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PREPARATION & CHARACTERIZATION OF ORAL FAST DISSOLVING FILM OF LEVOCETRIZINE DIHYDROCHLORIDE

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ABSTRACT

Aim of the present study was to develop the Fast Dissolving Oral Films of Levocetrizine Hydrochloride, a non sedative antihistamine drug. Chemically, Levocetrizine is the active enantiomer of Cetirizine. Fast dissolving oral films deliver drug directly in the vascular system and bypasses the hepatic first pass metabolism so dose of the drug may also reduce significantly. Fast dissolving films were prepared using solvent casting method, hydrophilic polymers (HPMC15cps, HPMC E-15 15cps, CMC, Lacroate, Sodium alginate, Eudragit L-100 & Chitosan) were selected as film forming agents and propylene glycol was used as plasticizer to give flexibility to the films. In FT-IR study no interaction was observed between drug and the excipients. Blank films were prepared and evaluated. Concentration of polymer was optimized during preliminary studies. Three blank films were selected for the incorporation of drug. After characterization the drug loaded films and studying their disintegration time & in-vitro drug release studies, among the formulations F1-F8, F1 was selected the best formulation as its disintegration and dissolution time was less and it release drug to a greater extent compared to other formulations with minimum time. As dose of the drug gets reduced from 5 mg to just 2 mg, therefore adverse effects of the drug may also get reduced. Therefore fast dissolving oral films can play an important role in oral drug delivery.

KEYWORDS: Mouth dissolving film, Levocetrizine, solvent casting method, Disintegration time, Drug release, Fast onset of action.

INTRODUCTION

Levocetirizine is a third-generation non-sedative antihistamine drug, developed from the second-generation anti-histamine cetirizine. Chemically, levocetirizine is an active

enantiomer of cetirizine. It is the L-enantiomer of the cetirizine racemate. Levocetirizine works by blocking histamine receptors. It does not prevent the actual release of histamine from mast cells, but prevents it binding to its receptors. This in turn prevents the release of other allergy chemicals and increased blood supply to the area, and provides relief from the typical symptoms of hayfever.[1] The fast dissolving drug delivery system is a new drug delivery technique to provide medicine to such patients i.e. pediatric, children, geriatrics etc. Fast-dissolving film have acquired great importance in the pharmaceutical industry due to their unique properties & advantages.[2, 3] As the fast dissolving film utilizes sublingual route, rapid absorption of the drug is possible, which finally lead to quick onset of drug action. Difficulty in swallowing is a common problem of all age group, especially elderly and pediatrics, because of physiological changes associated with these groups of patients. Solid dosage form that can be disintegrated, dissolved, or suspended by saliva in the mouth resulting easy swallowing can provide significant benefits to the pediatric and geriatric population, as well as other patients who prefer the convience of easily swallowable dosage form.[4- 8] In case of allergic condion rapid action of drug is required. The fast dissolving films fulfill the requirement of potential solid dosage form for levocetirizine in treating allergic conditions. It shows patient compliance, rapid on-set of action, increased bioavailability and good stability make these film popular as a dosage form of choice.[9-11] Prepared film were subjected to different evaluation parameters like physical properties, disintegration time, content uniformity and dissolution studies.

Advantages of orally disintegrating film

1. Improved patient compliance.
2. Rapid onset of action and may offer an improved bioavailability.
3. Useful for paediatric, geriatric and psychiatric patients.
4. Suitable during travelling where water is may not be available.
5. No specific packaging required, can be packaged in strips.
6. Smooth mouth feel and pleasant taste.
7. Conventional manufacturing equipment.
8. Cost effective.
9. Good chemical stability as conventional oral solid dosage form.

Need of the present Study

- The major problem faced by many patients with conventional tablet dosage form is difficulty in swallowing, especially in case of paediatric and geriatric patients.

- Hence, patients may not comply with prescription, which results in high incidence of ineffective therapy.
- The ODFs emerged from the desire to provide patient with more convenient medication, compliance over conventional tablet dosage form.
- Hence, there is an obvious need for the development of Mouth Disintegrating Film to overcome patient non-compliance.
- In the market conventional Levocetrizine 5 mg tablets are available but in the fast dissolving film 2 mg drug loaded, therefore fast dissolving film avoid the side effect such as sedation.
- It avoids the first pass effect.

