

**FORMULATION, OPTIMIZATION OF MOUTH DISINTEGRATING TABLETS
CONTAINING IBUPROFEN**Sandeep Chaudhary*¹, S. Satyanandam¹, M. A. Saleem¹ and Sushil Sah²¹Luqman College of Pharmacy, Gulbarga, Karnataka.²Birat Medical College, Biratnagar, Nepal.***Corresponding Author: Sandeep Chaudhary**

Luqman College of Pharmacy, Gulbarga, Karnataka.

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ABSTRACT

The main investigation of the study was to formulate super-disintegrating tablets which dissolve in mouth that contains Ibuprofen by using sodium starchglycolate, Croscarmellose sodium, Crospovidone and evaluate them for drug release. Various preparations were made by using super-disintegrating agents (2 mg, 4 mg, 6 mg, 8 mg & 10 mg). All the nine formulations are having good flow properties and are prepared by direct compression technique. Compatibility studies were conducted by using FTIR and all the excipients used in the formulation were compatible with the drug. The rate of dissolution as well as the drug release was found to be varying with the concentration of drug and polymer. The formulation with 10 mg i.e (F6) was found to be the best formulation among all the formulation.

KEYWORDS: Ibuprofen, super disintegrating agent, drug release.**INTRODUCTION**

Ibuprofen falls under potent NSAIDs. It is mainly used to get relief from pain and also used in Rheumatoid arthritis and osteoarthritis. If the drug is having shorter half life will eliminate very quickly and have altered plasma volume. Due to which the bioavailability of Ibuprofen is highly variable. Thus these two factors act as the rate determining step or the barrier to rapid onset of action upon oral ingestion of Ibuprofen.^[1]

Mainly in old age, it is seen difficult to swallow the tablet and also the patients require water for swallowing the tablet. Since the mouth dissolving tablets get disintegrate within the mouth, it doesn't require water for consumption. Hence it is simple, and having more patient acceptability. In recent era, fast dissolving tablets are having advantages over the conventional tablets.^[2,3]

MATERIALS AND METHODS

Ibuprofen was obtained from, Nepal pharma Ltd, Nepal. Croscarmellose sodium was obtained from Sarvotham care, Hyderabad. Crospovidone, Micro crystalline cellulose, Talc, Magnesium stearate was a gift sample of Lobba CHEMIE Pvt. Ltd, Mumbai. Mannitol was obtained from Fisher Scientific Pvt. Ltd, India. Single rotatory tablet machine (Cadmach machinery Co. Pvt. Ltd., Ahmedabad); disintegration test apparatus (2-USP-305), Campbell electronics, Mumbai).

Preparation of Ibuprofen tablets

Mouth Dissolving tablets of Ibuprofen were prepared by direct compression method. Drug and excipients were passed through sieve and blend was formed. By adding the sufficient Magnesium stearate the tablet was compressed using machine

Evaluation of Ibuprofen Tablets**a) Weight variation test**

20 tablets were weighed and also average weight was calculated and is compared.

b) Drug content

Drug content was found by transferring weighed amount of drug into volumetric flask and then volume was added by phosphate buffer. The solution was filtered and analyzed using UV.

c) Friability

Friability was determined by using Roche Friabilator by rotating to a speed of 25 rpm for 4 min or 100 rpm for 1 min.

d) Drug release

The in vitro drug release was determined by dissolution test apparatus USP (Electro lab) and UV- analysis.

