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Original Article

Development and Characterization of Fast Dissolving Tablet of Diflunisal by Solid Dispersion Method

Reshu Tiwari*, Satya Prakash Singh, Poonam Kushwaha and Shazia Usmani

Department of Pharmaceutics, Faculty of Pharmacy, Integral University, Lucknow–226026, India.

ABSTRACT

Aim and Objective: Solubility is the important physicochemical factors which affect the absorption of drug and therapeutic effectiveness. The poor solubility of drug substance in water and low absorption in aqueous GIT fluid leads to insufficient bioavailability. The purpose of present research work is to increase the aqueous solubility and dissolution rate of poorly water soluble drug. **Materials and Method:** Solubility of diflunisal enhanced by solid dispersion (kneading method) method using beta cyclodextrin as a carrier (also act as taste masking agent). Fast dissolving tablet of diflunisal was prepared by direct compression method using crospovidone as a superdisintigrant from optimized solid dispersion complexes. Prepared tablets were evaluated for various parameters: weight variation, hardness, friability, modified dispersion time, disintegration test, drug content and drug release. **Results and conclusion:** From the results obtained it has been concluded that prepared tablets from formulation F3 which contain 5% crospovidone as a superdisintigrant showed high dissolution rate and good flow property than other tablet prepared from solid dispersion.

Key words: Fast dissolving tablet, Diflunisal, Solid dispersion, β cyclodextrin, Direct compression, Crospovidone.

Correspondence :
Reshu Tiwari, Department of Pharmaceutics, Faculty of Pharmacy, Integral University, Lucknow–226026, India.
Phone no: +91-9451036956

E-mail: reshu328790302@gmail.com
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INTRODUCTION

For most therapeutic agents used to produce systemic effects, the oral route represents the perfect way of administration and having several advantages and high patient compliance in comparison to many other routes.[1] The advantages of fast dissolving dosage forms are increasingly being recognized in both, industry and academics.

The problem of swallowing is common phenomenon in geriatric patient due to fear of chocking, hand tremors and in young individuals due to underdeveloped muscular and nervous systems and in schizophrenic patients which leads to poor patient compliance. Difficulties in swallowing of tablet and capsule are also occurs when water is not available. For these reasons, tablets that can rapidly dissolve or disintegrate in the oral cavity have attracted a great deal of attention.[2]

Fast dissolving tablets (FDTs) dissolve or disintegrate in the oral cavity without the need of water. Most FDTs must include substances to mask the bitter taste of the active ingredient. It has been concluded that faster the dissolution, faster the absorption (only the unionized form of drug) and onset of action. Some drugs are absorbed from the oral cavity, pharynx and oesophagus as the saliva passes down into the stomach. Thus the bioavailability of drug is significantly more than those observed from conventional tablets dosage form. The time for disintegration of FDTs is generally considered to be less than one minute.[3]

In this present investigation diflunisal (DIF) was selected for the enhancement of solubility and bioavailability by improving its dissolution rate by preparing it in solid dispersion form.

DIF, a salicylate derivative, is a NSAID with pharmacologic actions similar to other prototypical NSAIDs. DIF possesses anti-inflammatory, analgesic and antipyretic activity. Though its mechanism of action has not been clearly established, most of its actions appear to be associated with inhibition of prostaglandin synthesis via the arachidonic acid pathway. DIF is used to relieve pain accompanied with inflammation and in the symptomatic treatment of rheumatoid arthritis and osteoarthritis.[4] Although NSAIDs are among the most frequently used drugs in the world, their oral administration is often limited because of their potential to cause adverse effects such as irritation and ulceration of the gastro-intestinal mucosa.[5] These problems are mainly caused because of the poor water solubility of these types of drugs. For this reason, considerable efforts have been made for the development of newer and better formulations for oral delivery systems of NSAIDs.[6]

Based on the above physicochemical and biopharmaceutical properties, DIF was selected for developing solid dispersions formulations for improving its solubility and dissolution rate.

