



## **Formulation and evaluation of Norfloxacin Dispersible tablets using Natural substances as Disintegrants**

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### **Abstract**

Dispersible tablets of Norfloxacin were prepared using natural substances as disintegrant such as Ispaghula husk powder, Cassia tora powder, Cassia tora powder (defatted), and Cassia nodosa powder in different concentration by direct compression method. Formulations were evaluated for the standard of dispersible tablets and were compared with marketed products. It was observed that all the formulations were acceptable with reasonable limits of standard required for dispersible tablets. The study reveals that natural gums used as disintegrants were effective in low concentration.

**Key Words:** Dispersible tablet, direct compression, Norfloxacin, natural disintegrants.

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### **Introduction:**

Dispersible tablets are uncoated tablets that produce a uniform dispersion or suspension in water at room temperature without stirring. With the increase in the average human life span, drug administration for elderly patients has become more important. Due to decline in swallowing ability with age; a great many elderly patients complain that it is difficult to take medication in the form of tablets. Recently useful dosage form such as rapidly disintegrating or dissolving tablet, have been developed & applied clinically. The dispersible tablets allow dissolution or dispersion in water prior to administration. Dispersible tablets are easier to administer or swallow than capsules for pediatric, dysphasic patients, mentally ill, unco-operative and nauseated patients, those with conditions of motion sickness, sudden episodes of allergic attack or coughing. Some times it may be difficult to swallow conventional products due to unavailability of water. Norfloxacin is a white or pale yellow, crystalline powder, which is freely

soluble in *acetic acid*; sparingly soluble in chloroform, very slightly soluble in water and insoluble in water.

Ispaghula husk consists of dried seeds of the plant known as *Plantago ovata*. It contains mucilage which is present in epidermis of the seed [1-5]. Some of the material such as Cassia tora and Cassia nodosa [6-9], which are nontoxic in nature, have nutritional value and used in the food material.

The present investigation was carried out to prepare dispersible tablets of Norfloxacin using *Plantago ovata* seed husk (Isapghula), Cassia tora and Cassia nodosa as a disintegrants to establish standards required for the dispersible tablet, to optimize the effective concentration of the disintegrant and to compare the formulations with marketed product.

### Materials and Methods:

Norfloxacin was provided as a gift sample by Ankur drugs & pharma Limited, Daman, Gujarat, Ispaghula husk powder, Cassia tora powder, Cassia nodosa powder were provided by Prasad Traders Pusad and Gautam Global, Dehra Dun, India, authenticated by Agakar research institute, pune. All the materials used were of standard analytical grade.

### Method:

#### A) Preparation of Dispersible Tablet [10-12]:

Dispersible tablets of Norfloxacin were prepared using direct compression method after incorporating different disintegrant named as Ispaghula husk powder, cassia tora powder, cassia tora defatted powder, cassia nodosa powder in a concentration 5%, 10%, 15%. The composition of formulation is given in Table No 1. The ingredients were thoroughly mixed and passed through sieve no. 22.

**Table1: Formulation of Dispersible Tablet of Norfloxacin**

Ingredients mg/ tab	Formulation of DT of Norfloxacin											
	I IH1	I IH2	I IH3	I CT1	I CT2	I CT3	I CTD1	I CTD2	I CTD3	I CN1	I CN2	I CN3
Norfloxacin	100	100	100	100	100	100	100	100	100	100	100	100
Lactose	117.5	105	92.5	117.5	105	92.5	117.5	105	92.5	117.5	105	92.5
Isapghula Husk	12.5	25	37.5	-	-	-	-	-	-	-	-	-
Cassia Tora	-	-	-	12.5	25	37.5	-	-	-	-	-	-
Cassia Tora (DF)	-	-	-	-	-	-	12.5	25	37.5	-	-	-
Cassia Nodosa	-	-	-	-	-	-	-	-	-	12.5	25	37.5
Talc	10	10	10	10	10	10	10	10	10	10	10	10
Mag. Stearate	10	10	10	10	10	10	10	10	10	10	10	10

**B) Evaluation of Formulated Tablet:**

The various formulations were evaluated for hardness, weight variation, friability, disintegration time, *Invitro* disintegration time, wetting time, uniformity of dispersion, drug content/content uniformity, and dissolution study.

