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**FORMULATION DEVELOPMENT AND  
CHARACTERIZATION OF FAST DISINTEGRATING  
TABLETS OF FELODIPIINE**

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**Abstract:**

*In the present work, an attempt has been made to develop fast disintegrating tablets of Felodipine. New generation super disintegrates Solutab, Explotab and Polyplasdone XL was selected as super disintegrates. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F4 formulation showed maximum % drug release i.e., 110.4 % in 2 min hence it is considered as optimized formulation. The F4 formulation contains Solutab as super disintegrate in the concentration of 30 mg. F8 formulation also showed maximum percentage drug release i.e., 105.4% in 4 min ,it contains Explotab as super disintegrate in the concentration of 30 mg.*

**Key words:** *Polyplasdone XL, super disintegrates, Felodipine.*

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**INTRODUCTION:**

The oral route of administration is considered as the most widely accepted route because of its convenience of self administration, compactness and easy manufacturing [1]. But the most evident drawback of the commonly used oral dosage forms like tablets and capsules is difficulty in swallowing, leading to patients incompliance particularly in case of paediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or travelling, especially those who have no access to water [2,3]. An orally disintegrating tablet (ODT) is a solid dosage form that contains medicinal substances and disintegrates rapidly (within seconds) without water when placed on the tongue. The drug is released, dissolved, or dispersed in the saliva, and then swallowed and absorbed across the GIT [4,5]. Recently European Pharmacopoeia used the term 'Orodispersible tablet' as a tablet that is to be placed in the mouth where it disperses rapidly before swallowing [6-8].

Orally disintegrating tablets are also called as mouth-dissolving tablets, fast disintegrating tablets, fast dissolving tablets, orodispersible tablets, rapimelts, porous tablets, quick dissolving tablet. Felodipine decreases arterial smooth muscle contractility and subsequent vasoconstriction by inhibiting the influx of calcium ions through voltage-gated L-type calcium channels. The vasodilatory effects of felodipine result in an overall decrease in blood pressure. Felodipine may be used to treat mild to moderate essential hypertension.

To formulate oro dispersible tablets of Felodipine for the improvement of solubility, dissolution rate & oral bioavailability, optimize optimum concentration of super disintegrating agent and perform various quality control evaluation parameters for the prepared tablets.

**MATERIALS AND MATERIALS:**

Felodipine was gift sample from Aurobindo Pharma, Hyderabad, Croscarmellose sodium, Sodium starch glycolate and Cropsovidone from Merk specialities Pvt Limited, Mumbai, India.

**Methodology:****Determination of UV Absorption Maxima:**

Felodipine solution was prepared in pH 6.8 phosphate buffer and diluted suitably. The UV spectrum of the solution was taken on Lab India 3200 UV/Vis double beam Spectrophotometer. The Solution exhibited UV maxima at 265 nm.

**Preparation of Standard Calibration Curve of Felodipine:**

100 mg of Felodipine was accurately weighed and dissolved in little amount of Methanol and make up the final volume up to 100 ml with pH 6.8 phosphate buffer(pH 1.2) to prepare stock solution. The 10 ml of stock solution was further diluted with pH 6.8 phosphate buffer in 100ml to get 100 $\mu$ g/ml (working standard). Then 0.5, 1, 1.5, 2 and 2.5 ml of working standard was taken in 10 ml standard volumetric flask and made up the volume with 0.1N Hcl to prepare 5 $\mu$ g, 10 $\mu$ g, 15 $\mu$ g, 20 $\mu$ g, and 25 $\mu$ g drug per ml solution. Then the absorbance was measured in a UV spectrophotometer at 265 nm against pH 6.8 phosphate buffer as blank. Calibration curve was constructed and shown in Fig. 1.

**Formulation of Felodipine Dispersible Tablet by Direct- Compression:**

Composition of preliminary trials for Felodipine Oro dispersible tablet by direct compression was shown in table 8. All the ingredients were weighed. Required quantity of drug and excipient mixed thoroughly in a polybag. The blend is compressed using rotary tablet machine-8 station with 6mm flat punch, B tooling. Each tablet contains 10 mg Felodipine and other pharmaceutical ingredients.

