconds, and improved dissolution profile, especially for formulations containing Tulsion 330, where nearly complete drug release (~99%) was observed within 4 minutes. This could be attributed to the excellent swelling and wicking properties of superdisintegrants. The optimized formulation, F8, containing a lower concentration of Tulsion 330, showed improved results, emphasizing the optimization of excipients, Rapid dissolution is advantageous for Terbinafine Hydrochloride, a poorly soluble drug with high first-pass metabolism, for which improved dissolution is known to improve bioavailability . Similar improvements in dissolution behavior have been observed for FDT formulations of Terbinafine, as discussed in earlier studies. The drug release profile showed a nearly zero-order pattern, indicating uniform drug release. The results of this study correlate well with earlier research, proving that the use of proper super disintegrants enhances the efficiency, rate of dissolution, and therapeutic efficacy of FDT formulations.

CONCLUSION

Formulation and optimization of fast dissolving tablets of Terbinafine Hydrochloride with improved physicochemical properties and efficacy have been successfully achieved in this study. The prepared formulations were found to comply with pharmacopoeial standards, and the use of appropriate superdisintegrants improved their disintegration and dissolution behavior significantly. Among the prepared batches, formulation F8 showed excellent efficacy compared to the other batches, with quick disintegration and maximum dissolution in a small interval of time. The newly developed fast dissolving tablets have shown potential for enhancing the solubility, dissolution rate, and bioavailability of Terbinafine Hydrochloride, thus increasing patient compliance, especially in patients with difficulty in swallowing tablets, and also in enhancing the therapeutic action compared to conventional tablets.

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