Formulation and Evaluation of fast dissolving tablets of Tiaprofenic

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***Abstract*—From the results of the present investigation, it can be concluded that fast dissolving tablets of Tiaprofenic acid were successfully formulated using wet granulation technique. All formulations exhibited acceptable pre- and post- compression characteristics. Among them, formulation F7 emerged as the optimized batch, owing to its shortest disintegration time, rapid and complete drug release, acceptable physical properties, and favorable release kinetics. The study confirms that croscarmellose sodium is a highly effective superdisintegrant for the development of fast dissolving tablets of Tiaprofenic acid. Therefore, formulation F7 can be considered a promising fast dissolving tablet formulation that may enhance patient compliance and provide rapid onset of therapeutic action.**

***Index Terms*—Tiaprofenic acid, Fast dissolving tablets, Super disintegrants, Croscarmellose sodium, Sodium starch glycolate, Crospovidone, Wet granulation, In-vitro disintegration, Dissolution studies, Release kinetics.**

I. INTRODUCTION

FAST DISSOLVING TABLETS

Drug distribution by oral route is chosen by the vast majority of patients. Oral solid dosage forms such as tablets and capsules are widely utilized around the world. According to statistics, almost 30% of patients have difficulty swallowing tablets and capsules. As soon as the dosing frames come into touch with spit, they begin to disintegrate, releasing the medication and lowering the overall water consumption. These unique features appeal to a wide range of patients, including children and the elderly. Many people of all ages, but especially the elderly and those with dysphagia, have trouble swallowing regular tablets and containers (Hannan PA *et al.*, 2016). Using sterile materials is unnecessary when using strong oral conveyance frameworks.

SALIENT FEATURES OF FDTS

- Does not require water for oral administration
- Have sufficient strength to withstand the rigors of the manufacturing process and post manufacturing handling
- Allow high drug loading
- Insensitive to environmental conditions such as humidity and temperature
- Adaptable and amenable to existing processing and packaging machineries
- Cost effective.
- Have a pleasant mouth feel (Kuchekar and Arumugam, 2001).

II. THE NEED FOR DEVELOPMENT OF FDTS

PATIENT FACTORS Fast dissolving dosage forms are suitable for those patients (particularly pediatric and geriatric patients) who are not able to swallow traditional tablets and capsules with an 8-oz glass of

water (Slowson and Slowson, 1985; Chang *et al.*, 2000).

THESE INCLUDE THE FOLLOWING:

- Patients who have difficulty in swallowing or chewing solid dosage forms
- Patients' incompliance due to fear of choking.
- Very elderly patients of depression who may not be able to swallow the solid dosage forms
- An eight-year-old patient with allergies desires a more convenient dosage form than antihistamine syrup
- A middle-aged patient undergoing radiation therapy for breast cancer may be too nauseous to swallow her H2- blocker
- A schizophrenic patient who may try to hide a conventional tablet under his or her tongue to avoid their daily dose of an atypical antipsychotic
- A patient with persistent nausea, who may be journey, or has little or no access to water.

III. CHALLENGES IN FORMULATING FDTS

Challenges to develop FDTs include palatability, mechanical strength and disintegration time, hygroscopicity, limited drug amount, aqueous solubility, tablet size, mouthfeel, and sensitivity to environmental conditions. Criteria for excipients used in FDT formulations include quick disintegration, no interaction with drug or other excipients, integrity and stability of the product, melting point within 30-35 °C, no interference with efficacy and organoleptic properties, and various forms of binders. Excipients in FDT preparation typically include super disintegrants, diluents, lubricants, and optionally swelling agents, permeabilizing agents, sweeteners, and flavoring agents.

IV. LITERATURE REVIEW

KANWATE *ET AL.*, (2024), developed fast dissolving tablets containing Cyproheptadine Hydrochloride, with the goal of achieving a high onset of action. Fast dissolving tablet of Cyproheptadine hydrochloride was prepared by using direct compression method, there were nine batches were prepared of fast dissolving tablets, by using super disintegrant as cross povidone, croscarmellose and SSG. The fast-dissolving tablets are evaluated for various parameters, the FDT of Cyproheptadine HCl containing cross povidone showed faster disintegration time at concentrations 5% as compare to other. Hence from all nine-formulation batch B3 showed better result like drug content, disintegrating time, drug release hence this is our optimized batch. Also, B3 was found stable during the stability study for 2 months. Hence prepared Fast dissolving tablet was stable in all conditions.