**Table 1: Formulation of Felodipine oro Dispersible Tablets**

INGREDIENT	F <sub>1</sub>	F <sub>2</sub>	F <sub>3</sub>	F <sub>4</sub>	F <sub>5</sub>	F <sub>6</sub>	F <sub>7</sub>	F <sub>8</sub>	F <sub>9</sub>	F <sub>10</sub>	F <sub>11</sub>	F <sub>12</sub>
<b>Felodipine</b>	10	10	10	10	10	10	10	10	10	10	10	10
<b>Croscarmellose sodium</b>	2	4	6	8	-	-	-	-	-	-	-	-
<b>Sodium starch Glycolate</b>	-	-	-	-	2	4	6	8	-	-	-	-
<b>Cropsovidone</b>	-	-	-	-	-	-	-	-	2	4	6	8
<b>Talc</b>	2	2	2	2	2	2	2	2	2	2	2	2
<b>Mg. Stearate</b>	2	2	2	2	2	2	2	2	2	2	2	2
<b>MCC PH102</b>	Q.S	Q.S	Q.S									
<b>TOTAL</b>	100	100	100	100	100	100	100	100	100	100	100	100

All ingredients are expressed in mg only

**Evaluation Parameters:****Precompression Parameters:****Drug- Excipient Compatibility Studies by FT-IR:**

The compatibility between the pure drug and excipients was detected by FTIR spectra obtained on Bruker FTIR Germany(Alpha T).The potassium bromide pellets were prepared on KBr press by grounding the solid powder sample with 100 times the quantity of KBr in a mortar. The finely grounded powder was then introduced into a stainless steel die and was compressed between polished steel anvils at a pressure of about 8t/in<sup>2</sup>. The spectra were recorded over the wave number of 8000 to 400cm<sup>-1</sup>.

**Bulk Density (D<sub>b</sub>):**

It is the ratio of total mass of powder to the bulk volume of powder. It was measured by pouring the weight powder (passed through standard sieve # 20) into a measuring cylinder and initial weight was noted. This initial volume is called the bulk volume. From this the bulk density is calculated according to the formula mentioned below. It is expressed in g/ml and is given by,

$$D_b = M / V_b$$

Where, M is the mass of powder

V<sub>b</sub> is the bulk volume of the powder.

**Tapped Density (D<sub>t</sub>):**

It is the ratio of total mass of the powder to the tapped volume of the powder. Volume was measured by tapping the powder for 750 times and the tapped volume was noted if the difference between these two volumes is less than 2%. If it is more than 2%, tapping is continued for 1250 times and tapped volume was noted. Tapping was continued until the difference between successive volumes is less than 2 % (in a bulk density apparatus). It is expressed in g/ml and is given by,

$$D_t = M / V_t$$

Where,

M is the mass of powder

V<sub>t</sub> is the tapped volume of the powder.

**Angle of Repose ( $\Theta$ ):**

The friction forces in a loose powder can be measured by the angle of repose ( $\theta$ ). It is an indicative of the flow properties of the powder. It is defined as maximum angle possible between the surface of the pile of powder and the horizontal plane

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

$$\Theta = \tan^{-1} (h / r)$$

Where,  $\Theta$  is the angle of repose.

h is the height in cm

r is the radius in cm

The powder mixture was allowed to flow through the funnel fixed to a stand at definite height (h). The angle of repose was then calculated by measuring the height and radius of the heap of

powder formed. Care was taken to see that the powder particles slip and roll over each other through the sides of the funnel. Relationship between angle of repose and powder flow property.

**Carr's index (or) % Compressibility:**

It indicates powder flow properties. It is expressed in percentage and is give by,

$$I = \frac{D_t - D_b}{D_t} \times 100$$

Where,

D<sub>t</sub> is the tapped density of the powder and

D<sub>b</sub> is the bulk density of the powder.

**Hausner Ratio:**

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

$$\text{Hausner ratio} = \frac{D_t}{D_b}$$

Where, D<sub>t</sub> is the tapped density, D<sub>b</sub> is the bulk density.

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

**Post compression Parameters:****Weight variation:**

20 tablets were selected randomly from the lot and weighted individually to check for weight variation. Weight variation specification as per I.P.