Disintegration time was determined using Thermonic Tablet Disintegration apparatus USP using distilled water as a disintegration medium. Each formulation was tested for uniform dispersion as per official standards. After disintegration beaker was shaken and this fluid was passed through the sieve no.22. Hardness of the tablet was tested Pfizer hardness tester and friability by Roche Friabilator. Drug content was determined by using UV spectrometer (Shimadzu) at 263 nm. The evaluation parameters shown in Table No 2.

**Table2: Evaluations date of formulated dispersible tablet of Norfloxacin**

Formulation	Hardness Kg/cm <sup>2</sup> (n=3)	Friability (%) (n=3)	Wt. Variation (%) (n=3)	Disinte. Time (Sec) (n=3)	Wetting Time (Sec) (n=3)	Drug content ±SD (n=3)
N IH 1	3.00	0.28	0.22	31	145	99.5±0.028
N IH 2	3.00	0.40	0.25	34	153	98.5±0.022
N IH 3	3.16	0.48	0.28	46	165	99.0±0.022
<b>NCT1</b>	2.66	0.40	0.34	65	190	99.3±0.027
NCT2	3.3	0.48	0.36	73	200	99.0±0.037
NCT3	2.83	0.48	0.40	80	223	99.0±0.015
<b>NCTD1</b>	3.33	0.40	0.41	73	220	99.5±0.025
NCTD2	3.16	0.48	0.48	87	246	99.0±0.034
NCTD3	2.66	0.60	0.50	96	264	99.0±0.034
<b>NCN1</b>	3.33	0.40	0.24	50	170	99.5±0.021
NCN2	3.26	0.52	0.31	58	183	99.4±0.021
<b>NCN3</b>	3.50	0.52	0.39	65	215	99.0±0.025
<b>N MKTD</b>	3.33	0.34	0.28	61	160	99.5±0.028

(Where N IH Is DT Norfloxacin With Ispaghula Husk NCT Is DT Norfloxacin With Cassia Tora, NCTD Is DT Norfloxacin With Cassia Tora(Defatted), NCN Is DT Norfloxacin With Cassia Nodosa, N MKTD Is Marketed DT Norfloxacin 1,2,3 Indicates 5%,10%,15% Concentration)

Comparison of Cumulative % Drug Release of Formulated and Marketed Isoniazid Dispersible Tablet was shown in figure 1.

**Figure1: Comparison of cumulative % drug release of formulated and marketed Norfloxacin dispersible tablet**

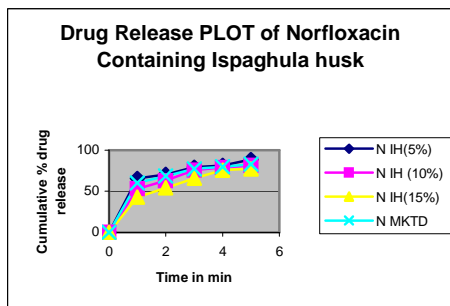


Figure1 (a) Cumulative %Drug Release of Norfloxacin Tablet Containing Ispaghula Husk as Disintegrant

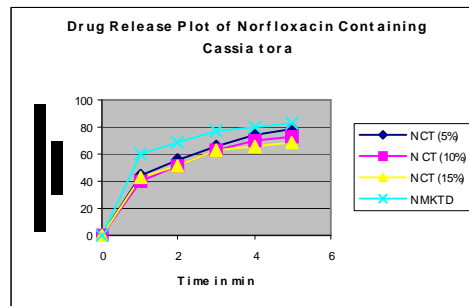


Figure1 (b) Cumulative %Drug Release of Norfloxacin Tablet Containing Cassia Tora as Disintegrant