Oral cavity as a site for drug delivery

a) Anatomy & nature of oral cavity: The oral cavity it may be divided in to two regions, the outer oral vestibule, bounded by the lips and cheeks and the oral cavity itself the borders being, and formed by the hard & soft palates, the floor of the mouth and tonsil.[12]

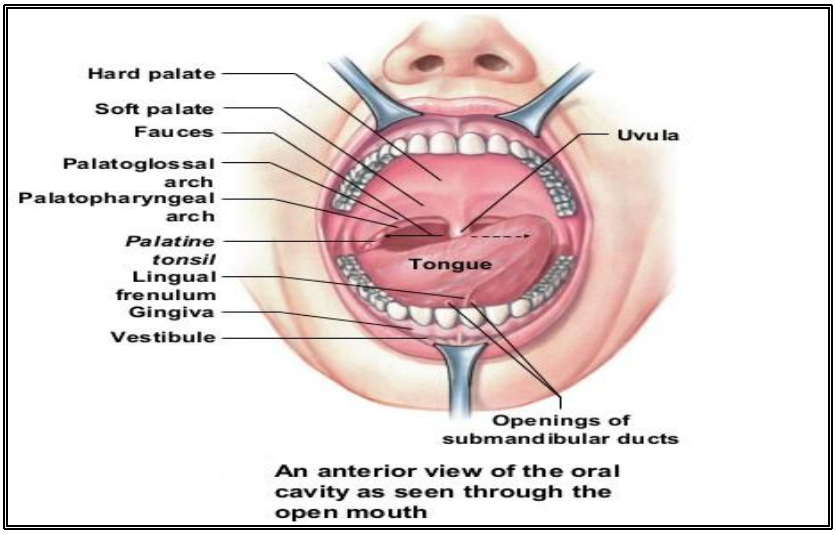


Figure 1: Schematic representation of the "open" oral cavity.

b) Physical description of oral cavity: As given figure-1, the mucosa that lines the oral cavity may be divided into three types, classified according to their function as

1. Masticator mucosa, which includes the mucosa around the teeth and on the hard palate and these regions have keratinized epithelium.

2. Lining mucosa, which covers the lips, cheeks, fornix, base of the oral cavity, lower part of tongue, buccal mucosa and the soft palate and these regions have non-keratinized epithelium.

3. Specialized mucosa, which covers the dorsum of the tongue with highly keratinized.[13]

c) Regional variation in the composition of oral mucosa: The difference in the structure thickness and blood flow depending on their location. Membrane that lines the oral cavity has a total area of 200 cm^2 and shows keratinized and non-keratinized tissue occupies about 50% and 30% respectively.[13,14]

d) Oral mucosa: The oral mucosa is composed of an outermost layer of stratified squamous epithelium (about 40-50 layers thick), a lamina propria followed by the sub mucosa as the intermost layer (Fig.1).

The composition of the epithelium varies depending on the site in the oral cavity. The mucosa of the gingival and hard palate are keratinized similar to the epidermis contain neutral lipids like ceramides and acylceramides which are relatively impermeable to water. The mucosa of the soft palate, the sublingual, and the buccal regions, however, are not keratinized contain only small amount of ceramides.[15]

e) Composition of mucus layer: Mucus is a translucent and viscid secretion which forms a thin gel, mean thickness of this layer varies from about 50-450 μm in humans secreted by the globet cells lining the epithelia or by special glands with mucus cell acini. It has the following general composition.[13,16]

Table No.1: Composition of mucus layer

Water	95%
Mineral salt	1%
Glycoprotein's and lipids	0.5-3%
Free proteins	0.5-1.0%

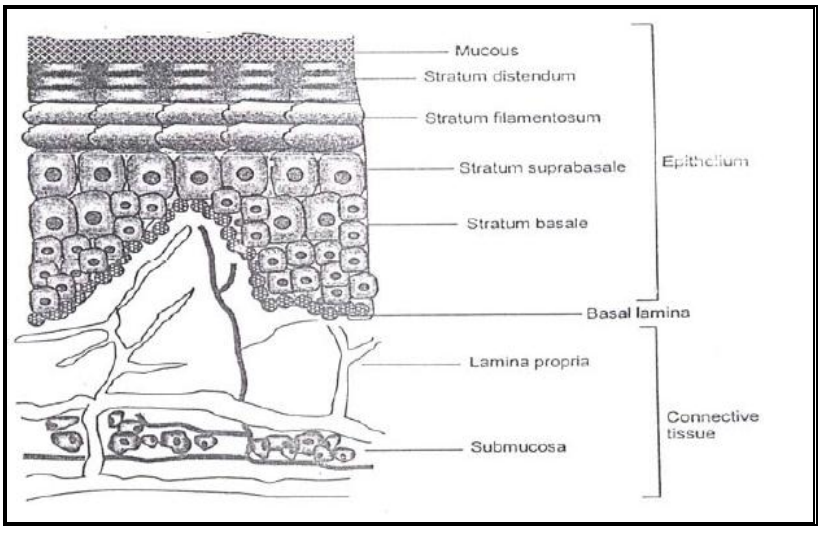


Figure 2: Schematic diagram of cross section of the oral mucosa.

f) Functions of mucus layer

1. Protective**:** Resulting particularly from its hydrophobicity.

2. Barrier: The role of the mucus layer as a barrier in tissue absorption of the drugs and influences the bioavailability.

