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Research Article

FORMULATION AND EVALUATION OF LORNOXICAM FAST DISSOLVING TABLET

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ABSTRACT
The goal of the present investigation was to design and evaluated taste mask oral disintegration tablet of lornoxicam, which is NSAID by sublimation & effervescent method using various excipients (menthol, camphor, citric acid and sodium bicarbonate) in different concentrations. In sublimation method drug:β-cyclodextrine complex was prepared by kneading method. Crosspovidone (5%) was used as superdisintegrants. The prepared formulations were evaluated for hardness, friability, and disintegration time, wetting time, drug content and in-vitro drug release studies. Fast dissolving tablet prepared by sublimation method with 10% menthol and effervescent method with 15 % sodium bicarbonate and 5% citric acid showed 98.95% in 6 minute and 98.36 % of drug release respectively.
KEYWORDS: Lornoxicam, Crosspovidone, camphor, Menthol, Sodium Bicarbonate, Citric acid

INTRODUCTION

Oral route of drug administration is the most appealing route for the delivery of drugs, Among the various dosage forms administer orally, tablets are the most preferred because of its ease of administration, manufacturing, accurate dosing & self medication etc. the main drawback of this dosage form for some patients, is the difficulty to sallow for these reason tablet that can rapidly dissolve or disintegrate in oral cavity have altered a great deal of attraction.[1]

Oral disintegration tablet with good taste and flavour increase the acceptability of bitter drugs by various group of population.[2] Thus taste masking of oral pharmaceutical by the various taste masking method like inclusion complex by β-cyclodextrin has become important tool to improve patient compliance and the quality of treatment especially in pediatrics & geriatric population.[3]

Lornoxicam is a nonsteroidal anti-inflammatory drug with analgesic properties and belongs to the class oxicams. The mode of action of lornoxicam is partly based on inhibition of prostaglandin synthesis (inhibition of the cyclo-oxygenase enzyme). Lornoxicam is absorbed rapidly and almost completely from the gastro-intestinal tract[4] lornoxicam wihich is bitter in taste. The objective of the present study was to mask the bitter taste of lornoxicam and prepare fast disintegration tablets by sublimation and effervescent method.

MATERIALS AND METHODS

Lornoxicam was obtained as a gift sample from Hetero drugs Ltd. (Hyderabad, India). Crosspovidone, cyclodextrin & other chemicals were obtain from locally and used.

Sublimation Method

Preparation Lornoxicam: β-cyclodextrin Complex

A mixture of lornoxicam and β-cyclodextrin (1:2) was ground in a glass container with minimum amount of water. The mixture was stirred for 5 min and dried at 60^0 C in a oven. After drying inclusion complex of lornoxicam with β-cyclodextrin was kept in the dessicator until further use.[5]

Preparation of lornoxicam FDT tablet

Weighed quantity of lornoxicam:β-cyclodextrin complex, crosspovidone, camphor, menthol (Table-I) were passed through sieve no. 60. Drug complex and all excipients were added geometrically and mix to obtain uniform mass of powder, which was compressed directly by using 7mm, punch Rimek Mini Press-I.

Sublimation was performed for all formulation at 60^0 C till all amount of subliming agent was removed from tablets.[6]

Characterization of complex for drug content

Drug content was determined by dissolving lornoxicam equivalent to 25 mg in 0.1 N HCl and volume was made up to 25 ml. The solution was further suitable diluted and analyzed at 376 nm using PG Instruments T-80 UV/ Visible spectrophotometer.[6]

Effervescent Methods

Weighed quantity of lornoxicam, anhydrous sodium bicarbonate, citric acid, crosspovidone (Table-II). Were passed through sieve no. 60. Drug and all excipients were added geometrically and mix to obtain uniform mass of powder, which was compressed directly by using 7mm, punch Rimek Mini Press-I.[7]

Evaluation of Tablets

Hardness

The hardness of tablets was determined by using monsonto hardnes tester[8].

Weight Variation

Weight variation was carried out by weighing 20 tablets individually and average weight was determined from which of deviation was calculated[9].

Friability test

Weighed 10 tablets were placed in dolphin friabilator and operated for 100 revolutions after which the tablets were dedusted and re-weighed and % friability was calculated[10].

Content Uniformity

Five tablets were crushed and lornoxicam equivalent to 4 mg was dissolved in 25 ml of Methanol in volumetric flask. The solution was further filtered and suitably diluted and analyzed at 376nm using PG instrument, T-80 uv/visible spectrophotometer[11].

Disintegration Time

The prepared formulation was subjected to disintegration test using dolphine disintegration apparatus in phosphate buffer (pH 6.8, 900 ml at 37°C) as the disintegrating medium[2].

***In-vitro* Dissolution Study of Tablets**

In-vitro dissolution studies was carried out by using USP Paddle method in phosphate buffer pH 6.8 (900ml) at 50 rpm and maintained at 37^0 C±0.5^0C for a period of 10 mins, samples were withdrawn at different time intervals, which was further suitably diluted and analyzed at 376 nm using Uv/ Vis spectrophotometer[12].

