

## Formulation and Evaluation of Dispersible Tablet of Ornidazole

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**Abstract:** This Present research with dispersible tablet can compromise the efficacy and safety of the treatment to children's and geriatric patients with masking the bitter taste of drug and developing its dispersible tablet. The purpose of this research work was to develop Dispersible tablet of Ornidazole by masking the bitter taste. Tablet containing drug and excipients were prepared by direct compression method. Excipients in combinations were incorporated to achieve the aim. Effect of different combinations was studied to optimize the ideal formulation. Drug excipients interaction studies were carried out by FTIR spectral analysis. The tablets were evaluated for their hardness, wetting time, disintegrating time and dissolution parameters. It was concluded that the tablets having the combination of Dried Mucilage (obtained from dried seeds of *ocimum bacilicum*) and Sodium starch glycolate met all the evaluation parameters and thus selected as the optimized formulation. Optimized formulation was undergone for stability testing as a parameter to predict the shelf life as per ICH guidelines and proved for its adequate shelf life.

**Keywords:** Ornidazole, Dispersible tablet, ICH guidelines.

### INTRODUCTION

Drug Delivery Systems (DDS) are strategic tool for expanding markets/indications, extending product life cycles and generating opportunities [1]. Oral route of delivery of drugs remains to be the most convenient and preferred route for administration [2].

This route of administration has two main challenges such as dysphagia and delivery of unpalatable drugs. Difficulty in swallowing or dysphagia is seen to afflict nearly 35% of the general population [3].

Many elderly patients may have difficulties in taking conventional dosage forms (tablets and capsules) because of their hand tremors and dysphagia. In order to assist these patients, several fast-dissolving drug delivery systems have been developed. Taste masking of oral pharmaceuticals has become an important tool to improve patient compliance and the quality of treatment especially in pediatrics and geriatric. Therefore, formulation of taste-masked products is a challenge to the pharmacists. Ornidazole is only available in adult strength; therefore the administration of accurate dosage for children is critical [4]. Ornidazole is a 5-nitroimidazole derivative which has the antimicrobial action and it is used in the treatment and prophylaxis of

anaerobic bacterial infections. Ornidazole is an intensely bitter drug. This Present research with dispersible tablet can compromise the efficacy and safety of the treatment to children's and geriatric patients with masking the bitter taste of drug and developing its dispersible tablet. The purpose of this research work was to develop Dispersible tablet of Ornidazole by masking the bitter taste and to study the effect of functionality differences of the different additives and their combinations used in the tablet formulation [5, 6].

### MATERIALS AND METHODS

#### Materials

Ornidazole was obtained as a gift sample from Ipca Labs Ltd. Ratlam; directly compressible Dried Mucilage were obtained from dried seeds of *ocimum bacilicum*, Sodium Starch Glycolate, Sodium Saccharine, Sucrose, Magnesium Stearate were obtained from Research Lab Fine Chem. Industries

Mumbai; All other chemicals used were of analytical grade [7, 8].

## EXPERIMENTAL PART

Dispersible tablets of ornidazole were prepared by direct compression method [8]. Accurately weighed ingredients were finely powdered and kept separately. The weighed ingredients were mixed by the principle of geometrical order to obtain a uniform mixture. The different ratios of the mixture are represented in Table 1 and the formulations were identified as F1, F2, F3, F4, F5 and F6 respectively [9, 10]. Each batch of powder mixture was undergone for compression using sixteen station single rotary tableting machine (SunmachPharma machinery pvt. Ltd., Ahmedabad) using biconvex round punches. The obtained tablet were collected and stored in well closed amber coloured bottle for evaluation [10].

**Table-1: Formulation chart for Dispersible tablet of Ornidazole**

Sr No.	Ingredients	F1	F2	F3	F4	F5	F6
1	Ornidazole	125	125	125	125	125	125
2	Dried Mucilage	125	375	625	375	375	375
3	Croscopvidone	50	50	50	50	-	-
4	Crosscarmellose sodium	-	-	-	-	50	-
5	Sodium Starch Glycolate	-	-	-	-	-	50
6	Sodium Saccharine	5	5	5	5	5	5
7	Sucrose	15	15	15	15	15	15
8	Magnesium Stearate	30	30	30	30	30	30
Total weight		350	600	850	600	600	600

## EVALUATION OF TABLETS

### Calibration curve

Calibration curve of ornidazole in buffer pH 0.1N HCL. Accurately weighed ornidazole was dissolved to make the solution in range of 2 to 12 µg/mL using the buffer solution. Absorbance of each concentration was measured using U.V. Spectrophotometer Jasco, Japan (Model V-530 & V-630) at 277 nm and the absorbance was plotted against concentration of drug solution [20, 21].