3. Adhesion: Mucus has strong cohesion properties.

4. Lubrication: It is necessary to compensate for the removal of the mucus layer due to digestion, bacterial degradation and solubilization of mucin molecules.[17]

g) Salivary secretion: There are mainly three glands which secrets saliva in the oral cavity such as parotid, sublingual, and sub-mandibular.

MATERIALS AND METHODS

Material

Table No.2: Materials used with their source

SR. NO	MATERIAL	PROPERTY	SOURCE
1.	LEVOCETRIZINE HYDROCHLORIDE	PURE DRUG	-
2.	HPMC, HPMC E15.	FILM FORMER	MEHER CHEMIE, LABO CHEMIE
3.	MCC, CROSSCARMELOSE SODIUM	DISENTEGRATION AGENT	OZONE INTERNATIONAL
4.	PROPYLENE GLYCOL, PEG-400, PEG-6000, GLYCERINE.	PLATICIZER	MEHER CHEMIE, OZONE INTERNATIONAL
5.	CITRIC ACID	SALIVA STIMULATING AGENT	VIKAS PHARMA
6.	ASPARTAME	SWEETNER AGENT	OZONE INTERNATIONAL

Equipment

Table No.3: Equipment used with their source

SR.NO	EQUIPMENT	MODEL NO.	MAKE
1.	Oven Rotek	-	LABINDIA
2.	Disintegration apparatus	DA-40	ELECTROLAB
3.	UV-SPECTROPHOTOMETER	UV-1800	SHIMADZU JAPAN
4.	DIGITAL BALANCE	BL-22OH	SHIMADZU JAPAN
5.	PH METER	PICO^{+}	LABINDIA
6.	MAGNETIC STIRRER	LMS-28OE	LABTOP
7.	SCREW GAUGE	-	ELECTROLAB
8.	SONICATOR	3-5 L 100H	PCI ANALYTICS

Infrared Spectroscopy (IR): Physical mixture of drug and excipients were prepared to study the compatibility. Drug polymer compatibility studies were carried out using IR spectroscopy.[18]

UV Spectroscopy: The UV spectrum of LCZD in PBS (P^H 6.8) was scanned in the range 400-200 nm. The spectrum indicated that the observed λ max of LCZD was 231 nm which was matched with pharmacopoeial value.[3]

Preparation & Selection of Blank Film for Formulation:

Table-4: Formulation Details of Blank fast dissolving film.

Ingredient(mg)/ Formulation	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8	F_9
CMC	100	250	500	750	250	500	750	-	-
Sodi. Alginate	-	-	-	-	-	-	-	250	250
Cross-povidone	-	-	-	-	-	-	-	-	50
Propylene Glycol	50	50	50	50	-	-	-	-	-
Glycerin	-	-	-	-	-	-	-	50	50
SSG	-	-	-	-	-	-	-	150	150
PEG-4000	-	-	-	-	50	50	50	-	-
Citric Acid	50	50	50	50	50	50	50	50	50
Aspartame	55	55	55	55	55	55	55	55	55
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

+ -Poor + +-Average + + +-Excellent

Table-5: Formulation Details of Blank fast dissolving film.

Ingredient(mg)/ Formulation	F_{10}	F_{11}	F_{12}	F_{13}	F_{14}	F_{15}	F_{16}	F_{17}	F_{18}
Sodi. Alginate	250	-	-	-	-	-	-	-	-
Eudragit L-100	-	250	-	-	-	-	-	-	-
Chitosan	-	-	250	-	-	-	-	-	-
Lacroate	-	-	-	250	-	-	-	-	-
HPMC	-	-	-	-	300	300	-	-	-
HPMC E-15	-	-	-	-	-	-	600	600	600
SSG	150	-	-	-	-	-	-	-	-
PEG-6000	-	-	-	-	-	-	-	-	50
Glycerin	-	-	-	-	50	-	50	50	50
Propylene Glycol	50	50	50	50	-	50	50	50	-
PEG-400	-	-	-	-	-	-	200	-	-
MCC	-	-	-	-	-	-	-	200	-
CSS	-	-	-	-	-	-	-	-	200
Citric Acid	50	50	50	50	50	50	50	50	50
Aspartame	55	55	55	55	55	55	55	55	55
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

+ -Poor + +-Average + + +-Excellent

Preparation of Fast Dissolving Film: Oral fast dissolving film of containing of levocetirizine dihydrochloride was prepared by the solvent casting method. The polymers (HPMC) and plasticizers (propylene glycol, glycerin) was dissolved in about sufficient quantity of distilled water in separate beaker to prevent the excessive air bubbles formation. In the second beaker levocetirizine was add and stir both solution 30 min. Then these two solutions mixed together and specified amount of other excipients such as saliva stimulating agent, sweetening agent, flouring agent etc.was added to that mixture as well as sufficient quantity of remaining water & stirred for 1 hour. After stirring kept for 30 min for sonication to remove all air bubbles from final solution. Then the final solution was casted on petridish and it was dried in the oven at 45^0C for 12 hr. The film was carefully removed from the Petridish, and cut according to the size required for single dose and testing (Dose: 2 x 2 cm).[19,20]