RESULTS AND DISCUSSION

Lornoxicam was taste masked by using β-cyclodextrin. The drug polymer complex was prepared by kneading method.Formulations were prepared by sublimation method and effervescent technique using various excipients (Menthol and Camphor in four different concentrations, Anhydrous sodium bicarbonate and citric acid respectively in three different concentrations). The characteristic of prepared fast disintegration tablets of lornoxicam is shown in tablet Table-III & IV.The % drug content of prepared formulations by sublimation and effervescent technique was carried out & found in the range of 96.34% to 99.01% and 97.34% to 99.78% respectively.Disintegration time of the prepared formulation by sublimation and effervescent techniques was 9 to 45 sec and 29 to 87 sec respectively.The disintegration time decrease as increase in the concentration of sublimating agent.Formulation LM-IV, which consist 10% menthol, prepared by sublimation method shown least disintegration time of 9 sec, which may be due to formulation of pores in the tablets.Wetting time was found in a range of 6 to 45 sec for sublimation and 47 to 76 sec for effervescent.In-vitro dissolution studies were preformed by USP paddle method using phosphate buffer pH 6.8. Formulation LM-IV prepared by sublimation method shown 98.36% of drug release in 6 min. where as formulation LE-III showed 98.36% drug release in 7 mins. The rapid disintegration, wetting and dissolution of formulation LM-IV prepared by sublimation method with 10% menthol may be due to the formulation of porous structure in tablet.

CONCLUSION

From the above results of disintegration time, wetting time and dissolution study, it is concluded that the adopted techniques are more suitable for formulation of fast dissolving tablets of lornoxicam. As the concentration of subliming agents increase the disintegration time and wetting time of tablets was decreased in case of sublimation techniques. Formulation LM-IV was the best in case of tablets prepared by sublimation method.

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Table 1: Formulation of lornoxicam fast dissolving tablets by sublimation method

Ingredient	LC-I	LC-II	LC-III	LC-IV	LM-I	LM-II	LM-III	LM-IV
Lornoxicam:β-cyclodexyrin Complex (mg)	12.2	12.2	12.2	12.2	12.2	12.2	12.2	12.2
Camphor (mg)	2.5	5	7.5	10				
Menthol (mg)					2.5	5	7.5	10
Crosspovidone (mg)	5	5	5	5	5	5	5	5
DC-Mannitol (mg)	48.3	45.8	43.12	40.8	48.3	45.8	33.3	40.8
MCC (mg)	30	30	30	30	30	30	30	30
Magnesium Stearate (mg)	1	1	1	1	1	1	1	1
Talc (mg)	1	1	1	1	1	1	1	1
Total	100	100	100	100	100	100	100	100

L – Lornoxicam, C-Camphor, M -menthol

Table 2: Formulation of lornoxicam fast dissolving tablets by effervescent method

INGREDIENT	LE-I	LE-II	LE-III	LE-IV	LE-V	LE-VI
Lornoxicam (mg)	4	4	4	4	4	4
Anhydrous sodium bicarbonate (mg)	5	10	15	5	10	15
Citric acid (mg)	5	5	5	10	10	10
Crosspovidone (mg)	5	5	5	5	5	5
MCC (mg)	25	25	25	25	25	25
DC-Mannitol (mg)	43	48	38	28	38	18
Magnesium Stearate (mg)	1	1	1	1	1	1
Talc (mg)	1	1	1	1	1	1
Aspartame (mg)	6	6	6	6	6	6
Total	100	100	100	100	100	100

L – Lornoxicam, E-Effervecent

Table 3: Evaluation of prepared tablets by sublimation method

Formulation Code	Hardness (Kg/cm^2) ±SD	Friability (%) ±SD	Weight Variation ±SD	Disintegration Time (sec) ±SD	Wetting Time (Sec) ±SD	Drug Content (%),±SD
LC1	3.8±0.09	0.45±0.07	99.56±0.03	45±0.23	45±0.89	96.34±0.09
LC2	3.8±0.06	0.81±0.09	101.4±0.06	34±0.14	32±0.78	97.78±0.89
LC3	3.9±0.04	0.54±0.12	100.08±0.05	21±0.26	19±0.45	97.67±0.78
LC4	3.4±0.07	0.12±0.29	99.24±0.06	14±0.38	10±0.25	99.01±0.37
LM1	3.6±0.03	0.76±0.05	100.80±0.04	35±0.28	37±0.29	97.67±0.27
LM2	3.7±0.04	0.34±0.22	101.85±0.06	18±0.12	26±0.89	98.78±0.39
LM3	3.9±0.06	0.89±0.5	102.80±0.06	16±0.03	12 ±0.15	99.08±0.16
LM4	3.4±0.01	0.67±0.07	98.8±0.08	9±0.67	6±0.19	98.67±0.26