RESULTS

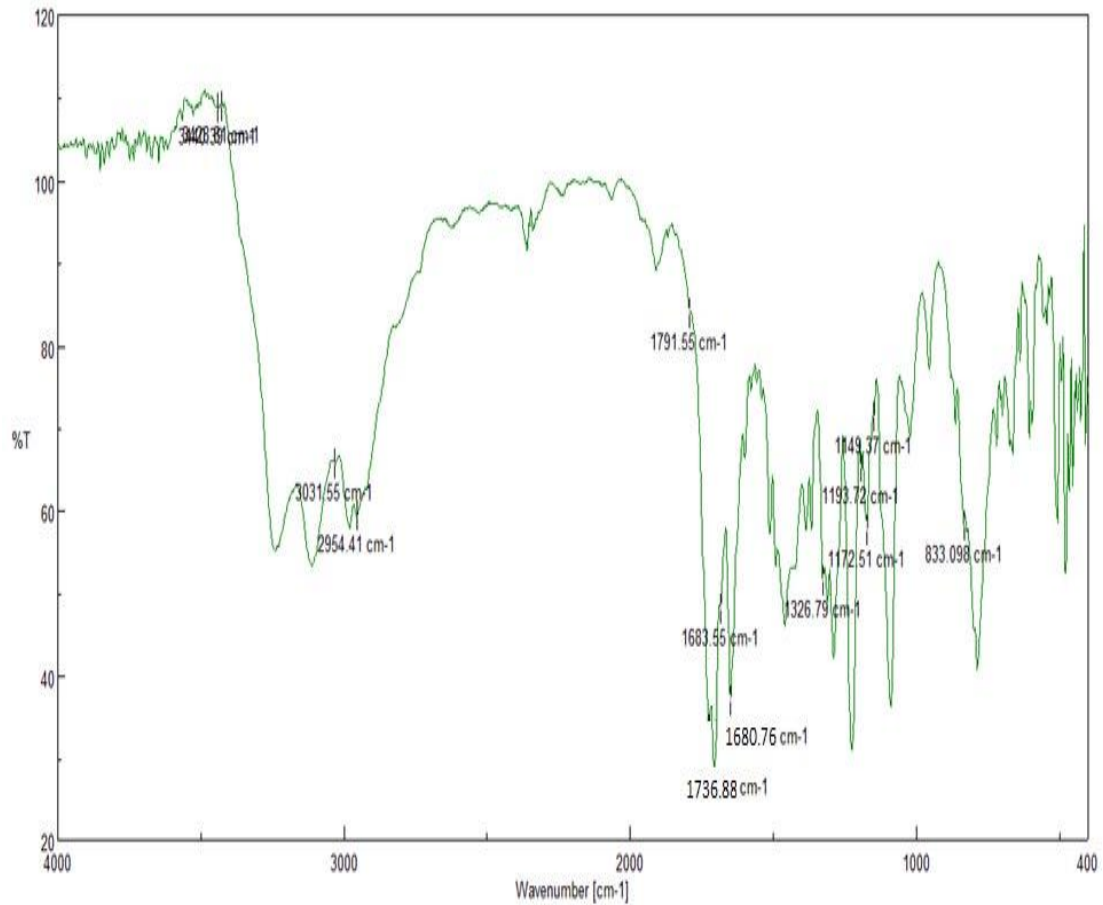


Fig. 1: FTIR spectra of Ibuprofen.