Table No.4: Formulation Details of Levocetrizine hydrochloride buccal Patches (F1-F8)

Ingredient(mg)/ Formulation	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8
LCZ	36	36	36	36	36	36	36	36
HPMC	300	350	400	450	300	350	400	450
Propylene Glycol	50	50	50	50	-	-	-	-
Glycerin	-	-	-	-	50	50	50	50
Citric Acid	50	50	50	50	50	50	50	50
Aspartame	55	55	55	55	55	55	55	55
Water	q.s	q.s	q.s	q.s	q.s	q.s	q.s	q.s

Evaluation Parameter of Films [21-24]: The prepared film was evaluated for following specifications.

Visual Inspection: Oral fast dissolving films were inspected manually for their transparency and air bubbles.

Weight: Oral fast dissolving film weighted on analytical balance.

Thickness: Film thickness was measured by using a micrometer screw gauge apparatus. A strip of 2 X 2cm was placed between the thickness rods and thickness was measured in five different positions.

Folding endurance: Folding endurance was measured by manually or practically for the prepared films. Take a 2X2cm films and folded repeatedly at the same place till it broke. The

no times the film could be folded at the same place without breaking gave the exact valve of folding endurance.

P^H: The P^H was determined by dissolving a film in 1-2 ml of distilled water and then the P^H of the obtained solution was measured by the P^H paper.

Dissolution studies: The release rate of the Levocetirizine dihydrochloride fast dissolving film was determined by the help of USP Dissolution Test Apparatus-II. The dissolution test was performed using 300 ml Phosphate Buffer Solution P^H 6.8, at 37 $\pm$ 0.5^0C with 50 rpm of the paddle speed. Aliquot 5 ml of the solution was collected from the dissolution apparatus at time interval of 1 min and at the same time add 5 ml or same amount of fresh dissolution medium. The Aliquot filtered through the whatman filter paper. The absorbance of the filtered solution was measured at 231 nm. The aliquot should be withdrawn at the zone between the surface of the dissolution medium and the top of rotating paddle not less than 1 cm apart from the vessel wall. Cumulative percent drug release can be calculated by using the equation obtained from the standard curve or % drug release formula. (A = Con. Of Std. / Abs. of Std. X Abs. of sample X volume of dissolution apparatus X Dilution factor / 1000, B = A-Value/Label claim X 100).

RESULT AND DISCUSSION

UV Spectroscopy: The UV spectrum of Levocetrizine hydrochloride in Phosphate buffer solution P^H 6.8 in the range of 400 – 200 nm. The spectrum indicated that the observed λmax of Levocetirizine hydrochloride was 231 nm which is matched with pharmacopoeial value.

Preparation of standard Calibration curve of Levocetrizine

Levocetrizine hydrochloride showed maximum absorption at wavelength 231 nm in PBS P^H 6.8. Standard curve was plotted by taking absorption of diluted stock solutions (5, 10, 15, 20, 25, 30 µg/ml) at wavelength 231 nm.

Conc.(mg/ml)	Abs.
5	0.198
10	0.364
15	0.538
20	0.695
25	0.867

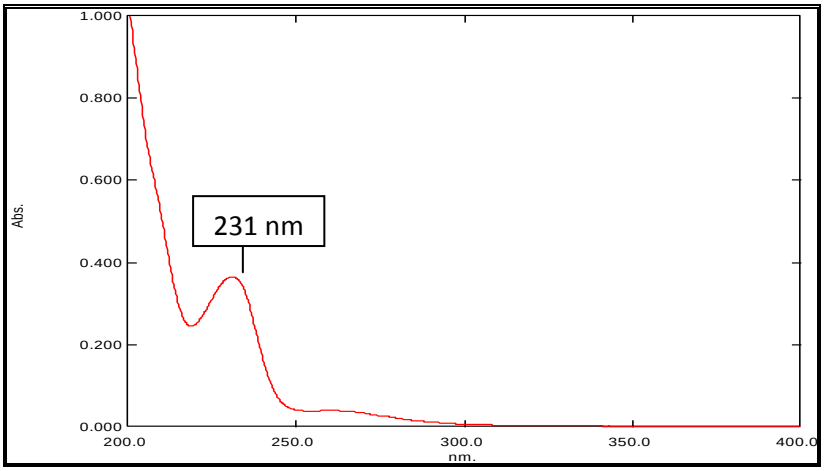


Fig.3: UV Spectra of LCZD in PBS (P^H 6.8)