### Compatibility studies

Compatibility between the drug and the excipients were studied using Fourier Transform Infrared (FTIR) spectrophotometer (Shimadzu) using KBr disc method [22].

### Physical characterisation

The stored tablet were analysed for the different parameters such as weight variation, hardness, and percentage friability [23].

### Uniformity of Dispersion

Tablets were placed in 100 ml of water and stirred gently until completely dispersed. A smooth dispersion is obtained which passes through a sieve

## Taste Masking Of Bitter Drug

Different approaches undertaken to mask the bitter taste of drug.

- **Direct compression by using sweeteners and flavours-** Taste is highly bitter in nature and could not be masked by using only sweetener hence there was need to change in approach [11].
- **Coating of API by using Polymer-** The taste of formulation was not found satisfactory, hence the need is to go with another technique [14].
- **Taste masking by microencapsulation-** Taste of the tablet was found to be very bitter, considered to be non-palatable [15].
- **Taste Masking by Repeated Coating/Adsorption-** taste was masked sufficiently by coating of dried mucilage to the drug, hence one more coating was provided to previously coated material [16, 18].

screen with a nominal mesh aperture of 710 µm (sieve number 22).

### In-vitro Disintegration time

Conventional DT apparatus was used for determination of disintegration time of dispersible tablet at 24° to 26° and operated for 3 minutes.

### In vitro Drug Release

The in vitro release tests were performed using the USP XXIV type II (paddle method) dissolution test apparatus (Electrolab TDT-08L, India). The tablets were placed in dissolution vessel containing 900ml of buffer (pH 0.1 N HCL) maintained at 37 ± 0.5°C. The paddle rotation speed was kept at 50 rpm. In all experiments, an aliquot of 5.0 ml dissolution samples was withdrawn at predetermined time intervals, and replaced with an equal volume of the fresh medium to maintain the total volume constant. Samples were diluted and filtered through a Whatman filter paper no.41 and assayed by UV spectrophotometry at 277 nm. Cumulative percentage of drug released from the tablets were calculated and plotted as a function of time [25].

### Stability studies

Accelerated stability studies were carried out for the optimized formulation in predicting the shelf

life. The study was carried out by ICH guidelines at a temperature 40°C/75%RH[26, 33].

## RESULTS AND DISCUSSION

Direct compression method was utilized here for the manufacturing of Dispersible tablets of ornidazole. Different batches of tablets were manufactured using different combination of superdisintegrants. Primary evaluation tests of the tablets were carried out and from the results, it is clear that the technique adopted is suitable of the process. Compatibility studies were carried out to study the chemical interaction between drug and the excipients. After interpreting the FTIR spectra, there was no interaction observed for the drug while combining with the excipients. From the FTIR spectral analysis, the

drug is compatible with the excipients[27]. The prepared tablets were taken for hardness evaluation using Monsanto Hardness tester[28]. From the results, the hardness of the tablets were found in the range of 30-40 N, proved for its adequate strength. Weight variation test performed for each tablet and the obtained report showed that the tablets having the weights in the range of 600-605 mg. All the tablets passed the weight variation test as the average percentage weight variation within the limit of IP standards[29]. Thicknesses of the tablet were measured and the obtained report proved that all the tablet having uniform thickness. The Smooth dispersion completely passes through Sieve number 22 which facilitate Uniformity of Dispersion[31]. The various results are reported in Table 2.

**Table 2: Various physical parameters of the Dispersible tablets of ornidazole**

Parameters	F1	F2	F3	F4	F5	F6
Weight	600±5mg	600±5mg	600±5mg	600±5mg	600±5mg	600±5mg
Thickness	3.60 ± 0.5	3.60 ± 0.3	3.60 ± 0.3	3.60 ± 0.3	3.60 ± 0.4	3.60 ± 0.2
Hardness	35± 0.5	32 ± 0.5	35 ± 0.5	31 ± 0.5	33 ± 0.5	30 ± 0.5
Disintegration Time (n=5)	75± 5 sec	59± 2 sec	72± 5 sec	48 ± 4sec	51 ± 4sec	45 ± 4sec
Friability	1.15 %	0.88%	0.48%	0.59%	0.55%	0.45%

In-vitro disintegration time is measured by the time taken to undergo complete disintegration. Rapid and uniform disintegration of tablets were observed in all the formulations [33, 35]. The report shows the disintegration time for all the formulations in the range of 45 to 75 seconds fulfilling the official standards [36]. Based on the in-vitro disintegration time, the formulation (F6) showed a fast disintegration time of 45 second. Thus the formulation can be selected as the ideal formulation [38].