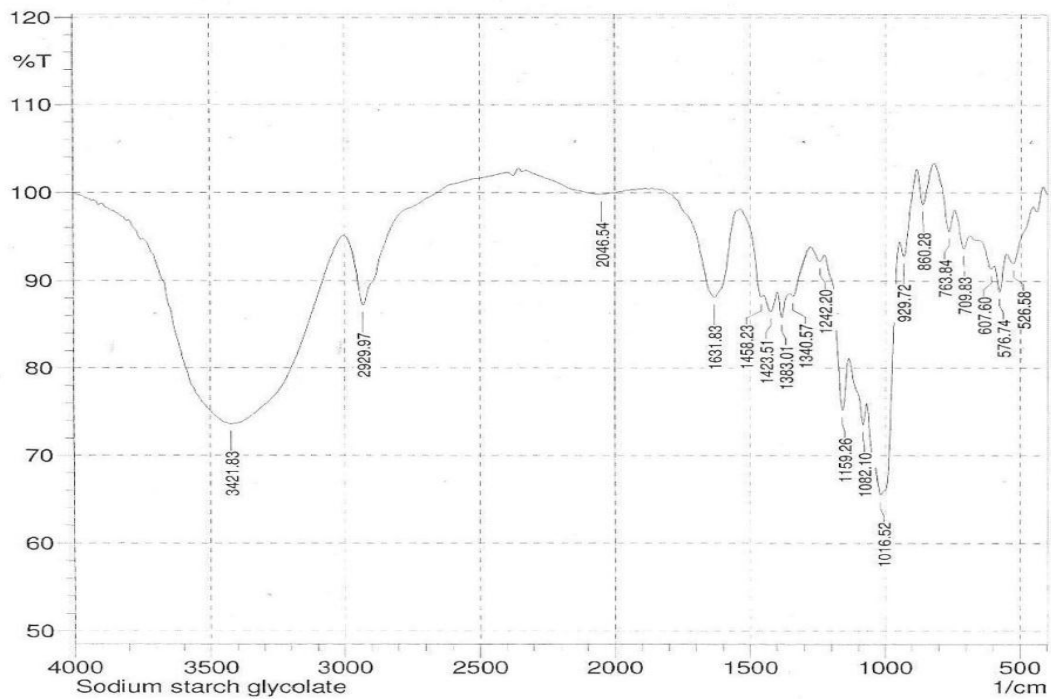


Fig. 2: FTIR of Sodium Starch Glycolate.

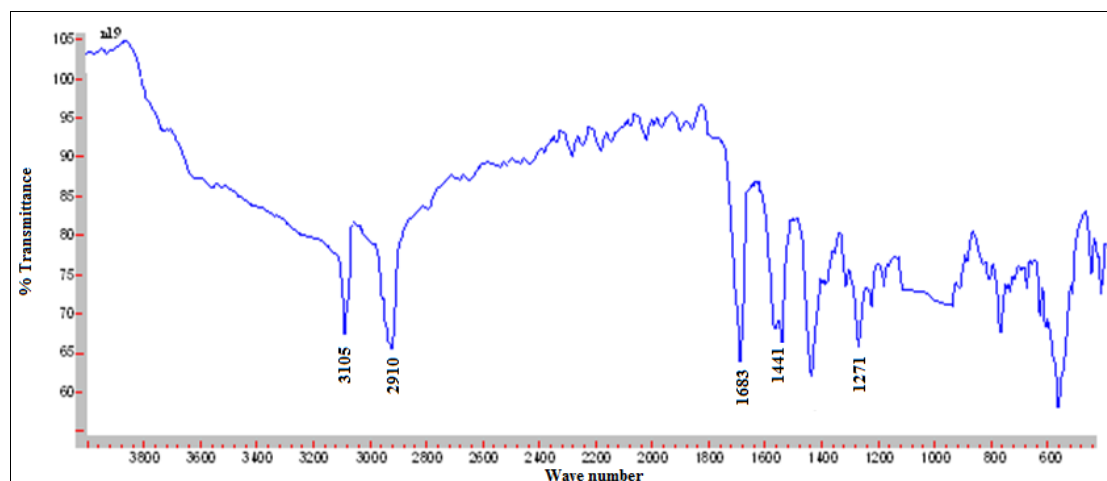


Fig. 3: FTIR spectra of Physical mixture of Ibuprofen and Sodium Starch Glycolate.

Table 1: FTIR Spectra data of drug and polymers.

Sl. No.	IR Spectrum	Peaks (cm ⁻¹)	Groups	Stretching / Deformation
1	Ibuprofen	3385.18	N-H	Stretching
		3030.27	C-H Aromatic	Stretching
		2968.55	C-H Aliphatic	Stretching
		1795.79	C=O Ester	Stretching
		1572.04	N-H	Bending
		1288.49	C-H Aliphatic	Bending
		1172.76	C-N	
		748.41	C-H Aromatic	Bending
2	Physical mixture of Ibuprofen and Sodium Starch Glycolate	3385.18	N-H	Stretching
		3036.06	C-H Aromatic	Stretching
		2929.97	C-H Aliphatic	Stretching
		1913.45	C=O Ester	Stretching
		1573.97	N-H	Bending
		1456.50	C=C Aromatic	Stretching
		1296.21	C-H Aliphatic	Bending
		1161.19	C-N	
3	Sodium Starch Glycolate	3385.18	N-H	Stretching
		3023.20	C-H Aromatic	Stretching
		2964.69	C-H Aliphatic	Stretching
		1913.45	C=O Ester	Stretching
		1575.89	N-H	Bending
		1454.38	C=C Aromatic	Stretching
		1242.20	C-H Aliphatic	Bending
		1165.04	C-N	
4	Physical mixture of Ibuprofen and Crospovidone	3385.18	N-H	Stretching
		3028.34	C-H Aromatic	Stretching
		2966.62	C-H Aliphatic	Stretching
		1851.72	C=O Ester	Stretching
		1573.97	N-H	Bending
		1454.38	C=C Aromatic	Stretching
		1284.63	C-H Aliphatic	Bending
		1170.83	C-N	
746.48	C-H Aromatic	Bending		

It was found that Ibuprofen was compatible with super disintegrants used in the formulation and there were no extra peaks observed.