**Hardness:**

Hardness or tablet crushing strength (fc), the force required to break a tablet in a diametric compression was measured using Monsanto tablet hardness tester. It is expressed in kg/cm<sup>2</sup>.

**Thickness:**

Three tablets were selected randomly from each batch and thickness was measured by using Vernier Caliper.

**Friability (F):**

Friability of the tablet determined using Roche friabilator. This device subjects the tablet to the combined effect of abrasion and shock in a plastic chamber revolving at 25 rpm and dropping a tablet at the height of 6 inches in each revolution. Pre weighed sample of tablets was placed in the friabilator and were subjected to the 100 revolutions. Tablets were dusted using a soft muslin cloth and reweighed. The friability (F) is given by the formula.

$$F = \frac{W_{\text{initial}} - W_{\text{final}}}{W_{\text{initial}}} \times 100$$

**In-Vitro Drug Release:**

*In-vitro* release studies were carried out using a modified USP XXIII dissolution test apparatus (Lab India, DS-800).

The dissolution fluid was 500ml of phosphate buffer pH 6.8 at a speed of 50rpm at a temperature of 37°C were used in each test. Samples of dissolution

medium (5ml) were withdrawn for every 2min and assayed for famotidine by measuring absorbance at 265 nm.

For all the tests 5ml of the test medium were collected at specified time intervals and replaced with same volume of phosphate buffer pH 6.8. Details:

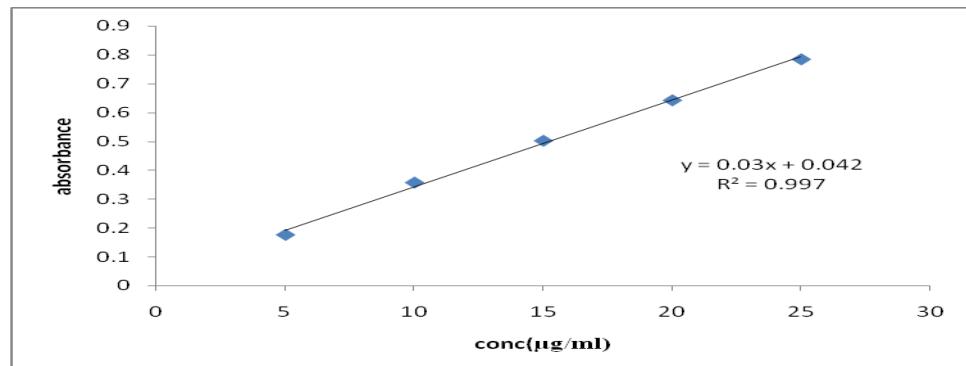
**RESULTS & DISCUSSION:**

Fig 1: standard graph of Felodipine in pH 6.8 phosphate buffer

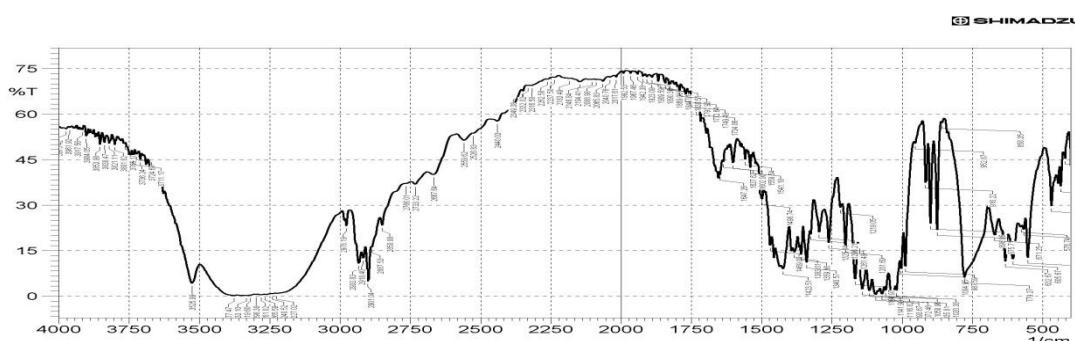
**Evaluation Parameters for Fast Dissolving Tablets of Felodipine:****Pre-compression parameters:**

