



## FORMULATION AND EVALUATION OF MOUTH DISSOLVING TABLETS OF FELODIPINE

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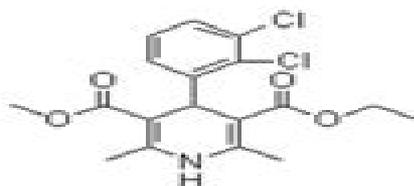
### ABSTRACT

Recent advances in Novel Drug Delivery Systems (NDDS) aim to enhance safety and efficacy of drug molecule by formulating a convenient dosage form for administration and to achieve better patient compliance. One such approach is fast disintegrating/ dispersing tablet formulation. In the present work, fast disintegrating tablets of Felodipine were designed with a view to enhance patient compliance by direct compression method. In the direct compression method, croscopolvidone (2-10% w/w) was used as super-disintegrant along with microcrystalline cellulose (5-20%w/w) as disintegrant and directly compressible mannitol to enhance mouth feel. Estimation of Felodipine in the prepared tablet formulations was carried out by extracting the drug with methanol and measuring the absorbance at 260nm. The prepared formulations were further evaluated for hardness, friability, drug content uniformity, wetting time, water absorption ratio and in vitro dispersion time. Based on in vitro dispersion time (approximately 8-14 s), one promising formulation was tested for in vitro drug release pattern (in pH 6.8 phosphate buffer) and drug excipient interaction (IR spectroscopy). Among all the formulations, promising formulation (DCF) the formulation prepared by direct compression method (containing 2% w/w croscopolvidone and 15% w/w microcrystalline cellulose) emerged as the overall best formulation.

**Key words:** Felodipine, Directly compressible mannitol, Fast disintegrating tablets, Croscopolvidone.

### INTRODUCTION

Felodipine is chemically 3-ethyl 5-methyl 4-[(2, 3-dichlorophenyl)-2, 6-dimethyl-1, 4-dihydropyridine-3,5-dicarboxylate.



Molecular formula of Felodipine is C<sub>28</sub>H<sub>31</sub>Cl<sub>2</sub>N<sub>2</sub>O<sub>4</sub>. It is a member of dihydropyridine class of calcium channel antagonists and it blocks voltage dependent calcium channels, hence it reduces blood pressure. It is used in the treatment of hypertension. Felodipine is a member of the dihydropyridine class of calcium channel antagonists (calcium channel blockers). It reversibly competes with nitrendipine and/or other calcium channel blockers for dihydropyridine binding sites, blocks voltage-dependent Ca<sup>++</sup> currents in vascular smooth muscle and cultured rabbit atrial cells, and blocks potassium-induced contracture of the rat portal vein.

### MATERIALS AND METHODS

#### Materials required

#### Chemicals and Drugs

Felodipine: Aarbindo-pharma limited.  
Mannitol (Pearlitol SD 200): Aarbindo-pharma limited  
MCC (PH 102): Aarbindo-pharma limited  
MCC (PH 102): Aarbindo-pharma limited  
Sodium stearyl fumarate: Aarbindo-pharma limited  
Talc: SD fine chemicals.  
Aspartame: Aarbindo-pharma limited  
Pineapple flavor: Aarbindo-pharma limited  
Potassium dihydrogen orthophosphate: SD fine chemicals.

#### Instruments

UV-spectrophotometer: T60 UV-Visible Spectrophotometer.  
Digital Balance: BL-22004, Shimadzu.  
Digital pH meter: Motex 152- R.  
Dissolution apparatus: Sisco Mumbai.

IR spectroscopy: Perkin Elmer FTIR, Series model-1615 Spectrometer.

Hot air oven: Sisco, Mumbai.

Hardness tester: PDone.

Friability Test Apparatus: Sisco, Mumbai.

Tablet-compression machine: Cadmach, 16 stations.

### METHODS

#### Preparation of standard calibration curve of felodipine in methanol and phosphate buffer solution (6.8pH)

25mg of Felodipine was accurately weighed and dissolved in 25ml of water and phosphate buffer into a volumetric flask (1000 mcg/ml) respectively. 1 ml of this solution was taken and made up to 100 ml with water and phosphate buffer solution, which gives 10 mcg/ml concentrations (stock solution). From this stock solution, concentration of 10, 20, 30, 40,50mcg/ml in water and phosphate buffer solution were prepared. The absorbance of the diluted solution was measured at 260 and 264 nm respectively and a standard plot was drawn using the data obtained. The correlation coefficient was calculated by linear regression analysis. The absorbances of the above concentration are shown in table-1 and table-2.

#### Formulation of fast disintegrating tablets

##### Direct compression<sup>1, 2</sup>:

Fast disintegrating tablets of Felodipine were prepared by direct compression according to the formulae given in table-3.

- All the ingredients were passed through 60 mesh sieve separately.
- The drug and MCC was mixed by small portion of both each time and blending it to get a uniform mixture and kept aside.
- Then the ingredients were weighed and mixed in geometrical order and tablets were compressed at 7 mm size to get a tablet of 120 mg weight using a Rotary Clit 10 station compression machine. The tablets were prepared according to the formulae shown in table-3.

#### Evaluation of tablets

##### Weight variation<sup>4, 5</sup>:

Twenty tablets were selected at random and average weight was determined. Then individual tablets were weighed and the individual weight was compared with an average weight. The results are shown in table-5.

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