Table 2: Physical parameters of Drug & Excipient.

Drug and Polymer	Angle of repose value	Bulk density value	Tapped density value	Carr's index value	Hausner's ratio value
Ibuprofen	23° 58 ^l	0.43	0.52	17.30	1.20
SSG	24° 22 ^l	0.42	0.53	20.75	1.26
Croscarmellose	23° 65 ^l	0.41	0.51	19.60	1.24
Crospovidone	21° 58 ^l	0.44	0.54	18.51	1.22

Angle of repose was found to be 21.58-24.33, whereas bulk density was found to be 0.42 - 0.44g/cc. In the same way, tapped density was found to be 0.51 - 0.54g/cc.

Carr's index was found to be 17.30 - 20.75 and Hausner's ratio was found to be 1.15 - 1.33 indicating compressibility of the tablet granules is good

Table 3: Results of thickness, hardness, friability and weight variation of Ibuprofen Mouth dissolving tablets.

Formulation Code	*Thickness (mm)	*Hardness (kg/cm ²)	Friability (%)	Weight Variation
F1	3.216±0.02	2.91±0.21	0.431±0.06	149.10±0.21
F2	3.207±0.02	3.11±0.15	0.418±0.05	151.09±0.38
F3	3.383±0.01	2.92±0.26	0.538±0.03	150.19±0.23
F4	3.176±0.01	3.01±0.35	0.472±0.08	150.32±0.75
F5	3.304±0.01	3.05±0.15	0.446±0.17	148.87±0.39
F6	3.258±0.01	2.91±0.23	0.516±0.06	150.34±0.11
F7	3.247±0.01	3.12±0.27	0.596±0.12	149.70±0.26
F8	3.252±0.01	3.01±0.31	0.521±0.08	150.44±0.73
F9	3.351±0.01	2.92±0.26	0.496±0.05	151.63±1.26

- All value in mean ±SD, n=3

Drug release

After the evaluation of the drug release of Ibuprofen tablet, the result which was found are given in the Table 6.2.5-6.2.7 and Figure 6.2.3-6.2.5.

Table 4: Drug release value of Ibuprofen mouth dissolving Tablets (F1-F3).

Sl. No.	Time	% drug release		
		F1	F2	F3
1	0	-	-	-
2	1	45.07±1.12	40.84±0.87	50.70±0.62
3	2	66.28±0.76	50.78±0.75	66.29±0.38
4	3	74.87±0.42	67.78±0.54	88.96±1.13
5	4	86.28±0.33	83.41±1.21	97.59±0.55
6	5	96.31±0.25	90.62±0.84	99.05±1.15

Table 5: *In vitro* drug release data of Ibuprofen mouth dissolving Tablets (F4-F6).

Sl. No.	Time	% drug release		
		F4	F5	F6
1	0	-	-	-
2	1	45.07±0.86	40.84±0.38	45.07±1.13
3	2	57.83±0.47	59.23±1.14	64.87±0.32
4	3	66.40±0.71	73.43±0.62	80.50±0.38
5	4	87.66±0.39	82.03±0.36	86.29±0.64
6	5	92.06±1.13	89.24±0.69	97.73±0.49

Total nine formulations were formulated F1 to F9 by using three different superdisintegrants in varying

concentrations. The formulations F1-F3 were formulated with the help of crospovidone in concentration 2.6 to

10.6% respectively. The formulations F4-F6 were formulated with the help of crosscarmellose sodium in concentration 2.6 to 10.6% respectively and the formulations F7-F9 were formulated with the help of sodium starch glycolate in concentrations 2.6%, 6.6%,

10.6% respectively. The formulations F1, F3, F6, containing CP and CCS showed more than 95% drug release. Among those three formulations F3 showed highest drug release of 99.05%.

Table 6: *In vitro* drug release data of Ibuprofen mouth dissolving Tablets (F7-F9).