Fig 2: FT-IR of Felodipine

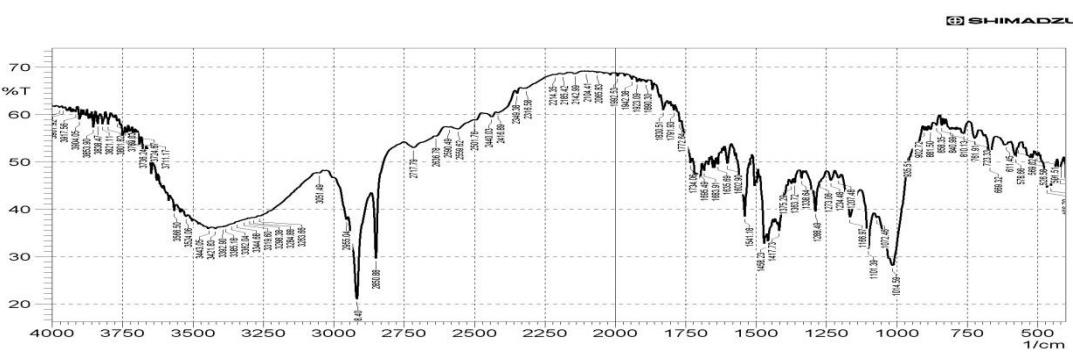


Fig 3: FT-IR of Physical Mixture

**Table 2:Pre-compression parameters**

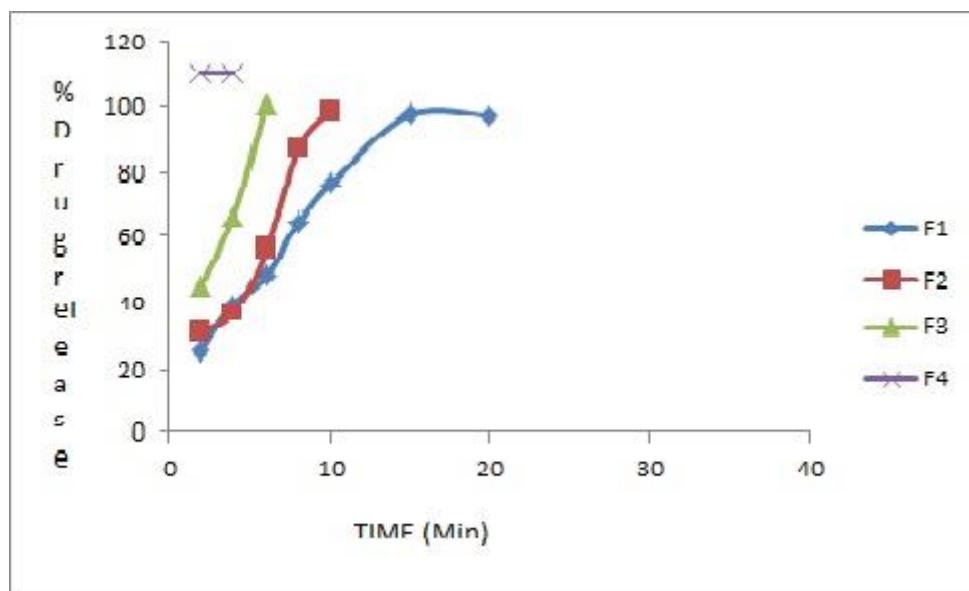
Formulations	Bulk Density (gm/cm <sup>2</sup> )	Tap Density (gm/cm <sup>2</sup> )	Carr's Index (%)	Hausner ratio	Angle Of Repose(θ)
<b>F<sub>1</sub></b>	0.45	0.55	18.18	1.22	27.91
<b>F<sub>2</sub></b>	0.47	0.55	14.54	1.17	28.23
<b>F<sub>3</sub></b>	0.50	0.58	13.79	1.16	29.34
<b>F<sub>4</sub></b>	0.46	0.55	16.36	1.19	26.71
<b>F<sub>5</sub></b>	0.50	0.58	13.79	1.16	29.34
<b>F<sub>6</sub></b>	0.47	0.55	14.54	1.17	28.23
<b>F<sub>7</sub></b>	0.50	0.58	13.79	1.16	29.34
<b>F<sub>8</sub></b>	0.41	0.50	18.34	1.21	26.78
<b>F<sub>9</sub></b>	0.48	0.56	18.02	1.21	26.78
<b>F<sub>10</sub></b>	0.43	0.53	18.86	1.23	27.42
<b>F<sub>11</sub></b>	0.48	0.59	18.64	1.22	25.85
<b>F<sub>12</sub></b>	0.51	0.60	15	1.17	26.48

