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Formulation and Evaluation of Lercanidipine Hydrochloride Anti-Hypertensive Mouth Dissolving Tablets

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ABSTRACT

Lercanidipine is an antihypertensive drug. It is a dihydropyridine class of calcium channel blockers. It is extremely bitter. The reason for this exploration was to build up a non-bitter orally breaking down the tablet of inadequately solvent medication viz Lercanidipine. The bitterness of the drug, is masked through complexing Tulsion 339 in various ratios. Sodium starch glycolate, crospovidone, and low substituted hydroxypropyl cellulose were selected as super disintegrants in the formulation. The formulated tablets were assessed for various properties like Drug content, crushing strength, friability, wetting time, water retention proportion, breaking downtime and in-vitro disintegration time and dissolution studies. The disintegration time was obtained in the range between 38.46-51.40 seconds. Release studies observed between 5 to 30 minutes. From the prepared formulations, formulation using Low substituted hydroxypropyl cellulose with 5% concentration showed 98.89% drug release within 30 minutes. Thus F9 was considered as best among the other formulations With effective dissolution and improved patient intake. Drug release Kinetic analysis (r2) based on the best curve fitting method for optimized lercandipine formulation showed first-order kinetics proves that the drug release depends upon its concentration.

INTRODUCTION:

The oral route of drug administration has been generally accepted and up to 50-60% of total dosage forms are administered orally. Solid dosage forms viz tablets and capsules are worldwide accepted dosage forms due to its precise dose, self medication, a non-invasive route which makes the solid dosage forms as patient user-friendly. However, the substantial drawbacks of these traditional dosage formulations include dysphagia for pediatric and geriatrics patients. This problem mainly encoun-ters 35% of the general population. These traditional tablets need water for administration. This issue causes difficulty in swallowing when water is not available. Hence Dispersible tablets play a dominant role for these purposes, which can quickly dissolve or disintegrate in the oral cavity and have drawn a good interest to the patients (Saini and Garg, 2019). The word "orodispersible tablet" was adapted by European Pharmacopoeia as a tablet to be inserted in the mouth where it easily disappears before swallowing, suggesting a maximum DT of 3 min as calculated in a conventional disintegration test apparatus. Other synonyms of ODT include quick melts, rapid melts, fast dissolving, fast disintegrating, rapid dissolve or mouth dissolving tablets (Mohanachan- dran et al., 2011).

The bitter taste of orally administered medicinal products often results in patient non-compliance with the use of medicinal products, especially for children and the elderly. Sadly, most medicines have a natural, bitter taste that can cause a burning sensation in the throat or mouth. In particular, a bitter taste can reduce patient compliance and thus reduce the efficiency of pharmacotherapy (Suryade- vara *et al.*, 2017).

The Drug Lercanidipine HCl used in the present study is a type-II biopharmaceutical classification system since it has low solubility and high permeability. It is recommended for relief of seasonal allergic rhinitis-related symptoms in adults and children 2 years of age and is intended for chronic idiopathic urticaria therapy in adults and children 6 months of age and older (Suresh *et al.*, 2007). Lercanidipine HCl shows low bioavailability so its aqueous solubility- it should be targeted by a Bioavailability Improvement strategy.

Chemically Lercanidipine Hydrochloride, a potent antihypertensive and antianginal drug of 2-[(3, 3-diphenylpropyl) methylamine]-1, 1- dimethylethylmethyl 1,4-dihydro-2,6dimethyl-4-(3-nitrophenyl)-3,5 pyridine carboxylic ester hydrochloride (Saini and Garg, 2019). It is used in the treatment of Hypertension, due to its selectivity and specificity on the smooth vascular cells.[1 2]

MATERIALS

Lercanidipine hydrochloride from nice chemical, crosspovidone from chemical , glass and scientific company erode, croscarmellose sodium (ccs) nice chemical , Microcrystalline cellulose (MCC) by loba chemical pvt limited, magnesium sterate by loba chemical, talc by chemical and scientific company erode, sucralose by nice chemical pvt limited. [3] [4] [5]