Application of solid dispersions is one of the strategies to increase the dissolution rate of drugs.[7,8] Solid dispersions consist of two (or more) component systems in which the drug is dispersed monomolecularly or as small particles in a hydrophilic matrix. Increased dissolution rate can be attributed to a strongly enhanced surface area of the drug for dissolution.[9] Solid dispersion techniques have been extensively used to increase the solubility of a poorly water-soluble drug. Solid dispersion (SD) is a viable and economic method to enhance bioavailability of poorly water soluble drugs and also it overcomes the limitations of other approaches.[10,11]

MATERIALS AND METHODS

Materials

Diflunisal was procured from Sigma Aldrich, Steinheim, Germany. β-Cyclodextrin is obtained from sd- fine chem limited, Mumbai. crospovidone is obtained from Balaji Products, Mumbai. All other chemicals used were of analytical grade.

Methods

Infra red spectroscopy studies (FTIR)

IR spectrophotometer was used for infrared spectroscopy analysis of DIF, β-Cyclodextrin (βCD) and physical mixture of drug and polymer. The samples were prepared in KBr disk by means of a hydrostatic press. The scanning range was 400-4000 cm^{-1}.[12,13]

Preparation of solid dispersion of diflunisal

Kneading method

Solid dispersion of DIF and β-Cyclodextrin (βCD) were prepared in the different ratio by kneading method. In this method the weighed quantity of DIF and βCD were taken into glass mortar and triturated for 30 mins with the addition of small quantity of methanol to make paste. The paste was allowed to stand for 45 mins and then dried in oven at 40^{0}C. The product obtained was pulverized and passed through sieve no. 40 and stored in desiccator for further study.[13]

Formulation of fast dissolving tablets

Fast dissolving tablets containing optimized solid dispersion were prepared by direct compression method using single punch tablet machine to produce convex faced tablets. A minimum of 40 tablets were prepared for each batch.[14] Tablets were prepared using 10 mm punch of the convex shaped punch of the single station tablet compression machine.[15] Composition of tablet were shown on Table 1.

Characteristics of solid dispersion complex:

I. Flow properties[16]

- ***Bulk density (D_b):*** Accurate weighed amount of solid dispersion preparation of different ratios were poured in to 25 ml of measuring cylinder and bulk volume was noted and then calculated by the following equation.

$$D_b = M/V_b$$

Where, M is the mass of powder, V_b is the bulk volume of the powder.

- ***Tapped density (D_t):*** Accurate weighed amount of solid dispersion preparation of different ratios were poured in to 25 ml of measuring cylinder and then tapped for 750 times and the tapped volume was noted and calculated by the following equation.

$$D_t = M/V_t$$

Where, M is the mass of powder, V_t is the tapped volume of the powder.

- ***Carr's index:*** The simplex way of measurement of the free flow of powder is compressibility, an indication of ease with which a material can be induced to flow is given by compressibility index of the granules was determined by Carr's compressibility index (I) which is calculated by using the formula.

$$Compressibility\ index = [(V_b - V_t)/ V_b]\times 100$$

- ***Hausner ratio:*** Hausner ratio is an indirect index of ease of powder flow. It is calculated by the following formula.

$$Hausner\ ratio = D_t/D_b$$

Where, D_t is the tapped density, D_b is the bulk density.

Lower Hausner ratio (<1.25) indicates better flow properties than higher ones (>1.25).

- ***Angle of repose:*** Angle of repose was determined using fixed funnel method. The solid dispersion was poured through a funnel that can be raised vertically until a maximum cone height (h) was obtained. Radius of heap (r) was measured and angle of repose was calculated by using the following equation.[16]

$$tan\ (q) = h/r$$

Where, q is the angle of repose, h is the height in cm., r is the radius in cm.

II. Evaluation of fast dissolving tablet

Tablet thickness: The thickness of 3 tablets from each batch was measured by using a vernier caliper and the mean of triplicate readings was taken as the mean tablets thickness.[3]

Tablet weight uniformity: 20 tablets were weighed individually and collectively from each batch using a digital balance, from which the mean were calculated and determined the percentage deviations.[16]

Hardness (Crushing strength): The crushing strengths of tablets were determined individually with the Monsanto hardness tester, following 3 tablets was used from each batch and the mean crushing strength was calculated.[3]

Friability: The friability of 6 tablets was determined using friabilator. Pre weighed tablets was placed in the friabilator and subjected to 100 revolutions This friabrilator was revolving at 25 rpm for 4 min. Tablets were dedusted using a soft muslin cloth and reweighed and % friability were calculated by the following formula[3]

$$Percentage\ friability = [(initial\ weight\text{-}final\ weight/initial\ weight)]\times 100$$

