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Formulation and Evaluation of Sustained Release Matrix Tablet of Fosinopril

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ABSTRACT
The study successfully developed sustained release tablets of Fosinopril using a validated UV spectrophotometric method for accurate drug quantification. The method showed a strong linear relationship within the tested concentration range, ensuring precise measurement. Solid dispersions with HP-β-cyclodextrin significantly enhanced the drug's solubility and dissolution, with the kneaded complex achieving over 90% release within an hour. Pre-compression characterization indicated good flow and compressibility of tablet blends, essential for efficient manufacturing. Post-compression evaluations confirmed tablets had uniform weight, appropriate hardness, low friability, and consistent drug content, meeting pharmacopeial standards. In vitro studies highlighted a controlled and sustained drug release over 12 hours, governed by diffusion and erosion mechanisms. Overall, the formulations offer improved dissolution profiles and controlled delivery of Fosinopril, potentially enhancing therapeutic efficacy and patient compliance.

Keywords: Fosinopril, sustained release tablets, UV spectrophotometry, HP-β-cyclodextrin, dissolution enhancement, drug release kinetics.

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C O N T E N T S

1. Introduction

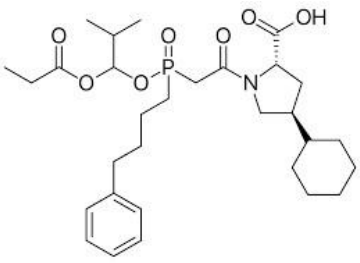

Fig.1: Fosinopril

Molecular Formula: $C_{30}H_{46}NO_7P$
Molecular Weight: 563.67 g/mol

IUPAC Name: (2S, 4S)-4-cyclohexyl-1-[2-[hydroxy(4-phenylbutyl)phosphoryl]acetyl]pyrrolidine-2-carboxylic acid
ChemSpider ID: 10482016
Density: Not readily available in public databases
Boiling Point / Vapour Pressure / Flash Point / Refractive Index: These are not typically reported for pharmaceutical solids like fosinopril
Polar Surface Area: ~103 Å² (estimated)
LogP (Octanol/Water): ~2.5 (estimated)
Generic Name: Fosinopril
Brand Names: Monopril, Dynacil, Elidiur, Fosinorm

Drug Category: ACE inhibitor (Angiotensin-Converting Enzyme Inhibitor)

Indications: Used to treat hypertension, congestive heart failure, and to slow progression of renal disease in hypertensive diabetics

Pharmacology: It's a prodrug converted to fosinoprilat, which inhibits ACE, reducing angiotensin II and lowering blood pressure

Potency: Comparable to enalapril; effective within 1 hour, peak effect in 2–6 hours, duration ~24 hours

Tolerability: Generally well tolerated; dose adjustment not needed in renal impairment due to dual hepatic and renal clearance

Contraindications: Pregnancy, history of angioedema related to ACE inhibitors, hypersensitivity to fosinopril

Adverse Effects: Dizziness, cough, fatigue, hypotension, hyperkalemia, and rare angioedema

Availability: Prescription-only medication, available in oral tablet form

2. Materials and Methods.

Table 1: List of Materials Used

S.NO.	Materials	Source
1	Fosinopril	Supplied By Mylan Labs
2	HP-β-Cyclodextrin	S.D. Fine Chemicals Limited, Mumbai
3	Crospovidone	S.D. Fine Chemicals Limited, Mumbai
4	Purified Talc	S.D. Fine Chemicals Limited, Mumbai
5	Magnesium Stearate	S.D. Fine Chemicals Limited, Mumbai
6	Micro crystalline cellulose	S.D. Fine Chemicals Limited, Mumbai

Table 2: List of Equipment's used

S.NO.	Equipment	Model
1	UV-spectrophotometer	Labindia Uv 3000+
2	Digital Balance	Scale-Tec
3	Digital pH meter	Systronic Electronics, Mumbai
4	Dissolution apparatus	Electrolab TDT-08L
5	Hot air oven	Tempo Instruments & Equipments, Mumbai
6	Hardness tester	Monsanto Hardness Tester
7	Friability test apparatus	Roche Friabilator Electrolab, Mumbai
8	Tablet punching machine	Cadmach, Ahmedabad

Analytical Method Development

Preparation of 6.8 phosphate bufffer

6.8gms of potassium di hydrogen ortho phosphate was taken in a 1000ml volumetric flask and dissolved with distilled water and make up to 1000 ml with distilled water and adjust pH upto 6.8 with Sodium hydroxide solution.