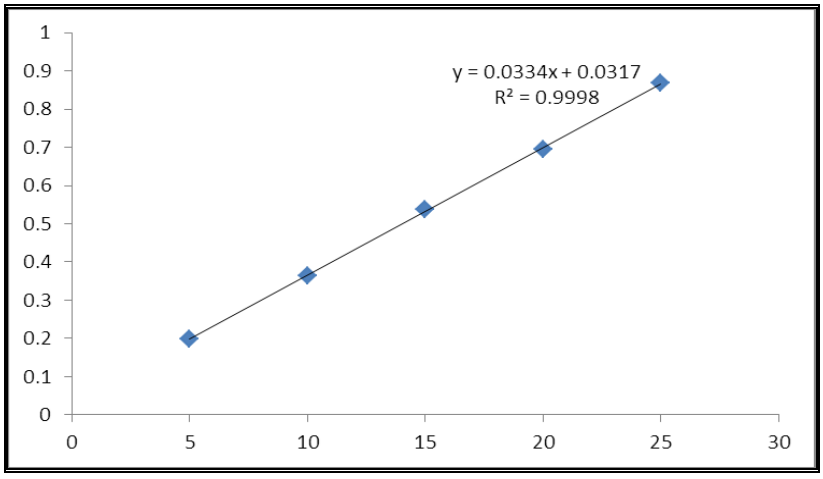
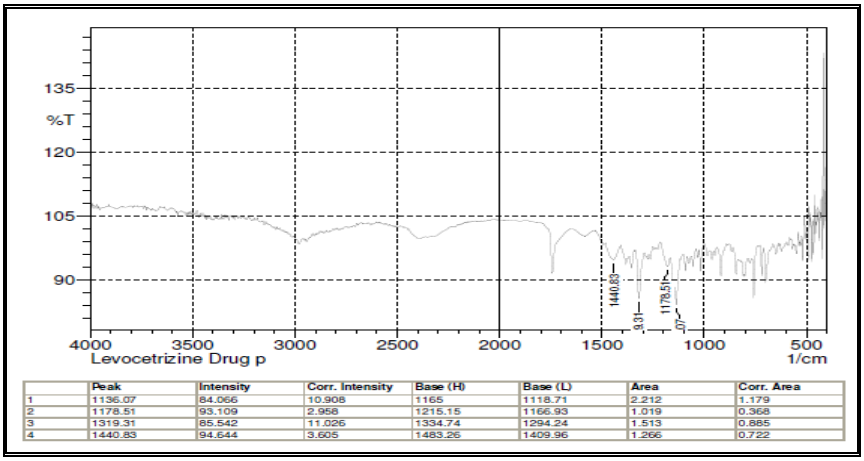


Fig. 4: Calibration curve of LCZD

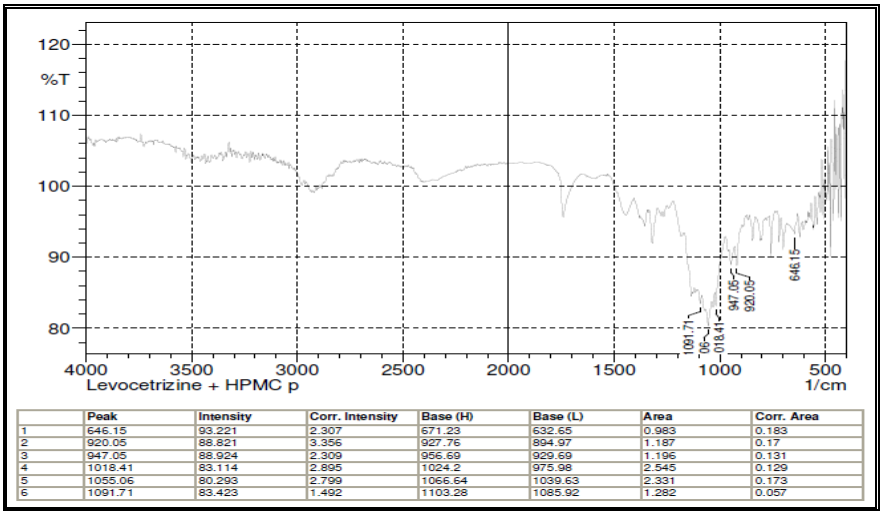
FTIR: FTIR studies were carried out for detection of drug polymer interaction. In the present study the IR study of pure drug Levocetirizine hydrochloride, Drug + HPMC were carried out to study the compatibility between them.



	Peak	Intensity	Corr. Intensity	Base (H)	Base (L)	Area	Corr. Area
1	1136.07	84.066	10.908	1165	1118.71	2.212	1.179
2	1178.51	93.109	2.958	1215.15	1166.93	1.019	0.368
3	1319.31	85.542	11.026	1334.74	1294.24	1.513	0.885
4	1440.83	94.644	3.605	1483.26	1409.96	1.266	0.722

Observed frequencies	Assignment
1070-1150	-O- Stretching
1020-1220	C-N Stretching (Amine)
1310-1360	C---N Stretching (Ter. Amine)
1395-1440	C-OH Stretching
730-770	C-H Stretching in aromatic ring

Fig. No.5: FTIR Spectra of Levocetirizine hydrochloride with Interpretation data.