Drug content uniformity: Drug content of fast dissolving tablets was calculated by weighing ten tablets of each formulation, pulverized to a fine powder. A quantity of powder equivalent to 10 mg of drug was dissolved in methanol and solution was filtered through a 0.45 μm whatmann filter paper. Drug content was determined by measuring the absorbance UV visible spectrophotometer after appropriate dilution with methanol. The drug content will be determined using calibration curve. The content uniformity studies were performed in triplicate.[3] Drug content was calculated by the following formula:

$$Drug\ content = 10CAu/As$$

Where C is concentration, Au is absorbance of drug sample, As is the absorbance of standard drug

Modified disintegration time: A petridish was filled with 10 ml of distilled water. The tablet was carefully placed in the center of petridish and then measured the time for the completely disintegration of tablet into fine particles.[3] (Figure 6)

In-vitro dispersion time: 6 tablets were placed in the disintigration apparatus specified in USP. The distilled water at 37^{0}C ± 2^{0}C was used as a disintegration media and time in second taken for complete disintegration of the tablet with no palpable mass remaining in the apparatus was measured in seconds.[13]

Table 1: Composition of tablet

Ingredients (mg)	F1	F2	F3	X1	X2	X3	C1	C2	C3
SD complex	40	40	40	62	62	62	90	90	90
Lactose	50	45	40	28	23	18	10	5	-------
Mannitol	15	15	15	15	15	15	15	15	15
Crospovidone	5	10	15	5	10	15	5	10	15
Talc	5	5	5	5	5	5	5	5	5
Sodium saccharine	5	5	5	5	5	5	5	5	5
Magnesium stearate	10	10	10	10	10	10	10	10	10
Total	130	130	130	130	130	130	140	140	140

Wetting time & Water absorption Ratio: A small piece of tissue paper was folded twice and placed in a small petridish containing 6 ml of distilled water. Place a tablet on the paper and the time required for complete wetting was measured. The wetted tablet was reweighed. Water absorption ratio (R) was determined by the using the following equation:

$$R = 100[(Wa-Wb) / Wb]$$

Wb; weight of the tablet before keeping in the petridish, Wa; weight of wetted tablet.[17]

***In-vitro* dissolution studies:** *In-vitro* dissolution study of fast dissolving tablets of DIF was performed according to USP type-II dissolution apparatus employing a basket at 50 rpm using 900 ml of simulated saliva of pH 6.8 at 37^{0}C ± 0.5^{0}C as dissolution medium. One tablet was used in each test. Aliquots of the dissolution medium 5 ml were withdrawn at specific time interval 0, 1, 2..... 15 minutes and replaced with the equal volume of fresh medium. The samples were filtered through 0.45 µm whatman filter paper and analyzed by measuring the absorbance at 252 nm. Drug concentration was calculated from the standard calibration curve and expressed as cumulative percent drug dissolved. The release studies were performed in triplicate.[13]

RESULTS

Infra red spectroscopy studies (FTIR):

Compatibility studies: From the compatibility studies for drug (Figure 1), for excipient (Figure 2) and for the physical mixture of drug and excipient (Figure 3) and excipient it was observed that there was no interaction between drug and excipient.