Materials Used

S.No	Materials	Suppliers / Manufacturer
1	Cross povidone / PVP Disintegrant	Chemico Glass & Scientifi company, Erode.
2	Croscarmellose sodium (CCS)	Loba Chemie Pvt Ltd
3	Sodium Starch Glycolate (SSG)	Nice chemicals
5	Microcrystalline Cellulose	Loba Chemie Pvt Ltd
6	Magnesium Stearate	Loba Chemie Pvt Ltd
7	Sucralose	Nice chemicals
8	Talc	Loba Chemie Pvt Ltd

INSTRUMENTS USED

Table. No.1: Instruments Used

S.No	Equipment	Manufacturer
1	Digital Balance	Shimadzu Analytical
2	Sieves	Indicot (India)
3	Tapped Density Tester	Electrolab
4	Mechanical Stirrer	Remi Motors, Mumbai
5	UV-Visible Spectrophotometer	LAB INDIA UV 3000+
6	Dissolution Test Apparatus	Labindia Analytical Instruments Pvt Ltd. Mumbai , Model- DISSO 2000
7	Temperature controller(hot air oven)	ROLEX
8	FTIR	BRUKER HTS-XT
9	Compression machine	Proton Mini Press
10	Vernier Calipers	Indicot
11	Disintegration Test Apparatus	ROLEX

PREFORMULATION

Preformulation testing is first step in the rational development of dosage forms of a drug substance. It can be defined as – "the investigation of physical and chemical properties of a drug substance alone and when combined with excipients". [7]

ORGANOLEPTIC PROPERTIES

A. COLOR AND NATURE

Transferred small quantity of the sample on a white piece of paper, spread the powder and examined it visually. Lercanidipine Hydrochloride is a white citrine-yellow crystalline powder.[9]

B.PARTICLE SIZE, SHAPE AND SURFACE AREA

Various physical and chemical properties of drug substances are affected by their particle size distribution and shapes. Size also plays a role in the homogeneity of the final tablet. When large differences in size. [10]

C. GENERAL TECHNIQUE FOR DISINTEGRATING PARTICLE SIZE

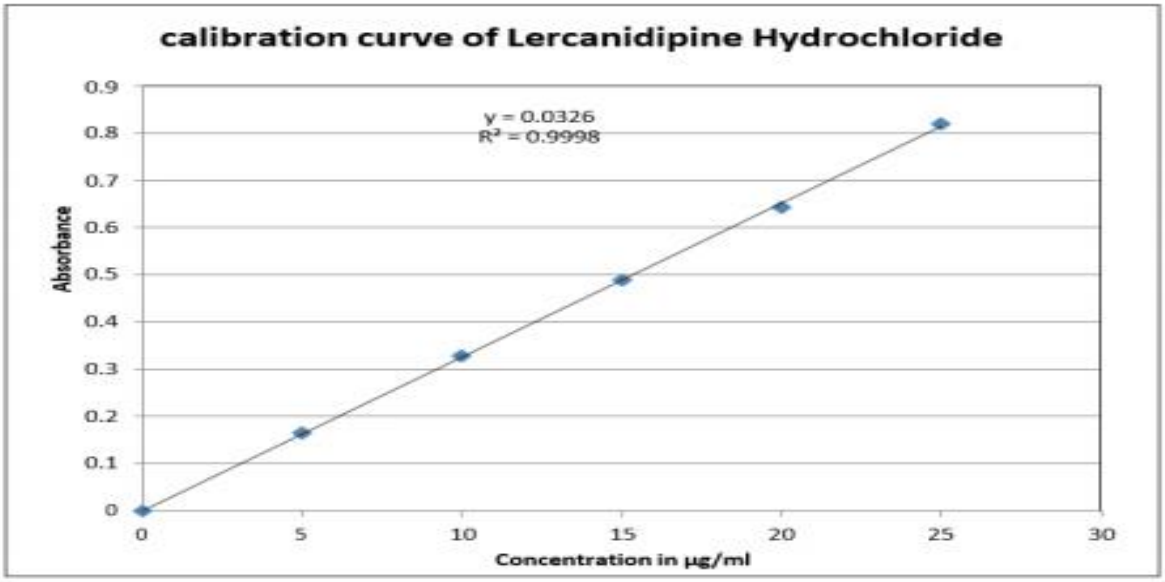
D. ANGLE OF RESPONSE

The angle of repose is defined as the maximum angle possible between the surface of a pile of powder and the horizontal plane. The angle Of Response of Lercanidipine hydrochloride is 29°27". [11]