**Table 3: Post-Compression parameters:**

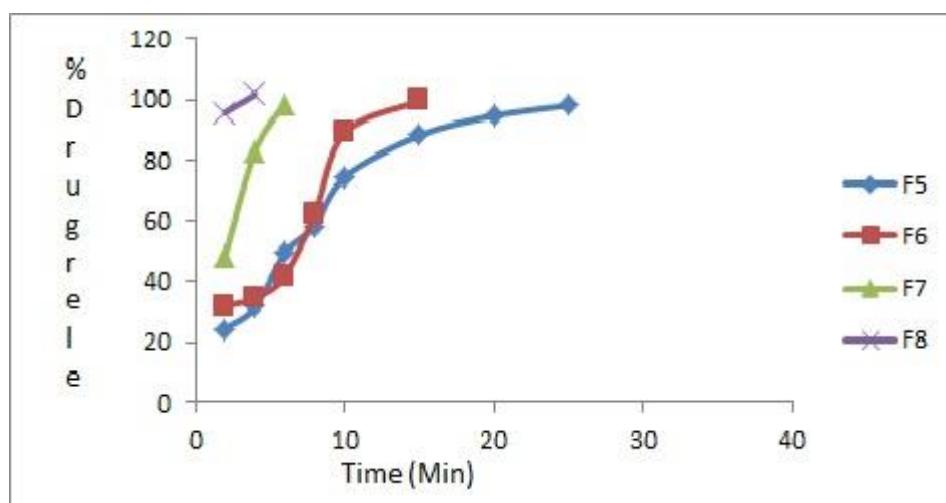
FD	Weight variation (mg)	Hardness (kg/cm <sup>2</sup> )	Thickness (mm)	Disintegration Time (sec)	Friability (%)	Assay (%)
F1	105.6	2.5	3.59	20.33	0.43	97.23
F2	104.3	2.3	3.64	22.66	0.34	98.55
F3	99.6	2.5	3.59	30.33	0.49	98.16
F4	100.8	2.6	3.58	19.00	0.47	99.34
F5	98.4	2.3	3.59	20.33	0.49	98.16
F6	102.9	2.4	3.64	22.66	0.34	98.55
F7	101.4	2.5	3.59	25.33	0.49	98.16
F8	102.5	2.3	3.56	17.00	0.34	99.25
F9	97.5	2.5	3.56	21.00	0.34	99.25
F10	103.8	2.4	3.55	15.99	0.43	98.6
F11	102.4	2.2	3.45	19.00	0.54	98.7
F12	98.5	2.5	3.54	16.76	0.43	98.5

**Table 4:In vitro dissolution data of Felodipine Oro dispersible Tablets**

Time(Min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12
2	25.4	30.8	45.72	110.4	24.3	31.7	48.3	95.7	14.9	28.4	39.5	78.9
4	39.6	36.72	66.16	110.3	31.6	34.5	82.9	101.8	28.4	35.2	76.3	89.4
6	48.6	56.16	101.16	-	49.3	41.9	98.7	-	33.1	48.9	96.2	99.2
8	64.3	87.4	-	-	58.3	62.4	-	-	59.7	66.8	99.7	-
10	76.4	98.5	-	-	74.3	89.1	-	-	79.3	78.1	-	-
15	97.6	-	-	-	88.1	99.5	-	-	88.9	86.4	-	-
20	97.1	-	-	-	94.6	-	-	-	93.5	100.3	-	-
25	-	-	-	-	98.1	-	-	-	98.1	-	-	-
30	-	-	-	-	-	-	-	-	-	-	-	-



**Fig 4:** Dissolution profile of formulations prepared with Explotab as super disintegrate



**Fig 5:** Dissolution profile of formulations prepared with Polyplasdone XL as super disintegrate

#### Standard Calibration curve of Felodipine:

It was found that the estimation of Felodipine by UV spectrophotometric method at  $\lambda_{\text{max}}$  224.0 nm in pH 6.8 phosphate buffer had good reproducibility and this method was used in the study. The correlation coefficient for the standard curve was found to be closer to 1, at the concentration range, 5- 25 $\mu\text{g}/\text{ml}$ . The regression equation generated was  $y = 0.03x + 0.042$  shown in figure 1.