	Peak	Intensity	Corr. Intensity	Base (H)	Base (L)	Area	Corr. Area
1	646.15	93.221	2.307	671.23	632.65	0.983	0.183
2	920.05	88.821	3.356	927.76	894.97	1.187	0.17
3	947.05	88.924	2.309	956.69	929.69	1.196	0.131
4	1018.41	83.114	2.895	1024.2	975.98	2.545	0.129
5	1055.06	80.293	2.799	1066.64	1039.63	2.331	0.173
6	1091.71	83.423	1.492	1103.28	1085.92	1.282	0.057

Fig. No.6: FTIR Spectra of Levocetirizine hydrochloride + HPMC.

IN-VITRO DISSOLUTION STUDIES

In present work, an attempt has been made to increase the % drug release of levocetirizine hydrochloride with changes in concentration of polymers & plasticizers by solvent casting method.

Table no.5: In-vitro dissolution study of Levocetirizine hydrochloride

Time(min)	% Drug release							
	F_1	F_2	F_3	F_4	F_5	F_6	F_7	F_8
1	25.26	25.96	25.96	56.45	18.13	31.31	11.53	23.90
2	67.58	48.62	48.62	58.10	28.43	41.20	23.90	31.73
3	70.87	60.57	56.45	65.11	37.5	51.92	43.26	47.80
4	95.19	91.48	58.10	79.94	46.97	61.40	46.56	49.86
5	95.60	129.3	81.18	93.54	54.80	71.70	55.22	64.69
6	-	-	-	-	72.11	75.41	63.87	69.64
7	-	-	-	-	74.58	75.82	72.11	77.06
8	-	-	-	-	78.70	79.94	76.23	93.13
9	-	-	-	-	82.41	79.94	77.06	94.78
10	-	-	-	-	83.24	82.82	77.47	95.60

All values expressed as mean ± SD (n=3), F = Formulation batch

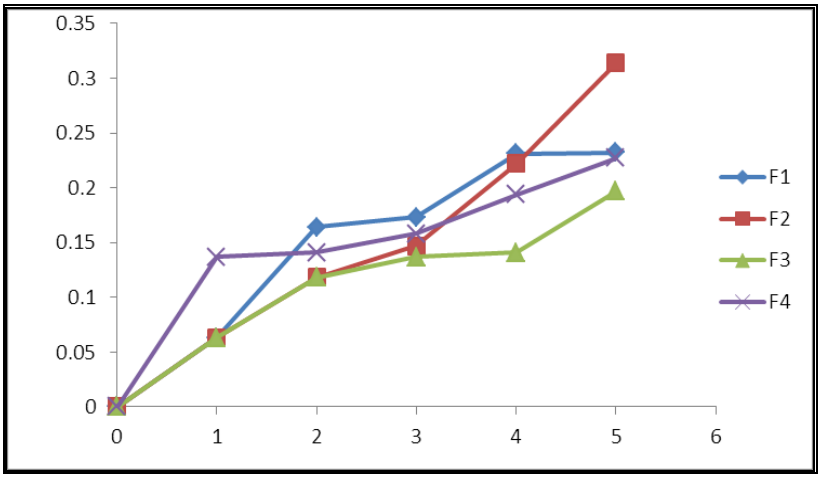


Fig. No.7: In-vitro dissolution study/profile Levocetirizine hydrochloride of batches F1-F4

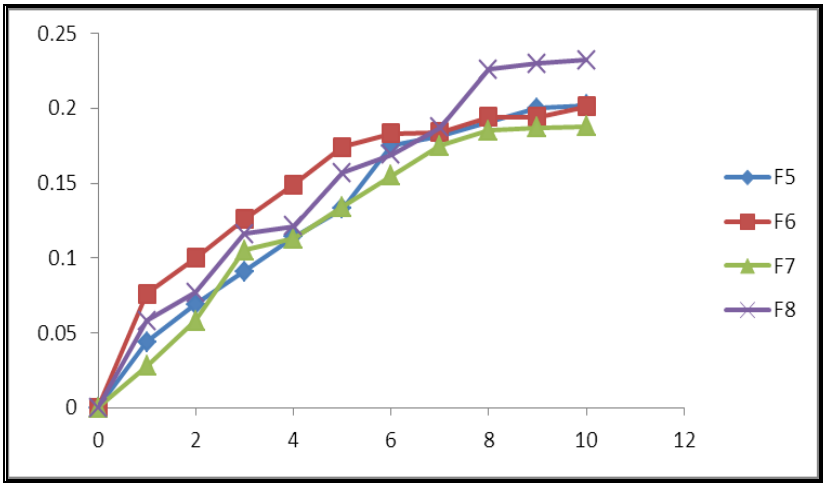


Fig. No.8: In-vitro dissolution study Levocetirizine hydrochloride of batches F5-F8

EVALUATION OF DISSOLUTION PROFILE OF MARKETED TABLETS:

- **CONGY-L**

Dissolution test protocol

Table No.6: Dissolution test protocol

Name of drug	**CONGY-L**
Dissolution apparatus	USP TYPE II
00Temperature	37 ± 0.5 ^{0}C
Basket speed	50 rpm
Tablet strength	5 mg LCZD
Dissolution medium	PBS P^{h} 6.8
Volume of dissolution medium	900 ml
Detection	231 nm
Volume of sample removed	5 ml
Sampling profile	1 – 5 min

Dissolution profile of marketed tablet

Table No.7: Dissolution profile of marketed product CONGY-l (Comparative study).