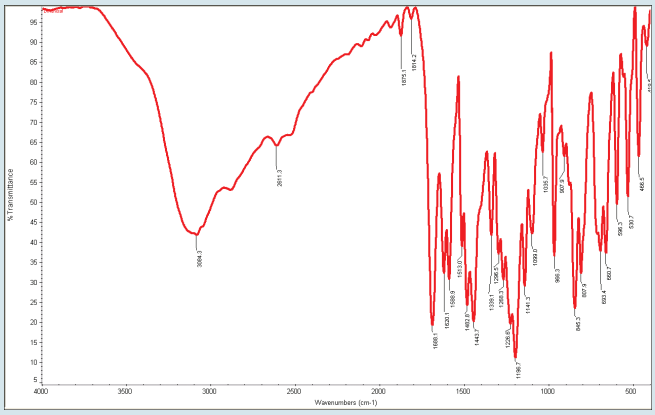

Figure 1: FTIR spectra of DIF

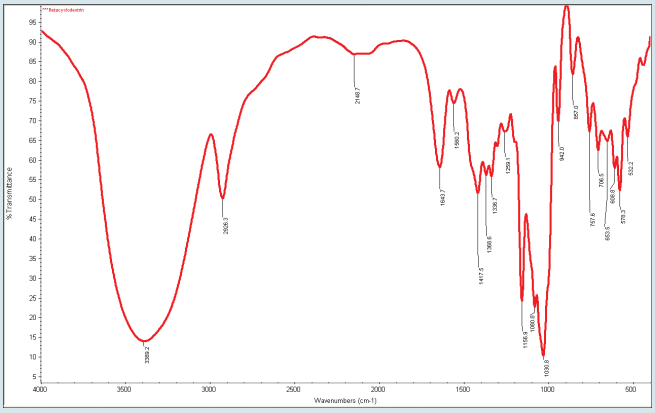

Figure 2: 2 FTIR spe ctra of β-CD

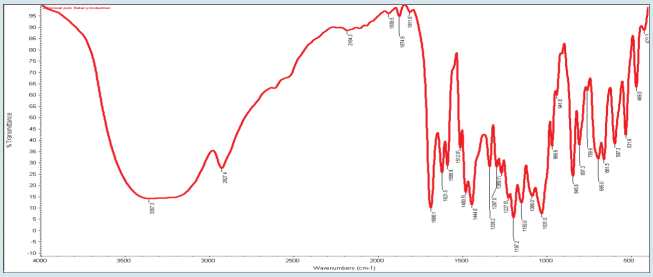

Figure 3: FTIR spectra of DIF + β-CD

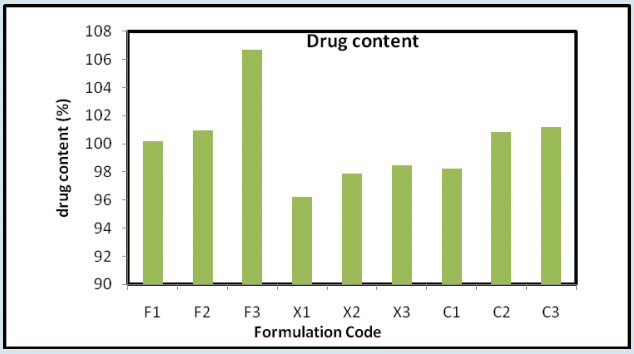

Figure 4: Percentage drug content

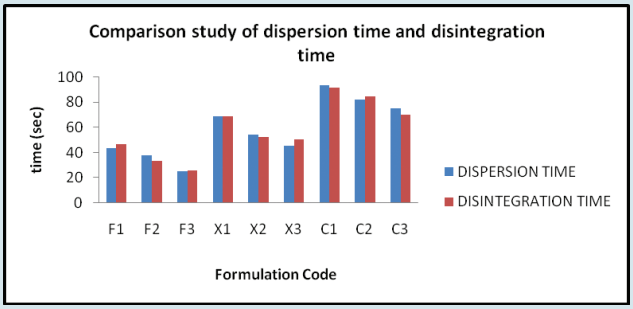

Figure 5: Comparison study of Dispersion time and disintegration time

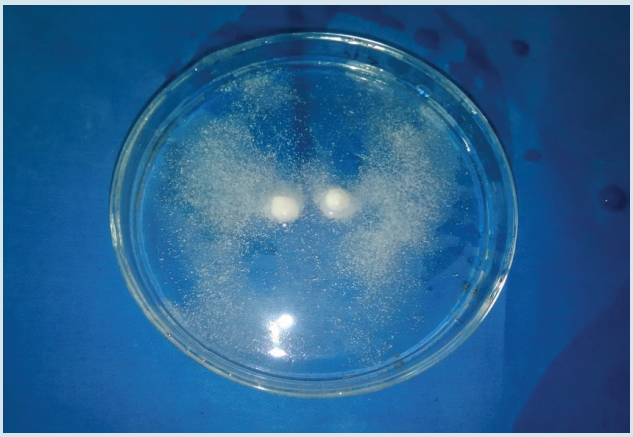

Figure 6: Disintigration of fast dissolving tablet

Table 2: Flow properties of SD complex

Drug: Polymer	Bulk density (g/cm³)	Tapped density (g/cm³)	Carr's index (%)	Hausner's ratio	Angle of repose (θ)
1:1	0.3154±0.0050	0.3751±0.0103	15±0.0108	1.1889±0.0214	27.77±0.2598
1:2	0.3100±0.0062	0.3693±0.0090	14±0.0152	1.1800±0.0176	29.10±0.5022
1:3	0.3077±0.0039	0.3665±0.0056	15±0.0100	1.1912±0.0292	29.38±0.2540