FLOW PROPERTIES AND CORRESPONDING ANGLES OF REPONSE. E. U V SPECTROSCOPIC METHOD FOR ANALYSIS OF LERCANIDIPINE HYDROCHLORIDE

Measured the absorbance of the above prepared standard solutions at 238 nm. Plotted a graph of concentration (in g/ml) on the X axis and absorbance (in nm) on the Y axis.[12] [13]

E. CALIBRATION CURVE OF LERCANIDIPINE HYDROCHLORIDE



F. DETERMINATION OF BULK DENSITY AND TAPPED DENSITY

A quantity of 5g of the powder (W) from each formula was introduced into a 25 ml measuring cylinder. After the initial volume was observed, the cylinder was allowed to fall under its own weight onto a hard surface from the height of 2.5 cm at 2-second intervals. The tapping was continued until no further change in volume was noted. The bulk density and tapped density were calculated using the following formulas.[14]

G. FRIABILITY TEST

20 tablets were weighed and subjected to rotation on the friability test apparatus. The drum rotated at a speed of 25 rpm for 4 minutes, then dedusted and reweighed the tablets. Percentage friability was calculated.[15]

Percentage of Friability (%F)=100 (1-w/w0) Where,

Wo = Initial weight,

W = Final weight.

H.HAUSNER's RATIO

Hausner's ratio indicates the flow properties of the powder and is measured by the ratio of tapped density to bulk density. Hausner's ratio was [16] determined by the given formula :

Hausner Ratio = Vb/Vt

Where,
Vb = initial or bulk volume
Vt = final or tapped volume

I. BULK DENSITY AND TAPPED DENSITY

Bulk Density and Tapped Density of Lercanidipine hydrochloride are 0.28 gm/ml and 0.23 gm/ml. [17]

J.POWDER COMPRESSIBILITY

The product compressibility of Lercanidipine hydrochloride is 18.92%.

The Housner Ratio of Lercanidipine hydrochloride is 1.19. [18]

K. MELTING POINT

The melting point of Lercanidipine hydrochloride is 185°C-188°C. [19]

L.SOLUBILITY

water: 9.3mg/100ml ethanol 95%:4.7g/lOOml ethanol 99% : 4.7g/lOOml dimethyl formamide: >lo0g/100ml [20]

M.DRUG -EXCIPIENT COMPATIBILITY STUDIES [21] [22]

A) Physical Observation:

There are no such changes in the physical observation after mixing of ingredients.

B) Drug Identification by FTIR:

The graph is compared with the standard FTIR graph given in pharmacopoeia or prescribed standards and confirmed through the corresponding peaks.[1] [36]

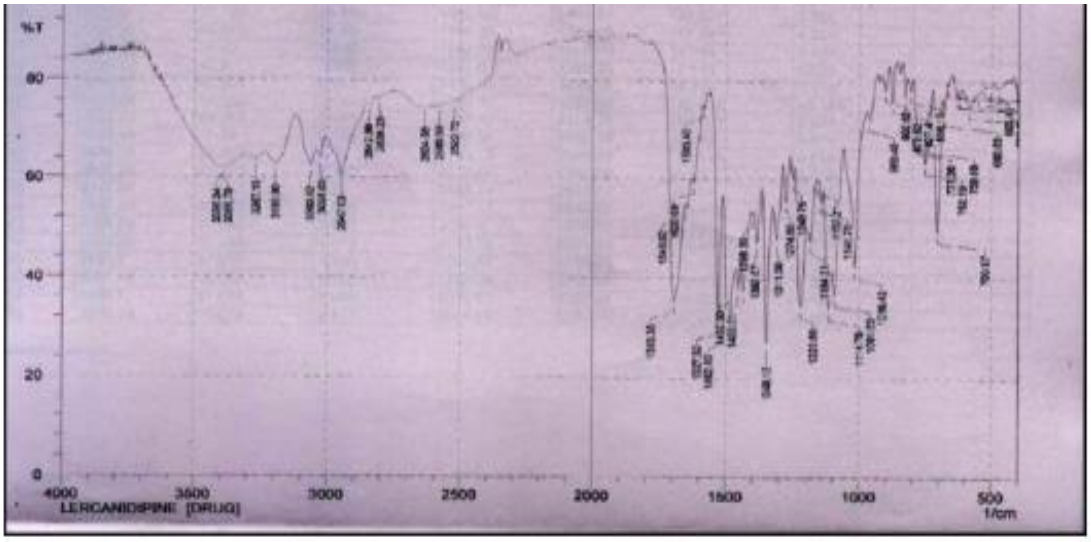


Figure: FTIR OF LERCANIDIPINE HYDROCHLORIDE

Figure: FTIR OF FINAL FORMULATION [23]