L – Lornoxicam, C-Camphor, M –menthol, * Average of three trials

Table 4: Evaluation of prepared tablets by effervescent method

Formulation Code	Hardness (Kg/cm2) ±SD	Friability (%) ±SD	Weight Variation ±SD	Disintegration Time (sec) ±SD	Wetting Time (Sec) ±SD	Drug Content (%),±SD
LE1	3.6±0.12	0.62±0.05	102.7±1.22	76±0.45	87±0.87	98.34±0.56
LE2	3.6±0.21	0.15±0.07	100.07±0.70	45±0.34	56±0.56	97.67±0.36
LE3	3.9±0.02	0.23±0.51	99.70±0.53	23±0.26	43±0.37	98.78±0.27
LE4	3.2±0.04	0.43±0.22	100.60±0.53	87±0.17	87±0.48	99.78±0.17
LE5	3.9±0.34	0.52±0.12	101.6±1.2	45±0.28	56±0.28	97.34±0.38
LE6	3.5±0.17	0.56±0.22	100.05±2.5	29±0.12	47±0.18	98.76±0.47

L – Lornoxicam, E-Effervescent *Average of three trials

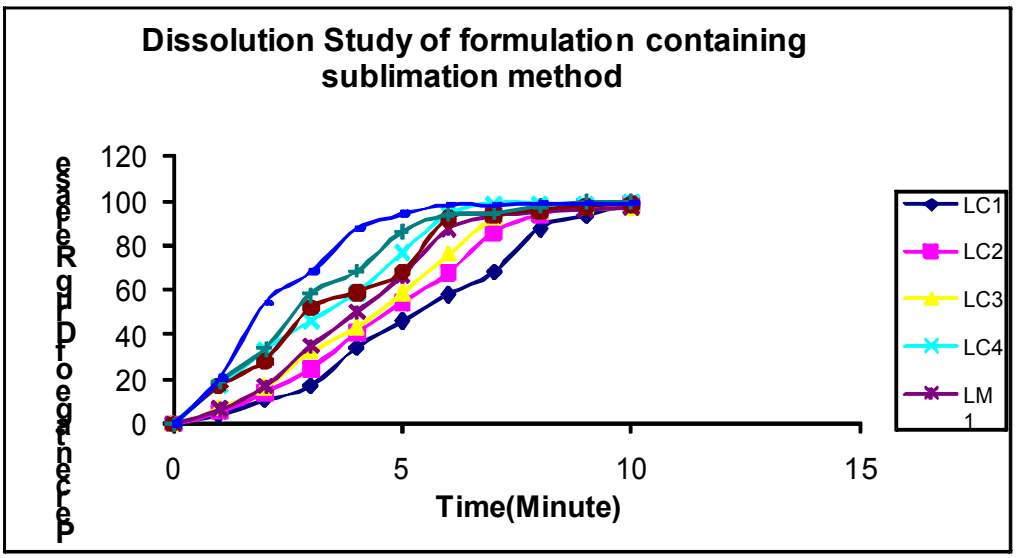

Figure 1: *In-vitro* dissolution profile of prepared tablets by sublimation method

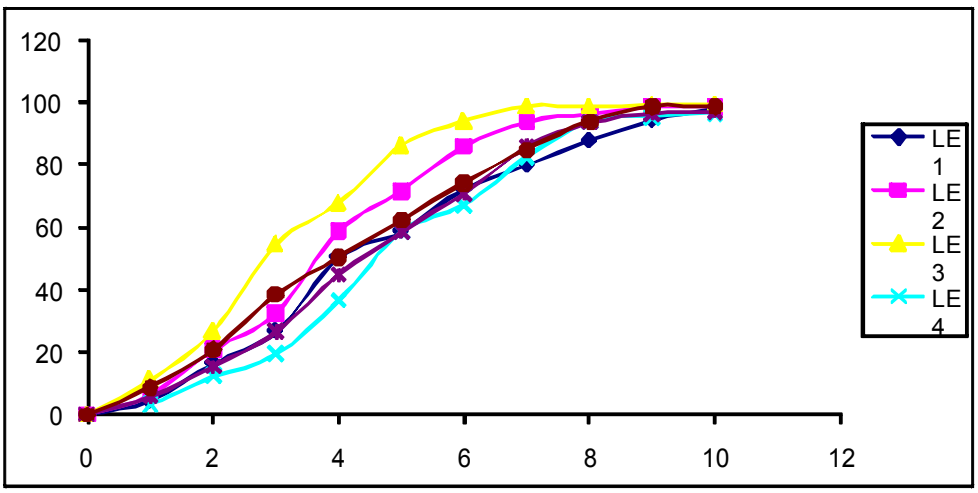

Figure 2: In- vitro dissolution profile of prepared tablets by effervescent method

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