

Formulation and Evaluation of Tinidazole Loaded Fast Dissolving Tablets

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Abstract: The current research work deals with the development of fast dissolving tablets of tinidazole using a blend of natural and synthetic polymers. Six formulations were prepared (T1-T6) by varying the composition of polymers in a ratio of 1:1 to 1:5. All the prepared formulations were evaluated for various parameters like hardness, weight variation, friability, content uniformity, disintegration time, in-vitro drug release study and also stability study. The study reveals optimum formulation blends and good in-vitro release profile showing rapid disintegration and rapid dissolution profile. The tablets showed t80% within 6mins with disintegration time within 1 min. the formulation blends can be used as a model to formulate other drugs of known potency and bioavailability profile. Fast dissolving tablets are a very ideal dosage form for children and other patients who have difficulty in swallowing and hence can be used with advantageous benefits to the patient.

Key words: Tinidazole, fast dissolving tablets, rapid dissolving, rapid action

1. Introduction

Oral route is the most preferred route for administration of drugs. Because it provides high patient compliance. **Dysphagia** is commonly found among all age groups. Due to this problem, approximately 67% population suffers. The main problem in swallowing may be due to the taste, size, and surface of dosage forms. The geriatric and pediatric patients experience difficulty in swallowing conventional tablets, which leads to poor patient compliance. During journey, sometime water is not available so the patient feels difficulty for intake the solid dosage form. Hence there is an urgent need to developed novel dosage form that improved the patient compliance. [1,2] The MDT is also known as fast melting, fast dispersing, rapid dissolve, rapid melt, and or quick disintegrating tablet. All MDTs approved by the Food and Drug Administration (FDA) are classified as orally disintegrating tablets. Recently, the European Pharmacopeia adopted the term Orodispersible tablet for a tablet that disperses or disintegrates in less than 3 minutes in the mouth before swallowing. Mouth dissolving of tablet results in quick dissolution and rapid absorption which provide rapid onset of action. Moreover, drug candidates that undergo pre-gastric absorption when formulated as MDTs may show increased oral bioavailability. It provides good stability, accurate dosing, and easy manufacturing. The excipients employed in MDTs are always hydrophilic in nature whereas drug may be either hydrophilic or hydrophobic. If the drug is hydrophilic, the dosage form is known as fast dissolving tablets otherwise if drug is hydrophobic it is known as fast disintegrating tablets.[3-5]

1.1 Advantages of MDTs [6,7]

- No need of water to swallow the tablet.
- Apart from it the drug is protected from degradation due to pH and GIT enzymes.
- It improves patient compliance.
- It provides rapid drug delivery from the dosage forms.
- Drug administration through buccal mucosa is easy.
- The large contact area of the oral cavity contributes to rapid and extensive drug absorption.
- Patient compliance is more.
- Having rapid onset of action which may leads to an improved bioavailability.
- Patient having difficulty in swallowing tablet can easily administer this type of dosage form.
- Useful for pediatric, geriatric and psychiatric patients.

2. Materials and methods

2.1 Materials

All materials and reagents used were of AR grade and good quality. The drug albendazole was procured from systropic ltd., baddi, HP, India. All equipments were available and used in the department of pharmaceuticals, GRD(PG)IMT, Dehradun.

2.2 Methods

Following study was done in relation to formulation of fast dissolving tablets. [8-11]

a) Preformulation study of drug:

Particle size, solubility, partition coefficient, melting point and drug excipient compatibility were determined by standard methods

b) Standard curve of drug tinidazole

Standard curve of tinidazole was prepared in buffer Ph medium 6.8 to mimic the salivary ph and hence give indication of measurement of drug concentration.

c) Formulation of fast dissolving tablets

Fast dissolving tablets were prepared by direct compression and the composition of the tablets is given as follows

Table No. 1 Formulation Composition

Ingredient/quantity	Formulation code					
	T1	T2	T3	T4	T5	T6
Drug	150	150	150	150	150	150
MCC	100	100	100	100	100	100
Cross povidone	25	50	25	-	-	15
Sodium starch glycolate	-	-	25	25	50	15
Cross carmellose sodium	-	-	-	-	-	15
Lactose	75	50	50	75	50	50
Starch	50	50	50	50	50	50
aspartame	10	10	10	10	10	10
Talc	1	1	1	1	1	1
Magnesium stearate	2	2	2	2	2	2

- All ingredients are mg

d) Evaluation parameters

All the prepared batches were evaluated for organoleptic features, hardness, friability, weight variation, disintegration time, content uniformity and in-vitro drug dissolution study by standard testing methods and procedures.