In-vitro dissolution studies were also carried out to optimise the ideal formulation. Test was carried out by USP Type II apparatus. The dissolution of ornidazole from the tablet is recorded in Table 3 and the corresponding plots are represented in Figure.No.1.From the parameters the formulation F6 showed good release profile for the time specified and selected as the ideal formulation[40]. The uniformity in the release profile may be due to the presence of super disintegrants in the correct ratio for the formulation. Thus it is selected as the ideal formulation

**Table-3: In-vitro dissolution profile of Levocetirizine mouth dissolving tablets**

Time Min.	Percentage Cumulative Drug Release					
	F1	F2	F3	F4	F5	F6
0	0	0	0	0	0	0
5	72.8±1.26	73.1±1.55	82.5±1.88	89.9±1.8	95.8±2.8	97.8±1.72
10	82.1±2.12	84.5±1.34	89.9±1.09	94.5±1.21	96.7±1.02	99.1±1.22
15	83.6±1.63	88.6±2.11	92.1±1.42	95.8±1.56	97.5±1.08	99.89±1.14
20	84.1±1.33	92.1±2.66	92.4±1.29	96.7±1.83	97.6±1.84	100.8±1.96
30	84.3±2.11	92.8±1.74	93.1±1.36	96.8±1.8	97.9±2.08	100.3±2.31
45	84.2±2.06	93.1±1.8	93.2±1.40	96.9±1.64	97.23±2.12	100.9±1.81

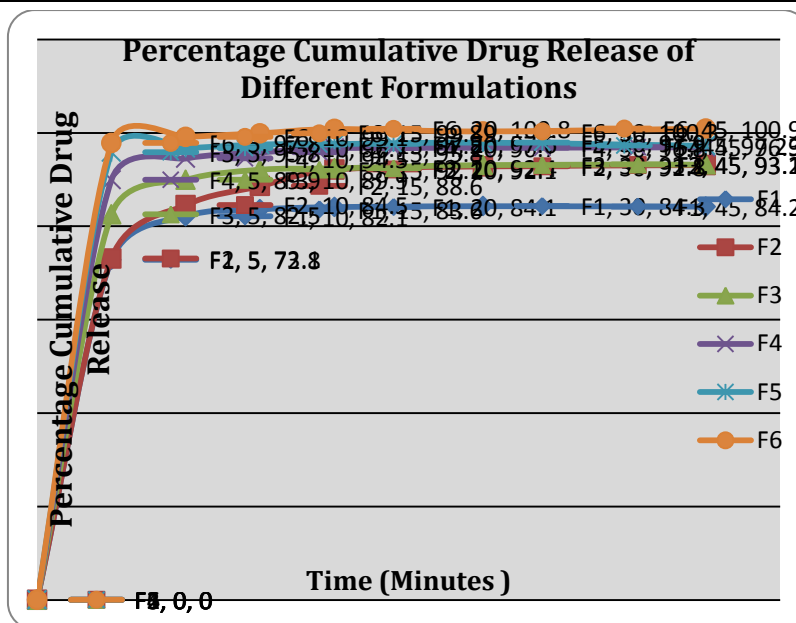


Fig-1: Percentage cumulative drug release from different formulations

Stability study for the optimized formulation was carried out for a period of 30 days at 40°C/75% RH according to ICH guidelines, in predicting the shelf life of the formulation. Physical appearance and drug content of the formulation were studied during this

period[41] From the results, it was found that the ideal formulation does not have major degradation and can be predicted for a good shelf life[41]. The obtained results were tabulated in Table 4.

Table-4: Stability testing parameters of the optimised formulation

Time(days)	Physical appearance	Drug Release (%)
0	Good	98.16±1.56
15	Good	97.56±1.62
30	Good	97.77±1.83

**CONCLUSION**

Ornidazole is generally possesses antidiarrheal actions. Presently, commercially these are available as conventional tablet. However, due to their intense bitter taste, the acceptability of ornidazole to paediatric applications is limited. In the present study it was, therefore, planned to mask the taste of ornidazole by Coating it with mucilage and formulation of its dispersible tablet dosage form for paediatric patients. The study was begun with the drug analysis. Procured samples of drug were characterised by IR spectral study, DSC study, melting point determination and its compatibility with other excipients is studied [36].

score 9.0 was awarded by all volunteers on the scale of perception of bitterness. Drug release study revealed that coating did not affect the release behaviour of drug at pH 1.2.

On the basis of above findings, it can be concluded that taste masking of Ornidazole could be successfully achieved by repeated coating of polymer to the drug. The dispersible tablets formulated in the present study using mucilage possessed the best taste acceptance, mouth feel, and other tablet attributes. The formulation is further evaluated by using accelerated stability study.

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