Table 3: Evaluation of tablet

Formulation code	Weight variation (mg)	Thickness (mm)	Hardness (kg/cm²)	Friability (%)
F1	Passes	2.6166±0.0057	3.3333±0.2886	0.1194±0.0392
F2	Passes	2.6166±0.0057	3.1000±0.2645	0.3059±0.1149
F3	Passes	2.6133±0.0115	3.1666±0.2886	0.2092±0.1317
X1	Passes	2.6066±0.0115	3.4333±0.4041	0.2231±0.1376
X2	Passes	2.6166±0.0057	3.3666±0.3214	0.2658±0.0993
X3	Passes	2.6136±0.0115	3.3333±0.2886	0.1345±0.0839
C1	Passes	2.6866±0.0057	3.5333±0.6506	0.1433±0.0011
C2	Passes	2.6900±0.0100	3.8333±0.2886	0.1385±0.0390
C3	Passes	2.6966±0.0057	3.6666±0.2886	0.2710±0.1266

Table 4: Drug content, disintigration test and in-vitro dispersion time

Formulation code	Drug content (%)	Disintegration time (sec)	Dispersion time (sec)	Wetting time (sec)	Water absorption ratio (%)
F1	100.2133±0.5533	46.7800±0.6965	43.4300±0.5144	53.3333±0.5773	84.2533±0.6256
F2	100.9467±0.1021	33.2433±0.7550	37.8333±0.5485	50.6666±0.5773	85.1133±0.7460
F3	106.7167±0.5216	25.5000±0.5963	25.1433±1.0248	43.3333±0.5773	94.8800±0.6614
X1	96.2200±0.3500	68.8266±0.7550	69.0667±0.5002	69.0766±0.8874	76.0266±0.8918
X2	97.8466±0.2490	51.9367±0.3295	53.8833±0.5739	65.8033±0.7252	77.1033±0.2742
X3	98.4700±0.0916	50.0700±0.1044	45.4166±0.7216	58.4933±0.8544	78.9300±0.8580
C1	98.2300±0.3634	91.6566±0.2977	93.4566±0.1000	101.6933±0.6017	51.0466±0.9762
C2	100.8167±0.5621	84.8766±0.2753	82.1066±0.1000	88.3800±0.5414	59.0433±0.8953
C3	101.1933±0.5714	70.2833±0.1858	75.0667±0.0585	82.0166±0.0288	60.1466±0.8025

Table5: Percentage drug release (F1–F3)

Time (min)	Cumulative drug release (%)		
	F1	F2	F3
0	0	0	0
1	4.0166±0.4146	3.8400±0.5311	3.200±0.7302
2	6.6466±0.5688	6.8385±0.6563	6.3166±0.9263
3	11.4666±0.7118	11.2986±1.1671	11.4200±0.4881
4	18.2300±0.5817	16.9580±0.4792	17.9500±0.3998
5	24.1600±0.5054	22.5200±0.4179	22.8400±0.3516
6	31.0166±0.4562	28.1966±0.3787	29.8166±0.3209
7	37.5866±0.4216	34.4933±0.3511	36.5100±0.2993
8	43.5166±0.3957	44.1800±0.3304	44.8066±0.2828
9	50.2133±0.3754	49.5100±0.3141	50.4600±0.2696
10	57.0066±0.3588	56.0100±0.3007	56.7366±0.2588
11	63.9300±0.3449	63.4800±0.2894	63.9800±0.2495
12	70.8433±0.3330	69.9266±0.2797	73.0533±0.2415
13	75.5433±0.3226	76.3733±0.2712	78.3533±0.2344
14	82.4866±0.3134	85.4866±0.2637	83.7566±0.2282
15	89.0900±0.3053	90.0333±0.2570	90.4933±0.2225

Table 6: Percentage drug release (X1–X2)