N. PRECOMPRESSION PARAMETERS [24] [25]

FORMULATIN CODE	BULK DENSITY	TAPPED DENSITY	CARR'S INDEX	HOUSNER'S RATIO	ANGLE OF RESPONSE
F1	0.535±0.011	0.668±0.014	19.91±0.13	1.24±0.052	23.32±0.23◦
F2	0.532±0.010	0.670±0.023	20.59±0.13	1.25±0.043	24.18◦±0.13◦
F3	0.532±0.004	0.661±0.023	20.23±0.28	1.24±0.058	21.16◦±0.21◦
F4	0.530±0.018	0.650±0.025	18.50±0.29	1.22±0.045	19.35◦±0.11◦
F5	0.533±0.014	0.661±0.023	18.42±0.18	1.22±0.021	25.35◦±0.15◦
F6	0.549±0.013	0.673±0.023	19.81±0.15	1.22±0.073	21.06◦±0.23◦
F7	0.532±0.018	0.650±0.025	18.15±0.08	1.19±0.058	21.06◦±0.23◦
F8	0.545±0.004	0.651±0.014	16.28±0.09	1.22±0.035	23.12◦±0.21◦
F9	0.533±0.013	0.650±0.011	18.50±0.15	1.24±0.023	24.32◦±0.23◦

O. POST COMPRESSION PARAMETERS [26]

Sr. No.	Formulation Code	Weight Variation (mg)	Uniformity Of Thickness	Hardness (Kg/cm2)	Friability %
1	F1	200±0.20	2.73±0.01	3.79±0.15	0.46±0.035
2	F2	198±0.89	2.71±0.04	3.62±0.26	0.47±0.015
3	F3	199±0.75	2.83±0.01	3.53±0.14	0.333±0.025
4	F4	200±0.23	2.76±0.03	3.96±0.25	0.60±0.015
5	F5	199±0.25	2.65±0.04	3.76±0.22	0.53±0.055
6	F6	200 ±0.20	2.53±0.05	3.84±0.26	0.40±0.065
7	F7	198±0.25	2.68±0.04	3.36±0.34	0.67±0.053
8	F8	199 ±0.75	2.79±0.07	3.71±0.25	0.40±0.065
9	F9	200 ±0.23	2.88±0.01	3.43±0.20	0.66±0.035

P. POST COMPRESSION PARAMETERS [27]

Sr No	Formulation Code	Wetting Time (Sec)	Water Absoption Ratio N=3	Invitro Disintegration Time (Sec)	Invitro Dispersion Time (sec)	Drug Content
1	F1	42.76±0.12	39.30±1.30	51.40±1.06	74.57±1.19	98.0
2	F2	35.52±1.73	37.16±1.51	49.71±1.02	71.71±1.43	99.3
3	F3	33.38±1.25	36.52±1.25	48.07±1.20	70.12±1.51	98.6
4	F4	34.19±1.02	27.10±1.41	52.81±1.21	72.74±1.36	99.13
5	F5	33.38±1.58	38.64±1.01	48.13±0.13	71.17±1.23	98.12
6	F6	38.66±1.58	35.31±1.02	41.19±0.98	65.12±1.20	98.3
7	F7	33.72±1.85	29.45±1.11	49..12±1.23	67..17±124	98.6
8	F8	32.65±1.72	33.71±1.20	40.81±1.15	63.18±1.05	98.8
9	F9	31.46±1.01	38.01±0.12	38.46±0.12	62.00±1.03	99.8

Q.DISSOLUTION PARAMETER[28]