KARODADE *ET AL.*, (2024), reviewed on comprehensive information on fast dissolving tablets, covering their definition, advantages, limitations, challenges, and available formulations. The design of an oral drug delivery system prioritizes convenience in administration and improved patient compliance, making it the preferred route of drug delivery despite certain drawbacks. Over the last decade, there has been a growing demand for Fast Disintegrating Tablets (FDTS), turning this field into a rapidly expanding area within the pharmaceutical industry. The formulation's popularity and effectiveness have led to the development of various FDT technologies. These technologies aim to achieve rapid tablet disintegration and mouth dissolution within five seconds, eliminating the need for chewing or water intake. This characteristic is particularly advantageous for populations such as pediatrics, geriatrics, and patients facing difficulties in swallowing conventional tablets and capsules. The formulation of an easily administrable dosage form, considering challenges like swallowing difficulties and low patient compliance, has driven the creation of orally disintegrating tablets. Traditional preparation methods include spray drying, freeze drying, direct compression, molding, and sublimation. In addition, new technologies have been devised to enhance the production of or dispersible tablets.

KRISHNA *ET AL.*, (2024), reviewed on explains the features of active ingredients and excipient used in the formulation of ODTs, discusses multiple ODT formulation and preparation techniques with their merits and demerits, and also, offers remedies for

problems associated with ODTs. Moreover, quality control steps and required considerations are presented.

GNANAPRAKAS *ET AL*., (2023), reviewed Fast disintegrating tablets (FDTs).
Fast disintegrating tablets (FDTs) have received ever-increasing demand during the last decade, and the field has become a rapidly growing area in the pharmaceutical industry. Oral drug delivery remains the preferred route for administration of various drugs. Recent developments in the technology have prompted scientists to develop FDTs with improved patient compliance and convenience. Upon introduction into the mouth, these tablets dissolve or disintegrate in the mouth in the absence of additional water for easy administration of active pharmaceutical ingredients. FDTs are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. FDTs ororally disintegrating tablets provide an advantage particularly for pediatric and geriatric populations who have difficulty in swallowing conventional tablets and capsules.

GAUTAM AND TALWAN, (2023), study focused on ideal criteria, the necessity for different FDT technologies to be developed, formulation issues, the applicability of excipient such as super-disintegrants, taste masking, and other excipient, as well as pre-formulation and post formulation characteristics. Fast disintegrating tablets (FDTs) have piqued the pharmaceutical industry's attention in recent decades, and the demand of this dosage form has risen as well. The oral route is still the favored route for medication. Most of the researchers have been encouraged to produce FDTs due to enhance patient compliance and low convenience. These dosage forms melt or disintegrate in the mouth and release active medicinal components without the need of water. Because of the popularity and utility of such formulations, many FDT technologies have been created.

V. EXPERIMENTAL WORK AND RESULT:

RESULT FOR EVALUATION OF PRECOMPRESSION PARAMETER

The pre-compression parameters of Tiaprofenic acid formulations (F1–F9) were evaluated to assess the flow properties and compressibility of the powder blends prior to tablet compression. Parameters such as loose bulk density (LBD), tapped bulk density (TBD), Carr's index, Hausner's ratio, and angle of repose provide a clear indication of powder handling characteristics.
The loose bulk density of the formulations ranged from 0.341 to 0.372 g/ml, while the tapped bulk density varied from 0.458 to 0.487 g/ml. The relatively small differences between LBD and TBD across all formulations indicate moderate particle rearrangement upon tapping and suggest acceptable packing characteristics of the blends.
The Carr's index values were found to be in the range of 21.51% (F2) to 29.16% (F6). Formulations F1, F2, F4, and F5 exhibited Carr's index values below 25%, indicating fair to good compressibility, whereas F3, F6, F7, F8, and F9 showed slightly higher values, suggesting passable flow properties. However, none of the formulations exhibited extremely poor compressibility.

TABLE 1: RESULTS OF PRE-COMPRESSION PARAMETERS OF TIAPROFENIC

Formulation code	Parameters				
	Loose Bulk density(gm/ml)	Tapped bulk density(gm/ml)	Carr's Index (%)	Hausner's Ratio	Angle of Repose
F1	0.345	0.458	24.67	1.328	43^0
F2	0.365	0.465	21.51	1.274	43^0
F3	0.341	0.473	27.91	1.387	44^0
F4	0.372	0.482	22.82	1.296	43^0
F5	0.362	0.463	21.81	1.279	45^0
F6	0.345	0.487	29.16	1.412	44^0
F7	0.348	0.484	28.10	1.391	44^0
F8	0.346	0.473	26.85	1.367	43^0
F9	0.342	0.463	26.13	1.354	44^0

VI. RESULT OF POST-COMPRESSION PARAMETERS

The post-compression parameters of all Tiaprofenic acid tablet formulations (F1–F9) were evaluated to assess their physical integrity, uniformity, and drug content after compression. The results demonstrated that all formulations met acceptable pharmacopeial limits, indicating suitability for further in-vitro and in-vivo evaluation.