Time (min)	Cumulative drug release (%)		
	X1	X2	X3
0	0	0	0
1	3.4500±0.4592	3.0266±0.9172	3.3000±0.6199
2	7.6500±2.4225	7.0766±0.5359	6.7485±0.9228
3	12.8466±1.6234	11.7933±1.4932	10.4752±1.5138
4	17.6366±1.6349	17.8533±1.4524	15.0647±1.5726
5	25.1133±2.8364	23.9166±2.2702	21.0333±1.2120
6	30.9700±3.4343	31.7166±3.7265	27.3066±2.0693
7	38.0733±4.3153	37.5633±2.7707	35.6966±2.3987
8	43.9533±3.2088	45.3200±2.6653	43.1366±2.7710
9	50.0200±3.3827	51.5800±1.5159	50.3433±1.2973
10	56.1866±3.2446	59.2166±2.6667	58.2300±1.2856
11	63.4600±2.4845	65.5100±4.4411	63.5933±3.2982
12	69.7133±2.0939	72.2500±3.5123	70.9433±2.2115
13	76.0533±3.6213	78.0133±4.4189	77.4766±2.2742
14	82.6400±2.4284	82.6633±2.9729	83.3033±1.1764
15	88.4200±0.1835	89.1366±0.0923	89.3066±0.2638

Table 7: Percentage drug release (C1–C2)

Time (min)	Cumulative drug release (%)		
	C1	C2	C3
0	0	0	0
1	2.7733±0.7767	4.2766±1.2613	3.4933±0.6124
2	5.9100±1.1850	6.8866±0.3868	7.1900±0.8118
3	9.2266±2.1836	10.4600±1.7792	13.2533±3.1870
4	13.7800±2.8354	14.9666±2.7691	18.4466±1.8963
5	19.5433±2.9039	20.7233±2.8553	24.6100±2.4409
6	24.9166±2.4055	26.7600±2.9333	30.3600±2.9776
7	31.7500±1.1501	33.6966±2.3295	35.5826±2.0038
8	37.5266±2.1404	38.9500±4.9812	40.6066±2.4761
9	43.2433±3.4399	46.0733±6.0526	47.7066±2.9619
10	49.6533±4.1015	52.166±5.4353	54.0966±5.0452
11	56.8100±5.3601	58.9133±6.6609	60.3933±3.5802
12	62.3733±5.7146	65.7000±5.2977	67.9300±4.0510
13	68.9600±3.1917	71.3700±4.0297	74.3233±4.0265
14	77.8566±1.9990	79.1633±3.0475	79.7866±1.1446
15	84.5500±1.1829	86.2266±0.2893	87.2900±0.1553

Preformulation studies: The flow properties and other derived properties evaluated for all the 3 formulations were proved to be within limits showing good flow properties. The physical properties like bulk density, tapped density, angle of repose, Hausner's ratio and compressibility index were calculated and tabulated in Table 2. The values were found to be within the range of 0.3154±0.005 to 0.3077±0.0039, 0.0.3751±0.0103 to 0.0.3665±0.0056, 23.14°±0.0108 to 15.10±0.01, 1.1889±0.0214 to 16.1912±0.0292, 27.77±0.2598 to 29.38±0.0.2540.

Physical properties: The formulated batches were evaluated for physicochemical parameters like hardness, thickness, weight variation, friability, drug content uniformitity, Wetting Time, Water absorption ratio, disintegration time and dispersion time. The values obtained for that studies are tabulated in Table 4. Comparison study of disintgration time and dispersion time were shows that the F3 are the fast dispersible and fast disintigrated formulation (Figure 5).

In-vitro drug release studies: *In vitro* drug release studies were performed for all the prepared formulation by using Phosphate buffer (pH 6.8) as dissolution medium and measuring drug concentration UV-Spectrophotometrically at 252 nm. The comparative *in vitro* dissolution study of prepared fast dissolving tablet shows maximum drug release 90.49% at the end of 15 min (Figure 7, 8 and 9). The values were given in Table 5, 6 and 7.

CONCLUSION

Fast dissolving tablets dissolves in the saliva within a few seconds. Among the 9 formulations F3 were the best formulation. F3 formulation was disintegrate in 25.5 sec. and dispersion time was 25.14 sec. F3 formulations were completely wetted in 43.33 sec. and showed the high dissolution rate with 106.94 % drug content and good flow property than other tablet prepared from solid dispersion.