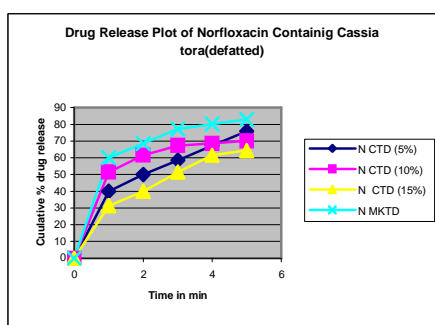


Figure1(c) Cumulative %Drug Release of Norfloxacin Tablet Containing Cassia tora Disintegrant

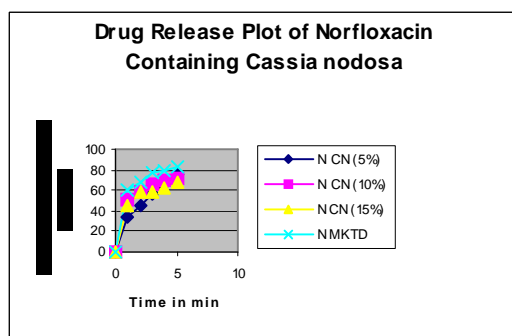


Figure1 (d) Cumulative %Drug Release of Norfloxacin Tablet Containing Cassia nodosa as Disintegrant

### C) Dissolution studies:

Dissolution studies were performed using a dissolution test apparatus USP XXII. (Basket assembly) at 100 rpm using 750 ml of acetate buffer(pH- 4.0) and temperature was maintained at  $37 \pm 0.5^\circ$  through out the study. Ten millimeter of the sample was withdrawn at a regular interval and replaced with an equal volume of phosphate buffer. Samples were filtered and drug content was estimated by UV spectrophotometer at 278nm. Dissolution data shown in table 3.

**Table 3: In Vitro Study of Selected Formulated and Marketed dispersible Tablet of Norfloxacin**

Formulation Code	Time (Min)	Dissolution Efficiency (%)	Uniformity of Dispersion
<i>N IH 1</i>	1	88.68	PASSES
	2		
	3		
	4		
	5		
<i>NCT 1</i>	1	78.67	PASSES
	2		
	3		
	4		
	5		
<i>NCTD 1</i>	1	70.09	PASSES
	2		
	3		
	4		
	5		
<i>NCN 1</i>	1	71.52	PASSES
	2		
	3		
	4		
	5		
<i>N MKTD</i>	1	82.96	PASSES
	2		
	3		
	4		
	5		

(Where N IH Is DT Norfloxacin With Ispaghula Husk, NCT Is DT Norfloxacin With Cassia Tora, NCTD Is DT Norfloxacin With Cassia Tora(Defatted), NCN Is DT Norfloxacin With Cassia Nodosa, N MKTD Is Marketed DT Norfloxacin, 1 Indicates 5% Concentration Respectively)

### Result and Discussion

The % drug content was found to be between 99.00% to 100.00%, which was within acceptable limits. The hardness was found to be 2.5Kg/ cm<sup>2</sup> to 4.0 Kg/ cm<sup>2</sup>, Percent friability was less than 1% in the entire formulation and values obtained lies between 0.28 –0.52. All the formulations

disintegrated between 31-80 seconds. Disintegration pattern of the IH, CT, CTD, and CN showed satisfactory and uniform dissolution Fig.2.

The study reveals that formulations prepared by using 5% Isapghula husk exhibited good dissolution and uniform dispersion characteristics necessary for dispersion tablets as compared to marketed, conventional tablets of Norfloxacin.

### Conclusion

In conclusion, overall result suggests that a 5% Isapghula husk shows better disintegration as compared to marketed.

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