Time (min)	F1	F2	F3	F4	F5	F6	F7	F8	F9	Marketed preparation
0	0	0	0	0	0	0	0	0	0	0
5	35.53 ±1.25	50.41 ±1.11	50.85 ±1.23	52.63 ±1.62	53.58 ±1.11	70.35 ±1.11	71.1± 1.11	72.98 ±1.12	75.58±1.15	50.57±1.12
10	42.34 ±1.10	52.56 ±1.13	55.87 ±1.21	54.38 ±0.87	58.68 ±0.98	77.93 ±0.89	77.65 ±0.93	79.78 ±1.53	81.93±0.98	65.35±1.15
15	43.38 ±0.86	60.78 ±1.17	63.63 ±0.53	64.63 ±0.85	64.86 ±1.53	86.93 ±1.13	82.53 ±1.05	84.84 ±1.55	91.63±0.83	68.43±0.89
20	46.53 ±0.95	63..48±1.11	68.67 ±0.79	72.63 ±1.25	71.57 ±1.12	89.93 ±0.89	83.13 ±1.01	85.58 ±1.13	93.57±1.51	75.78±1.5
25	49.56 ±1.15	65.89 ±0.98	73.33 ±0.83	75.98 ±1.13	78.13 ±1.13	91.75 ±1.51	85.13 ±1.13	88.89 ±1.11	95.63±1.48	85.78±1.01
30	54.83 ±1.12	71.35 ±0.91	75.23 ±1.12	80.13 ±0.78	79.23 ±1.11	92.58 ±0.58	93.23 ±1.11	95.73 ±1..10	98.78±1.11	85.23±1.10

R. DIFFERENT IN DISSOLUTION AND KINETIC PARAMETERS OF OPTIMIZED FORMULATION F9 [29]

FORMULATION CODE	ZERO ORDER	FIRST ORDER	HIGUCHI MODEL	KORSEMEYER
F9	0.595	0.94	0.851	0.710

S. STABILITY STUDY OF TABLET OF OPTIMIZED FORMULATION F9 [30]

Sr No	Parameters	Controlled F9	F9	
			After 15 Days	After 1 Month
1	HARDNESS(Kg/cm2)	3.43±0.20	3.42±0.28	3.91±0.16
2	DRUG CONTENTS	99.8	99.8	99.7
3	IN VITRO DRUG INTIGRATION TIME	38.46±0.12	39.45±0.94	39.46±0.91
4	WETTING TIME	31.46±1.01	33.71±1.25	33.72±1.06

T. STABILITY STUDY OF IN VITRO DISSOLUTION OF F9 FORMULATION AT ROOM TEMPERATURE. [31] [32] [38]

Sr No	Time (Min)	Controlled F9	Cumulative % Drug Release F9	
			After 15 Days	Afterr 1 Month
1	0	0	0	0
2	5	75.58±1.14	74.56±1.17	74.48±1.117
3	10	81.93±0.97	81.92±0.98	81.90± 0.89
4	15	91.63±0.81	91.62±0.83	91.61±0.15
5	20	93..57±1.51	92.56±1.51	92.55±1.12
6	25	95.63±1.47	95.61±1.50	95.31±1.31
7	30	98.78±1.10	98.11±1.10	98.05± 1.11

CONCLUSION

The present study involves formulation and evaluation of immediate release tablets of Lercanidipine Hydrochloride. Endeavours with respect to Direct compression method used for formulating tablets was best suitable to achieve 100% results.

Preformulation studies involving organoleptic bulk density, angle of repose, tapped density, compressibility index, hausner ratio, melting point range, pH and solubility were carried out as per USP specifications.

Polymers such as CrosPovidone, Croscarmellose Sodium (CCS), Sodium Starch Glycolate (SSG), Starch 1500 were utilized in the trails. All the physical evaluations carried in preformulation studies were carried out on all the four different polymers utilized. All the formulations exhibited values within the acceptable range.

Tablets were evaluated for weight variations, hardness, friability, thickness and Dissolution studies.

Release studies were carried out in Phosphate buffer, for 30 minutes. Evaluated samples for all the three polymer systems. Results indicated that formulation F12, gave 99.14% release within 8 minutes which is formulated with CrosPovidone alone. Assay was carried out for formulation F12 and was found to be 99.42%.

Remaining formulations gave fluctuating release profiles. The formulation F12 was considered to be better among the trails accomplished.

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