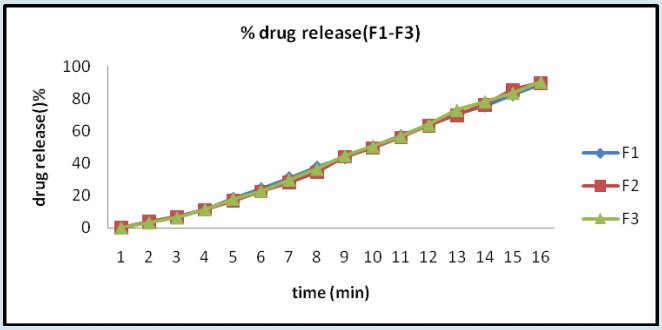

Figure 7: Percentage drug release (F1-F3)

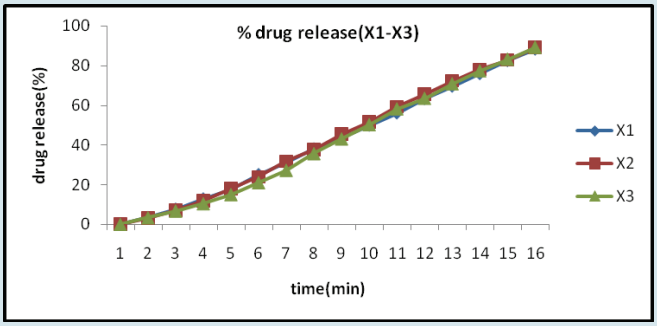

Figure 8: Percentage drug release (X1-X3)

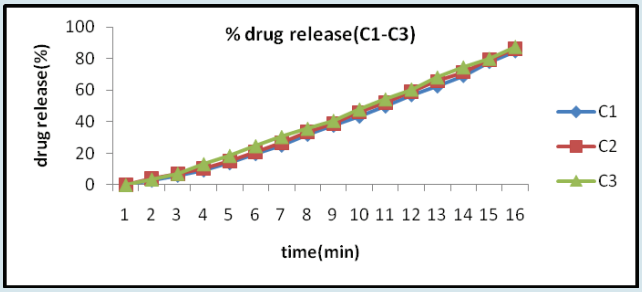

Figure 9: Percentage drug release (C1-C3)

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CONFLICT OF INTEREST

The authors declare that no conflict of interest.

ABBREVIATION USED

FDT: Fast dissolving tablet; **NSAID:** Non steroidal anti inflammatory drug; **DIF:** Diflunisal; **SD:** Solid Dispersion; **Bcd:** Beta cyclodextrin; USP: United State Pharmacopoeia;

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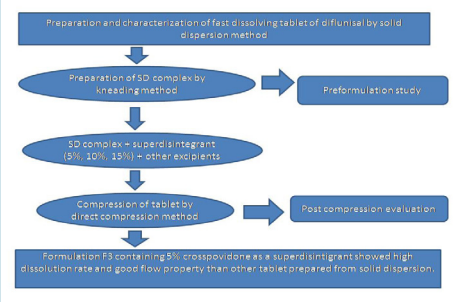
SUMMARY

- From this work it was concluded that the solubility of diflunisal was enhanced by the solid dispersion method and prepared fast dissolving tablets shows the maximum drug relaease with lower the concentration of excipient with high concentration of superdisintigrant.

PICTORIAL ABSTRACT



ABOUT AUTHORS

Reshu Tiwari: Did her M.Pharm. (Pharmaceutical Science and Technology) from Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh. Presently, she is involved in research area of fast dissolving drug delivery.

Dr. Poonam Kushwaha: Obtained Ph.D. from Integral University, Lucknow and is currently working as Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh, India. Her main interest area of research is nanotechnology and targeted drug delivery.

Dr. Shazia Usmani Obtained Ph.D. from Integral University, Lucknow and is currently working as Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh, India. Her main interest area of research is pharmacognosy and phytochemistry.

Dr. Satya Prakash: Singh obtained Ph.D. from Berhampur University, Odisha and is currently working as Assistant Professor, Faculty of Pharmacy, Integral University, Lucknow, Uttar Pradesh, India. His main interest area of research is nanotechnology and targeted drug delivery.