#### Fourier Transform-Infrared Spectroscopy:

From the FTIR data it was evident that the drug and super disintegrates, other excipients doses not have any interactions. Hence they were compatible results shown in figures 2 & 3.

The data's were shown in Table 2. The values for angle of repose were found in the range of 25°-30°. Bulk densities and tapped densities of various

formulations were found to be in the range of 0.41 to 0.50 (gm/cc) and 0.50 to 0.58 (gm/cc) respectively. Carr's index of the prepared blends was fall in the range of 13.79% to 18.64%. The Hausner ratio was fall in range of 1.16 to 1.22. From the result it was concluded that the powder blends had good flow properties and these can be used for tablet manufacture.

Tablets of each batch were subjected to weight variation test, difference in weight and percent deviation was calculated for each tablet. The average weight of the tablet is approximately in range of 107 to 98.5, so the permissible limit is  $\pm 10\%$  (110-90mg). The results of the test showed that, the tablet weights were within the pharmacopoeia limit.

**Hardness test:**

Hardness of the three tablets of each batch was checked by using monsanto hardness Tester and the data's were shown in above table.The results showed that the hardness of the tablets is in range of 2.5 to 3.00 kg/cm<sup>2</sup>, which was within IP limits shown in table 3.

**Thickness:**

Thickness of three tablets of each batch was checked by using Vernier Caliper and data shown in Table. shown in table 3.

**Friability:**

Tablets of each batch were evaluated for percentage friability and the data's were shown in the Table.The average friability of all the formulations lies in the range of 0.30 to 0.51% which was less than 1% as per official requirement of IP indicating a good mechanical resistance of tablets shown in table 3..

**In vitro disintegration time:**

Tablets of each batch were evaluated for in vitro disintegration time and the data's were shown in the Table.The results showed that the disintegration time of prepared tablets were in the range of 12.66 to 30.33 seconds shown in table 3.

**In vitro Dissolution studies:**

Invitro dissolution studies were carried out by using 500ml of 0.1 N HCl in USP dissolution apparatus by using paddle method. The dissolution studies were carried out for about 30 min.The dissolution data for all the formulations were given in the table 4.

From the tabular column it was evident that the formulations prepared with super disintegrate Solutab showed maximum % drug release in 2 min i.e.110.4% (F4 formulation and the concentration of super disintegrate is 30 mg).The formulations prepared with Explotab showed maximum percentage drug release in 4 min i.e., 105.4 % (F8 formulation and the concentration of super disintegrate is 30 mg).The formulation's prepared with Polyplasdone XL showed maximum percentage drug release in 6 min i.e.,99.2%. Irrespective of super disintegrate type the disintegration time decreases and Dissolution time also decreases as the concentration of super disintegrate increases. The dissolution profile was represented in table 4 and graphs 4 and 5.

**CONCLUSION:**

In the present work, an attempt has been made to develop fast disintegrating tablets of Felodipine.

New generation super disintegrates Solutab, Explotab and Polyplasdone XL was selected as super disintegrates. All the formulations were prepared by direct compression method using 6mm punch on 8 station rotary tablet punching machine. The blend of all the formulations showed good flow properties such as angle of repose, bulk density, tapped density. The prepared tablets were shown good post compression parameters and they passed all the quality control evaluation parameters as per I.P limits. Among all the formulations F4 formulation showed maximum % drug release i.e., 110.4 % in 2 min hence it is considered as optimized formulation. The F4 formulation contains Solutab as super disintegrate in the concentration of 30 mg. F8 formulation also showed maximum percentage drug release i.e., 105.4% in 4 min ,it contains Explotab as super disintegrate in the concentration of 30 mg.

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