Determination of Fosinopril λ_{max} in 6.8 phosphate buffer:

Working standard: 100mg of Fosinopril was weighed and dissolved in 10ml methanol and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.

Dilution 2: From the dilution1, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 10µg/ml concentrated solutions. This solutions was scanned at range of 200-400nm wavelength light corresponding scan spectrum curve was noted .the corresponding wavelength having highest absorbance is noted as λ_{max}

Construction of calibration curve of Fosinopril in 6.8 phosphate buffer

Working standard: 100mg of Fosinopril was weighed and dissolved in 10ml water and then make up to the volume with 6.8 phosphate buffer, it give 1000µg/ml concentrated stock solution.

Dilution 1: From the working standard, 10ml solution was diluted to 100ml with 6.8 phosphate buffer, it will give 100µg/ml concentrated solution.

Dilution 2:

From dilution 1, take 0.2, 0.4, 0.6, 0.8, and 1ml of solution was diluted up to the mark with 6.8 phosphate buffer in 10ml volumetric flask to obtain 2, 4, 6, 8 and 10µg/ml concentrated solutions. This solutions absorbance was noted at 238nm.

Preparation of the Solid Dispersions

1. **Physical mixture method:** Drug with polymers in different molar ratios (1:1 and 1:2) were mixed in a mortar for about one hour with constant trituration, passed through sieve No. 80 and stored in desiccators over fused calcium chloride.
2. **Kneading method:**
   Drug with polymers in different molar ratios (1:1 and 1:2) was taken. First cyclodextrin is added to the mortar, small quantity of 50% ethanol is added while triturating to get slurry like consistency. Then slowly drug is incorporated into the slurry and trituration is further continued for one hour. Slurry is then air dried at 25°C for 24 hours, pulverized and passed through sieve No. 80 and stored in desiccators over fused calciumchloride.
3. **Co-precipitate method:**
   Drug was dissolved in ethanol at room temperature and polymer was dissolved in distilled water. Different molar ratios of Drug with polymers (1:1 and 1:2) were taken. The mixture was stirred at room temperature, for one hour and then slowly evaporated on a boiling water bath. The inclusion complex precipitated as a crystalline powder was pulverized and passed through sieve No. 80 and stored in a desiccator till free from any traces of the organic solvent.

Evaluation Studies on Solid Dispersions

Drug Content Estimation:

Cyclodextrin inclusion complex, a quantity of powder equivalent to 100 mg of Fosinopril was weighed transferred

to a 100 ml volumetric flask. The drug is dissolved in methanol by vigorously shaking for 15 minutes. Then the volume is adjusted to the mark with water and the solution is filtered. From prepared solution take 0.1ml in 10ml volumetric flask and make up to mark with water. The Fosinopril content was determined by measuring the absorbance at 238nm after appropriate dilution. The drug content was calculated using the standard calibration curve. The mean percent drug content was calculated as an average of three determinations. Calculate the quantity in mg of Fosinopril in the portion taken by the formula

***In vitro* dissolution studies for solid dispersions**

Dissolution Profile:

- Apparatus: USP - type II (Paddle)
- Medium: 900 ml of 6.8 phosphate buffer
- Speed: 50 rpm
- Temperature of Medium : 37°C ±1°C
- Sampling time points: 5,10,15, 20, 30 , 40, 50 & 60 min
- Withdrawn the 5 ml samples through a 0.45µ filter at different intervals of time, suitably diluted and assayed for Fosinopril at 238nm using a UV spectrophotometer & replace with same volume of buffer. The dissolution experiments were conducted in triplicate

Preparation of Sustained Release Tablets of Fosinopril

Processing steps involved in direct compression method:

The Fosinopril SR tablets were prepared by following the General Methodology as given below:

1. All ingredients (Drug+HP-Beta cyclodextrin complexes + polymer + DCP) were weighed accurately and co sifted by passing through #22 sieve, blended in a Poly Bag for 5 min.
2. The above blend was lubricated with # 40 Sieve passed Talc and Magnesium stearate.
3. The final blend was then compressed into tablets using 16 station tablet compression machine with an average hardness of 6.0kg/cm^2,by using 8mm to 12mm dies

Table 3: Formulation codes for the solid dispersions prepared by various methods

S.NO.	Composition	Method of Preparation of solid dispersions		
		Physical mixture	Kneading method	Co-precipitate method
1	**API (Fosinopril)**			
2	API: HP-β –CD (1:1)	**PM-1**	**KM-1**	**CP-1**
3	API: HP- β –CD (1:2)	**PM-2**	**KM-2**	**CP-2**

Table 4: Formulae of Fosinopril SR Tablets

Ingredients	Formulation code								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug: HP-Beta cyclodextrin(1:2)	12	12	12	12	12	12	12	12	12
HPMC K4M	8	16	24	-	-	-	-	-	-
HPMC K15M	-	-	-	8	12	24	-	-	-
HPMC K100M	-	-	-	-	-	-	8	12	24
DCP	136	128	120	136	128	120	136	128	120
Talc	2	2	2	2	2	2	2	2	2
Mg.Stearate	2	2	2	2	2	2	2	2	2
Total wt (mg)	160	160	160	160	160	160	160	160	160

Table 5: Angle of Repose Limits

Flow Property	Angle of Repose (degrees)
Excellent	25–30
Good	31–35
Fair—aid not needed	36–40
Passable—may hang up	41–45
Poor—must agitate, vibrate	46–55
Very poor	56–65
Very, very poor	>66

Table 6: Compressibility Index Limits

Compressibility Index (%)	Flow Character	Hausner's Ratio
≤ 10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very Poor	1.46-1.59
> 38	Very, very Poor	> 1.60

Table 7: Dissolution Parameters

Parameter	**Details**
Dissolution apparatus	USP -Type II (paddle)
Medium	6.8 Phosphate buffer and
Volume	900 ml
Speed	50rpm
Temperature	37± 0.5 ºC
Sample volume withdrawn	5ml
Time points	1, 2, 4, 6, 8, 10, 12hours
Analytical method	Ultraviolet Visible Spectroscopy
λ_{max}	238nm

Table 8: Drug release kinetics mechanism

Diffusion exponent(n)	Mechanism
0.45	Fickian diffusion
0.45 < n <0.89	Anomalous(Non- Fickian) diffusion
0.89	Case II transport
n > 0.89	Super Case II transport

3. Results and Discussion

Construction of Standard calibration curve of Fosinopril in 6.8 phosphate buffer: The absorbance of the solution was measured at 238nm, using UV spectrometer with 6.8 phospphate bufffer as blank. The values are shown in table no 10. A graph of absorbance Vs Concentration was plotted which indicated in compliance to Beer's law in the concentration range 2 to 10 µg/ml.

Table 9: Standard Calibration graph values of Fosinopril in 6.8 phosphate buffer

Conc. (µg/ml)	**Absorbance**
0	0
2	0.091
4	0.188
6	0.281
8	0.382
10	0.469

Standard plot of Fosinopril by taking absorbance on Y – axis and concentration (µg/ml) on X – axis, the plot is shown fig.

4. Conclusion

The study had shown that the external support given by the physician and family members had a greater influence on cancer patients to adapt well to the situation of having had a life-threatening disease and to undergo their treatment more positively. Our study revealed that the cancer cases are high and it showed increasing trend which suggests that the population based cancer registries to be made at all levels of health care to identify the time trends so that prevention measures can be implemented at the community level. Epidemiological information on cancer including the pattern and socio-demographic factors is fundamental in determining the priorities for cancer control in the given population group. The cancer registries in India take into account only representative sample of the whole country. This study shows that there is marked difference in the cancer pattern of our hospital in comparison with the national statistics. Hence factors leading to such high incidence should be analyzed and steps towards prevention of this type of cancer should be taken to reduce the morbidity and mortality of cancer. Further, more such research can be conducted all over the country to find the cancer pattern of different areas and thus pave the way for effective preventive measures

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