Tablet hardness values ranged from 3.4 ± 0.10 to 3.6 ± 0.16 kg/cm², reflecting adequate mechanical strength to withstand handling and transportation while ensuring satisfactory disintegration. The uniform hardness across formulations suggests consistent compression force and proper binder distribution.

Tablet thickness was found to be between 0.645 ± 0.008 and 0.765 ± 0.012 mm, with minimal variation, indicating uniform die fill and reproducible tablet geometry. Such consistency is essential for dose uniformity and patient acceptability.

The weight variation results ranged from 247 ± 2.7 to 258 ± 3.1 mg, and all formulations complied with pharmacopeial requirements, confirming uniform powder flow and accurate tablet filling during compression.

TABLE 2: RESULTS OF POST-COMPRESSION PARAMETERS OF ALL FORMULATIONS

Formulation	Hardness (kg/cm²)	Thickness (mm)	Weight Variation (mg)	Friability (%)	Drug Content (%)
F1	3.5 ± 0.12	0.645 ± 0.008	250 ± 3.2	1.56 ± 0.06	97.75 ± 0.58
F2	3.4 ± 0.15	0.715 ± 0.010	252 ± 2.8	1.57 ± 0.05	98.65 ± 0.64
F3	3.6 ± 0.10	0.658 ± 0.009	248 ± 3.0	1.56 ± 0.04	97.45 ± 0.52
F4	3.6 ± 0.14	0.752 ± 0.011	249 ± 2.6	1.48 ± 0.05	96.45 ± 0.61
F5	3.5 ± 0.11	0.658 ± 0.007	256 ± 3.5	1.43 ± 0.06	97.75 ± 0.55
F6	3.5 ± 0.13	0.674 ± 0.008	258 ± 3.1	1.52 ± 0.05	98.65 ± 0.63
F7	3.4 ± 0.16	0.765 ± 0.012	253 ± 2.9	1.55 ± 0.04	99.62 ± 0.48
F8	3.6 ± 0.12	0.669 ± 0.009	248 ± 3.4	1.53 ± 0.05	98.12 ± 0.56
F9	3.4 ± 0.14	0.712 ± 0.010	247 ± 2.7	1.52 ± 0.06	98.88 ± 0.59

IN-VITRO DRUG RELEASE DATA FOR OPTIMIZED FORMULATION F7

The in-vitro drug release study of the optimized Tiaprofenic acid tablet formulation F7 was carried out to evaluate the release behavior and dissolution efficiency of the formulation. The cumulative percentage drug release was determined at different time intervals and revealed a rapid and complete release pattern.

Formulation F7 exhibited a high initial drug release of 66.45% within the first minute, indicating a pronounced burst effect. This rapid release can be attributed to the fast disintegration time of F7, as well as the optimal concentration of disintegrant, which promotes rapid penetration of the dissolution medium and efficient tablet breakup.

At 5 minutes, the cumulative drug release increased to 79.98%, while 93.32% of the drug was released within 10 minutes, demonstrating a fast dissolution profile. Nearly complete drug release (98.45%) was achieved within 15 minutes, confirming the effectiveness of the formulation in achieving rapid drug availability.

The logarithmic transformation of cumulative drug release and remaining drug content showed a consistent decline in the percentage of drug remaining over time, further confirming efficient and progressive drug release from the tablet matrix. The linear increase in drug release with respect to the square root of time suggests that diffusion, along with rapid tablet disintegration, may play a significant role in the release mechanism.

The optimized formulation F7 demonstrated rapid, reproducible, and nearly complete drug release, correlating well with its shortest disintegration time among all formulations. These results indicate that formulation F7 is suitable for achieving rapid onset of action and enhanced therapeutic efficacy of Tiaprofenic acid.