Sl. No.	Time	% drug release		
		F7	F8	F9
1	0	-	-	-
2	1	38.02±1.17	43.66±0.38	43.66±0.75
3	2	60.63±0.53	66.28±0.24	67.69±0.36
4	3	72.02±0.22	74.86±0.53	80.50±0.61
5	4	83.43±1.24	86.28±0.65	86.29±0.46
6	5	87.83±0.63	94.90±0.42	92.10±0.23

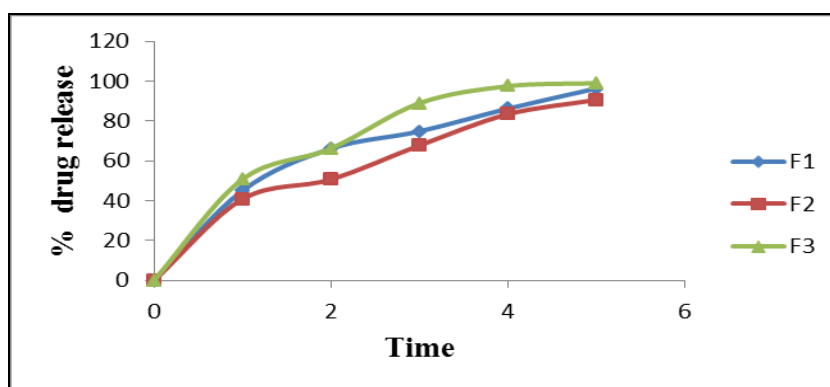


Fig. 4: Drug release value of Ibuprofen mouth dissolving Tablets (F1-F3).

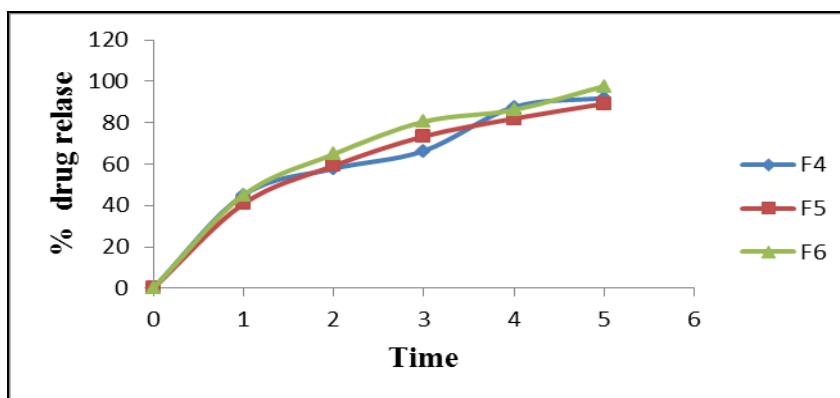


Fig. 5: Drug release of Ibuprofen mouth dissolving Tablets (F4-F6).

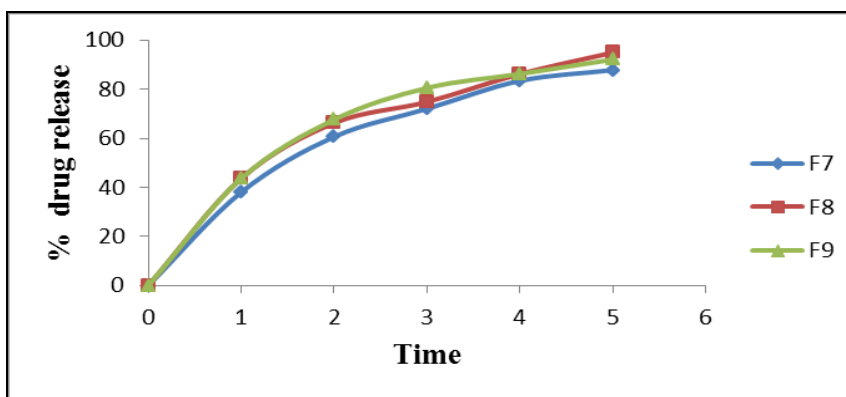


Fig. 6: Drug release of Ibuprofen mouth dissolving Tablets (F7-F9).

CONCLUSION

Rate of drug release is interfered by the nature and amount of drug and polymer. The rate of drug release is directly proportional to the concentration of superdisintegrants. The drug and polymer compatibility study was done by FTIR and drug and polymer were found compatible to each other. Ibuprofen prepared by this technique has more bioavailability and patient compliance than other dosage form.

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CONFLICT OF INTEREST: Nil.

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