Results and discussion

The results of the prepared formulations are given as

Table No. 2 Results of Evaluation Parameters

Evaluation parameter	Formulation code					
	T1	T2	T3	T4	T5	T6
Hardness (kg/cm ²)	3.5	4.3	4.6	3.9	4.5	4.6
Friability (%)	1.3	1.1	0.9	0.8	0.7	0.87
weight variation (%)	±2.3	±3.5	±3.2	±4.6	±4.8	±2.1
Content uniformity (%)	97.6%	93.2%	98.6%	98.3%	94.6%	95.8%
Disintegration time (sec)	37	43	39	36	38	41
T 80% (mins)	6 mins	6.5 mins	6.7 mins	6.4 mins	6.7 mins	6.8 mins

Figure No. 1 Hardness & Friability

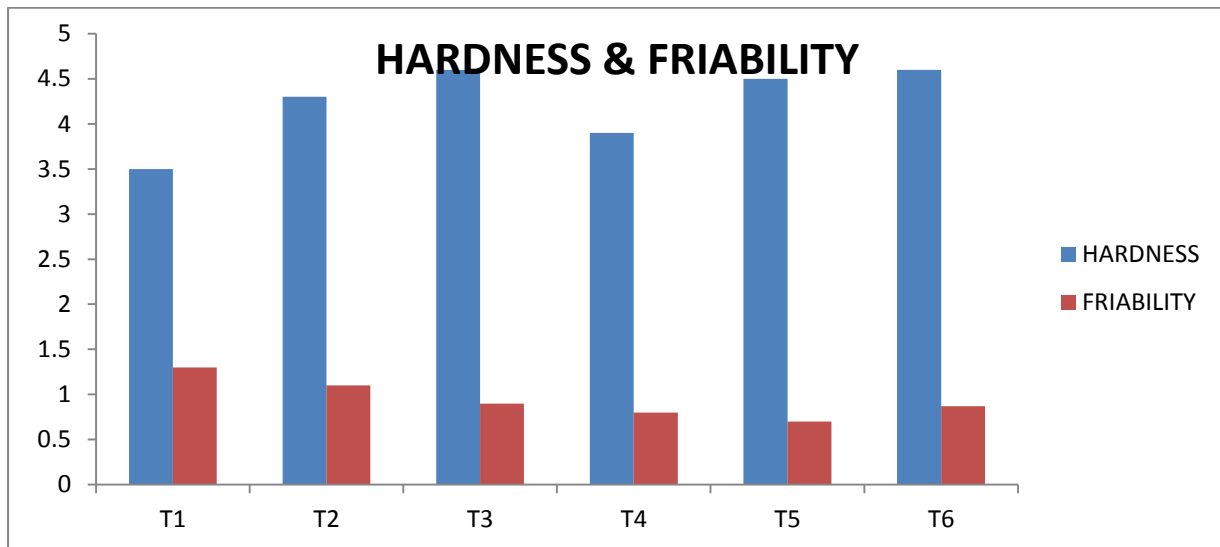


Figure No. 2 Weight Variation & Content Uniformity

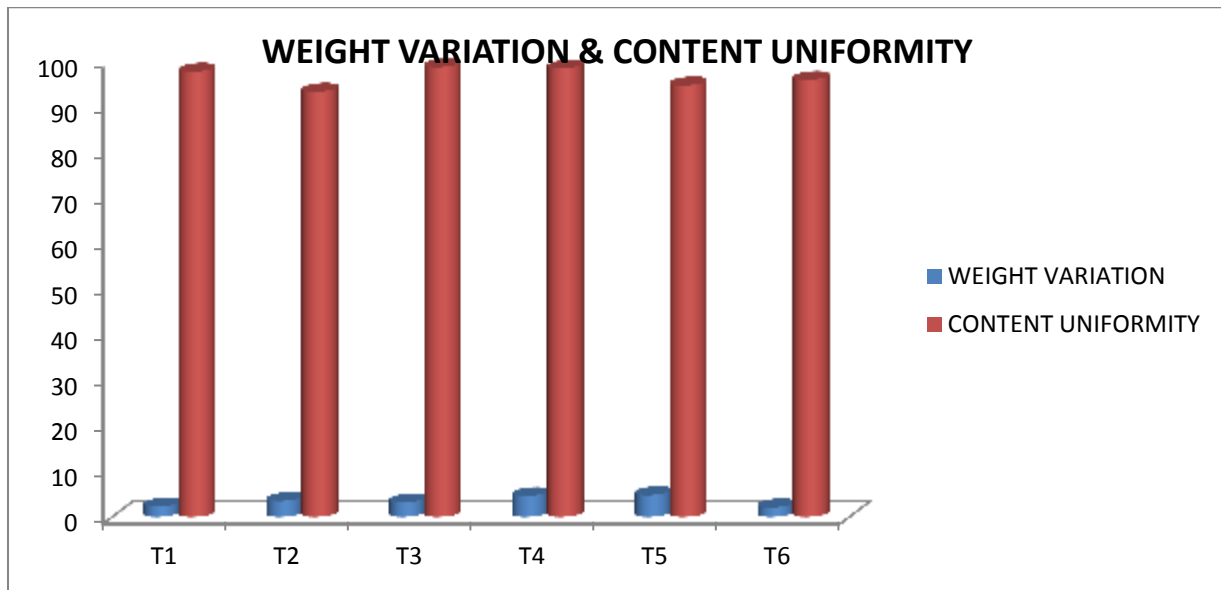