TABLE 3: *IN-VITRO* DRUG RELEASE DATA FOR OPTIMIZED FORMULATION F7

Time (min)	Square Root of Time(h)$^{1/2}$	Log Time	Cumulative*% Drug Release	Log Cumulative % Drug Release	Cumulative% Drug Remaining	Log Cumulative% Drug Remaining
1	1	0	66.45	1.822	33.55	1.526
5	2.236	0.699	79.98	1.903	20.02	1.301
10	3.162	1	93.32	1.970	6.68	0.825
15	3.873	1.176	98.45	1.993	1.55	0.190

N=6 mean±S.D

ZERO ORDER RELEASE KINETICS OF FORMULATION F7

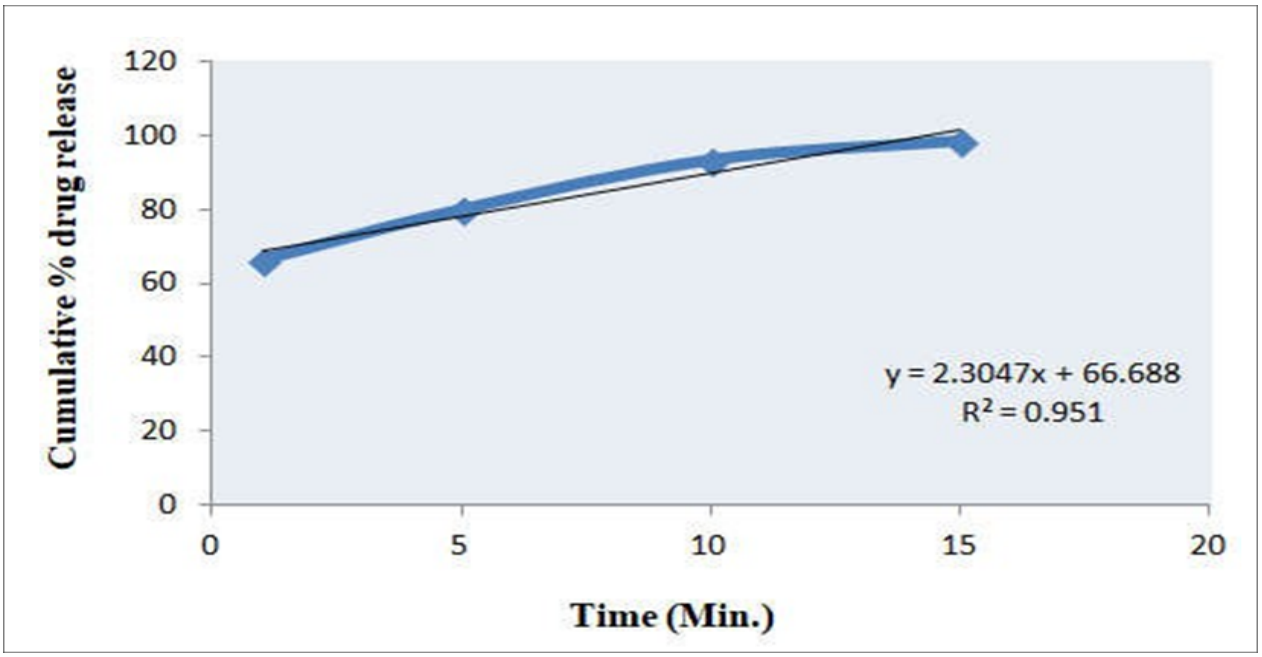

FIGURE :1 ZERO ORDER RELEASE KINETICS OF FORMULATION F7

VII. CONCLUSION

Tiaprofenic acid was subjected to comprehensive preformulation and analytical characterization to establish its suitability for tablet formulation and further pharmaceutical development.

The sensory characteristics of Tiaprofenic acid showed that the drug appeared as a white to off-white crystalline powder with a bitter taste, confirming its typical organoleptic properties. Solubility studies revealed that Tiaprofenic acid is slightly soluble in water and poorly soluble in 0.1 N HCl, indicating limited solubility in acidic media. However, it showed free solubility in ethanol, methanol, and chloroform, and was soluble in phosphate buffer pH 6.8, demonstrating improved solubility under neutral to slightly alkaline conditions. These findings justified the selection of phosphate buffer pH 6.8 as the dissolution medium for in- vitro release studies. From the results of the present investigation, it can be concluded that fast dissolving tablets of Tiaprofenic acid were successfully formulated using wet granulation technique. All formulations exhibited acceptable pre- and post-compression characteristics. Among them, formulation F7 emerged as the optimized batch, owing to its shortest disintegration time, rapid and complete drug release, acceptable physical properties, and favorable release kinetics. The study confirms that croscarmellose sodium is a highly effective superdisintegrant for the development of fast dissolving tablets of Tiaprofenic acid. Therefore, formulation F7 can be considered a promising fast dissolving tablet formulation that may enhance patient compliance and provide rapid onset of therapeutic action.

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