Time (min)	% Drug release	
	CONGY-L	F2
1	1.2	25.96
2	12.36	48.62
3	69.23	60.57
4	119.91	91.48
5	132	129.3

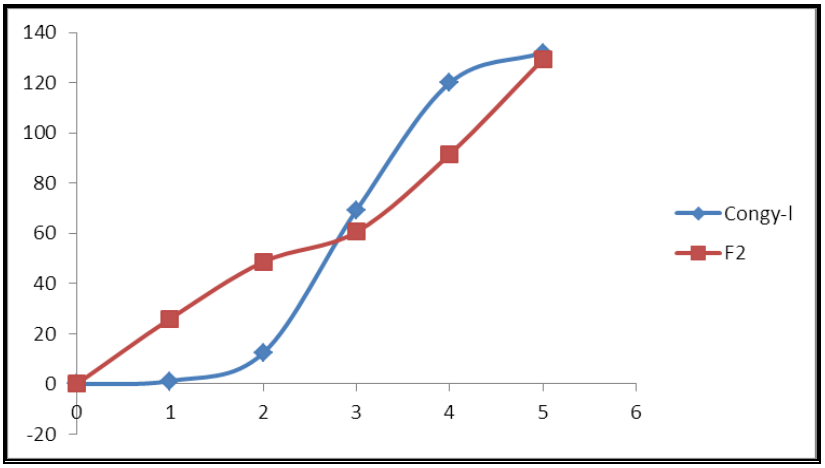


Fig.No.9: Dissolution profile of Marketed product with Formulation batch F2

STABILITY STUDY

The stability study conducts by ICH guideline. It showed No significance change in properties of the optimized formulation & the drug release. Short term stability studies were performed in a Stability chamber over a period of 3 weeks (21 days) on the promising Fast Dissolving Film formulations F1, F2, F4 & F8. Sufficient number of films formulation were packed in stability container and kept in a Stability chamber at Temperature 45^0c & RH 75%. Samples were taken on 21st day for drug content estimation; also the thickness, weight, folding endurance and in-vitro disintegration studies were performed to determine the drug release profile.

Table No.8: Stability parameter of Fast dissolving film

Formulations	Tack Test	Appearance	Weight (mg)	Thickness (mm)	Folding endurance	D.T (sec)	Surface P^H	Con.uniformity
F1	Non tacky	Transparent	19	70	105	09	6-7	2
F2	Non tacky	Transparent	24	80	114	14	6-7	2
F4	Non tacky	Transparent	27	100	148	42	6-7	2
F8	Non tacky	Transparent	28	100	131	32	6-7	2

All values expressed as mean ± SD (n=3), F = Formulation batch

Table no.9: in-vitro release data of stability formulation F1, F2, F4 & F8.

Time/Formulation (min)	% Drug Release			
	F1	F2	F4	F5
1	24.21	25.56	55.45	22.19
2	66.58	47.69	58.10	30.62
3	69.77	58.47	65.11	46.65
4	92.15	93.12	79.54	48.76
5	95.10	125.1	93.44	63.96
6	-	-	-	65.46
7	-	-	-	76.60
8	-	-	-	92.31
9	-	-	-	94.87
10	-	-	-	95.06