Figure No. 3 Disintegration Time

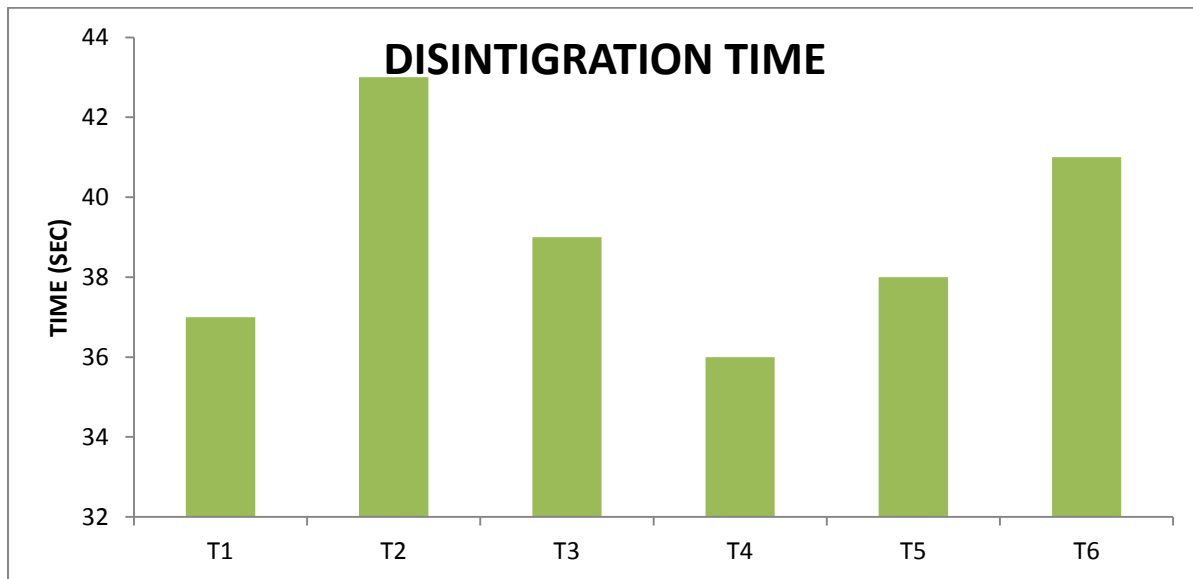
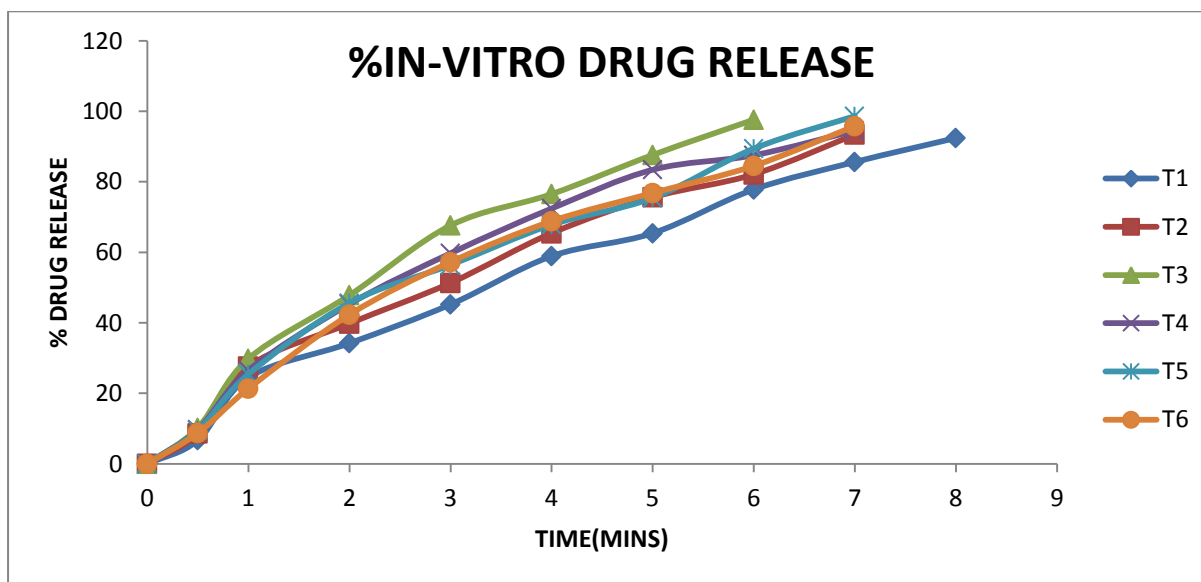


Figure No. 4 In-Vitro Release of Formulations



Conclusion

All the prepared batches were found to be consistent, stable and show a good rapid release profile. All evaluation parameters results were found to be within acceptance criteria and the formulations can be further evaluated for stability studies under long term profile. The results are encouraging and prove the effectiveness of the selected polymeric combinations which can be successfully utilized of other formulations as well

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