All values expressed as mean ± SD (n=3), F = Formulation batch

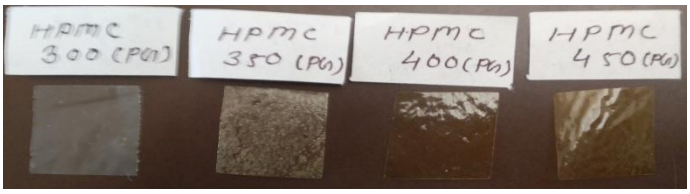


Fig.No.10: Formulation No. F1, F2, F3, F4

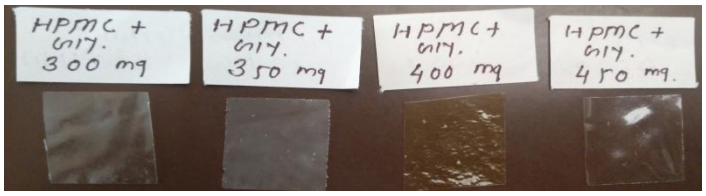


Fig.No.11: Formulation No. F5, F6, F7, F8

Table No.10: Evaluation parameter of Fast dissolving film

Formulations	Tack Test	Appearance	Weight (mg)	Thickness (mm)	Folding endurance	D.T (sec)	Surface P^H	Con.uniformiy
F1	Non tacky	Transparent	20	70	110	11	6-7	2
F2	Non tacky	Transparent	24	80	128	15	6-7	2.01
F3	Non tacky	Transparent	26	90	136	23	6-7	2
F4	Non tacky	Transparent	28	100	142	46	6-7	2.02
F5	Non tacky	Transparent	19	60	91	8	6-7	2
F6	Non tacky	Transparent	21	70	115	17	6-7	2
F7	Non tacky	Transparent	26	80	117	22	6-7	2.04
F8	Non tacky	Transparent	28	100	125	33	6-7	2

All values expressed as mean ± SD (n=3), F = Formulation batch

DISCUSSION

In the present research work Design and characterization of polymeric FDF for buccal delivery of Levocetrizine dihydrochloride were prepared to improve efficacy of Levocetrizine

dihydrochloride by improving its bioavailability also by reducing its dose unlike in concentration. Levocetrizine dihydrochloride buccal FDF were prepared using HPMC in different concentrations by solvent casting technique, the prepared fast dissolving film were evaluated for various parameters and the results of these parameters were given in Table No.9 8 and they are discussed in detail in the following section of this chapter.

Physical appearance and surface texture of fast dissolving film: These parameters were checked simply with visual infection of fast dissolving film and by feel or touch. The observation suggests that the FDF are having smooth surface and they are elegant enough to see.

Weight uniformity of fast dissolving film: The weight of FDF was determined using digital balance and the average weight of all fast dissolving films. FDFS prepared with HPMC in the concentration 300-450 mg and also in combination of PEG & Glycerol of 50 mg were weighed about 19-28 mg (n=3) respectively.

Thickness of fast dissolving film: The thicknesses of the fast dissolving film were measured using screw gauge. The thickness of the fast dissolving films prepared with HPMC in the concentration 300-450 mg and also in combination of PEG & Glycerol of 50 mg the thickness of the FDFS prepared respectively are 70-100 mm respectively.

Folding Endurance of FDF: The folding endurance of the FDF was determined by repeatedly folding a small strip of the FDF at the same place till it broke. The folding endurance of the FDFS prepared with HPMC in the concentration 300-450 mg and also in combination of PEG & Glycerol of 50 mg was 91-142 (n=3) respectively.

Surface pH of fast dissolving film: Surface pH was determined by the FDF were allowed in contact with 1ml of distilled water. The surface pH was noted by pH meter near the surface of FDF solution. The surface pH of the FDF prepared with HPMC was found to in-between 6-7 P^H (n=3).

Drug-Polymers interaction studies of FDF

Spectrum No1.Pure drug

The infrared spectrum of Levocetirizine dihydrochloride recorded in a KBr pellet on Perkin Elmer Infrared Spectrophotometer. From the Infrared frequencies & the respective assignments given drug are compatible.

Spectrum No2.LCZD + HPMC

The infrared spectrum of pure drug & hydroxy propyl methyl cellulose recorded in a KBr pellet on Perkin Elmer Infrared Spectrophotometer. From the Infrared frequencies & the respective assignments given drug are compatible.

Drug Content uniformity of FDF

Levocetrizine dihydrochloride FDF prepared with HPMC in various concentrations and were subjected to the uniform dispersion of drug throughout the patch. In each case three FDF were used and the average drug content was calculated. The drug was dispersed in the range of 2-2.04 (n=3). Suggesting that drug was uniformly dispersed in all FDF. The S.D. value calculated for such formulation is very less which suggest that the results are reproducible and accuracy in the method used to prepare the FDF.

In vitro Drug Release of FDF

All the buccal FDF of Levocetrizine dihydrochloride prepared were subjected to *in vitro* drug release studies for a period of 1-10 min.

The formulation F1, F2, F3, F4, F5, F6, F7 and F8 which are prepared using with HPMC in the concentration 300-450 mg and also in combination of PEG & Glycerol of 50 MG released 95.60%, 129.35, 81.18%, 93.54%, 83.24%, 82.82%, 77.47% & 95.60% at the end of 10 min respectively. The detail *in vitro* released data were shown in table No-5 & drug release profile 7, 8.

CONCLUSION

The fast dissolving film of Levocetirizine hydrochloride obtained by the solvent casting method showed acceptable mechanical properties and satisfactory drug release within 5 min. The prepared film was transparent with smooth surface without any drug excipients interaction. The high % drug release of the film in 6.8 phosphate buffer as well as observed improved pharmacokinetic profile of LCZ in film dosage form as compare to conventional tablet. Formulation No. F–1, 2, 4, 8shows better result (% Release) than other.

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